ANNUAL SHOT REPORT 2023

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)

Steering Group Chair	Professor Mark Bellamy
SHOT Medical Director	Dr Shruthi Narayan
SHOT Operations Manager	Mrs Caryn Hughes
SHOT Haemovigilance Data Manager	Ms Debbi Poles
SHOT Haemovigilance / Patient Blood Management Specialist	Ms Emma Milser
SHOT Clinical Incidents Specialist	Mr Simon Carter-Graham
SHOT Laboratory Incidents Specialists	Mrs Victoria Tuckley
	Mrs Nicola Swarbrick
SHOT Incidents Specialist	Mrs Vera Rosa
SHOT Data Specialist	Mr Darren Hall
SHOT Administrator	Ms Raquel Planus Lopez
National Coordinator for Transfusion-Transmitted Infections (UK Health Security Agency)	Mrs Tali Yawitch

Working Expert Group (WEG) & Writing Group, on behalf of the SHOT Steering Group

Chair: Dr Shruthi Narayan

Dr Peter Baker, Professor Mark Bellamy, Dr Andrew Bentley, Dr Paula Bolton-Maggs, Dr Catherine Booth, Dr Su Brailsford, Mr Simon Carter-Graham, Mrs Heather Clarke, Dr Anicee Danaee, Dr Jennifer Davies, Miss Chloe Davison, Dr Sharran Grey, Dr Heli Harvala, Dr Sarah Haynes, Mrs Caryn Hughes, Dr Anne Kelly, Dr Tom Latham, Dr Puneet Malhotra, Ms Josephine McCullagh, Ms Emma Milser, Mrs April Molloy, Dr Helen New, Mrs Terrie Perry, Dr Jayne Peters, Ms Debbi Poles, Dr Fiona Regan, Mr Chris Robbie, Dr Susan Robinson, Mrs Vera Rosa, Dr Megan Rowley, Dr Joseph Sharif, Mrs Charlotte Silver, Mrs Nicola Swarbrick, Ms Tracey Tomlinson, Mrs Victoria Tuckley, Dr Alison Watt, Mrs Tali Yawitch

Steering Group (SG) during 2023

Chair: Professor Mark Bellamy

Dr Shubha Allard	National Blood Transfusion Committee Royal College of Pathologists
Dr Lynne Anderson	Scottish Clinical Transfusion Advisory Committee
Lt Col Lucinda Blake	Defence Medical Services
Dr Su Brailsford	UK Health Security Agency
Mr Suman Shrestha	Royal College of Nursing
Mr Graham Donald	Lay member
Prof David Roberts	British Blood Transfusion Society
Ms Kerry Dowling	UK Transfusion Laboratory Collaborative
Dr Ruth Gottstein	Royal College of Paediatrics and Child Health
Ms Mervi Jokinen	Royal College of Midwives
Mrs Anne Lockhart	Institute of Biomedical Science
Prof Andrea Piccin	Northern Ireland Blood Transfusion Service
Dr Stephen Thomas	Joint Professional Advisory Committee
Dr Gail Miflin	UK Forum
Dr Erum Khan	Royal College of Obstetricians and Gynaecologists
Dr Caroline Evans	Royal College of Anaesthetists
Dr James Reid	Royal College of Physicians
Dr Pete Hersey	Faculty of Intensive Care Medicine
Mr Chris Robbie	Medicines and Healthcare Products Regulatory Agency
Dr Susan Robinson	British Society for Haematology
Ms Katy Veale	UK National External Quality Assessment Service (UK NEQAS)
Ms Nina Vinall	Expertise in Patient Safety
Honorary Steering Group Members	
Dr Hannah Cohen	Founder Member and former Steering Group Chair
Dr Dafydd Thomas	Former Steering Group Chair
Dr Lorna Williamson	Founder Member
Dr John Barbara	Founder Member
Prof John Lumley	Founder Member
Dr Brian McClelland	Founder Member
Dr Derek Norfolk	Founder Member
Dr Clare Taylor	Former SHOT Medical Director
Dr Sue Knowles	Former Interim Medical Director of SHOT
Dr Dorothy Stainsby	Former National Medical Coordinator of SHOT
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.

Requests for further information should be addressed to:

Non-infectious hazards
SHOT Office
Manchester Blood Centre
Plymouth Grove
Manchester
M13 9LL
Tel +44 (0) 161 423 4208
Website www.shotuk.org
X/Twitter @shothv1
Enquiries shot@nhsbt.nhs.uk

Infectious hazards
Mrs Tali Yawitch
Scientist (Epidemiology)
Joint NHSBT/UKHSA Epidemiology Unit
61 Colindale Avenue
London NW9 5EQ
Email Tali.Yawitch@nhsbt.nhs.uk

Disclaimers:

Case studies: the information in Annual SHOT Report case studies is provided to SHOT by reporters. All reports are anonymised and SHOT relies on reporters submitting correct and accurate information. SHOT does not accept responsibility for any inaccuracies which may arise from incorrect information being submitted.

Data interpretation: There are many factors that can influence the number of reports submitted to SHOT, including awareness of what to report, and staffing levels within organisations. Combined with a lack of accurate real time denominator data about transfusions across the UK, this makes interpretation of the fluctuations in number of reports very difficult. The comparisons made to reporting numbers from previous years are based on actual numbers submitted only and should be interpreted with caution.

Copyright notice

Please cite this work as:

Narayan, S. et al., 2024. The 2023 Annual SHOT Report, Manchester: Serious Hazards of Transfusion (SHOT) Steering Group. https://doi.org/10.57911/605r-em59

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.

Published July 2024

ISBN 978-1-9995968-6-6

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

Printed on paper from responsible sources.

print & plant

A collaborative initiative to restore forests around the globe.
For more information please visit: www.e-arc.co.uk/environment

Contents

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

1 Foreword

I am writing this foreword on the day the final report of the Infected Blood Inquiry (IBI) has been released. I have listened to the live stream presentation, of around an hour, by the chair of the Inquiry, Sir Brian Langstaff. His presentation was both eloquent and concise. Every moment of it was compelling, yet it barely scratched the surface of the report the Inquiry produced, which runs to seven volumes. I have had the opportunity to read the summary pages, and skim through volume one. The report is comprehensive, but even so cannot hope to be exhaustive. It is wide ranging and detailed; acknowledging the depth of tragedy and human suffering which necessitated the Inquiry. For those of you who do not have time to read the report, I highly recommend Sir Brian's live stream, which is available through the IBI website.

Several important themes come through. There were major failings illustrated in the report around consent, around patient autonomy, and around medical paternalism. Medical record keeping and audit were likewise found to have been seriously inadequate. The IBI report describes in detail what happened, the nature of the response at the time, and what should happen going forward (IBI, 2024). In part, the report's recommendations address political remedies, and recommend how processes should be changed and improved. The future role of SHOT and haemovigilance processes more widely are outlined in volume one of the report (pages 261 through 267). These conclude with the recommendation:

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

The IBI report goes on to underline the desirability of establishing the outcomes of every transfusion of blood components. Had this been achieved at the time of the principal events described in the report, Sir Brian writes, it is likely that alarm bells would have rung sooner. The Scottish 'Account for blood' scheme is described, and most importantly, current major threats, including transfusion-associated circulatory overload (TACO) are cited. The desperate and urgent need for effective IT solutions is also mentioned. Sir Brian recommends:

Establishing the outcome of every transfusion

(i) That a framework be established for recording outcomes for recipients of blood components. That those records be used by NHS bodies to improve transfusion practice (including by providing such information to haemovigilance bodies)

> *Success in achieving this will be measured by the extent to which the SHOT reports for the previous three years show a progressive reduction in incidents of incorrect blood component transfusions measured as a proportion of the number of transfusions given.*

(ii) To the extent that the funding for digital transformation does not already cover the setting up and operation of this framework, bespoke funding should be provided

(iii) That funding for the provision of enhanced electronic clinical systems in relation to blood transfusion be regarded as a priority across the UK

These goals align closely with the current philosophy of SHOT, and the priorities we have identified over recent years. This year's Annual SHOT Report, including data until the end of December 2023, emphasises that errors continue to account for most reports. Near miss events make up a large proportion of the total incidents. As laid out in the report of the IBI, reporting of all new incidents is crucial. This year's Annual SHOT Report relates that transfusion delays and pulmonary complications

(both TACO and non-TACO) remain leading causes of transfusion-related deaths in the UK, accounting together for over 76% of the deaths reported.

Notwithstanding that, the absolute risk of death remains relatively low, at 1 in 58,000 components issued. Harms are at least five times more common. It is unlikely that this situation can be improved upon with current low levels of resourcing, with under-reporting, and while SHOT collates data and produces reports, but lacks an effector arm.

In conclusion, I would like to quote two sentences from Sir Brian's comments at the report launch which, for me, are the absolute essence of the culture we should nurture.

'Most, if not all, infections would have been prevented if patient safety had been paramount throughout'.

'The public should be trusted with the truth'.

It is timely for Trusts and Health Boards in the UK to take full account of Sir Brian's findings in the IBI, and ensure that SHOT recommendations are effectively implemented. I commend this year's Annual SHOT Report to you.

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

Reference

Infected Blood Inquiry (IBI), 2024. *The Report HC 569-I,* London: Crown. Available at: https://www.infectedbloodinquiry.org.uk/reports/inquiry-report (Accessed 20 May 2024).

Participation in United Kingdom (UK) Haemovigilance 2

Authors: Debbi Poles and Shruthi Narayan

Abbreviations used in this chapter

ACE	Acknowledging continuing excellence in transfusion
FFP	Fresh frozen plasma
MB-FFP	Methylene-blue treated FFP
MHRA	Medicines and Healthcare products Regulatory Agency
NHS	National Health Service
SABRE	Serious adverse blood reactions and events
SaBTO	Advisory Committee on the Safety of Blood, Tissues and Organs
SD-FFP	Solvent-detergent FFP
UK	United Kingdom

Key SHOT messages

- High levels of participation in haemovigilance reporting to SHOT continues despite challenges faced by staff
- Variations exist in the patterns and frequency of reports received across the UK

Recommendation

- Participation benchmarking data should be reviewed to inform local improvements. These discussions should be included in local and regional transfusion meetings

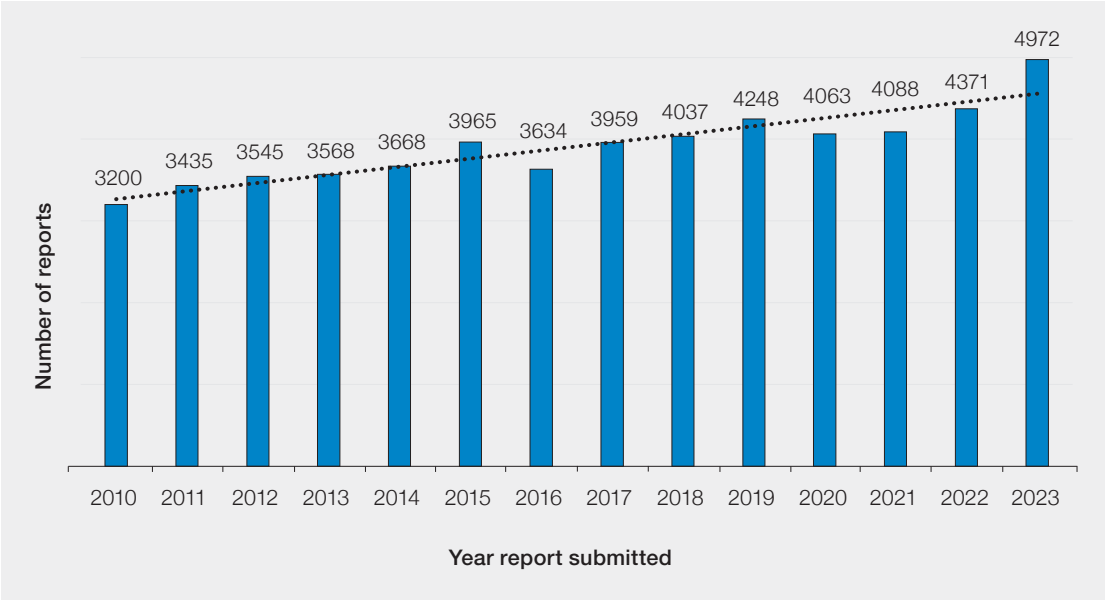
Action: Haemovigilance reporters and local governance teams

Introduction

Haemovigilance reporting and benchmarking play a vital role in promoting transparency, accountability, and continuous improvement in blood transfusion practices. This ultimately benefits patients, donors and staff with improved experiences and outcomes. Participating healthcare organisations contribute valuable data that can be analysed to identify trends, patterns, and areas for improvements in transfusion practices.

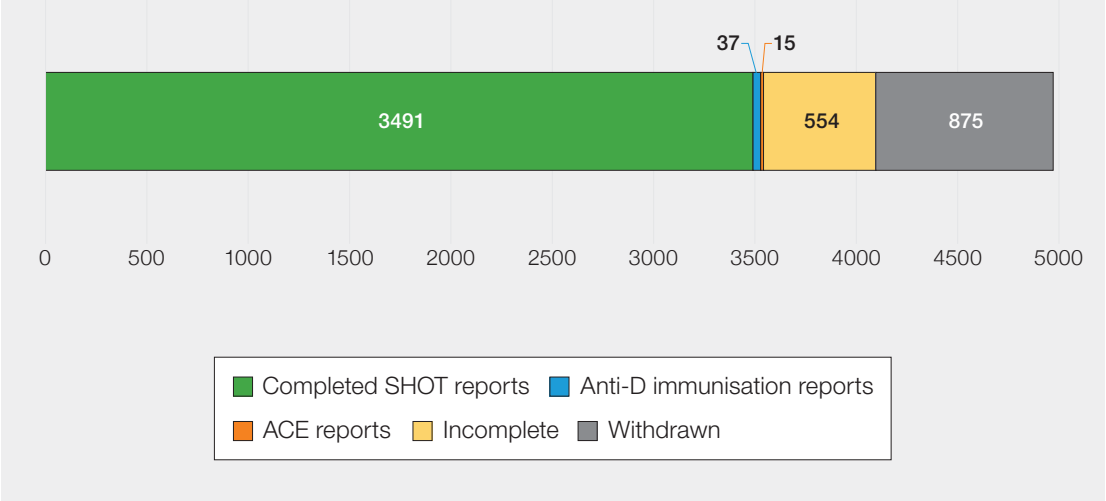
Participation in UK haemovigilance reporting has risen in 2023. There were 4972 reports submitted via the SABRE online reporting system in 2023, which is an increase of 601 (13.7%) compared to 4371 in 2022. This is the largest annual increase since 2017, however, given the relative dip in reporting seen in 2020 and 2021, this is more likely to reflect a restoration of the previous upward trajectory that was suppressed during the pressures of the COVID-19 pandemic.

Figure 2.1: Haemovigilance reports submitted by year 2010-2023



Of these 4972 reports, 3491 (70.2%) were completed by the reporter and have been analysed and included in this 2023 Annual SHOT Report. Additionally, there were 37 completed anti-D immunisation reports, and 15 completed ACE reports. The remaining 1429 reports were either withdrawn (875) or incomplete at the cut-off date for inclusion (554). Common reasons for withdrawal of reports from the SHOT analysis are reactions that were assessed to be mild or more likely related to underlying condition, or errors that were MHRA-reportable only (Ryan, et al., 2022).

Figure 2.2: The status of reports submitted to SHOT during 2023 (n=4972)



ACE=acknowledging continuing excellence

Reporting to SHOT and the MHRA

There are differences in reporting criteria for both organisations, and the 4972 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. Figure 2.3 highlights the main differences and commonalities in reporting criteria between the two organisations.

Further information regarding the numbers of reports accepted by SHOT and the MHRA can be found in the supplementary information on the SHOT website (https://www.shotuk.org/shot-reports/report-summary-and-supplement-2023/).

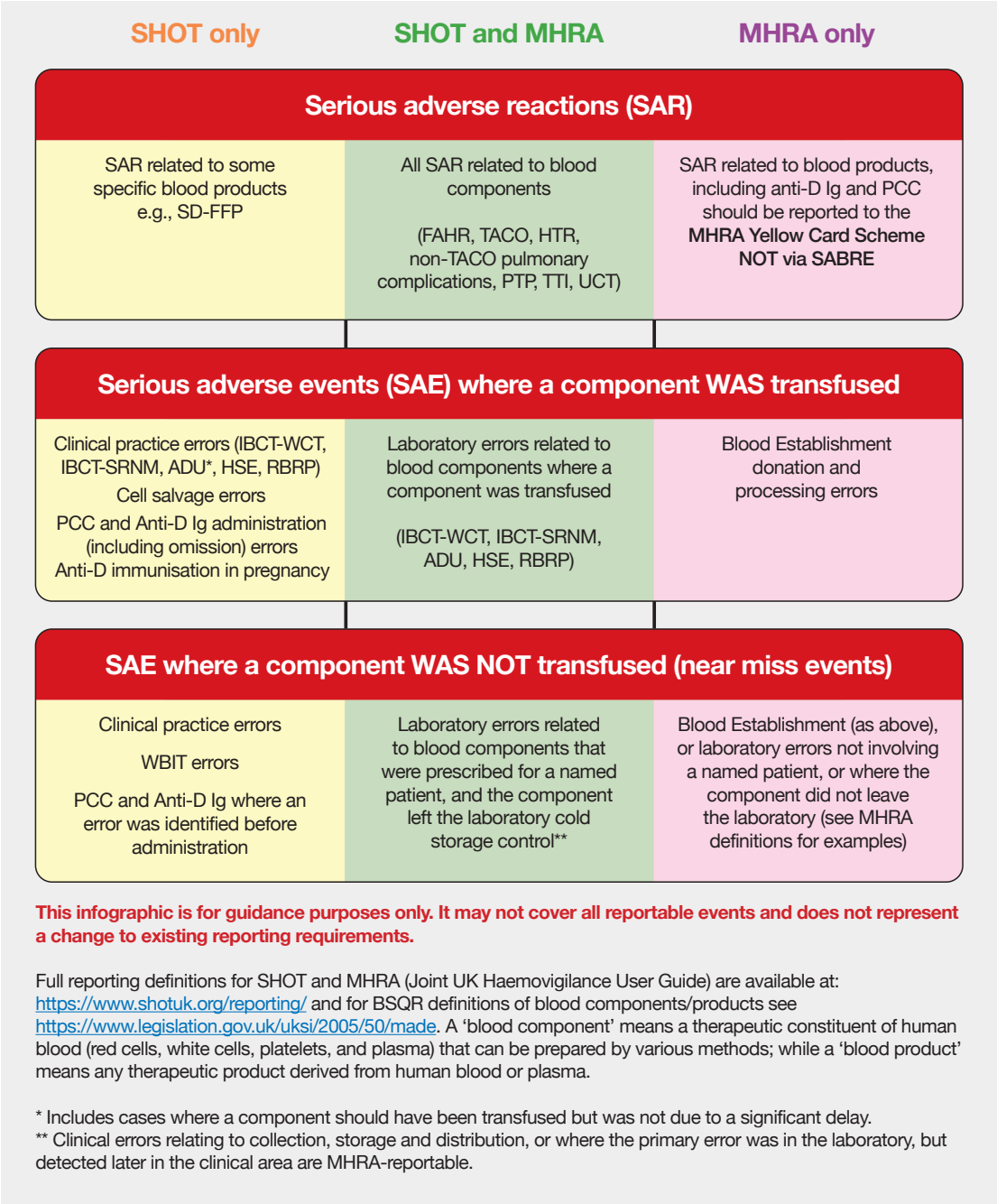


Figure 2.3: SHOT and the MHRA reporting criteria

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=immunoglobulin; 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

Blood component issue data 2023

Table 2.1 lists the total number of blood components issued from the UK Blood Services in 2023, and the number of SD-FFP (Octaplas®) units issued in each country.

Table 2.1: Blood components and SD-FFP issue data for the calendar year 2023 in the UK

	Red cells	Platelets	FFP	SD-FFP	Cryoprecipitate	Totals
NHS Blood and Transplant	1,351,959	250,530	169,875	53,710	40,739	**1,866,813**
Northern Ireland Blood Transfusion Service	42,238	8,886	4,523	772	934	**57,353**
Scottish National Blood Transfusion Service	138,372	23,890	14,588	3,490	3,208	**183,548**
Welsh Blood Service	72,932	8,248	7,628	1,490	258	**90,556**
Totals	**1,605,501**	**291,554**	**196,614**	**59,462**	**45,139**	**2,198,270**

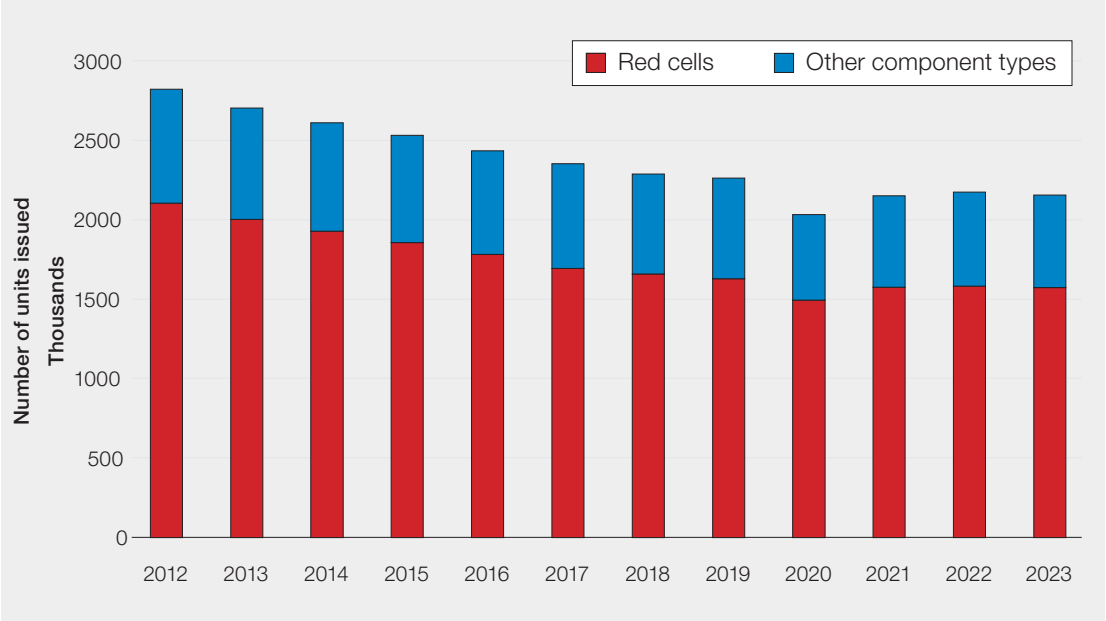
SD=solvent-detergent; FFP=fresh frozen plasma

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

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

There were no MB-FFP units issued in any of the UK Blood Services in 2023. This follows the SaBTO report where the requirement for MB-FFP was withdrawn in 2019 (Thomas, et al., 2022), so this has been removed from Table 2.1.

Figure 2.4a: Blood component issue data in the UK 2012-2023



Includes solvent-detergent fresh frozen plasma

While this provides the issue data for the various blood components, it is important to note that there continues to be a differential demand for some of the blood components. For example, the demand for O D-negative red cells as a percentage (of the overall demand) continues to rise and demand may exceed supply, thus putting additional pressure on Blood Services.

SHOT
Serious Hazards of Transfusion

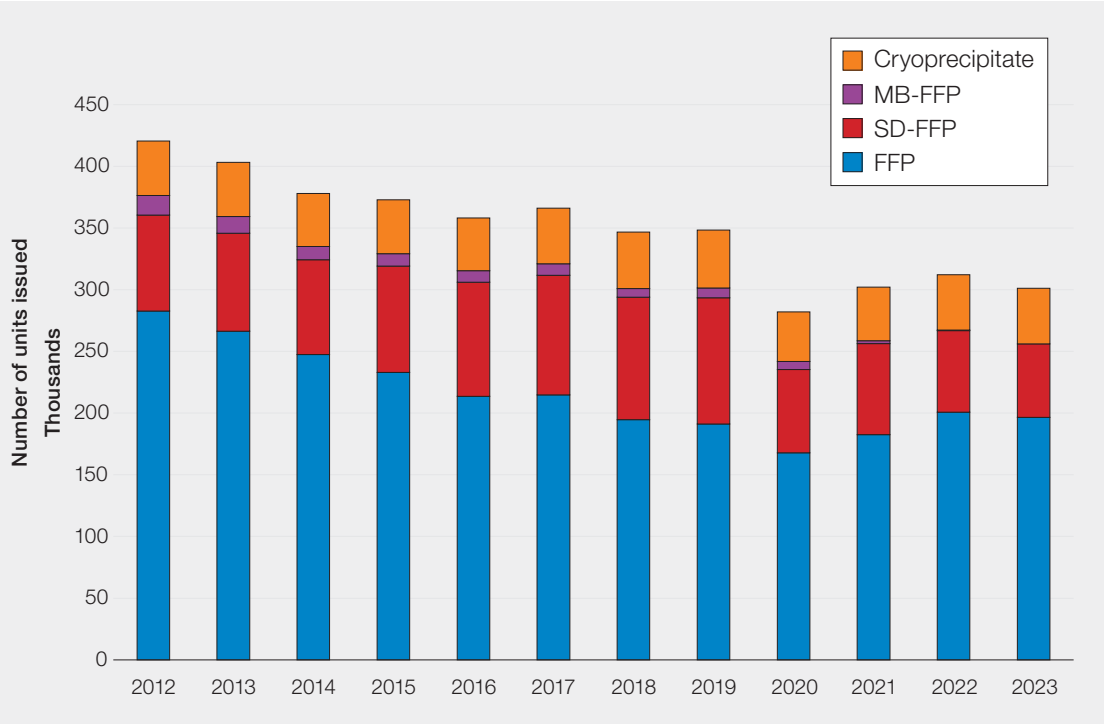


Figure 2.4b: Non-cellular component issue data in the UK 2012-2023

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

SHOT reporting by UK country

Full tables containing the breakdown of data from 2023 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-2023/).

Cases included in the 2023 Annual SHOT Report n=3833

The total number of reports analysed and included in the 2023 Annual SHOT Report is 3833. This is an increase of 334 from the 3499 reports analysed in the 2022 Annual SHOT Report (Narayan, et al., 2023). In addition to these 3833 reports, there were 42 reports of immunisation against the D-antigen during pregnancy. These are counted separately as part of a stand-alone study.

The number of reports with potential for patient harm (excluding 'near miss' and 'right blood right patient') is 2154, an increase of 285 from 2022 (n=1869).

Analysis has been carried out on the reports included in the 2023 Annual SHOT Report to look at the number of reports per region/country in each main reporting category, plus cell salvage. Figure 2.5 demonstrates that there is some variability between regions in the percentage of reports across different report types, with near miss reports accounting for between 29.0% and 47.4% of reports in each geographical area.

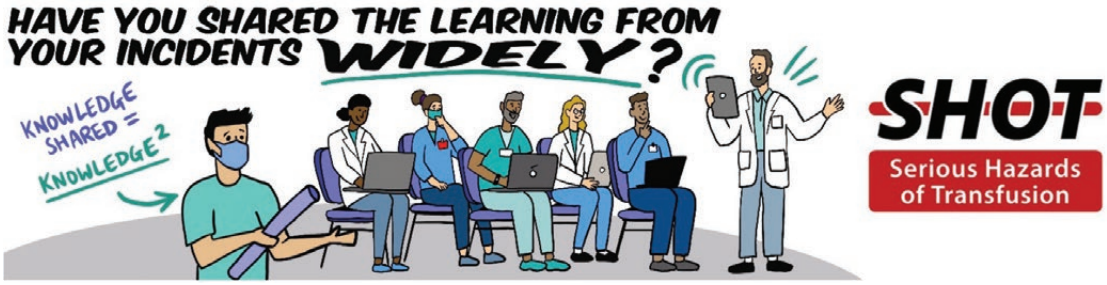
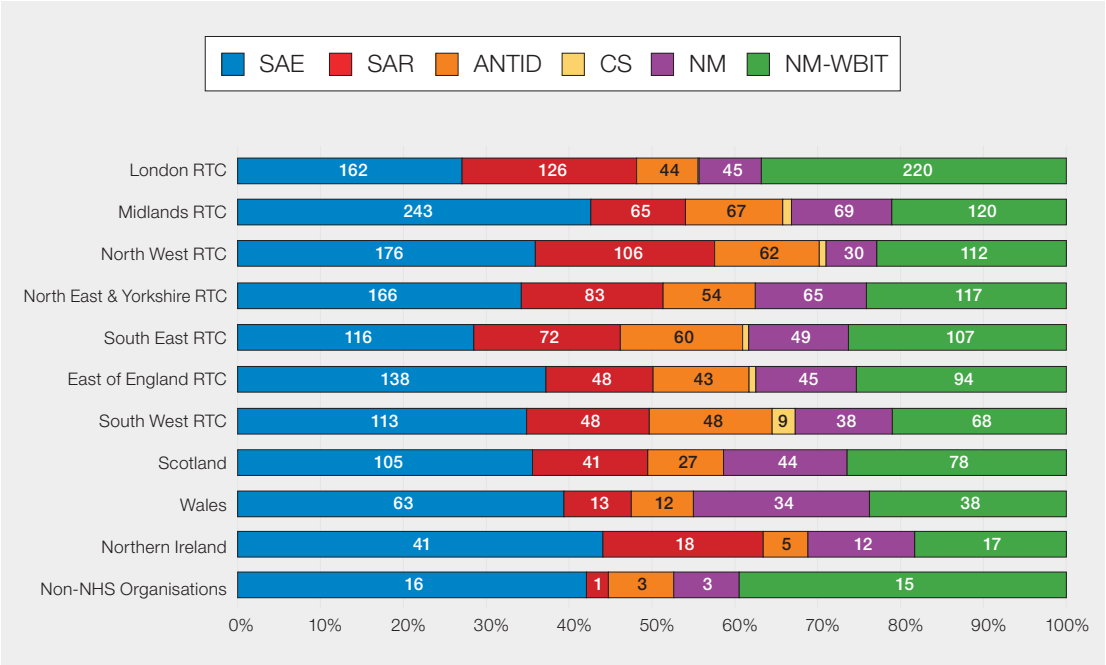


Figure 2.5: Number and percentage of reports in each region/country by category in 2023



ANTID=anti-D immunoglobulin errors; CS=cell salvage; NM=near miss; RTC=regional transfusion committee; SAE=serious adverse event; SAR=serious adverse reaction; WBIT=wrong blood in tube

Note: numbers for CS are too small to be displayed on the figure for most RTC areas

Understanding the contributory factors associated with variations can help identify best practices, areas for improvement, and potential risks, leading to enhanced patient safety and quality of care. Additionally, benchmarking fosters collaboration and knowledge sharing among healthcare professionals resulting in advancements in transfusion medicine.

Reporting organisations in 2023

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

In 2023 there were two NHS Trusts/Health Boards that did not submit any reports. One of these organisations was a medium level blood user (issued with less than 7,000 components in 2022), and the other was a low blood user (issued with less than 1,500 components in 2022).

There were 26 non-NHS organisations that submitted 65 reports in 2023 which is an increase from 2022 (48 reports from 19 non-NHS organisations). This includes healthcare organisations situated in the Channel Islands who are not considered to be a part of the UK and therefore are not regulated by the MHRA. However, they still report to SHOT and incidents submitted are included in this Annual SHOT Report.

SHOT participation benchmarking data

SHOT first began publishing participation benchmarking data in 2011, with the aim of promoting awareness of reporting levels and breadth of reporting (i.e., reporting across a wide range of different categories). Reporters are encouraged to review their individual reports to understand how many reports they submit in each of the 4 main categories of reporting (SAE, SAR, NM, and anti-D), and to benchmark their overall reporting levels against other similar sized organisations.

In 2011 there were 21/188 (11.2%) organisations that submitted reports in less than 2 of the 4 main categories and only 60/188 (31.9%) reported across all 4 categories. This suggested that some

organisations were not fully participating across all areas of haemovigilance. In 2022, there was a reduction in organisations submitting in fewer than 2 reporting categories, 6/173 (3.5%) and a move towards more comprehensive participation, with 83/173 (48.0%) reporting in all 4 main categories (Poles & Narayan, 2024).

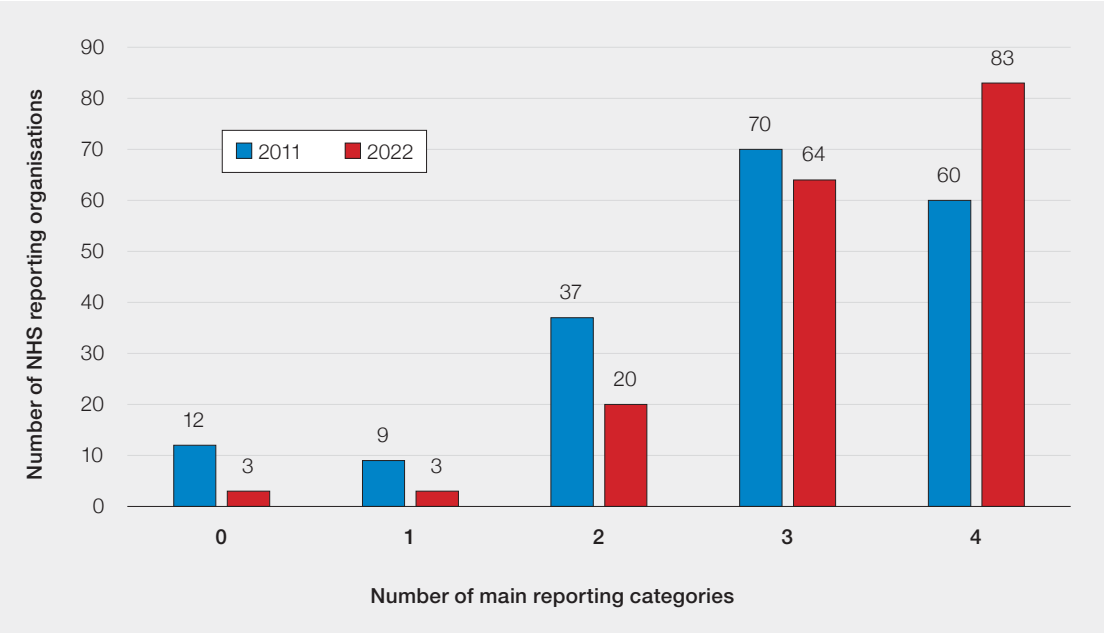


Figure 2.6: Number of NHS organisations submitting in reporting categories 2011 versus 2022

The full 2023 participation benchmarking data for individual organisations will be available to view on the SHOT website in the autumn of 2024. Benchmarking haemovigilance participation data is important for assessing compliance and engagement with haemovigilance reporting, identifying disparities, monitoring progress, potentially informing policy decisions, and promoting accountability. It helps drive quality improvement and ultimately enhances patient safety in blood transfusion practices.

SHOT also provides monthly participation data, 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.

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

SHOT
Serious Hazards of Transfusion

Improvements to the SHOT reporting database

The online SHOT reporting system (supplied by Dendrite Clinical Systems Ltd) was upgraded at the end of 2023 to modernise the user interface and improve the reporting experience. One of the main changes was to colour code the questions for status. Unanswered questions are coloured in red, and completed questions are green. It is hoped that this will encourage more complete reporting and in turn, improve the quality of the data analysed in the Annual SHOT Report.

A user-satisfaction survey to assess reporters opinions on the new interface will be conducted in the second half of 2024.

Planned future developments include implementation of dashboards which will provide real-time visibility of key metrics such as the number of reports submitted by time period, reporting category, location etc. These will enable stakeholders to make informed decisions and readily identify areas where tangible actions are needed. These dashboards may help facilitate local improvements with regard to reporting benchmarking and further actions.

Conclusion

SHOT is grateful for and appreciates the dedication of healthcare staff who contribute towards and participate in haemovigilance reporting and related activities. This speaks volumes about their commitment to patient safety and quality care. It demonstrates their recognition of the importance of monitoring and improving blood transfusion practices amidst challenging circumstances. Their efforts contribute to a culture of vigilance, continuous learning, and improvement in transfusion practice, ultimately benefiting patient outcomes.

Recommended resources

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

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

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

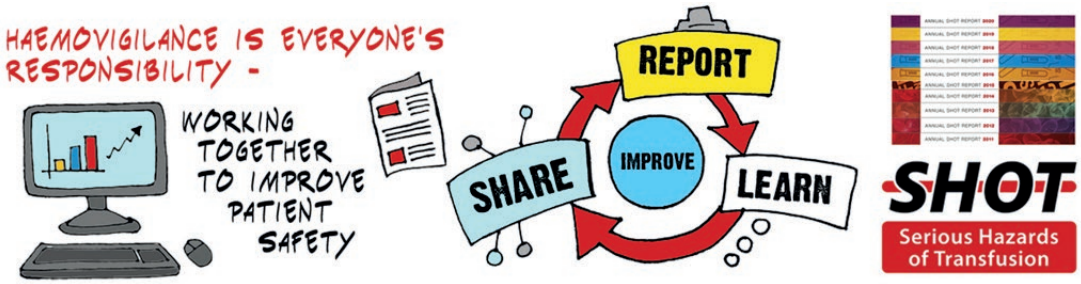
References

Narayan, S. et al., 2023. *The 2022 Annual SHOT Report,* Manchester: Serious Hazards of Transfusion (SHOT) Steering Group. doi: https://doi.org/10.57911/605r-em59.

Poles, D. & Narayan, S., 2024. *Looking back to plan ahead: Reflections on over a decade of SHOT UK haemovigilance participation benchmarking data.* Athens, International Haemovigilance Network (IHN). Available at: https://ihn-org.com/ihn-symposium/posters/ (Accessed 01 July 2024).

Ryan, J., Poles, D., Davies, J. & Narayan, S., 2022. *Why has my SHOT report been withdrawn?.* Glasgow, British Blood Transfusion Society (BBTS). Available at: https://www.shotuk.org/shot-publications-2/shot-publications-posters (Accessed 11 April 2024).

Thomas, S. et al., 2022. Importation of plasma and use of apheresis platelets as risk reduction measures for variant Creutzfeldt-Jakob disease: The SaBTO review. *Transfusion Medicine,* 32(1), pp. 24-31. doi: https://doi.org/10.1111/tme.12840.



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

Authors: Shruthi Narayan and Debbi Poles

Abbreviations used in this chapter

ABOi	ABO-incompatible	**SD-FFP**	Solvent-detergent treated fresh frozen plasma
CAS	Central alerting system	**SRNM**	Specific requirements not met
IBCT	Incorrect blood component transfused	**TACO**	Transfusion-associated circulatory overload
NHS	National Health Service	**UK**	United Kingdom
NM	Near miss	**WBIT**	Wrong blood in tube
RBRP	Right blood right patient	**WCT**	Wrong component transfused

Key SHOT messages

- Errors (including near miss) continue to account for the vast majority of reports. In 2023, 3184/3833 (83.1%) of all reports were due to errors with a substantial increase (24.1%) in laboratory errors where the error was not detected prior to transfusion (transfused errors)
- A steep increase in the transfused laboratory errors in the IBCT-WCT (65.1%) and IBCT-SRNM (43.1%) categories in comparison to 2022 is concerning and warrants urgent action. Staffing issues, gaps in staff knowledge, poor skill mix, lone working, ineffective IT, communication issues and poor safety culture have been reported as contributory factors in these incidents
- Near miss events continue to account for a large proportion, 1420/3833 (37.0%) of the incidents reported to SHOT
- An increase in the febrile, allergic and hypotensive reactions was noted as compared to previous years. No changes were evident in the number of haemolytic reactions reported to SHOT. All staff involved in transfusions must be competent and confident in recognising and appropriately managing transfusion reactions in recipients
- Transfusion delays and pulmonary complications (TACO and non-TACO) continue to be the leading causes of transfusion-related deaths in the UK. These two categories together accounted for 29/38 deaths reported (76.3%)
- The risk of death related to transfusion in the UK is approximately 1 in 58,000 components issued and the risk of serious harm is approximately 1 in 11,000 components issued. This includes SD-FFP data
- ABO-incompatible red cell transfusions continue to occur as a result of suboptimal safety checks throughout the process. Using a patient side pre-administration checklist correctly can prevent incorrect transfusions in most cases

Given the continuing increasing trend in safety incidents reported, the recommendations from last year remain pertinent.

Recommendations

- 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 nations), hospital transfusion teams

- The recommendations from the UK-wide national patient safety alerts on preventing transfusion delays (SHOT, 2022) and TACO (MHRA and SHOT, 2024) must be implemented effectively to improve patient safety and address avoidable patient harm from these causes

Action: Hospital chief executives and medical directors, hospital transfusion teams

Introduction

The SHOT haemovigilance data from 2023 show worrying trends which reflect the increasing pressures healthcare staff continue to face in the UK. These are elaborated on further in this chapter and throughout the 2023 Annual SHOT Report. The risk of death related to transfusion in the UK is approximately 1 in 58,000 components issued, and the risk of serious harm is approximately 1 in 11,000 components issued.

Avoidable errors continue to account for most of the reports 3184/3833 (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.

Figure 3.1: Errors account for most reports in 2023 (n=3184/3833)

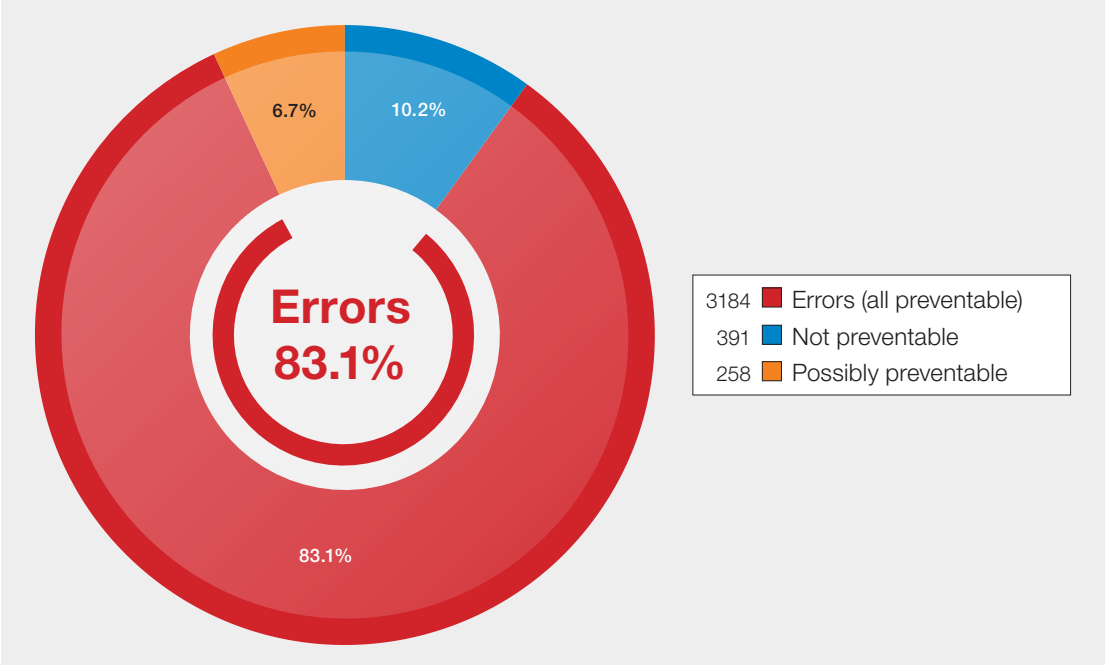


Figure 3.2 shows the percentage of no harm incidents in the errors reported to SHOT in recent years. It is concerning to note a dip in the percentage of no-harm incidents in 2023 which conversely means an increase in potential patient-harm incidents reported. This highlights the urgent need for actions to improve transfusion safety.

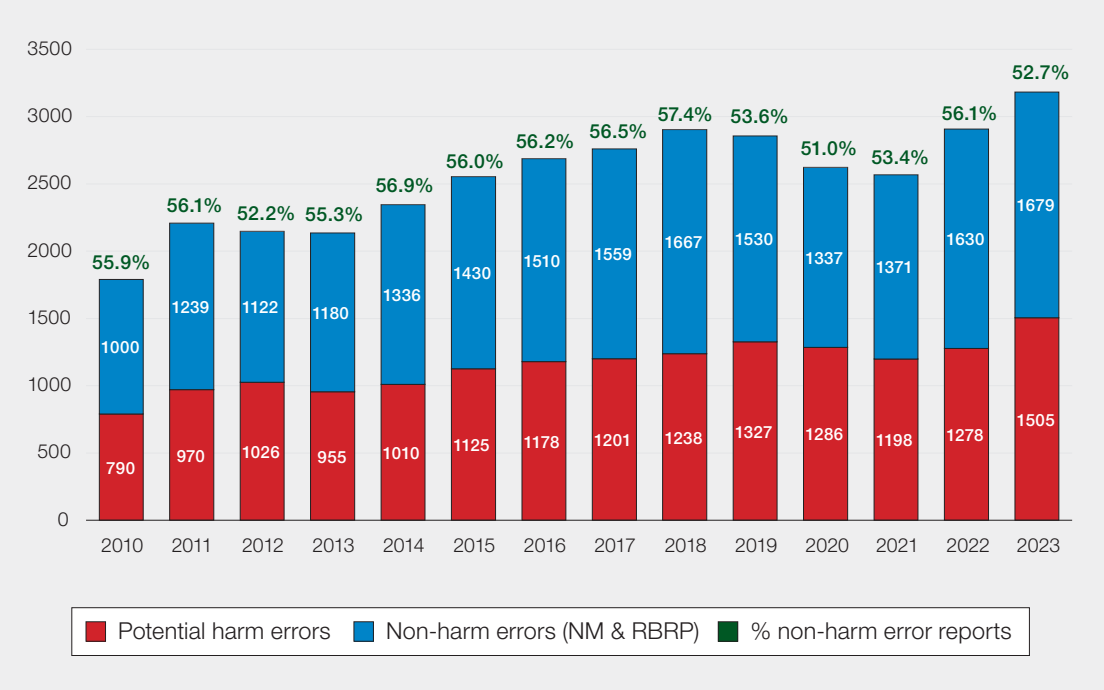


Figure 3.2: No patient-harm and potential patient-harm incidents 2010-2023

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

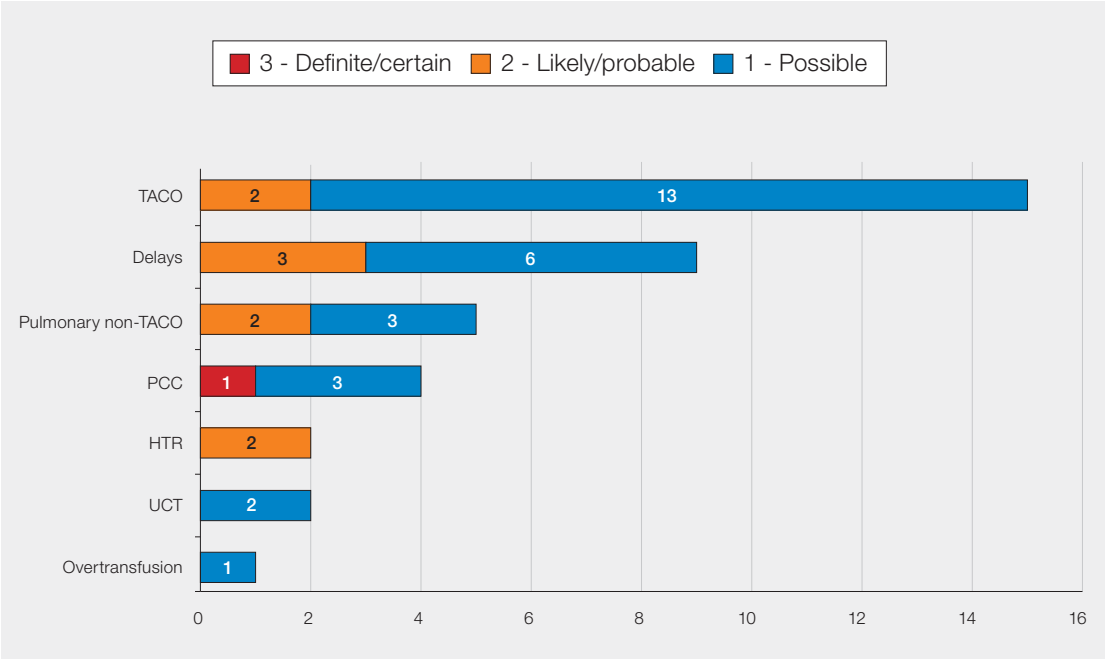
Non-harm incidents include near miss (NM) and right blood right patient (RBRP) errors

Deaths related to transfusion n=38

All serious reactions reported to SHOT are assessed for imputability i.e., the relationship of the blood transfusion to the reaction. The imputability criteria can be found in the SHOT definitions document (see 'Recommended resources').

Pulmonary complications and transfusion delays were the most common causes of transfusion-related deaths reported to SHOT in 2023, accounting for 29/38 (76.3%) of total deaths. In 2023, TACO (n=15) was responsible for the highest number of deaths in a single category reported to SHOT, followed by delays (n=9). A UK-wide national patient safety alert has recently been issued to address rising deaths from TACO (MHRA and SHOT, 2024). There has been a slight reduction in the number of deaths due to delays in 2023. It is too early to tell if the impact of the recommendations in the SHOT CAS alert (SHOT, 2022) have helped to reduce these, but it is hoped that this downward trend will continue. Non-TACO pulmonary cases accounted for 5 patient deaths. Key factors identified in the transfusion-related deaths are discussed in the relevant chapters of this Annual SHOT Report. Figure 3.3 shows the distribution of deaths related to transfusion reported in 2023 with imputability.

Figure 3.3: Deaths related to transfusion with imputability reported in 2023 (n=38)



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

A detailed review of the preventable factors in the transfusion-related deaths reported in 2023 can be found in the supplementary information on the SHOT website (https://www.shotuk.org/shot-reports/report-summary-and-supplement-2023/).

Figure 3.4 shows the trend in the transfusion-related deaths reported to SHOT since 2010. It is concerning to note an increasing trend in the deaths reported especially related to transfusion delays and pulmonary complications. While this could be attributed to improved reporting, the increase in the deaths post pandemic possibly reflects the worsening challenges faced in healthcare. Delayed healthcare access with sicker patients, worsening staffing issues with difficulties in staff recruitment and retention resulting in a mismatch between staff availability and workload; accelerated and abbreviated staff training; poor IT and other supporting resources could all be contributory. UK-wide national patient safety alerts addressing preventable transfusion delays and TACO have been issued. These provide system-level improvement actions to help improve patient safety.

It is important to note that 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 means addressing key constraints in each of these areas. Transfusion incidents reported to SHOT are commonly errors caused by faulty systems, processes, and conditions. The key to 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. These safety messages and recommendations have been reinforced repeatedly in recent Annual SHOT Reports (Narayan, et al., 2021; Narayan, et al., 2022; Narayan, et al., 2023) and remain pertinent as they have not been addressed meaningfully.

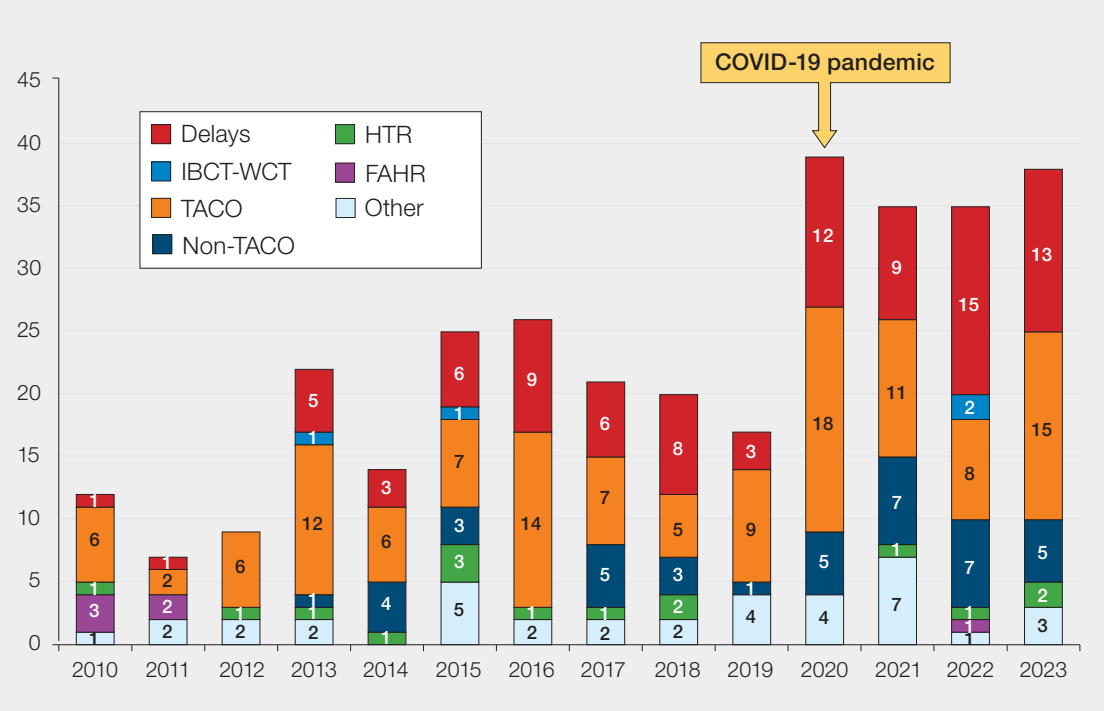


Figure 3.4: Transfusion-related deaths 2010 to 2023 (n=320)

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

Delays include 1 delay related to PCC in 2019, 2 in 2022 and 4 in 2023; 'Other' includes 1 each for post-transfusion purpura, transfusion-associated graft-versus-host disease (2012) and anti-D Ig related; there were 9 in the avoidable, over or undertransfusion category, 3 transfusion-transmitted infections, and 22 deaths related to other unclassified reactions

Major morbidity n=197

Febrile, allergic, or hypotensive transfusion reactions continue to account for most of the cases with major morbidity, 119/197 (60.4%) followed by TACO, 20/197 (10.2%). These are detailed further in the respective chapters in this Annual SHOT Report. Major morbidity is defined in the SHOT definitions document which is reviewed and updated annually (see 'Recommended resources').

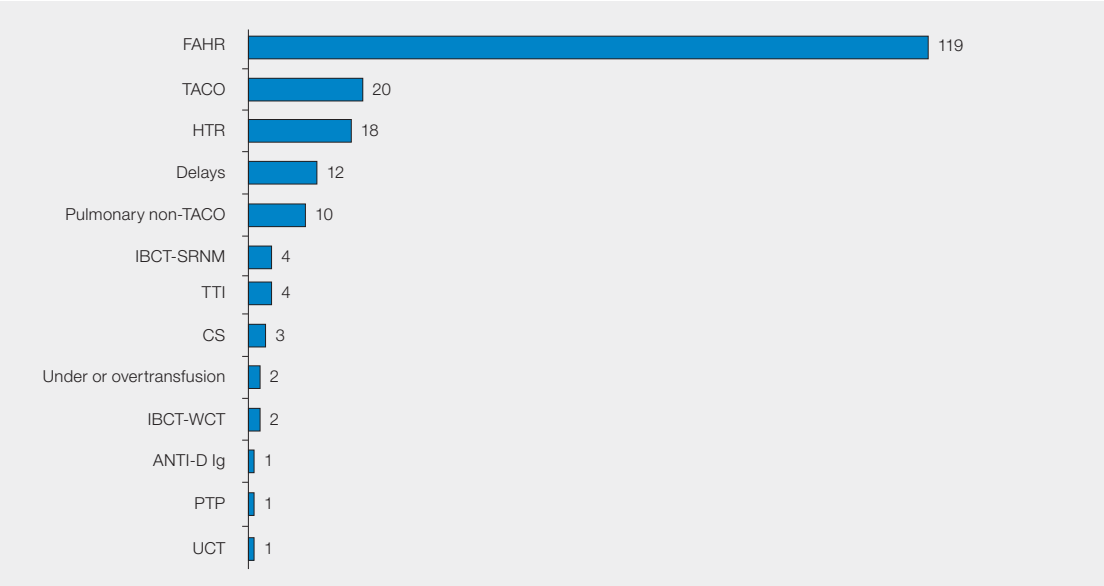


Figure 3.5: Ranking of categories to show number of serious reactions in 2023 (n=197)

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; IBCT-WCT=IBCT-wrong component transfused; CS=cell salvage; PTP=post-transfusion purpura; TTI=transfusion transmitted infections; UCT=uncommon complications of transfusion

Costs of SHOT-reported events resulting in major morbidity and death (where it is likely or definite that the reaction was caused by the blood component)

Acknowledgements: Dr Elizabeth A Stokes, Health Economics Research Centre, Nuffield Department of Population Health, University of Oxford and Prof Lise J Estcourt, Medical Director for Transfusion, NHS Blood and Transplant

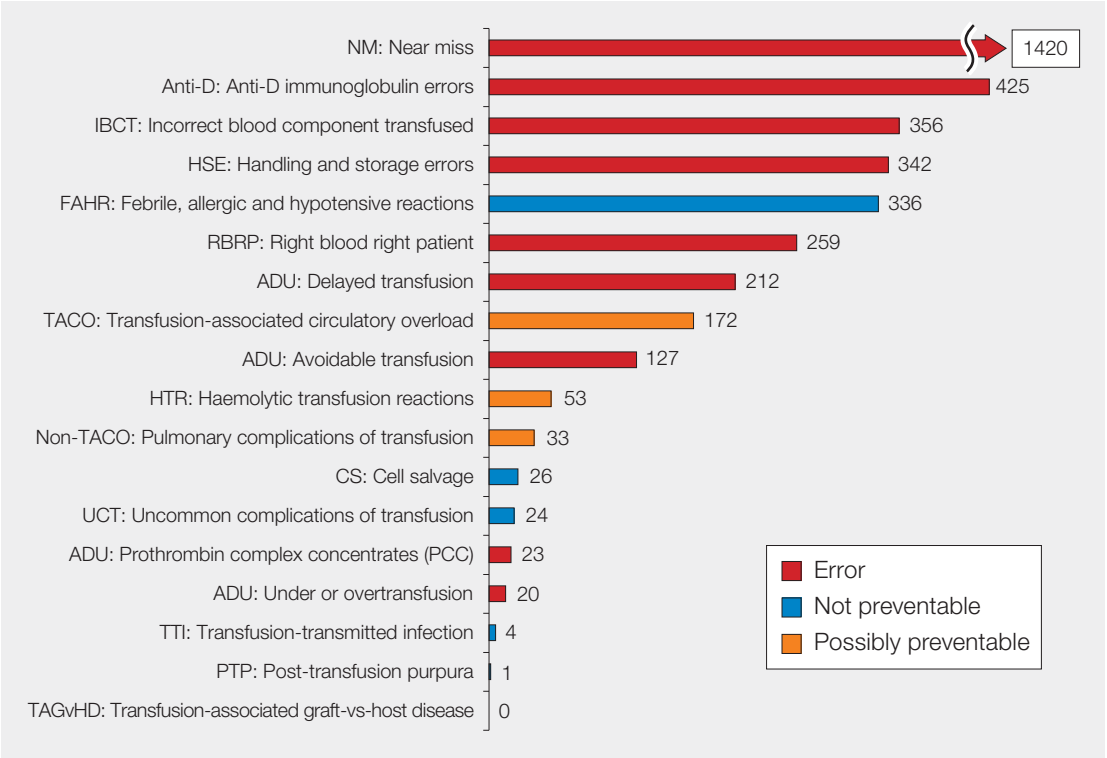
This study's aim is to estimate the costs of acute management of SHOT-reported events resulting in major morbidity or death from the hospital perspective. All transfusion-related deaths reported to SHOT in 2018-2022 where it was likely or definite that the reaction was caused by the blood (imputability 2 or 3) have been reviewed; and all cases with major morbidity reported to SHOT in 2021- 2022, where the adverse reaction was definitely attributable to the blood.

Preliminary findings: from 9 deaths and 19 cases of major morbidity reported in 2022, the average costs (range) per case were £5,319 (£0 - £36,899). The key cost drivers were intensive care bed days and medications. The findings will be written up for publication.

Summary data and risks associated with transfusion

Data collected in 2023 are shown in Figure 3.6. Near miss reports continue to be the largest category of reports, 1420/3833 (37.0%), however, this is a slight reduction on the overall percentage of reports in 2022 (39.0%). Reporting and investigating near misses helps identify and control risks before actual harm results, providing valuable opportunities to improve transfusion safety. Cumulative haemovigilance data from SHOT between 1996-2023 are shown in Figure 3.7.

Figure 3.6: Summary data for 2023, all categories (includes RBRP and NM) (n=3833)



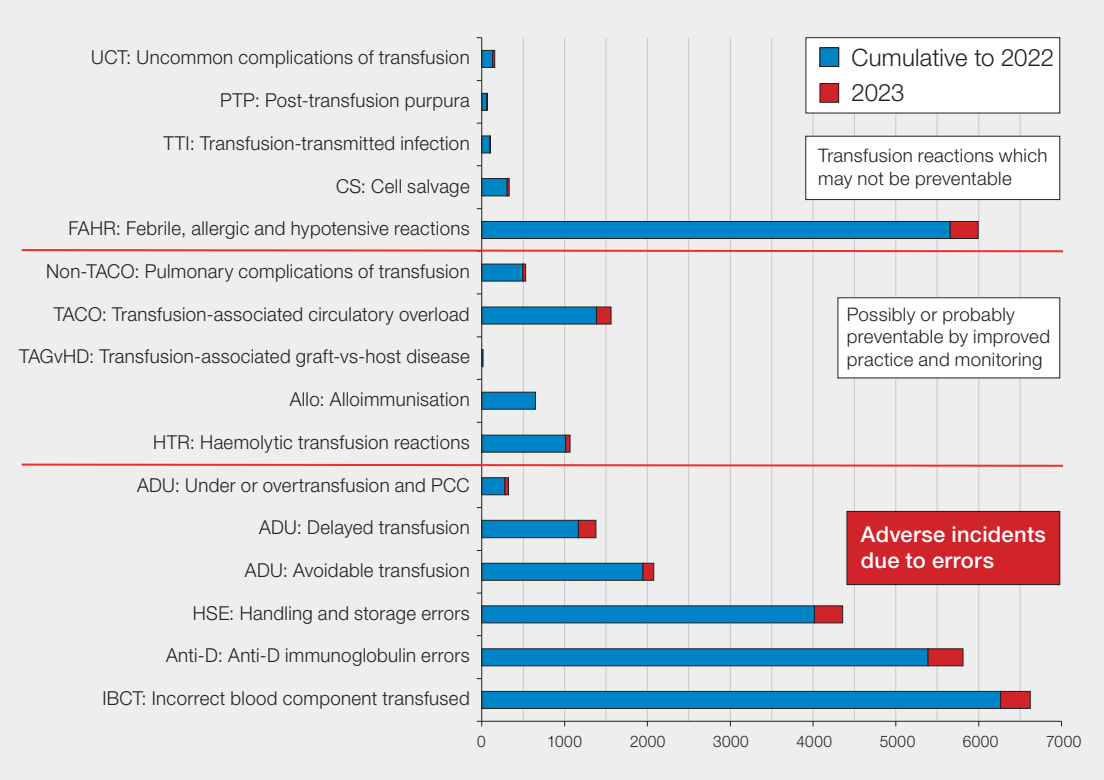


Figure 3.7: Cumulative data for SHOT categories 1996-2023 (n=31025)

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

ABO-incompatible (ABOi) transfusions n=10

In 2023, there were 7 ABOi red cell transfusions reported and 3 ABOi plasma transfusions, with 2 major morbidities following ABOi red cell transfusion. There was no clinical reaction in the remaining cases. Figure 3.8 shows the number of ABOi red cell transfusions reported to SHOT in the last decade and Figure 3.9 shows the number of ABOi plasma transfusions reported. Figure 3.10 shows the outcome of ABOi red cell transfusions reported to SHOT since reporting began in 1996.

All 7 ABOi red cell cases reported in 2023 were in adult transfusion recipients and all following primarily clinical errors. Four were related to blood collection errors, and 3 to administration errors. The 3 administration errors resulted from a lack of pre-transfusion safety checks which provide a final opportunity to detect mistakes prior to administration.

Of the ABOi plasma transfusions, 2 were due to component selection errors in the transfusion laboratory, with group O plasma components being transfused to a group A and a group B recipient respectively. The 3rd case occurred in 2011 following a historical WBIT and was identified in 2023.

These cases are explored in more detail in Chapter 10, Incorrect Blood Component Transfused (IBCT) and Chapter 15, Laboratory Errors.

Figure 3.8: Number of ABO-incompatible red cell transfusions 2014-2023

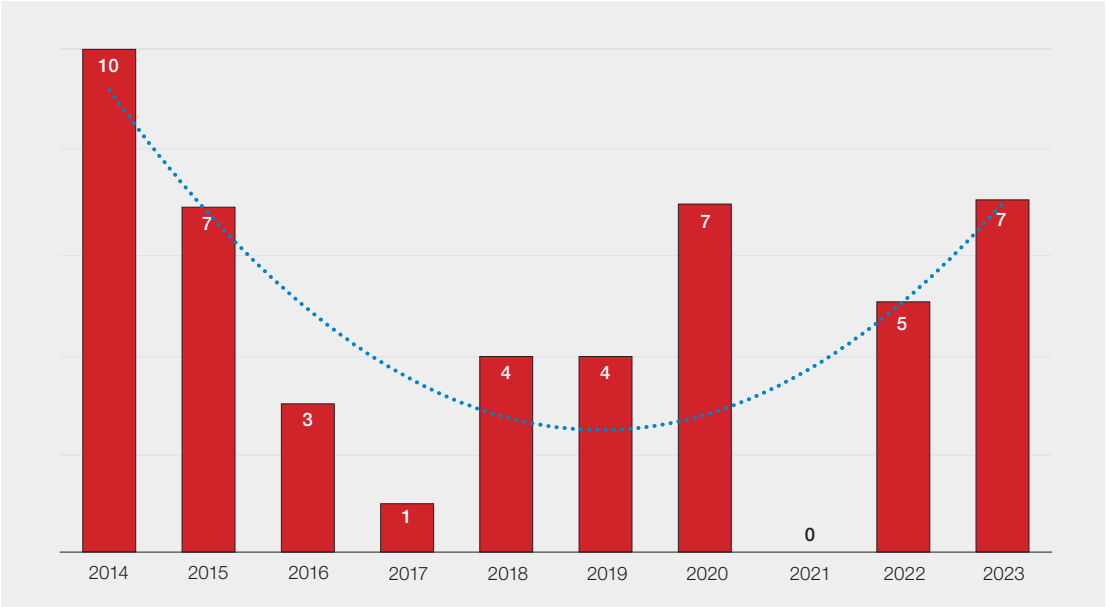


Figure 3.9: Number of ABO-incompatible plasma transfusions 2014-2023

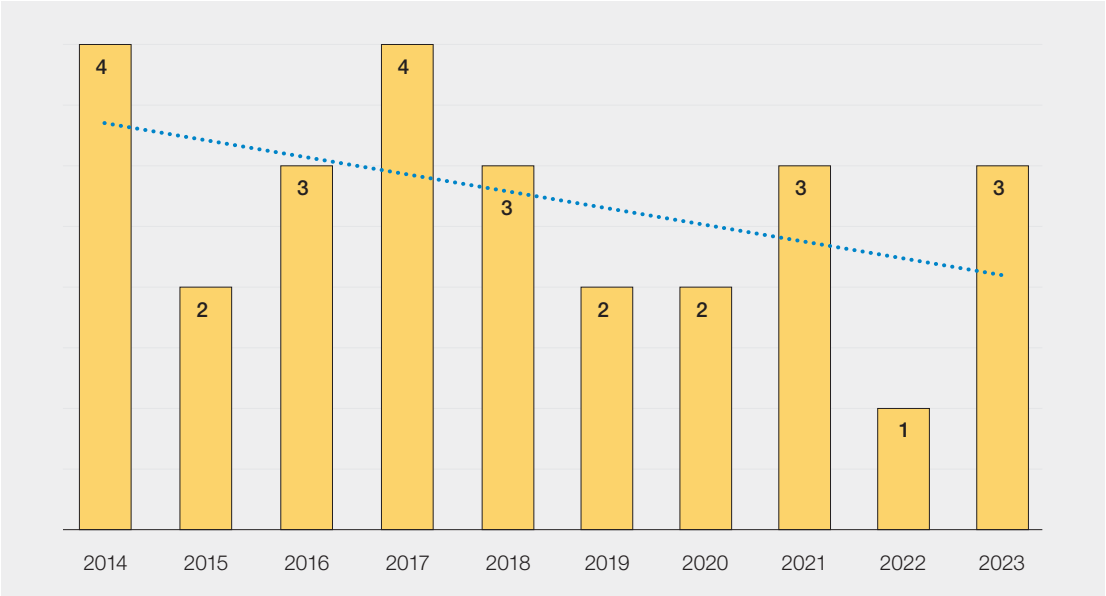
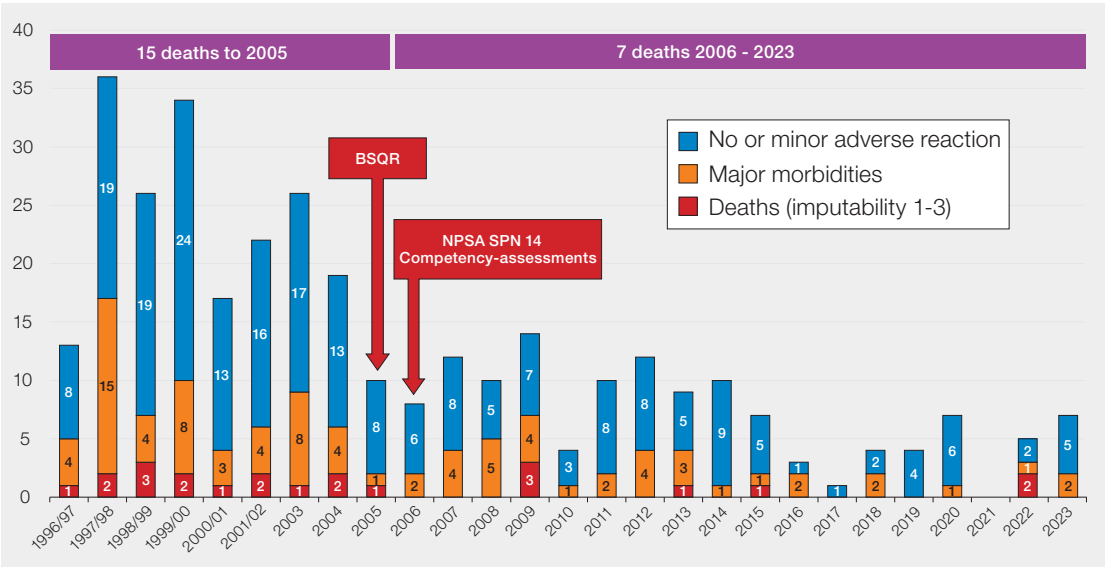


Figure 3.10: Outcome of ABO-incompatible red cell transfusions in 26 years of SHOT reporting



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

Transfusion of group A red cells to group O patients was associated with the greatest risk of major morbidity, 15/46 (32.6%), 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 3.11 below.

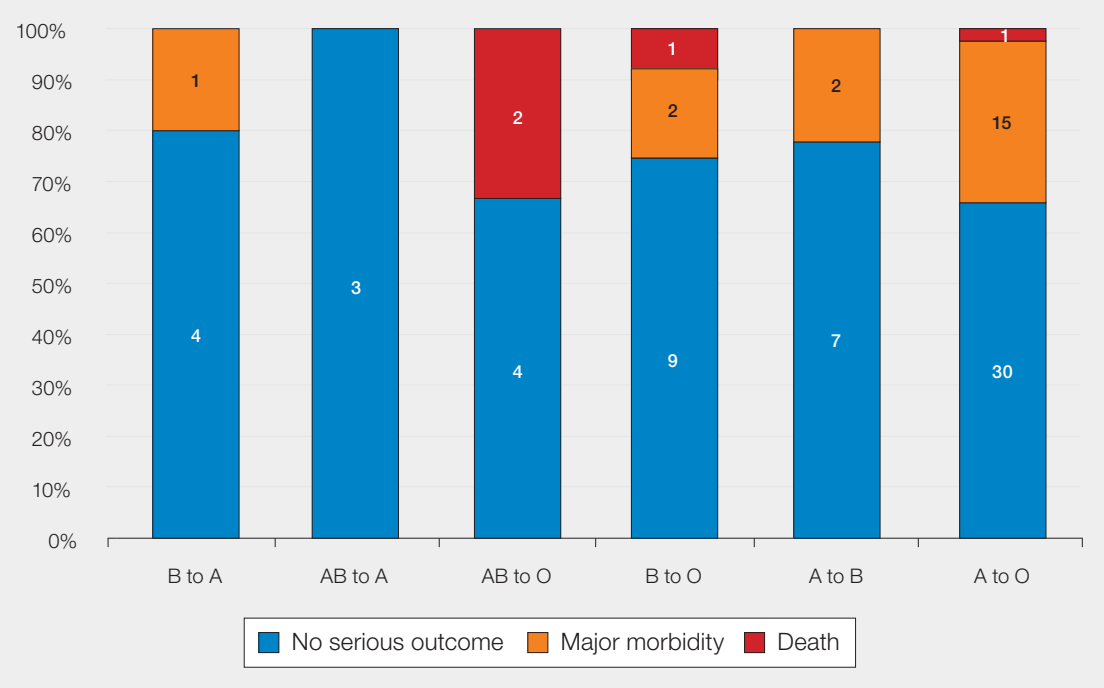


Figure 3.11: ABO-incompatible transfusions and outcome by groups 2010-2023 (n=81)

NHS England is in the process of reviewing the Never Events list and framework. This aims to clarify whether the current framework is an effective mechanism to drive patient safety improvement. Further details can be found at this link: https://www.england.nhs.uk/long-read/never-events-framework-consultation/. SHOT has provided input into this consultation, supporting review of the framework with continued inclusion of ABOi events, and facilitating appropriate system-level improvements to help prevent these.

Data from 2016-2023 show that although there were 31 ABOi red cell transfusions, there were 2390 near misses where an ABOi transfusion could have resulted. The majority of these were WBIT incidents which constitute the largest subset of near miss cases reported to SHOT in 2023, 986/1420 (69.4%), and these are discussed in Chapter 13a, Near Miss – Wrong Blood in Tube (WBIT). These may not be detected routinely unless there is a historical record in the transfusion laboratory and demonstrate the importance of the group-check policy (Milkins, et al., 2013). These errors, which could have lethal outcomes, highlight the risk of not undertaking positive patient identification at the time of collecting and labelling pre-transfusion samples. As is evident from the iceberg representation (Figure 3.12), these occur much more frequently and afford more opportunities to learn than the rarer serious adverse events. When WBIT are not identified or investigated, they represent missed opportunities that can contribute to future risks of potentially lethal ABOi.

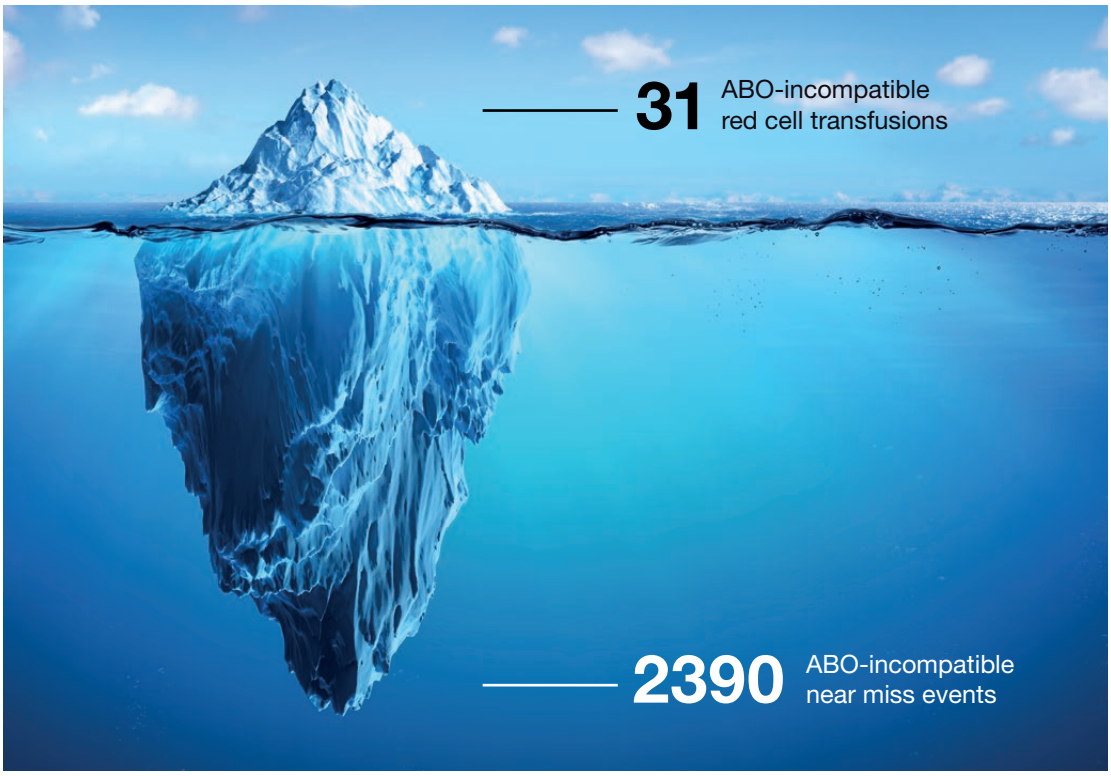


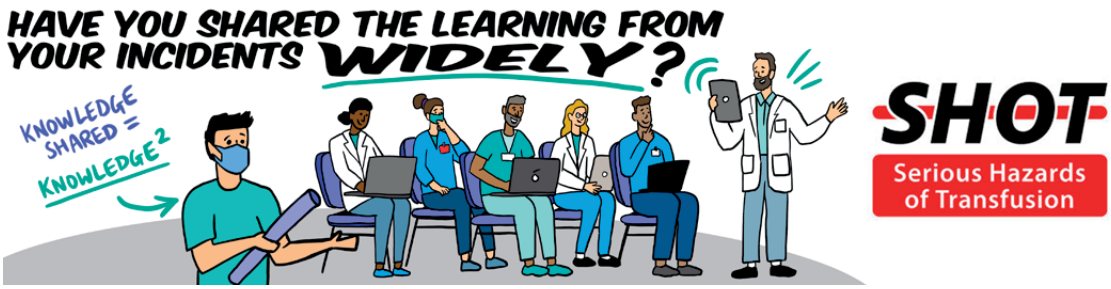
Figure 3.12: ABO-incompatible red cell transfusions 2016-2023: few events (n=31) but many near misses (n=2390)

Recognising WBIT as potential harm events, identifying and addressing causal and contributory factors is crucial to improve patient safety and prevent future ABOi transfusions that could result in patient death.

Conclusion

Worrying signals are emerging from the haemovigilance data with increasing numbers of preventable errors and potential harm incidents. While it is encouraging to see improved haemovigilance reporting, it is evident that staff have absolutely no spare capacity and are stretched beyond breaking point with an increasing number at risk of burn out. A shortage of skilled workers, demoralised healthcare staff and poorly-resourced healthcare organisations with unreliable or ineffective IT systems reflect an NHS in crisis and an urgent need for reset. A coordinated approach to improve safety should focus on increasing and supporting the clinical and laboratory workforce, fostering an environment where existing staff can flourish and collaborate, and ensuring reliable IT systems. The NHS must be staffed and funded appropriately to deliver optimal care for patients. 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 and promoting a holistic approach to safety is vital in helping bridge this gap.

Further information and data can be found in the supplementary information on the SHOT website (https://www.shotuk.org/shot-reports/report-summary-and-supplement-2023/).



Recommended resources

SHOT Bite No. 1a and 1b: Incident Investigation
SHOT Bite No. 17: Near Miss
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/

SHOT Definitions
https://www.shotuk.org/reporting/

References

Medicines & Healthcare products Regulatory Agency (MHRA) and Serious Hazards of Transfusion (SHOT), 2024. *Central Alerting System: Reducing risks for transfusion-associated circulatory overload.* [Online] Available at: https://www.cas.mhra.gov.uk/ViewandAcknowledgment/ViewAlert.aspx?AlertID=103249 (Accessed 08 April 2024).

Milkins, C. et al., 2013. Guidelines for pre-transfusion compatibility procedures in blood transfusion laboratories. *Transfusion Medicine,* 23(1), pp. 3-35. doi: https://doi.org/10.1111/j.1365-3148.2012.01199.x.

Narayan, S. et al., 2021. *The 2020 Annual SHOT Report,* Manchester: Serious Hazards of Transfusion (SHOT) Steering Group. doi: https://doi.org/10.57911/FN15-ME02.

Narayan, S. et al., 2022. *The 2021 Annual SHOT Report,* Manchester: Serious Hazards of Transfusion (SHOT) Steering Group. doi: https://doi.org/10.57911/QZF9-XE84.

Narayan, S. et al., 2023. *The 2022 Annual SHOT Report,* Manchester: Serious Hazards of Transfusion (SHOT) Steering group. doi: https://doi.org/10.57911/WZ85-3885.

Serious Hazards of Transfusion (SHOT), 2022. *Central Alerting System: Preventing transfusion delays in bleeding and critically anaemic.* [Online] Available at: https://www.cas.mhra.gov.uk/ViewandAcknowledgment/ViewAlert.aspx?AlertID=103190 (Accessed 08 April 2024).

4 Key Messages and Recommendation

Authors: Caryn Hughes, Jennifer Davies and Shruthi Narayan

Abbreviations used in this chapter

ABOi	ABO-incompatible
CIEHF	Chartered Institute of Ergonomics & Human Factors
GMC	General Medical Council
HCPC	The Health and Care Professions Council
HSSIB	Health Service Safety Investigations Body
ID	Identification
IT	Information technology
JPAC	Joint United Kingdom (UK) Blood Transfusion and Tissue Transplantation Services
LIMS	Laboratory information management system
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
NMC	Nursing and Midwifery Council
PID	Patient identification
RCP	Royal College of Physicians
SaBTO	Advisory Committee on the Safety of Blood, Tissues and Organs
SOP	Standard operating procedure
TACO	Transfusion-associated circulatory overload
UK	United Kingdom
UKTLC	UK Transfusion Laboratory Collaborative
WBIT	Wrong blood in tube

Key SHOT messages

- **Making safe transfusion decisions and ensuring patients are well informed:** Transfusions are very safe and effective when used appropriately. All staff involved in the transfusion pathway need to have relevant knowledge, appropriate to their role, of blood components, indications for use, alternate options available, risks and benefits, possible reactions and their management. Unnecessary transfusions must be avoided. Patients or their carers must be informed about the risks, benefits and alternatives to transfusions
- **Addressing transfusion errors**: Errors continue to be the source of most SHOT reports (83.1%). While transfusions are largely safe, errors can result in patient harm. Communication issues, assumptions and distraction compounded by staffing issues, ineffective and misuse of IT and poor safety culture contribute to errors. Errors must be investigated using human factors principles-based incident investigations and appropriate improvement measures implemented
- **Ensuring clinical and laboratory transfusion teams are well resourced:** Adequate numbers of appropriately trained staff must be available to ensure safe transfusions; there should be contingency planning for staffing levels below a minimum level and for times of high workload. Safe staffing levels matched to the workload with well-resourced systems are vital for ensuring high quality care for patients and safety. Together they form the foundation for an effective healthcare system that prioritises patient safety above all else
- **Addressing knowledge gaps, cognitive biases, and holistic training:** Transfusion training with a thorough and relevant transfusion knowledge base should be available to all clinical and laboratory staff. They should also receive training in patient safety principles, application of human factors principles and quality improvement approaches. It is important that staff understand how cognitive biases and assumptions contribute to poor decision making so that they can be mitigated appropriately

- **Policies and processes:** Policies, guidelines/decision making aids and SOP need to be simple, clear, easy to follow and explain the rationale for each step. These should be up to date, accessible and reflect current national guidelines and recommendations. This will ensure staff are engaged and more likely to follow process, thereby avoiding any workarounds or deviations
- **Safety culture:** Fostering a strong and effective safety culture that is 'just, restorative and learning' is vital to reduce transfusion incidents and errors, enhancing patient safety. Staff should be able to confidently raise concerns, discuss issues and promote innovative ideas for improvement. Regular monitoring of the safety culture and its impact on patient safety; and staff wellbeing should be in place to ensure timely improvement actions are implemented
- **Learning from near misses:** Reporting and investigating near misses helps identify and control risks before actual harm results, providing valuable opportunities to improve transfusion safety. The appropriate response to a near-miss with potential for high-risk transfusion event includes: (1) reporting to haemovigilance agencies as required, (2) investigating near misses, (3)developing and implementing a corrective and preventative action plan and (4) monitoring the effectiveness of interventions
- **Shared care:** Clear, timely and comprehensive communication between all teams and hospitals involved in the patient-care pathway is vital in ensuring patient safety. Robust and transparent processes must be in place for safe and effective transfer of information at all points in the patient care pathway
- **Investigating incidents and focussing on improvements:** Investigations must be systematic and thorough, using human factors principles and systems thinking in order to identify systems-based corrective and preventative actions. Systemic and organisational problems should be fully investigated, as staff-related actions are unlikely to resolve underlying systemic issues. Learning from the incidents should be shared widely
- **Safety checks before transfusions:** The pre-transfusion patient-side safety check provides a final opportunity for staff to identify errors ensuring the right component with the right specification is transfused to the right patient; the TACO risk assessment facilitates appropriate mitigating measures in vulnerable patients at high risk of TACO. These checks serve as safety pauses to ensure staff safeguard patient well-being and prevent potentially life-threatening complications. These are not tick-box exercises
- **Patients as safety-partners:** Staff must ensure that they involve, engage, and listen to patients as 'partners' in their own care and decision-making to support safe transfusions. Engaging patients, their families, and carers as 'safety partners' helps co-create safer systems, identify, and rectify preventable adverse events

The 2023 Annual SHOT Report highlights continuing error trends with 83.1% reports in 2023 related to avoidable errors. Continuing reports of preventable ABOi transfusions, transfusion delays, avoidable transfusions and TACO are sobering to read. A steep increase in the laboratory transfused errors reported and the worrying signals evident from the recent SHOT-UKTLC survey on safety culture in the transfusion laboratories cannot be ignored and call for urgent action (see 'Recommended resources').

All staff involved in blood transfusions should have a basic knowledge of blood components, indications for use, alternative options available, risks and benefits, possible reactions, and their management. This

will help staff to have meaningful discussions with patients, carers and families; support shared decision-making and consent in accordance with the SaBTO recommendations (SaBTO, 2020). Anecdotal reports of suboptimal consent practices are evident in this report where patients were not adequately informed about the risks, alternatives, or potential consequences of transfusions. Consent in transfusion is crucial to facilitate shared decision-making with patients being able to make informed choices about their care. A recent national comparative audit of the NICE Quality Standard QS138 revealed that only 475/1356 (35%) of transfused patients had evidence of receiving both written and verbal information about the risks, benefits, and alternatives to transfusion (compared to 26% in the 2021 audit). All hospitals should urgently review local consent practices, initiate improvements, and ensure optimal consent and shared decision making for safe patient care. Table 4.1 highlights the key aspects that need to be covered when consenting patients for transfusions. See 'Recommended resources' at the end of this chapter for links to the national comparative audit and patient information pages on the SHOT and JPAC websites.

Table 4.1: Key aspects to be covered when consenting patients for transfusion

	Key aspects to be covered when consenting patients for transfusion
1	Patient and/or family/carer have been provided with relevant information about blood transfusions that would help in their decision-making process
2	The reason for the transfusion has been discussed
3	The benefits of the transfusion have been explained
4	Transfusion risks, both short and long-term risks have been discussed with the patient and/or family/carer (including any additional risks pertinent to long term multi-transfused patients)
5	The risks, benefits, and consequences of NOT accepting blood transfusion have been elaborated
6	Transfusion issues specific to the patient have been highlighted
7	Relevant alternative options have been discussed including how they might reduce the need for a transfusion
8	The transfusion process has been explained
9	The need for any specific requirements for blood components and rationale, including need for anti-D Ig post transfusion as appropriate has been elaborated and relevant patient information leaflet has been provided
10	Patient and/or family/carer has also been informed that once transfused, they are no longer eligible to donate blood
11	Patients and carers/family have been given the opportunity and been encouraged to ask questions
12	Patient and/or family/carer is aware that if they change their mind at any point before the transfusion, they are entitled to withdraw their consent, and this should be documented and managed appropriately
13	Synopsis of discussions and decisions taken documented in patient's clinical notes

The Safe Transfusion Checklist that is available to download from the SHOT website covers key aspects of the transfusion process at the patient side and the ABCDE approach to transfusions support safe decisions and helps avoid unnecessary transfusions (https://www.shotuk.org/resources/current-resources/).

Errors in transfusion persist due to a combination of factors including complex processes, communication issues, lack of standardisation, inadequate training, or resources including suboptimal implementation or use of transfusion IT. Failing to identify and implement system-focussed 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 while striving to deliver safe care amidst all the challenges. These have also been highlighted throughout the report. It is encouraging to see a wider recognition of the importance of human factors and ergonomics principles but more needs to be done to embed 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.

Key SHOT recommendations for 2023

The following main recommendations have been drafted to address the recurring themes identified in the analysed SHOT reports that impact transfusion safety. Previous SHOT recommendations remain pertinent, and organisations must endeavour to progress implementation of the same if gaps are identified.

Addressing patient identification errors to enhance transfusion safety

Patient misidentification poses a risk to patient safety and has the potential to result in significant harm. Errors are often the result of multiple factors and patients are at greater risk of misidentification in certain settings or situations for e.g., handovers, shared care between hospital and clinical settings and in emergencies. All staff involved in patient care should be aware of the key patient identification criteria as per local policies and national guidelines (Robinson, et al., 2018).

PID errors occur at all stages of the transfusion process. Examples include clinical staff incorrectly transcribing or missing vital patient demographics when completing request forms and sample labelling, maternal and cord blood samples being incorrectly labelled and laboratory staff not transcribing and inputting data accurately into the LIMS during the booking-in of samples. Many PID errors are the result of inadequate systems suggesting that investigations into PID errors must be designed to highlight and resolve these system failures, i.e., identifying and addressing the human factors and ergonomics aspects.

Inaccurate and incorrect patient identification is commonly identified in near miss WBIT cases. These frequently go undetected and can potentially have fatal consequences making accurate PID and sample labelling in the preanalytical stage of the transfusion process imperative. Incomplete PID processes were recognised as a contributory factor in 2 ABOi cases reported in 2022, both of which resulted in patient fatalities (Narayan, et al., 2023). The use of a pre-transfusion checklist prior to administration has been recommended in previous Annual SHOT Reports and is the final opportunity to identify a PID error before the transfusion begins. This is especially important during emergency situations when additional pressure and distractions are likely. It is vital that staff perform PID steps accurately and completely during all stages of the transfusion process and wherever possible, involve the patient.

While electronic blood-tracking systems are increasingly being implemented and used in healthcare to support safe transfusion practices, it is doubtful that technology alone will reduce the risk of patient misidentification (HSSIB, 2024). Patient identification processes, including related technology can improve patient safety only by ensuring that systems incorporate the needs of patient groups that are at greater risk of misidentification. Additionally, IT systems must be correctly implemented, configured, and used by trained and competent staff. To be effective, they must interface with electronic patient record systems.

Analysis of both clinical and laboratory cases demonstrate gaps in knowledge relating to the importance of performing accurate and complete patient identification. Staff should recognise the risk of patient misidentification and its subsequent impact on all aspects of patient care including transfusion support. It is necessary for NHS Trusts/Health Boards to promote a reliable, just, learning safety culture to ensure PID policies are implemented, followed, and monitored (Tase, et al., 2013).

SHOT
Serious Hazards of Transfusion

Main recommendation 1: Addressing patient identification errors to enhance transfusion safety

Transfusion is a complex multi-step process involving healthcare staff from varied clinical settings with differing levels of knowledge and skills**.** Ensuring that patients are accurately and correctly identified and communicating this information throughout the transfusion process is challenging. SHOT emphasises that all staff involved in the transfusion process should adhere to correct PID procedures in accordance with local transfusion policies. Accurate and complete identification of patients receiving transfusions is essential for patient safety and should be reflected in clinical and laboratory settings and embedded in transfusion practice.

Actions required:

Hospital senior management should:

- Ensure PID procedures and policies are regularly reviewed and updated and include high-risk settings, situations, and patient groups where the risk of patient misidentification is greater
- Ensure adequate funding and resources are available for the implementation and maintenance of effective fully functional IT systems used in PID processes in clinical and laboratory settings
- Foster a safety culture between multidisciplinary teams and ensure adequate support for clinical and laboratory teams with well-resourced services
- Ensure that electronic patient record systems are compliant with relevant risk management standards (such as DCB0129, DCB0160 and DCB1077)
- Regularly evaluate the effectiveness of PID processes by consistently auditing practice in clinical and laboratory settings

Hospital transfusion teams should:

- Review all transfusion-related patient identification errors and establish the causes of patient misidentification
- Recognise what changes are required to support staff when PID errors happen
- Ensure that knowledge of PID processes is included and emphasised in training and competency assessments to all staff involved in transfusion and are embedded in practice

Clinical staff should:

- Be supported by training which includes the knowledge and importance of undertaking accurate and correct PID processes during each step of the transfusion process
- Wherever possible undertake positive patient identification by proactively involving patients in their care
- Perform PID checks at critical steps in the transfusion pathway i.e., sample taking and labelling, collection of components and pre-administration checks
- Undertake all appropriate PID checks by using a pre-transfusion checklist prior to administering a transfusion at the patient side. This should include accurately checking the patient's identity against the prescription and the blood component compatibility label

Pathology laboratory management should:

- Ensure that procedures are in place and SOP reflect PID processes in the transfusion laboratory at safety critical steps in the transfusion pathway. These include pre-analytical processes, component selection and labelling, and at point of issue
- Embed the use of a laboratory exit check such as PAUSE (Narayan, et al., 2022), or equivalent to ensure that that all previous steps have been completed correctly and that unit is safe for issue to the clinical area
- Ensure that the LIMS incorporates PID processes and is used to its full potential to support transfusion safety

Safe staffing to support safe transfusions

Appropriate staffing is a key element in provision of a safe transfusion service, from the donor to the patient, involving medical, nursing, scientific and support staff. Appropriate staffing is not just about numbers of staff, but also requires the right skill mix and forward planning. The importance of appropriate staffing was reinforced by the Francis Report into failings at Mid Staffordshire NHS Foundation Trust in England (Francis, 2013). Capacity planning is critical to understanding safe staffing levels for a transfusion laboratory (Dowling, et al., 2024). In England, the National Quality Board (2016) set out expectations relating to getting nursing, midwifery, and care staffing right. This provided a governance and oversight framework alongside recommended evidence-based tools, resources, and examples of good practice, to support NHS providers in delivering safe patient care and the best possible outcomes for their patients. The Health and Care (Staffing) (Scotland) Act 2019 came into force on 1 April 2024 (Scottish Government, 2019). This groundbreaking legislation sets out requirements for safe staffing across all health and care services in Scotland. The Act places a legal duty on NHS and care providers to make sure there are always suitably qualified staff working in the right numbers for safe and effective care. It also imposes a duty on the Scottish government to ensure there are enough registered nurses, midwives, and medical professionals available to enable employers to ensure safe staffing. The Nurse Staffing Levels (Wales) Act 2016 protects nurse staffing levels in Wales and was the first law of its kind in the UK making Health Boards and NHS Trusts legally responsible for providing enough nursing staff in their nursing services and those they commission (NHS Wales, 2017). Similar campaigns are ongoing in Northern Ireland to secure staffing in healthcare.

The Royal College of Physicians published Guidance on Safe Medical Staffing in 2018, following concerns that levels of medical staffing had fallen dangerously low (RCP, 2018). There is no set minimum staffing level for any of the professions, this is dependent on many factors including workload, levels of information technology, and the complexity of the service provision within the organisation. Appropriate staffing is critical to supporting a positive safety culture within an organisation, where excellence in patient care is supported by a listening culture, good leadership and a workforce that feels empowered to raise concerns. A positive safety culture will struggle to flourish where the workforce is stretched and overburdened.

In a survey of healthcare staff in 2022 (Ibbetson, 2022), 966 out of 1016 (95%) staff stated that their workplace had been affected by staff shortages due to COVID-19. Of the NHS staff whose workplace had been affected by staff shortages, 71% said that current staff were working overtime or doing extra shifts, 38% said that their workplace was bringing in agency staff to cope with shortages, and 36% said

that staff were being redeployed from nearby locations to assist. Although the number in the survey was relatively small, similar signals are seen in a survey performed by the UKTLC in 2022 (SHOT, 2022). The NHS is facing an unprecedented staffing crisis. In its inquiry on the health and social care workforce in July 2022 (section 3.2), the House of Commons Health and Social Care Committee reported that the NHS had lost two million full-time equivalent days to sickness in August 2021 (Health and Social Care Committee, 2022). These included more than 560,000 days to anxiety, stress, depression, or another psychiatric illness. Workforce challenges are not only related to sickness absence, but high numbers of staff also continue to leave their profession, disillusioned with pay, conditions and training to support them in their roles. In the NHS England staff survey 2023 only 31.23% of respondents stated they were satisfied with their level of pay, 32.40% stated that there were enough staff at their organisation for them to do their job properly and 57.41% felt supported to develop their potential (NHSE, 2024). Plans to turn the tide and address workforces shortages have been published for the devolved nations (NHS Long Term Workforce, 2023; National Workforce Strategy for Health and Social Care in Scotland, 2022; NHS Wales Workforce, 2023; Workforce Strategy, 2018), however, these long term plans have made little difference in the short term, and patient waiting lists continue to rise (The King's Fund, 2023).

Innovative solutions to address deficiencies in staffing levels have included accelerated training, using unregulated staff to make decisions about patient treatment (GMC, 2024) and virtual clinics. These are well-intentioned but can have unintended consequences that put patient care at risk. Other innovative solutions include automation and information technology that can be used to support practice and optimise staff efficiencies. Although innovative solutions may be effective, where they are employed, implementation processes must consider potential risks and accountability.

A mismatch between workload and staffing levels is implicated in many cases described throughout the 2023 Annual SHOT Report. It is evident that an appropriate workforce, supported by a good safety culture and a listening leadership, is the keystone to a safe service. A systems-thinking approach that builds an environment that makes it easier for staff to do the right thing and harder to do the wrong thing (see Chapter 8, Human Factors and Ergonomics in SHOT Error Incidents), incorporation of effective information technology systems (see Chapter 16, Errors Related to Information Technology) and optimisation of automation in the laboratory (see Chapter 15, Laboratory Errors) are also key to supporting a safe service.

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

Main recommendation 2: Safe staffing to support safe transfusions

Healthcare leaders should review their organisations workforce needs to ensure that appropriate staffing is in place with future planning, including digital transformation to support a safe transfusion service. The review should consider the needs of the organisation, using tools relevant to the individual professions and must include clear time-bound actions plans where gaps are identified.

Actions required:

Hospital senior management should:

- Have a process in place that measures and monitors appropriate staffing levels across the organisation to support safe transfusion practice
- Identify and address challenges relating to recruitment and retention of clinical and laboratory staff
- Spearhead a good safety culture and have processes in place to monitor and measure the effectiveness of the culture and staff engagement
- Support implementation of effective and validated innovative solutions to address the mismatches between workload and staffing levels, including IT and automation

Clinical and laboratory management should:

- Have processes in place to identify where there are staffing issues that impact on service provision and escalate risks to the senior management team
- Have capacity plans in place that identify minimum staffing levels for a safe service, including time required for any quality, training and supervisory related activities
- Have documented forward and succession plans that include agreed timelines and are regularly reviewed for compliance and any changes within the workforce
- Ensure protected time is provided for staff training and competency assessment within the working hours
- Support a good safety culture, a listening management team and provide feedback on staff suggestions

Clinical and laboratory staff should:

- Raise concerns to relevant management personnel when safety risks relating to staffing levels are identified
- Engage in regular meetings with relevant management personnel, including 1:1 meetings and appraisals

Effective timely communications to ensure safe transfusions

Effective communication is critical for safe patient care. Patients need to feel secure and empowered enough to communicate honestly and openly with their care providers to receive effective treatments. Clinical staff need to convey treatment plans and health education clearly, accessibly, and empathetically so that patients can receive optimal care. Staff should share information ethically and responsibly to protect patient confidentiality. This includes accurate documentation of patient information and effective handovers during shift changes. Healthcare organisations need to apply culturally responsive measures to bridge communication gaps between stakeholders. Additionally, patient involvement in decision-making and understanding their care plan is crucial for their safety and well-being.

All healthcare staff must have the knowledge, skills, understanding and confidence they need to be able to share and use health and care information. The professional standards from the GMC, the NMC Code and HCPC standards for conduct, performance, and ethics mandate specific communication standards in healthcare to uphold patient safety (GMC, 2024; NMC, 2015; HCPC, 2023). These ensure

that healthcare staff adhere to established guidelines for effective communication, documentation, and patient engagement throughout the care process. Compliance with these mandates helps minimise errors, enhance care coordination, and ultimately improve patient outcomes. However, communication issues (between clinical staff and patients; different teams/care providers and between clinical and laboratory staff) are repeatedly highlighted in Annual SHOT Reports as contributory to errors and incidents and must be addressed.

Main recommendation 3: Effective, timely communications to ensure safe transfusions

Effective communication is crucial for safe patient care. Timely, clear, and concise communication can help prevent avoidable transfusion errors, foster collaboration, facilitate shared decision-making and enhances the overall quality of care provided to patients. Clear and succinct messaging with active listening, structured handovers, team huddles and safety briefings with optimal use of technology to support safe communications is vital for patient safety. Staff should receive appropriate training on effective communication skills including cultural sensitivity and feedback mechanisms must be in place to ensure continuing improvement in processes.

Actions required:

Hospital senior management should:

- Have an oversight of the communication policies, processes and practices in place to support patient care within their teams
- Ensure they review the effectiveness of communications at least annually
- Ensure that staff are appropriately trained and competent to communicate effectively with colleagues, patients and families
- Promote a just, learning safety culture and promote sharing of good practices with a collective, inclusive, and compassionate leadership
- Encourage patients and staff to raise concerns as well as provide constructive feedback

Staff learning and development teams should:

- Provide support and training for all staff in effective communication skills
- Ensure procedures and templates are available to facilitate structured communication
- Provide a platform to share learning and best practices across the whole organisation

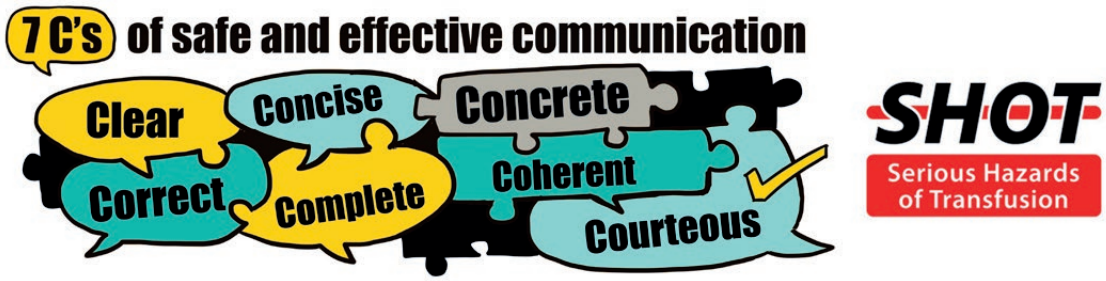
Clinical and pathology laboratory management should:

- Ensure staff are trained in effective communication skills and have regular update training as appropriate
- Ensure structured handovers are in place to facilitate safe communication of relevant patient information between teams (between clinical teams within a hospital, between clinical and laboratory teams, when patient is transferred between hospitals)

- Ensure regular feedback is sought from patients and staff about effectiveness of communication. This should be part of regular reviews of the processes in place to ensure safe communication at all points of the patient pathway with timely improvement actions to address gaps identified

Clinical and laboratory transfusion staff should:

- Follow a structured handover when passing on information related to patient care at all points (between shifts, between teams and during interhospital transfers). All communications must be specific, concise, relevant and timely
- Identify solutions with effective and appropriate use of IT to improve communications for safer patient care
- Undertake regular audits of communication practices for example: consent practices, discharge communications, management of patients in shared care, quality of handovers in both clinical and laboratory areas



Conclusions

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 have a safety culture that promotes learning from experience including instances of unsafe, suboptimal and excellent care. The long term aims of a haemovigilance 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. Making system-wide changes is absolutely essential.

Recommended resources

A-E decision tree to facilitate decision making in transfusion
Safe Transfusion Checklist
https://www.shotuk.org/resources/current-resources/

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

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

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/)

SHOT, UKTLC safety culture survey in transfusion laboratories in the UK
https://www.shotuk.org/resources/current-resources/shot-surveys/

National Comparative Audit: 2023 Audit of NICE Quality Standard QS138 and Vein to vein audit contact details
https://hospital.blood.co.uk/audits/national-comparative-audit/

References

Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO), 2020. *Guidelines from the expert advisory committee on the Safety of Blood, Tissues and Organs (SaBTO) on patient consent for blood transfusion.* [Online] Available at: https://www.gov.uk/government/publications/blood-transfusion-patient-consent/guidelines-from-the-expert-advisory-committee-on-the-safety-of-blood-tissues-and-organs-sabto-on-patient-consent-for-blood-transfusion (Accessed 07 May 2024).

Chartered Institute of Ergonomics & Human Factors (CIEHF), 2024. *Fatigue risk management for health and social care.* [Online] Available at: https://ergonomics.org.uk/resource/fatigue-risk-management-for-health-and-social-care.html (Accessed 02 May 2024).

Dowling, K. et al., 2024. UK Transfusion Laboratory Collaborative: Minimum standards for staff qualifications, training, competency and the use of information technology in hospital transfusion laboratories 2023. *Transfusion Medicine,* 34(1), pp. 3-10. doi: https://doi.org/10.1111/tme.13029.

Francis, R., 2013. *Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry. Executive summary,* London: The Stationery Office. Available at: https://assets.publishing.service.gov.uk/media/5a7ba0faed915d13110607c8/0947.pdf (Accessed 02 May 2024).

General Medical Council (GMC), 2024. *Delegation and referral.* [Online] Available at: https://www.gmc-uk.org/professional-standards/professional-standards-for-doctors/delegation-and-referral/delegation-and-referral (Accessed 02 May 2024).

General Medical Council (GMC), 2024. *Professional standards*. [Online] Available at: https://www.gmc-uk.org/professional-standards (Accessed 07 May 2024).

Health & Care Professions Council (HCPC), 2023. *Communication.* [Online] Available at: https://www.hcpc-uk.org/standards/standards-of-conduct-performance-and-ethics/revised-standards/communication/ (Accessed 07 May 2024).

Health and Social Care Committee, 2022. *Workforce: recruitment, training and retention in health and social care,* London: Order of the House. Available at: https://committees.parliament.uk/publications/23246/documents/171671/default/ (Accessed 07 May 2023).

Health Services Safety Investigations Body (HSSIB), 2024. *National learning report: Positive patient identification.* [Online] Available at: https://www.hssib.org.uk/patient-safety-investigations/positive-patient-identification/national-learning-report/ (Accessed 08 April 2024).

Ibbetson, C., 2022. *Nine in ten NHS workers say their workplace has seen staff shortages due to COVID-19.* [Online] Available at: https://yougov.co.uk/health/articles/40783-nine-ten-nhs-workers-say-their-workplace-has-seen-?redirect_from=%2Ftopics%2Fhealth%2Farticles-reports%2F2022%2F02%2F02%2Fnine-ten-nhs-workers-say-their-workplace-has-seen- (Accessed 02 May 2024).

Narayan, S. et al., 2022. *The 2021 Annual SHOT Report,* Manchester: Serious Hazards of Transfusion (SHOT) Steering Group. doi: https://doi.org/10.57911/QZF9-XE84.

Narayan, S. et al., 2023. *The 2022 Annual SHOT Report,* Manchester: Serious Hazards of Transfusion (SHOT) Steering group. doi: https://doi.org/10.57911/WZ85-3885.

National Quality Board (NQB), 2016. *Supporting NHS providers to deliver the right staff, with the right skills, in the right place at the right time,* England: NHS England. Available at: https://www.england.nhs.uk/wp-content/uploads/2013/04/nqb-guidance.pdf (Accessed 02 May 2024).

National Workforce Strategy for Health and Social Care in Scotland, 2022. *National Workforce Strategy for Health and Social Care in Scotland,* Scotland: The Scottish Government. Available at: https://www.gov.scot/binaries/content/documents/govscot/publications/strategy-plan/2022/03/national-workforce-strategy-health-social-care/documents/national-workforce-strategy-health-social-care-scotland/national-workforce-strategy-health-social-care-scotland/govscot%3Adocument/national-workforce-strategy-health-social-care-scotland.pdf (Accessed 02 May 2024).

NHS England (NHSE), 2024. 2023 *NHS National Staff Survey*. [Online] Available at: https://www.gov.uk/government/statistics/2023-nhs-national-staff-survey (Accessed 07 May 2024).

NHS Long Term Workforce, 2023. *NHS Long Term Workforce Plan.* [Online] Available at: https://www.england.nhs.uk/publication/nhs-long-term-workforce-plan/ (Accessed 02 May 2024).

NHS Wales, 2017. *Nurse Staffing Levels (Wales) Act 2016. Statutory Guidance,* Wales: Wales Government. Available at: https://www.legislation.gov.uk/anaw/2016/5/enacted (Accessed 07 May 2024).

Nursing & Midwifery Council (NMC), 2015. *The Code. Professional standards of practice and behaviour for nurses, midwives and nursing associates,* London: Nursing & Midwifery Council. Available at: https://www.nmc.org.uk/globalassets/sitedocuments/nmc-publications/nmc-code.pdf (Accessed 07 May 2024).

Robinson, S. et al., 2018. The administration of blood components: a British Society for Haematology Guideline. *Transfusion Medicine,* 28(1), pp. 3-21. doi: https://doi.org/10.1111/tme.12481.

Royal College of Physicians (RCP), 2018. *Guidance on safe medical staffing. Report of a working party,* London: Royal College of Physicians. Available at: https://www.bgs.org.uk/sites/default/files/content/resources/files/2018-07-13/2018_safe-medical-staffing_report.pdf (Accessed 07 May 2024).

Scottish Government, 2019. *Health and Care (Staffing) (Scotland) Act 2019.* [Online] Available at: https://www.legislation.gov.uk/asp/2019/6/section/2/enacted (Accessed 07 May 2024).

Serious Hazards of Transfusion (SHOT), 2024. *UKTLC.* [Online] Available at: https://www.shotuk.org/resources/current-resources/uktlc/ (Accessed 02 May 2024).

Tase, T. H., Lourenção, D. C. d. A., Bianchini, S. M. & Tronchin, D. M. R., 2013. Patient identification in healthcare organizations: an emerging infection. *Revista Gaucha de Enfermagem,* 34(3), pp. 196-200. doi: https://doi.org/10.1590/S1983-14472013000300025.

The King's Fund, 2023. *Waiting times for elective (non-urgent) treatment: referral to treatment (RTT).* [Online] Available at: https://www.kingsfund.org.uk/insight-and-analysis/data-and-charts/waiting-times-non-urgent-treatment (Accessed 02 May 2024).

Workforce Strategy, 2018. *Workforce Strategy - Workforce Information.* [Online] Available at: https://www.health-ni.gov.uk/publications/workforce-strategy-workforce-information (Accessed 02 May 2024).

5 The Infected Blood Inquiry and Haemovigilance

Authors: Shruthi Narayan, Caryn Hughes and Emma Milser

With contributions from SHOT Steering Group and Working Expert Group members

Abbreviations used in this chapter

AOMRC	Academy of Medical Royal Colleges
IBI	Infected Blood Inquiry
MHRA	Medicines and Healthcare products Regulatory Agency
NHS	National Health Service
NHSBT	NHS Blood and Transplant
NICE	National Institute for Health and Care Excellence
TTI	Transfusion-transmitted infection
UK	United Kingdom

Recommendation

- Complete implementation of the IBI report recommendations to improve healthcare systems and optimise safety. The effectiveness of the implementation should be monitored regularly

Action: All professional organisations related to healthcare in the UK and all relevant bodies responsible for various recommendations as detailed in the report

Introduction

The IBI was an independent, public, statutory inquiry established to examine the circumstances in which men, women and children treated in the NHS were given infected blood and infected blood products, particularly in the 1970s and 1980s. Sir Brian Langstaff chaired the Inquiry, and the final report was published on 20 May 2024 (IBI, 2024). SHOT released a statement following the release of the IBI Report (See 'Recommended resources').

It has been humbling, upsetting, and moving to hear and read the report's findings, evidence and lived experiences of the Infected and Affected. The SHOT Steering Group and Working Expert Group members would like to acknowledge the scale of the tragedy and extend their heartfelt compassion. We are considering the findings and recommendations from this comprehensive report. We are committed to working with the MHRA as the regulator and other key stakeholders, including patients, and pledge to assist and support effective implementation of all recommendations related to haemovigilance.

Recommendations relating to haemovigilance and transfusion safety

It is encouraging to see several recommendations in the IBI Report supporting haemovigilance, patient blood management, transfusion education, laboratory support and digital transformation within transfusion. Many of these recommendations align closely with the philosophy of SHOT, and priorities we have identified over recent years. There were several themes that emerged from the final report of the IBI. Sir Brian Langstaff identified the first theme as the failure to make patient safety the paramount focus of decision making and action. The report contains several wide-ranging recommendations that addresses the wider healthcare system and practices, not just transfusion medicine (IBI, 2024). The following infographic summarises the main themes from the safety messages and recommendations from the report. Recommendation 7 focusses on 'Patient Safety: Blood Transfusions'.

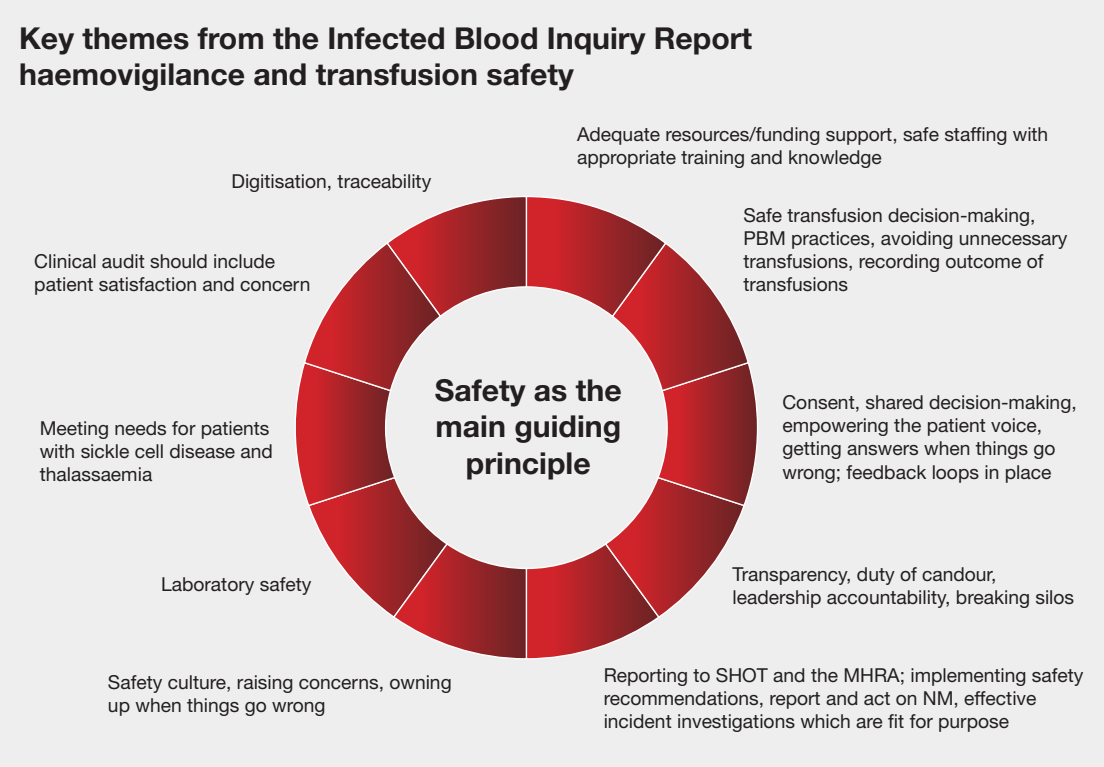


Figure 5.1: Key themes from the IBI Report related to haemovigilance and transfusion safety (IBI, 2024)

MHRA=Medicines and Healthcare products Regulatory Agency; NM=near miss; PBM=patient blood management

The Inquiry report has put the spotlight on haemovigilance, acknowledging the importance and value of reporting and learning from incidents and implementing SHOT recommendations to improve transfusion safety. Recommendation 7e states:

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

Partnering with patients to enhance safety

Giving patients a voice is one of the main messages from the IBI Report (IBI, 2024). Recommendation 10 focuses this and lists several measures for action.

Engaging patients, their families, and carers as 'safety partners' to co-create safer systems, identify, and rectify preventable adverse events was one of the main recommendations in the 2021 Annual SHOT Report (Narayan, et al., 2022). It is time to transform healthcare by elevating the patient's voice to its rightful place of importance – their voices hold the key to creating a healthcare system that is not only effective but also compassionate and truly patient-centred. Shared decision-making should become the norm and patients must be active partners in their care and in improving organisational safety. This begins with a commitment to listen and to learn from those who experience care firsthand. Transparent and open communication is the foundation of trust. Healthcare providers must embrace this recommendation, enhance communication skills, understand the diverse backgrounds of their patients, and build stronger, meaningful relationships with patients, carers and families with appropriate use of technology. Feedback mechanisms must be in place to ensure the healthcare system evolves with the needs and insights of those it serves. By giving patients a voice, we honour their experiences and insights, creating a healthcare system that is safer, more effective, and profoundly more compassionate.

Several resources have been developed to support consent and shared decision-making for transfusion (See 'Recommended resources'). However, a recent 2023 national comparative audit of NICE Quality Standard QS138 showed that only 475/1356 (35.0%) transfused patients had evidence of receiving both written and verbal information about the risks, benefits, and alternatives to transfusion (compared to 26% in the 2021 audit) (NHSBT, 2024; NICE, 2016). This highlights the need to urgently improve and implement systems to ensure appropriate informed consent for transfusions and promote shared decision-making.

A new mobile application called 'MyTransfusion' is in development. This has been co-created with input from patient representatives and transfusion experts and is expected to be released later this year and aims to support the shared decision-making process.

TTI risk-reduction measures

The UK Blood Services are among the safest in in the world and several measures have been implemented to minimise the risk of TTI. Improvements in the transfusion pathway including stringent donor selection, arm cleaning, diversion of initial part of the donation, microbiological screening tests, optimal storage and transport, quality-control processes and safe management of any suspected TTI cases have helped minimise the risk of TTI in the UK blood supply. Several resources have been released recently capturing the safety measures to ensure microbiological safety and trends in infections reported (See 'Recommended resources').

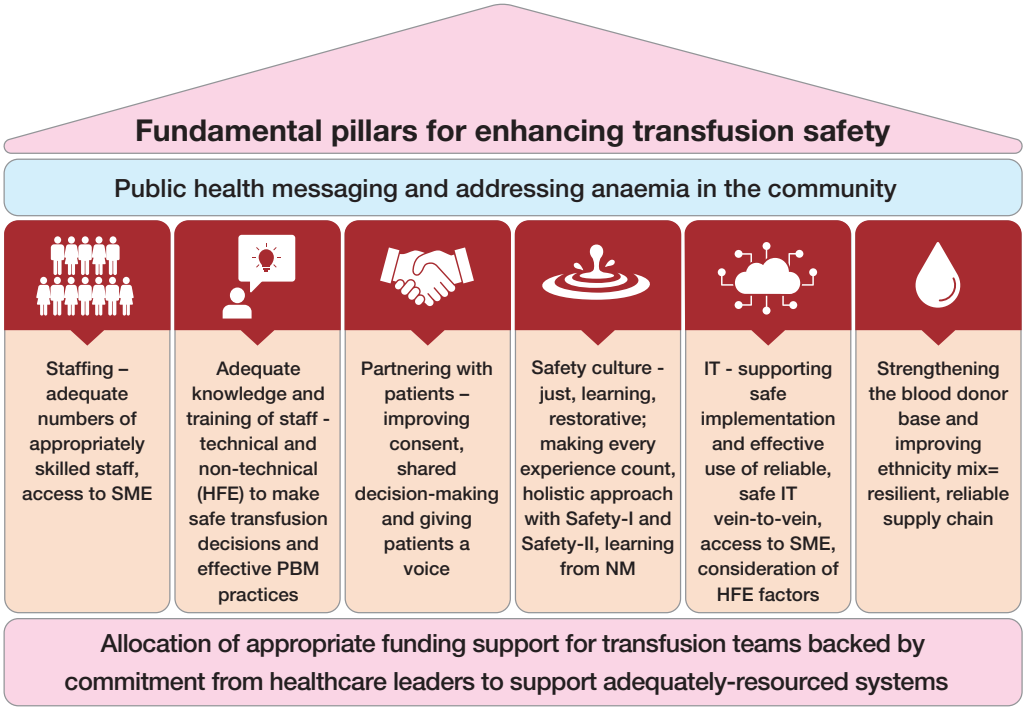
Conclusion

The recommendations from the IBI report are crucial for addressing the failures of the past and significantly enhancing the safety and trustworthiness of healthcare systems. We must ensure effective implementation of the recommendations to prevent similar incidents in the future. This begins with meaningful engagement and partnering with patients, and ensuring that the healthcare system is transparent, accountable, and provides high-quality care. The Report is not just a document but a call to action, urging all of us to reinforce our commitment to safety which should be the main guiding principle for decision-making in healthcare. It provides us with a clear roadmap for achieving excellence in transfusion safety and we should use the insights from this report to drive impactful changes, promote innovation and foster a culture where safety is paramount.

Several safety initiatives across the UK in the last couple of decades have helped improve transfusion safety (See 'Recommended resources'). There, however, cannot be any complacency and the real work lies ahead to address the increasing challenges we are facing in an NHS that is in crisis. A recent AOMRC report states, 'If we do not act with urgency, we risk permanently normalising the unacceptable standards we now witness daily, to the detriment of us all' (AOMRC, 2022). We must take action to prevent further avoidable harm and make meaningful strides towards building a system that protects and promotes health for everyone with engagement, collaboration with patients and rebuilding trust with continued vigilance.

Based on the emerging themes from serial Annual SHOT Reports and aligned with the IBI Report, tangible actions are needed in all areas captured in the illustration below to truly improve transfusion safety in the UK.

Figure 5.2: Fundamental pillars enhance transfusion safety in the UK



Applicable to both clinical and laboratory transfusion teams

HFE=Human factors and ergonomics; IT=information technology; NM=near miss; PBM=patient blood management; SME=subject matter expert

The Thirlwall inquiry recently published a damning summary of progress made by the NHS and government across 30 inquiries, including Mid-Staffordshire NHS Foundation Trust – dating back to 1967 (Thirlwall Inquiry, 2024). The analysis found that just 302 of more than 1,400 recommendations had been adopted. We stand at a critical juncture, one where words must transform into actions and promises must become reality. It is our collective responsibility to ensure the recommendations from the Inquiry do not gather dust but are actively pursued and implemented. Let us honour the voice of all the Infected and the Affected, their experiences should be catalysts for change.

Recommended resources

Statement from SHOT in response to the Infected Blood Inquiry Report
Statement from SHOT in response to the IBI report - Serious Hazards of Transfusion (shotuk.org)

Transfusion safety initiatives across the UK
Current Resources - Serious Hazards of Transfusion (shotuk.org)

Patient information page on the SHOT website
https://www.shotuk.org/patients/

Consent for transfusion – information for patients
Transfusion Information for Patients (transfusionguidelines.org)

Support available through the Inquiry from the British Red Cross
Psychological support provided by the Inquiry | Infected Blood Inquiry.

Managing the safety of the blood supply video
SHOT Videos - Serious Hazards of Transfusion (shotuk.org)

Infected Blood Inquiry website
Homepage | Infected Blood Inquiry

Transfusion-Transmitted Infections (TTI) Cumulative Data
Cumulative SHOT Data by Category - Serious Hazards of Transfusion (shotuk.org)

References

Academy of Medical Royal Colleges (AOMRC), 2022. *Fixing the NHS - Why we must stop normalising the unacceptable*, London: Academy of Medical Royal Colleges. Available at: https://www.aomrc.org.uk/wp-content/uploads/2022/09/Fixing_the_NHS_210922.pdf (Accessed 20 June 2024).

Infected Blood Inquiry (IBI), 2024. *The Report HC 569-I* , London: Crown. Available at: https://www.infectedbloodinquiry.org.uk/reports/inquiry-report (Accessed 20 June 2024).

Narayan, S. et al., 2022. *The 2021 Annual SHOT Report,* Manchester: Serious Hazards of Transfusion (SHOT) Steering Group. doi: https://doi.org/10.57911/QZF9-XE84.

National Institute for Health and Care Excellence (NICE), 2016. *Blood transfusion – Quality standard [QS138]*. [Online] Available at: https://www.nice.org.uk/guidance/qs138 (Accessed 20 June 2024).

National Health Service Blood and Transplant (NHSBT), 2024. *2023 National Comparative Audit of NICE Quality Standard QS138*. [Online] Available at: https://hospital.blood.co.uk/audits/national-comparative-audit/reports-grouped-by-year/2023-national-comparative-audit-of-nice-quality-standard-qs138/ (Accessed 20 June 2024).

Thirlwall Inquiry, 2024. *The Thirlwall Inquiry - Review of Implementation of Recommendations from Previous Inquiries into Healthcare Issues prepared by the Thirlwall Inquiry Legal Team*, UK: Crown. Available at: Table-of-Inquiries-Reviews-and-Recommendations-made-and-whether-they-were-implemented.pdf (thirlwall.public-inquiry.uk) (Accessed 20 June 2024).

6 Acknowledging Continuing Excellence in Transfusion (ACE) n=15

Author: Simon Carter-Graham

With contributions from: Members of the SHOT team and ACE WEG

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
BMS	Biomedical scientist
CT	Computed tomography
DAT	Direct antiglobulin test
ED	Emergency department
GI	Gastrointestinal
GP	General practitioner
G&S	Group and screen
Hb	Haemoglobin
HCA	Healthcare assistant
Ig	Immunoglobulin
MDT	Multi-disciplinary team
MH	Major haemorrhage
MOH	Major obstetric haemorrhage
OSHA	Occupational Safety and Health Administration
PCC	Prothrombin complex concentrates
TACO	Transfusion-associated circulatory overload
WBIT	Wrong blood in tube

Key SHOT messages

- It is encouraging to see an increase in the number of reports where organisations have shared excellent practice and learning
- Key themes include positive process change, collaboration, and excellent communication between teams

Recommendations

- All healthcare organisations should embrace a Safety-II approach (learning from excellence and day-to-day events) as a complement to Safety-I. It is necessary to analyse where and when things go wrong, whilst proactively seeking to promote good practice by celebrating when things go right and developing ways to support, augment and encourage this
- All healthcare organisations should regularly measure safety culture in clinical and laboratory teams with appropriate improvement actions, provide education and resources to support an effective safety culture based on a proactive approach to patient safety

Action: Senior management and leadership teams in all healthcare organisations

Introduction

SHOT ACE is an example of learning from excellence, emphasising studying successful outcomes or practices to improve safety. It is about shifting the focus from solely analysing failures to understanding what works well and replicating those strengths and behaviours. This approach promotes a more positive and proactive learning culture. It is encouraging to see a steady increase in the number of reports submitted to SHOT in this category.

In 2023 there were 15 reports accepted under a wide range of ACE sub-categories. As with previous years, the cases reported reflect the continued commitment of healthcare staff who work tirelessly to deliver safe and appropriate transfusions despite the challenges faced within healthcare settings.

This year's ACE chapter captures the importance of acknowledging and celebrating excellence, with the aim to encourage organisations to focus on the things that are going well rather than when things go wrong. This approach offers an opportunity to learn from good transfusion practice and ultimately improve patient care. Furthermore, it aims to highlight the importance of incorporating civility and safety indicators in workplace processes as well as fostering and embedding a safety culture in everyday practice.

ACE cases 2023

Table 6.1 shows a summary of cases accepted under ACE in 2023 and the themes identified which make the events noteworthy. Full case descriptions can be found in the supplementary information on the SHOT website (https://www.shotuk.org/shot-reports/report-summary-and-supplement-2023/).

While the name of the category SHOT ACE suggests that it tends to identify extremely good (i.e., excellent) examples of work/practices, submitted reports are actually capturing everyday excellence; examples of good communication, collaboration, and innovation to address patient-care issues or a human approach resulting in a positive outcome, occurring in often difficult circumstances amidst staff shortages, high workload and poor IT. The SHOT team would like to acknowledge the hard work, dedication, and teamwork that transfusion staff in both clinical and laboratory areas demonstrate whilst caring for patients despite all the challenges. This chapter is a celebration of these efforts.

Table 6.1: Acknowledging continuing excellence (ACE) case summaries 2023 (n=15)

Case number	Summary	ACE themes
	Transfusion practice - clinical	
1*	Major haemorrhage in ED. Excellent multidisciplinary communication. Rapid issue of PCC.	Collaboration Communication Patient focus
2	Major haemorrhage in theatres. Excellent multidisciplinary communication. Porter supervisor and recovery nurse went above and beyond duty.	Collaboration Communication Patient focus
3	Nurse and HCA challenged a doctor who had not correctly identified a patient when taking a pre-transfusion blood sample and had left the patient's side with the unlabelled sample.	Patient focus Relatable education
4	Major haemorrhage patient dealt with by a team unfamiliar with this situation. Rapid action was taken on the low Hb result (41g/L). Whole team including porters and transfusion laboratory staff acted coherently and efficiently.	Collaboration Communication Patient focus
5	Doctor completed a prompt review of a patient with TACO. Always provides very detailed clinical reviews and has an excellent awareness of transfusion adverse events thus ensuring prompt reporting to SHOT.	Collaboration Communication Patient focus
	Transfusion practice - laboratory	
6*	Excellent communication and collaboration during two extremely challenging major trauma cases. Anaesthetists and surgeons made sure all involved staff were thanked for the fantastic job they did.	Communication Collaboration Patient focus
7	The clinical team stated the biomedical staff did exceptionally well and assisted with great communication throughout a MOH and issued blood products in a timely manner under difficult circumstances.	Communication Collaboration Patient focus
8	Fetal bleed detected in patient's G&S sample as part of a pre-delivery screen. BMS showed superior knowledge in advising clinicians. Mother was given the appropriate dose of anti-D Ig.	Communication Collaboration Patient focus
9	BMS identified WBIT based on the patient's haematocrit for a patient who had not previously had a G&S sample sent. This prevented the incorrect samples from being processed and an incorrect blood group being recorded in the patient's file.	Communication Collaboration Patient focus
	Teamwork and collaboration	
10*	New process in place to ensure patients have their transfusion specific requirements assessed and managed with any requirements being communicated to the MDT, the patient, and their GP being informed and involved in the process.	Innovation Collaboration Positive change Patient focus
11	BMS staff suggested and designed a form to aid carrying out the process of phenotyping for multiple red cell antigens involving the use of multiple anti-sera reagents with different techniques and incubation requirements. Previously only detailed individually by referral to the manufacturer's product information sheet for each anti-sera.	Innovation Collaboration Positive change Patient focus
12	MDT work within the hospital and Blood Service to crossmatch for a patient experiencing a haemorrhage. The antibody screen had proved positive and the group was inconclusive and DAT positive. Due to the complex result a total of 28 units were crossmatched in order to obtain compatible units.	Collaboration Patient focus Communication
13	Two MH occurred around 19:30. On top of these two further code reds were called in shortly afterwards. The laboratory team worked extremely well together demonstrating exceptional practice and excellent communication skills. Two members of staff went above and beyond by staying an extra 2 hours after a 12-hour shift to help their colleagues.	Collaboration Patient focus Communication
14	Pregnant patient with pancytopenia (36^{+4}/40). The patient had markedly low B12 and folate levels and required an emergency caesarean section overnight and multiple blood components. The BMS was lone working at the time of delivery. It was an exceptional example of truly multidisciplinary teamwork.	Collaboration Patient focus Communication
15*	A specific protocol was developed for authorisation of PCC where intracranial haemorrhage has been confirmed on CT or life-threatening GI bleed has been identified and 1000IU of PCC can be administered immediately allowing time to discuss further PCC requirement with the consultant haematologist. Audit results identified that 67% patients now receive PCC within 1 hour of the decision being made.	Innovation Collaboration Positive change Patient focus Relatable education

**Please see the supplementary information on the SHOT website for a detailed discussion of these cases (https://www.shotuk.org/shot-reports/report-summary-and-supplement-2023/)*

Communication and civility

Excellent communication was noted between the clinical area and the transfusion laboratory in several of the ACE cases, especially in MH situations where effective communication is vital to ensure co-ordinated care for transfusion safety. In several incidents the staff involved were commended for their skills and commitment to patient safety. In these incidents it is clear that civility played a part. In very stressful situations, the language and tone of what is said between colleagues is very important as incivility can adversely impact patient care and safety. Civility is often regarded as kindness and a sense of security. When this is lacking, safety may be compromised resulting in a negative clinical impact for patients (Porath & Pearson, 2013). In 1 case, a healthcare professional challenged the unsafe practice of a colleague, preventing a potential error. This shows that difficult conversations can be had with positive outcomes.

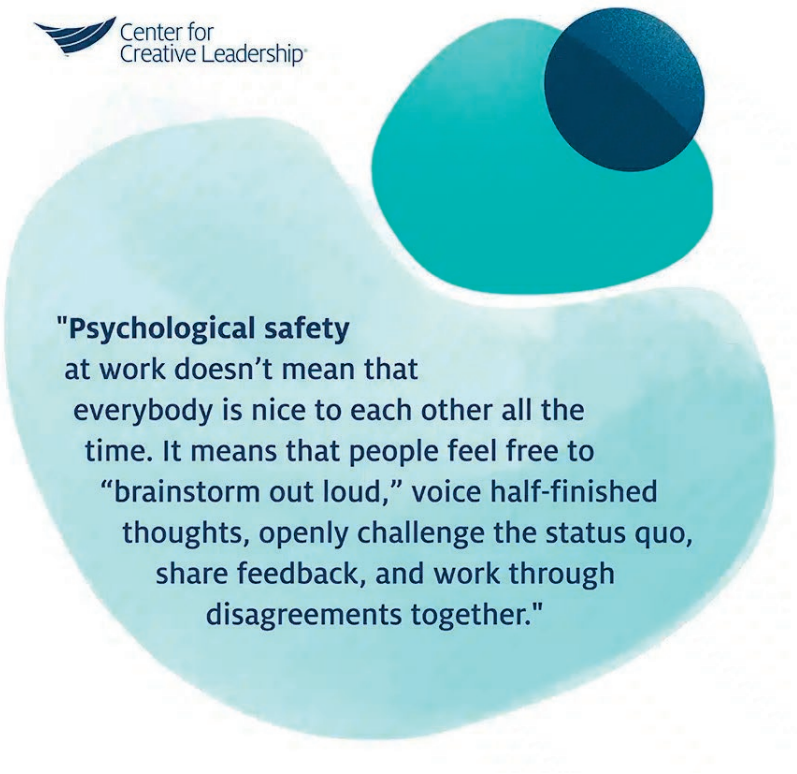


Figure 6.1: What is psychological safety at work? How leaders can build psychologically safe workplaces

Reproduced with permission from by the Center for Creative Leadership, Originally published in 'What Is Psychological Safety at Work? How Leaders Can Build Psychologically Safe Workplaces'

To ensure psychological safety for all staff, leaders need to show compassionate leadership and understand the experiences and needs of their workforce. There is clear evidence that compassionate leadership results in more engaged and motivated staff with high levels of wellbeing, which in turn results in high quality care (West, 2021). Civility in the workplace and psychological safety is discussed in more detail in the ACE chapter of the 2021 Annual SHOT Report (Narayan, et al., 2022).

Positive procedural changes

In 3 cases, changes were made to recognised protocols such as the way PCC use was standardised and made more efficient.

In 1 case, the process for ensuring patient's specific transfusion requirements were met was improved. Updates were made to ensure the appropriate training was given to the relevant staff.

Safety indicators in healthcare: leading/lagging indicators

Safety indicators in healthcare encompass a wide range of measures that assess various aspects of patient care, organisation processes and factors impacting safety. Leading indicators are proactive,

preventative, and predictive measures that provide clues to future incidents. They also offer evidence on the effectiveness of a safety management system. Preventative actions can then be undertaken before an error or incident occurs. According to OSHA (2019) '*Whilst lagging indicators can alert you to an error or to the existence of a hazard, leading indicators are important because they can tell you whether activities are effective at preventing incidents'*. Some examples of leading indicators include near miss reporting rates, safety culture surveys, equipment maintenance schedules, while incident rates and patient outcomes are lagging indicators. By utilising both leading and lagging indicators, healthcare organisations can implement a balanced approach to safety management focusing on both proactive prevention and reactive response to optimise patient care and staff wellbeing. Figures 6.2 and 6.3 show the key differences between the lagging and leading indicators for safety.

Figure 6.2: Lagging versus leading indicators

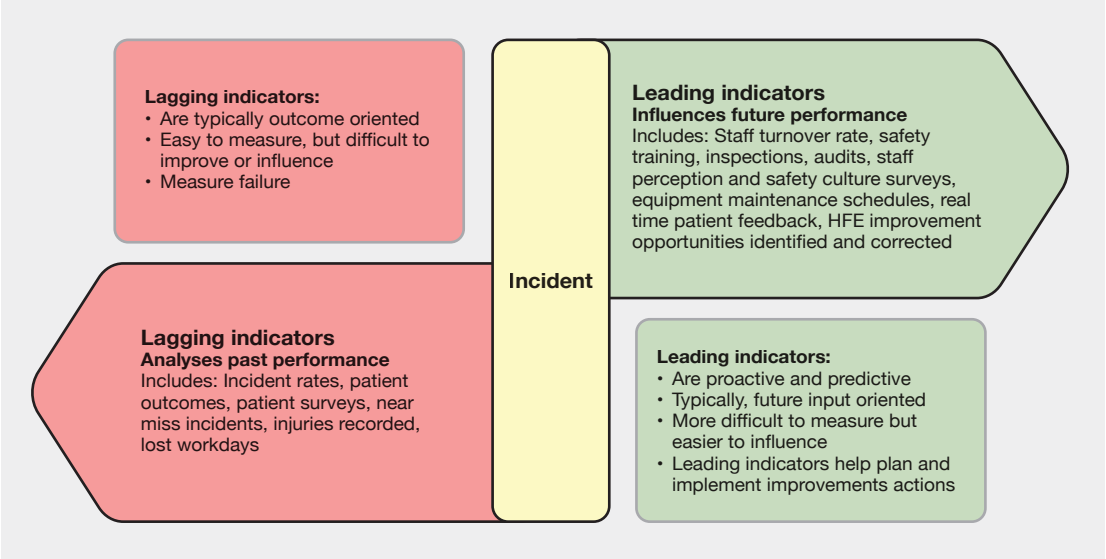
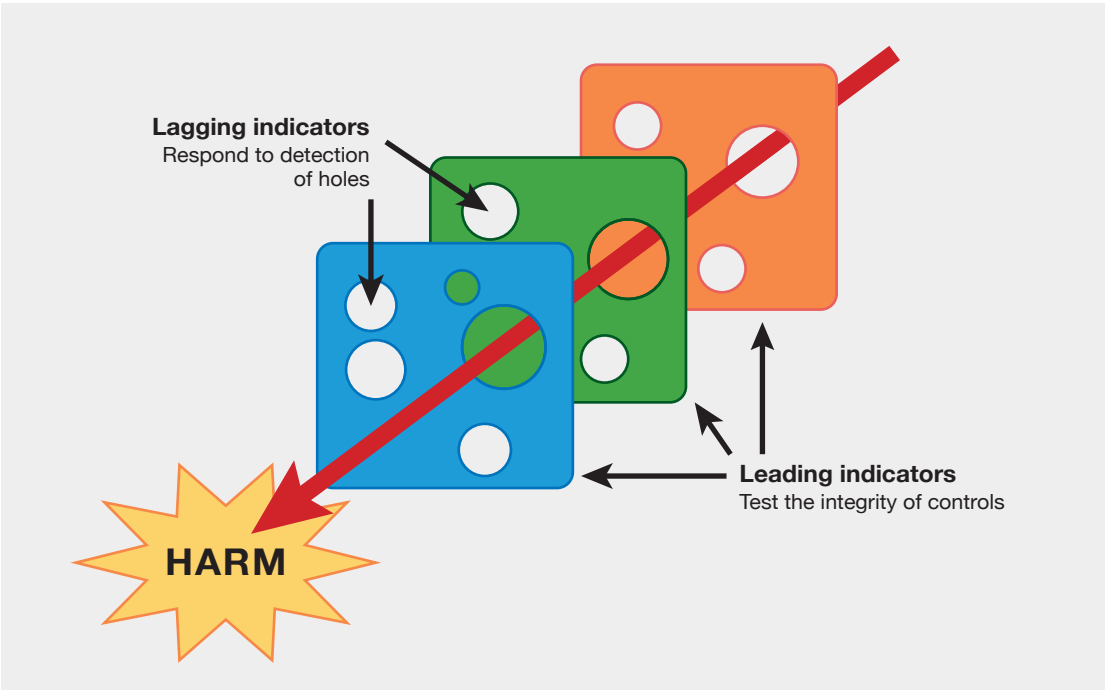


Figure 6.3: Safety performance indicators and the Swiss cheese model



Source: https://risktec.tuv.com/knowledge-bank/measuring-safety-safety-related-key-performance-indicators/, The 'Swiss cheese model' of accident causation was originally proposed by James Reason focussing on the systemic failures of safeguard and barriers that can result in patient harm

Further information on this can be found in the supplementary information on the SHOT website (https://www.shotuk.org/shot-reports/report-summary-and-supplement-2023/).

Safety culture

Building a strong safety culture is essential in reducing transfusion errors, improving patient outcomes, and promoting a positive work environment for healthcare professionals. Regular measurement of safety culture in healthcare is essential for fostering a culture of continuous improvement, enhancing patient safety, and maintaining organisational effectiveness. Any concerning signals from safety culture surveys (SHOT, 2024) require prompt urgent, proactive action to address identified issues, prevent harm, engage stakeholders, and enhance safety for all patients, blood donors and staff.

A strong, just, no-blame, learning safety culture promotes open communication, teamwork, continuous improvement, and a focus on learning from experiences to enhance patient care and outcomes (See 'Recommended resources' at the end of the chapter). Figure 6.4 outlines tangible ideas to improve safety culture.

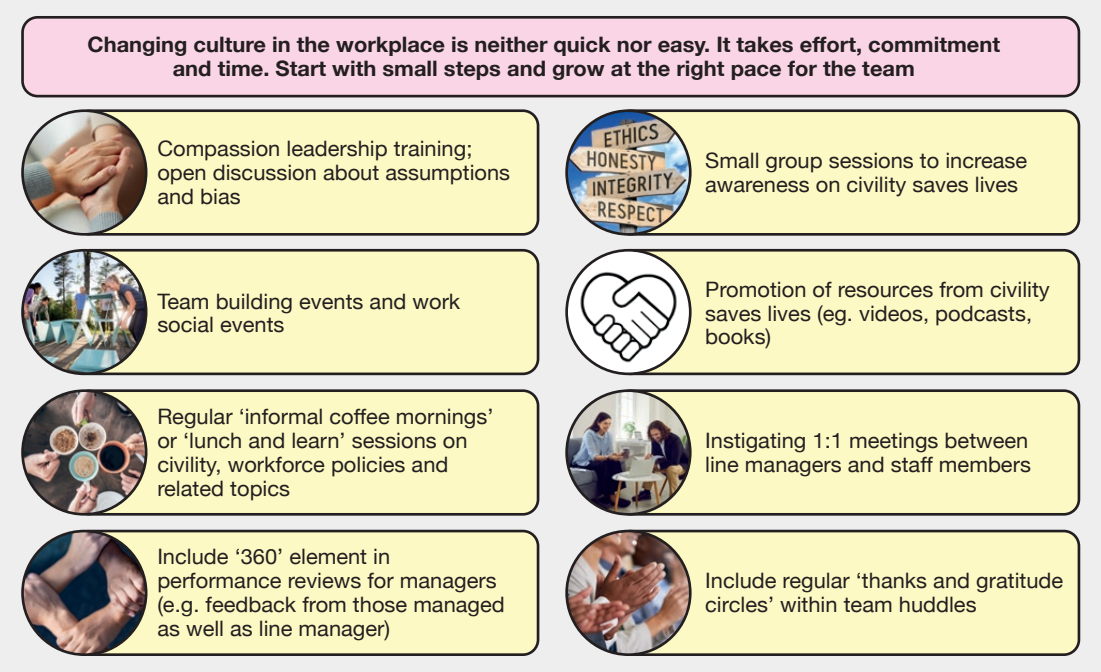


Figure 6.4: How changing safety culture in the workplace can improve transfusion safety

For information about the 2023 UK-wide transfusion laboratories safety culture survey please see 'Recommended resources'.

Conclusion

Widespread learning from excellence is important for all organisations as it allows individuals and teams to understand what works well and replicate those successes. By analysing and recognising excellence, we can identify best practices, develop strategies for improvement and foster a culture of continuous learning and growth. This approach helps to reinforce positive behaviours and achievements, leading to greater staff engagement, efficiency, innovation, and overall success. Additionally, celebrating excellence can boost morale and motivation within teams, creating a supportive and positive work environment. Promoting a learning culture where staff learn from day-to-day events enhances resilience, provides valuable insights, allows adaptation, and supports a growth mindset. Staff should receive training to be able to use tools to support learning from day-to-day events and excellence, thereby paving the way for a holistic approach to safety.

While more teams and organisations are adopting learning from excellence, it is important to recognise the impact of system changes on patients and staff involved. Feedback loops must be in place to ensure the impact of these changes are captured and acted upon promptly.

Recommended resources

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

SHOT Bite No. 23: Civility in Healthcare (2023)
SHOT Bite No. 24: Speaking up for safety (2023)
SHOT Bite No. 26: Acknowledging Continuing Excellence (ACE) (2023)
https://www.shotuk.org/resources/current-resources/shot-bites/

Learning from Excellence
https://learningfromexcellence.com/

NHS Innovation Service
https://innovation.nhs.uk/innovation-guides/

Life Sciences Hub, Wales
https://lshubwales.com/

InnoScot health
https://innoscot.com/

Civility in the workplace
https://www.civilitysaveslives.com/

References

Narayan, S. et al., 2022. *The 2021 Annual SHOT Report,* Manchester: Serious Hazards of Transfusion (SHOT) Steering Group. doi: https://doi.org/10.57911/QZF9-XE84.

Occupational Safety and Health Administration (OSHA), 2019. *Using Leading Indicators to Improve Safety and Health Outcomes* [Online], s.l.: OSHA. Available at: https://www.osha.gov/sites/default/files/publications/OSHA_Leading_Indicators.pdf (Accessed 11 April 2024).

Porath, C. & Pearson, C., 2013. The price of incivility. *Harvard Business Review*, 91(1-2), pp. 114-121. Available at: https://hbr.org/2013/01/the-price-of-incivility (Accessed 16 May 2024).

Serious Hazards of Transfusion (SHOT), 2024. *UKTLC.* [Online] Available at: https://www.shotuk.org/resources/current-resources/uktlc/ (Accessed 02 May 2024).

West, M., 2021. *Compassionate Leadership: Sustaining Wisdom, Humanity and Presence in Health and Social Care*. s.l.:The Swirling Leaf Press. Available at: https://swirlingleafpress.com/compassionate-leadership/ (Accessed 08 May 2024).

Donor Haemovigilance

7

Main authors: Dr Jayne Hughes, Specialty Doctor, SNBTS and Dr Champa Manchanayake, Specialty Doctor, SNBTS

With contributions from the Donor haemovigilance chapter writing group comprising:
Dr Shruthi Narayan, SHOT Medical Director and Consultant Donor Medicine, NHSBT
Dr Liezl Gaum, Specialty Doctor, NHSBT
Jessica Ryan, Senior Nurse Practitioner, Clinical Support Team, NHSBT
Julie Curry, Training Advanced Practitioner in Donor Care, WBS
Dr Hasarika Dodampegamage, Specialty Doctor, WBS
Dr Kathryn Maguire, Consultant in Transfusion Medicine, NIBTS
Dr Asma Sadiq, Specialty Doctor, NIBTS

Definition:

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

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

Abbreviations used in this chapter

AABB	Association for the Advancement of Blood & Biotherapies
DV	Delayed vasovagal reaction
EBA	European Blood Alliance
GP	General practitioner
ISBT	International Society of Blood Transfusion
IHN	International Haemovigilance Network
JPAC	Joint United Kingdom (UK) Blood Transfusion and Tissue Transplantation Services Professional Advisory Committee
MHRA	Medicines and Healthcare products Regulatory Agency
NHSBT	National Health Service Blood and Transplant
NIBTS	Northern Ireland Blood Transfusion Service
PfM	Plasma for Medicine
PLT	Platelets
SAED	Serious adverse event of donation
SDC	Serious donor complication
SNBTS	Scottish National Blood Transfusion Service
UK	United Kingdom
WBS	Welsh Blood Service

Recommendations

- All UK Blood Services should work collaboratively to ensure best practice in the prevention and management of donor adverse events is developed and shared. Measures such as the implementation of the severity grading tool and the development of standard questions for donor adverse event follow up will facilitate this aim
- Effective donor education has a key role in reducing the frequency and severity of adverse events. All donors should be educated to speak up if they feel unwell or experience arm symptoms during and after donation

- Staff dealing with blood donors should have adequate knowledge about potential complications and be able to identify and manage them promptly on session

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

Introduction

Blood donation in the UK is a voluntary non-remunerated act that is essential to support patient care across all disciplines. Although generally safe, complications do sometimes occur. Appropriate donor care includes giving donors information about the material risks of blood donation, implementing measures to minimise those risks, and providing appropriate clinical management for any adverse reactions which occur.

Serious adverse events of donation

SAED are complications or events where a donor experiences serious harm, or very rarely, result in donor death. The ten SAED categories are listed in Table 7.2. SAED are also given an imputability score, 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

Data from 2023

UK donations

A total of 1,808,690 donations were collected by the four UK Blood Services in 2023 (Table 7.1). As well as whole blood and component donations, this includes 24,104 plasma donations collected by NHSBT for the manufacture of medicinal products.

Donations from 2023		NHSBT	SNBTS	WBS	NIBTS	UK
Whole blood	Donations from male donors	738,706	69,392	38,193	21,638	867,929
	Donations from female donors	698,272	78,797	40,606	21,004	838,679
	Donations from new donors	171,635	7,892	6,020	3,207	188,754
	Donations from repeat donors	1,265,343	140,297	72,779	39,435	1,517,854
	Total whole blood donations	**1,436,978**	**148,189**	**78,799**	**42,642**	**1,706,608**
Apheresis	Donations from male donors	PLT 58,541 PfM 16,386	6,293	2,061	3,189	86,470
	Donations from female donors	PLT 6,805 PfM 7,718	328	384	377	15,612
	Donations from new donors	PLT 8,807 PfM 9,874	0	85	0	18,766
	Donations from repeat donors	PLT 56,539 PfM 14,230	6,621	2,360	3,566	83,316
	Total apheresis donations	**PLT 65,346 PfM 24,104**	**6,621**	**2,445**	**3,566**	**102,082**
Total number of donations in 2023		**1,526,428**	**154,810**	**81,244**	**46,208**	**1,808,690**

Table 7.1: Cumulative donation data from the four UK Blood Services in 2023 (n=1,808,690)

NHSBT=National Health Service Blood and Transplant; SNBTS=Scottish National Blood Transfusion Service; WBS=Welsh Blood Service; NIBTS=Northern Ireland Blood Transfusion Service; UK=United Kingdom; PfM=Plasma for Medicine; PLT=platelets

Table 7.2 summarises the number of SAED by category for all four UK Blood Services combined for the period January 2023 to December 2023.

SAED category	2023					2022
	NHSBT[1]	SNBTS	WBS	NIBTS	UK	UK
01 Death within seven days of donation	0	0	0	0	**0**	**2**
02 Hospital admission within 24 hours of donation	2	0	1	0	**3**	**11**
03 Injury resulting in a fracture within 24 hours of donation (including fractured teeth)	7 (includes 4 with DV[2])	2 (includes 2 with DV[2])	0	0	**9**	**8**
04 Road traffic collision within 24 hours of donations	0	0	0	0	**0**	**4**
05a Problems relating to needle insertion persisting for more than one year (this mainly includes suspected or confirmed nerve and tendon injuries)	23	7	3	1	**34**	**24**
05b Problems relating to needle insertion requiring hospitalisation/intervention (this mainly includes vascular complications)	0	0	0	0	**0**	**0**
06 Acute coronary syndrome diagnosed within 24 hours of donation	2	0	0	0	**2**	**5**
07 Anaphylaxis (component donation)	1	0	0	0	**1**	**0**
08 Haemolysis (component donation)	0	0	0	0	**0**	**0**
09 Air embolism (component donation)	1	0	0	0	**1**	**0**
10. Other event related to donation resulting in: • Hospital admission, • Intervention, or • Disability or incapacity lasting more than one year and not included above	3	0	0	0	**3**	**1**
Total reported SAED	**39**	**9**	**4**	**1**	**53**	**55**

Table 7.2: SAED by category in 2023 (All SAED included here irrespective of imputability)

1 Data includes 3 imputability 0a SAED (1x category 02 Hospital admission; 2x category 06 Acute coronary syndrome), all reported by NHSBT
2 DV: delayed vasovagal reaction – i.e., a vasovagal reaction occurring after the donor has left the donation session

NHSBT=National Health Service Blood and Transplant; SNBTS=Scottish National Blood Transfusion Service; WBS=Welsh Blood Service; NIBTS=Northern Ireland Blood Transfusion Service; UK=United Kingdom; SAED=serious adverse events of donation

As in 2022, problems related to venepuncture lasting more than one year (category 05a) account for the majority of SAED and are typically due to nerve injury, although 2 cases from NHSBT were suspected to be tendon injuries. Arm pain events have increased in 2023, but the reasons behind this are not clear. Improved awareness and reporting may be a factor. It should be noted, that of the 34 cases reported, 25 donors developed symptoms (pain or paraesthesia) immediately at venepuncture but only 13 informed session staff at the time. In 10 of these cases, the needle was withdrawn, but in 3 cases donation continued. Further details about the category 05a SAED are given in the data tables in the supplementary information on the SHOT website (https://www.shotuk.org/shot-reports/report-summary-and-supplement-2023/).

Learning point

- Donors must be encouraged to speak up if they experience pain or paraesthesia at the time of venepuncture. Donation should be stopped, and the needle carefully withdrawn if the donor has immediate symptoms suggestive of nerve or tendon injury

Table 7.3 summarises the total number of donations and SAED reported for each of the four UK Blood Services in 2023. The rate of SAED was 0.29 per 10,000 donations, irrespective of imputability, or 0.28 per 10,000 donations excluding imputability scores of 0a or 0b.

Table 7.3: Summary of total donations for the four UK Blood Services and total numbers of SAED for 2023

	NHSBT	SNBTS	WBS	NIBTS
Total donations (whole blood and apheresis)	1,526,428	154,810	81,244	46,208
Total number of SAED in the calendar year 2023	39	9	4	1
Total number of SAED excluding those scored with an imputability of 'unlikely' or 'not related to blood donation'	36	9	4	1
Rate of total SAED per 10,000 donations in UK for 2023 (all submitted reports irrespective of imputability)		0.29		
Rate of SAED per 10,000 donations in UK for 2023 excluding those with imputability of 'unlikely' or 'not related to donation		**0.28**		

Comparison of trends with previous years

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

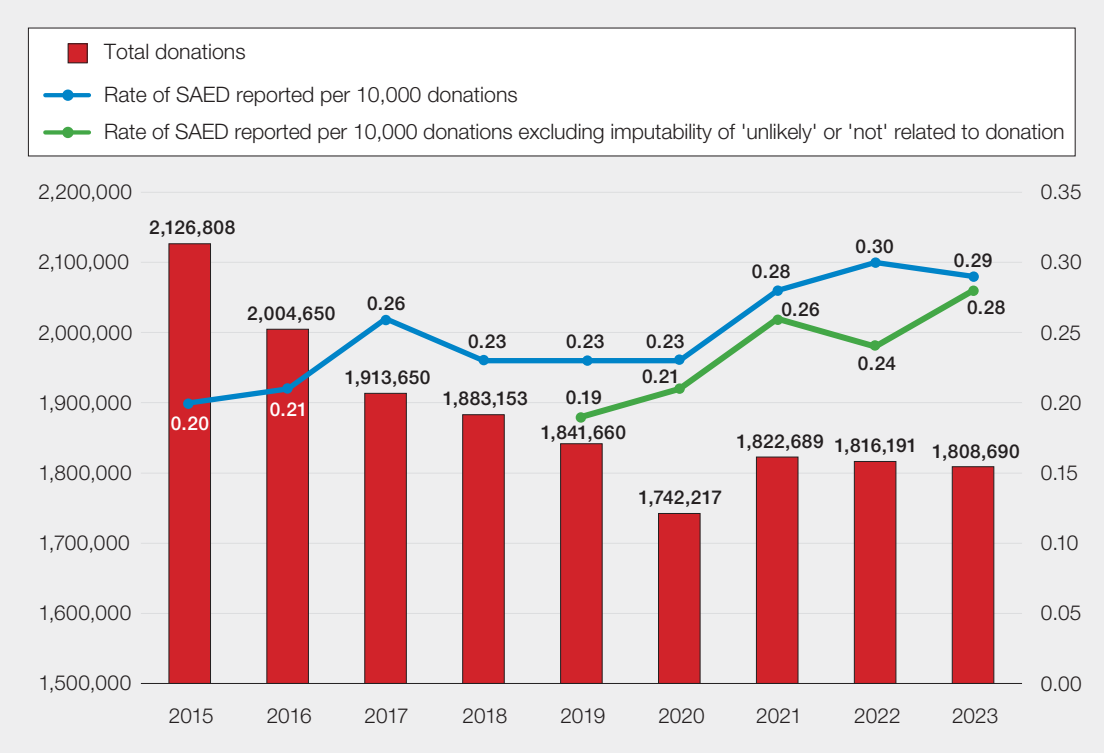


Figure 7.1: Rate of SAED reported per 10,000 donations in the UK 2015-2023

SAED=serious adverse event of donation; UK=United Kingdom

Overall SAED rates are unchanged from 2022, but this masks a rise in rates for SAED with imputability 1-3 to 0.28 per 10,000 donations (from 0.24 per 10,000 donations in 2022). This rise may reflect better reporting, but other factors should be considered, and appropriate actions taken to reduce the frequency and severity of donor adverse events. Areas to address include donor education, staff training, monitoring of donor adverse events, regular audits with improvements to the session environment and procedures. Shared learning across the four UK Blood Services promotes adoption of best practices and facilitates improvements.

Implementation of donor adverse event severity grading

The UK Blood Services have agreed to implement the validated donor severity grading criteria developed by the AABB Donor Haemovigilance Working Group and endorsed by ISBT, IHN and EBA (Townsend, et al., 2020). Donor adverse events will be recorded according to the new grading criteria which rate severity of donor adverse events by grades 1-5, with 1 through 5 being associated with mild, moderate, severe, life-threatening and death. Any event of grade 3 or above will be reported as a SDC. Once implemented by all the Blood Services, the reporting of SDC will replace the previous SAED categories. It is anticipated that the new grading system will result in more SDC being reported and recorded than in previous years.

Individual UK Blood Services are implementing severity grading over different timescales. During this transition period, services may record either SDC or SAED. It is hoped that by 2025, the new system will be fully implemented across the UK.

Plasma for Medicine project

Since April 2021, NHSBT has been collecting both sourced and recovered plasma for the purpose of manufacturing PfM. In October 2020, a comprehensive review of the evidence to reassess the safety of UK plasma to manufacture plasma-derived medicinal products was undertaken, and the results presented to the Commission on Human Medicines (MHRA, 2021). In April 2021, under the advisement of the MHRA, the Government directed NHSBT to recommence the collection of plasma, to produce lifesaving medicines, for the benefit of UK patients. Based on the scientific review, blood regulators and operators have been urged to take account of the safety profile when considering fractionation

of UK plasma, and to revise their guidelines on the deferral of donors who have lived in, or received a transfusion in, the United Kingdom (Thomas, et al., 2023).

As with whole blood donations, PfM is an invasive procedure that can result in donor adverse events, and therefore, as for other blood donations, requires careful monitoring and management of donors during their donation. Adverse events related to donors feeling faint or losing consciousness are consistently reported at 1.4%. This is similar to rates seen in whole blood donors. Bruising is the most common adverse event in plasma donors and rates are higher than in either whole blood or apheresis platelet donors (5.0% in PfM donors vs 0.9% whole blood and 2.5% platelet). Further details and relevant graphs can be accessed in the supplementary information on the SHOT website (https://www.shotuk.org/shot-reports/report-summary-and-supplement-2023/).

Illustrative case

Case 7.1: Venepuncture-related pain and paraesthesia but no abnormalities on electromyography or nerve conduction studies

A regular male whole blood donor, who had donated fifteen times previously, reported persistent problems with his donation arm when he returned to donate five months later. The donor remembered experiencing a sharp pain at the time of needle insertion but this improved during the donation process and this was not reported to staff. A full donation was taken. Post donation, minor bruising in the right antecubital fossa and the medial aspect of right forearm was experienced. Since donation, the donor described having a painful cramp and tingling sensation when holding a phone to his ear for long periods or when lifting weights. The donation arm was painful with elbow flexion but not at rest. He occasionally woke in the mornings with discomfort in his arm if his hand or elbow came under his weight. There was no loss of power or coordination, no swelling, or lump.

The donor was subsequently assessed by his GP for numbness in his right thumb/thenar eminence and pain on elbow flexion against resistance. He was seen by a consultant neurologist and a clinical neurophysiologist, 10 months after donation. Neurological examination, electromyography and nerve conduction studies were all normal. He also had a normal magnetic resonance imaging scan of his right forearm. The donor has been withdrawn from future blood donations.

Venepuncture-related arm problems do occur and can have debilitating long-term effects due to ongoing pain and restricted function. Needle-related complications include haematoma, arterial puncture, and painful arm, which may result from nerve irritation through a haematoma or from direct injury to a nerve or other structure (Working Group on Donor Vigilance of the ISBT Working Party on Haemovigilance, 2014). Peripheral nerve injuries are defined by a persistent burning, shooting, electrical-type pain or paraesthesia in a specific nerve distribution, which begins immediately while the needle is in situ, or can be delayed for several hours thereafter. Published evidence suggests that 30–70 donors per 100,000 donations will develop a nerve injury (Newman, 2013; Sorensen, et al., 2008). Of these around 5 per 100,000 may develop long-term symptoms.

Donation staff must be aware of these possible complications and advise donors accordingly during acquisition of informed consent. Some donors may be reluctant to report any venepuncture-related pain or discomfort. It is therefore important that staff check with the donor if they have any of these symptoms, as the needle should be removed immediately to minimise the risks of any long-term injury. Guidance for the management of donors who do sustain a possible nerve injury is available on the JPAC website (See 'Recommended resources' at the end of this chapter).

This donor had several investigations, all of which were normal. There is some evidence that nerve injury can still be present despite normal nerve conduction studies. A recent study by Kang et al. (2023) focused on the limitations of electrophysiological tests as diagnostic tools. Individuals for whom normal data were obtained in the nerve conduction studies were eventually diagnosed with nerve swelling on ultrasonography. These false-negative results imply that electrophysiological tests cannot be used as an independent method for diagnosing or determining the clinical severity of venepuncture-related nerve injuries. Assessment of clinical symptoms alongside knowledge of cutaneous nerve distribution

provides significant indicators for inferring nerve damage. In cases where electrophysiological tests are normal, ultrasonography may reveal morphological damage to the corresponding nerves and should be considered.

Conclusion

While blood donation is generally very safe, donor complications sometimes occur either during or after blood donation. Most of these are non-severe and resolve promptly but are still unpleasant for the donor. SAED occur infrequently and may result in long-term or permanent disability or injury to the donor. Preventing these adverse events must be a priority and when donor complications do occur, they should be managed promptly and appropriately. Continuing donor haemovigilance and embedding lessons learnt from surveillance helps improve quality and safety for all blood donors.

Blood Services should encourage donors to make early contact with the clinical team 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 resource

Post donation management of blood donors with nerve injury related to donation
Post-donation management of blood donors with nerve injury related to donation V2.pdf (transfusionguidelines.org)

References

Kang, M. S. et al., 2023. Clinical, Electrophysiological, and Sonographic Findings in Patients With Nerve Injury After Vessel Puncture. *Journal of Clinical Neurology,* 19(4), pp. 371-375. doi: 10.3988/jcn.2022.0285.

Medicines and Healthcare products Regulatory Agency (MHRA), 2021. *Critical risk assessment report: use of UK plasma for the manufacture of immunoglobulins and vCJD risk.* [Online] Available at: https://www.gov.uk/government/publications/critical-risk-assessment-report-use-of-uk-plasma-for-the-manufacture-of-immunoglobulins-and-vcjd-risk/critical-risk-assessment-report-use-of-uk-plasma-for-the-manufacture-of-immunoglobulins-and-vcjd-risk (Accessed 25 April 2024).

Newman, B., 2013. Arm Complications After Manual Whole Blood Donation and Their Impact. *Transfusion Medicine Reviews,* 27(1), pp. 44-49. doi: https://doi.org/10.1016/j.tmrv.2012.05.002.

Sorensen, B. S., Johnsen, S. P. & Jorgensen, J., 2008. Complications related to blood donation: a population-based study. *Vox Sanguinis,* 94(2), pp. 132-137. https://doi.org/10.1111/j.1423-0410.2007.01000.x.

Thomas, S. et al., 2023. Safety profile of plasma for fractionation donated in the United Kingdom, with respect to variant Creutzfeldt–Jakob disease. *Vox Sanguinis,* 118(5), pp. 341-413. doi: https://doi.org/10.1111/vox.13416.

Townsend, M. et al., 2020. Development and validation of donor adverse reaction severity grading tool: enhancing objective grade assignment to donor adverse events. *Transfusion,* 60(6), pp. 1231-1242. https://doi.org/10.1111/trf.15830.

Working Group on Donor Vigilance of the International Society of Blood Transfusion (ISBT) Working Party on Haemovigilance, 2014. *Standards for Standard for Surveillance of Complications Related to Blood Donation,* s.l.: Association for the Advancement of Blood & Biotherapies (aabb).

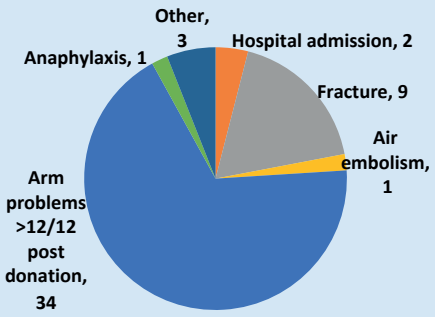
Serious adverse events following blood donation reported to the UK Blood Services in 2023

In 2023 the UK Blood Services collected approximately 1.8 million donations (whole blood and apheresis); this includes plasma collected for fractionation at NHSBT. Fifty-three serious adverse events of donation (SAED) have been reported last year and includes all categories of imputability; this equates to a rate of 0.29 per 10,000 donations, or 1 in 34,126 donations. Of the 53 cases reported, 3 were not related to blood donation. The remaining 50 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 2023

SAED categories

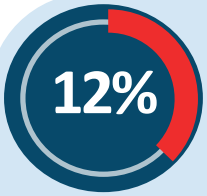
Excluding SAED with an imputability of 0a and 0b



SAED were seen in both female (30/50, 60%) and male donors (20/50, 40%).
3 SAED were reported in first time donors, all of these being whole blood donors.

6/9 fractures were related to delayed vasovagal reactions. Female donors accounted for all of these cases. None were first time donors.

There were no reports of any deaths or road traffic collisions, or haemolysis due to component donation, reported in 2023.



6/50 SAED were as a direct result of a delayed vasovagal reaction.

34/50 SAED reported were related to persistent arm problems more than one year post donation.
All were whole blood donors.

47/50 donors were withdrawn from future donations. 3 donors were not withdrawn. This includes 2 donors with arm pain who were allowed to return if donating from their other arm.

3/50 SAED were in component donors (1 platelets, 2 plasma for medicine). The rate of apheresis SAED is 1 in 34,027 donations, similar to the overall SAED rate.

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.

Effective donor education has a key role in reducing the frequency and severity of adverse events.

Whole blood and component donation is safe but complications do sometimes occur. The overall incidence of SAED remains low. The rate of SAED in UK for 2023 is 0.28 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: Human Factors

8 Human Factors and Ergonomics in SHOT Error Incidents n=3184

Authors: Emma Milser and Alison Watt

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

CAPA	Corrective and preventative actions
HFE	Human factors and ergonomics
HFIT	Human factors investigation tool
HR	Human resources
IT	Information technology
MHRA	Medicines and Healthcare products Regulatory Agency
NHS	National Health Service
NHSE	NHS England
PSIRF	Patient Safety Incident Response Framework
RCA	Root cause analysis
UKTLC	United Kingdom Transfusion Laboratory Collaborative
WBIT	Wrong blood in tube
YCFF	Yorkshire Contributory Factors Framework

Key SHOT messages

- It is encouraging to see a continued rise in the use of HFE frameworks for incident investigations and consideration of systemic contributory factors
- Within a restorative just culture, staff undertaking reflection as an action from investigations may limit learning and can be perceived as punitive
- Long-term actions to reduce risk (e.g., IT solutions, improved staffing) should continue to be considered with improvement plans in place even if they cannot be readily resolved

Recommendation

- Healthcare organisations should introduce and promote a restorative just culture, with buy-in from leadership at all levels. This shifts the focus from blaming staff to wider organisational learning, with the objective of repairing trust and relationships damaged after an incident

Action: Hospital senior management

Introduction

A good, learning, just safety culture in healthcare is vital to ensure patient and staff safety. It values transparency, encourages reporting of errors or near misses and prioritises staff training and support to prevent harm to patients. Just culture within many organisations remains retributive, organised around rules, policies and violations, thus becoming a blunt HR instrument, with no wider learning. In comparison, a restorative just culture is a learning approach to deal with adverse events, which focuses not on blame, but on controlling harm done and repairing trust and damaged relationships (Dekker, et al., 2022). Restorative just culture concentrates on impacts, needs and obligations (Table 8.1).

Table 8.1: Comparison of retributive and restorative just culture

Retributive just culture	Restorative just culture
What rule is broken?	Who is impacted?
How bad is the breach?	What do they need?
What should be the consequences?	Who is going to meet that need?
Employee has to settle/pay account	Get employee to tell/share account
Focuses on past and blame	Focuses on future
Accountable for compliance	Accountable for setting people up to succeed
Tries to stop things going wrong	Enhances capacities that make things go right
Meets hurt with more hurt	Meets hurt with healing

The table above is a summary taken from the work done by Sidney Dekker (https://sidneydekker.com/) and Mersey Care (https://www.merseycare.nhs.uk/restorative-just-learning-culture)

Mersey Care NHS Foundation Trust is widely acknowledged for being a centre of excellence and sharing their journey to create and maintain a restorative 'just and learning' culture where colleagues feel supported and empowered to learn when things do not go as expected, rather than blamed (Mersey Care NHS Foundation Trust, 2024). This approach has demonstrated some impressive outcomes, including improvements in staff retention, particularly important when organisations are faced with continuing workforce shortages. Key to improving culture at the organisation has been leadership buy-in at all levels, and the newly released NHS leadership competency framework for board members (NHSE, 2024) includes a competency domain specifically for skills and behaviours required to create a compassionate, just, and positive culture. In Wales, the National Policy on Patient Safety Incident Reporting & Management (NHS Wales Executive, 2023) supports a just culture for healthcare organisations and staff so they may feel encouraged to recognise, report and learn from patient safety incidents. It recognises that the exploration of incident reporting can facilitate healthcare organisations to share learning from incidents, help identify emerging risks and act as a mechanism for oversight and provide reassurance when substantial harm has occurred. Healthcare improvement in Scotland provides an overarching approach by advocating learning from adverse events through reporting and review – A national framework for Scotland (Healthcare Improvement Scotland, 2019). The principle of this overarching framework includes learning from adverse events, promoting good practice, a system focussed approach, promoting a just and safety culture and supports building on the fundamental values of care, compassion, respect, transparency, accountability, excellence, and teamwork. Northern Ireland have not adopted PSiRF but a patient safety incident framework, led by the Department of Health, is currently being developed.

The NHS England Patient Safety Incident Response Framework (PSIRF) (NHSE, 2023) has included compassionate engagement and involvement of those affected by patient safety incidents as a foundational pillar and thus offers promise of increased attention to restorative just culture within England's safety work (Lounsbury & Sujan, 2023). A checklist developed from Dekker's work on restorative just culture can be found on his website (Dekker, 2022).

Learning point

- Resources are readily available for organisations to use, such as Dekker's checklist and the Mersey Care website, to help implement a restorative just culture

Analysis of SHOT error reports in 2023 showed 'reflective learning' appears in almost 5% of cases (155/3184). The recommendation from the 2022 Annual SHOT Report that reflective learning should not be used as a stand-alone action remains pertinent, especially when developing a restorative just culture (Narayan, et al., 2023).

Case 8.1: Individual staff member was asked to reflect despite report showing wider staffing and organisational issues

A sample from a patient in ED grouped as O D-positive, historic group A D-positive. A WBIT incident was identified because the staff member who performed phlebotomy realised that they had bled the wrong patient and escalated to a senior clinician who informed laboratory staff. Due to workload pressures, the samples were labelled remotely from the patient with inadequate patient identification and patient notes from the neighbouring bed space were used. The ED had an operational escalation process in place due to extreme pressures. Patients were being seen on the ambulance corridor and there was only one nurse and one nursing assistant. The member of staff involved had to undergo retraining, competency-assessment, and completed a reflection tool.

The most important contributory factor in Case 8.1 was recorded in the HFIT as local working. The question regarding one thing to make this incident less likely to happen again, was answered with the need for an electronic end-to-end process for identifying patients prior to taking samples or administering blood. A staff member undergoing retraining and reflection is unlikely to impact the working conditions or the aspiration to secure an electronic system for sampling and administration. This mismatch continues to be observed regularly in incident reports and is incongruous with the principles of a restorative just culture.

To ensure a restorative just culture, it is essential to consider and question if the rules that staff are expected to follow are themselves 'just', and if the rule-makers understand 'work as done' rather than 'work as imagined'. Healthcare professionals face the challenge of navigating a maze of policies, striving to provide quality care while keeping up with an ever-expanding set of guidelines (Carthey, et al., 2011) making non-compliance a significant risk. Exploring this further, Johnstone (2017) surmised that it would take 2000 years for a USA anaesthetist to read all the relevant guidelines, and for these very reasons, a restorative just culture can fail. A just restorative culture cannot be fully implemented until staffing issues are addressed.

A joint SHOT and UKTLC Laboratory Safety Culture Survey was undertaken in November 2023 and the summary report and findings can be viewed on the SHOT website SHOT Surveys - Serious Hazards of Transfusion (shotuk.org). Concerning signals are evident from this safety culture survey and key recommendations have been provided to improve this. Organisations must encourage a just culture and have a clear strategy to listen to staff, support them, and actively work to create safe, positive work environments. This is not just about staff wellbeing, it is about ensuring the highest quality care for patients and promoting safe care.

Analysis of the SHOT HFIT

The SHOT HFIT was updated in January 2023 to remove scoring following an analysis shown in the 2022 Supplementary Information, Figure 7.4. https://www.shotuk.org/shot-reports/report-summary-and-supplement-2022/. This demonstrated that irrespective of scoring, the percentages given for each factor were almost identical. The updated tool asks reporters to answer yes or no for the contributory factors involved and provide any relevant information instead of providing a score.

A total of 3184 error cases were included in 2023, which is an increase in the error cases reported in 2022 (n=2908). Throughout SHOT's historical analysis of HFE, there has been evidence of an over-emphasis on individual behaviours, but analyses of both the 2022 and 2023 data showed an improved appreciation of system and organisational factors. Figure 8.1 shows consideration across the breadth of factors, with an increase of 14.4% attributed to situational factors and an increase of 5.1% to communication and culture. The increase in allocation of situational factors and decrease in local working, organisational and external factors compared to 2022 is slightly concerning as it may indicate that factors are being over-selected in the first category without full consideration of the other categories. As this has coincided with scoring being removed for 2023, the trend will be monitored to determine if any changes are required to the HFIT question set.

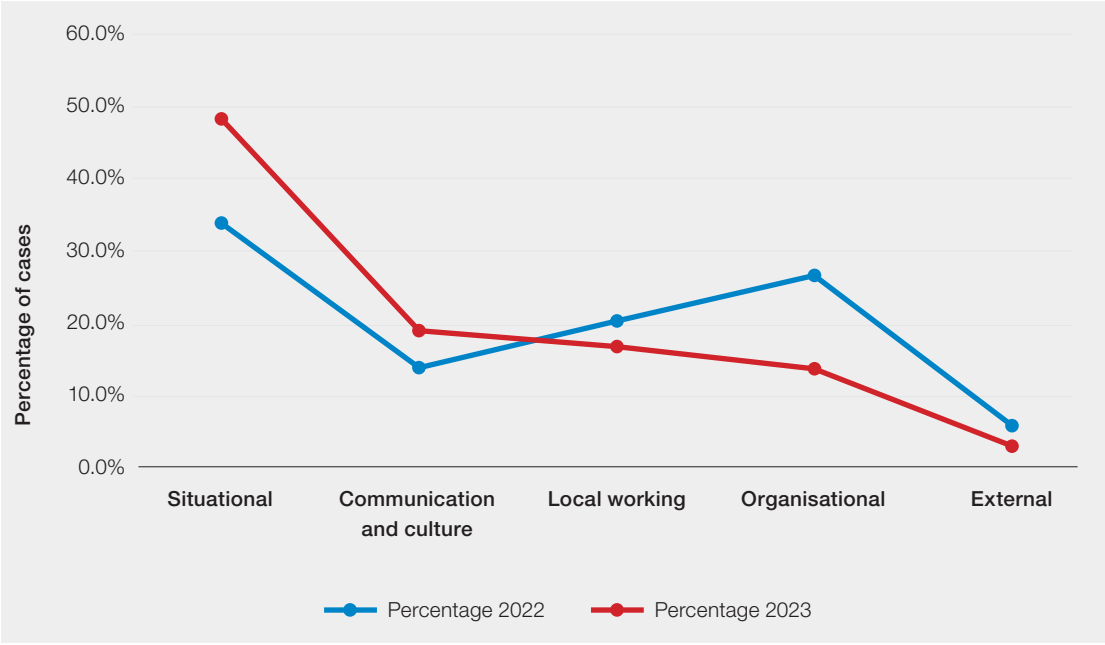


Figure 8.1: A comparison of HFIT categories assigned by SHOT reporters in 2022 and 2023

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 2023 2376/3184 (74.6%) cases specified that HFE principles or a framework/model was used to investigate incidents and a further 382/3184 (12.0%) indicated they were planning to in the future. Figure 8.2 shows this is a slight increase compared to 2022 (67.0% used, 14.7% planning) and 2021 (70.0% used, 12.8% planning) but these figures indicate that many cases are investigated without using a formal framework to consider human factors.

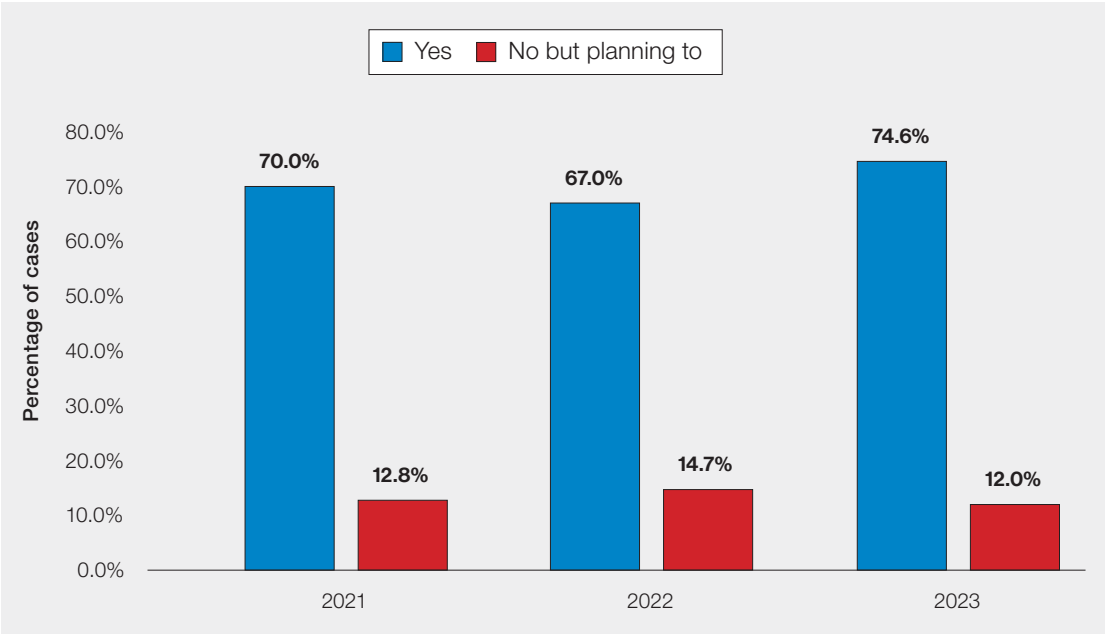
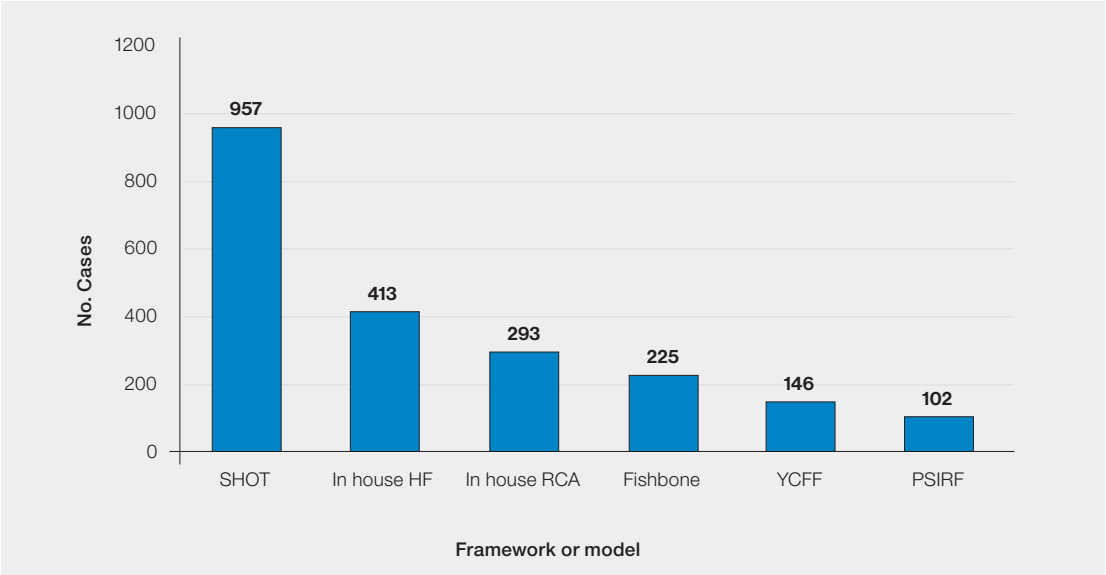


Figure 8.2: Percentage of cases investigated using HFE principles or framework

Of those using a HFE framework, 2227/2376 (93.7%) provided data about the type that was used. The most common response 957/2227 (43.0%) used the SHOT HFIT questions, which were adapted from the evidence-based YCFF framework (Improvement Academy, 2022) and 146/2227 (6.6%) used the YCCF framework, making it the fifth most commonly used. Figure 8.3 shows that apart from using SHOT questions, the top frameworks used were most commonly in-house HFE and RCA tools. It should be noted that it is an outdated concept to use RCA tools that encourage searching for a single root cause (Peerally, et al., 2017).

PSIRF was introduced in England in 2022 to replace the NHSE Serious Incident Framework and understandably, in that year, PSIRF was selected as the framework in only a handful of investigations, 14/1717 (0.8%). For 2023, this has risen to 102/2227 (4.6%) as organisations in England transition and implement the framework. A document is available to answer questions regarding the recording, reporting and investigation of transfusion-related adverse incidents 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 (Department of Health, 2005).

Figure 8.3: Top six human factors frameworks used for incident investigation as submitted by SHOT reporters in 2023



HF=human factors; PSIRF= Patient Safety Incident Response Framework; RCA=root cause analysis; YCFF=Yorkshire Contributory Factors Framework

The SHOT HFIT questions, and the analyses in this chapter, are only included for reports in established error categories, but it can be demonstrated that some reaction cases may also be error-based. For the first time this year, a TACO case has been included in the supplementary information using the HFIT main headings to examine the significance of the HFE involved. This case can be found in the supplementary information on the SHOT website (https://www.shotuk.org/shot-reports/report-summary-and-supplement-2023/).

A general observation from the analysis of contributory factors provided in reports was that residual COVID-19 pressures remain apparent, affecting both workforce and processes. This has been demonstrated in Chapter 15, Laboratory Errors. A report on wider workforce and patient safety issues, including the impact of temporary staffing in England was published by the HSSIB in March 2024 (HSSIB, 2024).

Conclusion

It is vital that senior management in healthcare organisations recognise the importance of an understanding of HFE and that there is a growing evidence base, and thus business case, for introducing a restorative just culture. Within a restorative just and learning culture, the continued use of actions targeting individual staff members is unsuitable. Recognition and implementation of system-level interventions are paramount. Action plans should be in place to facilitate long-term interventions, such as vein-to-vein IT solutions, even if these actions cannot be easily closed on quality management systems.

SHOT
Serious Hazards of Transfusion

Recommended resources

SHOT Human Factors and Ergonomics (HFE) module
https://learninghub.nhs.uk/catalogue/NHSBT-Learning-Zone

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

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

References

Carthey, J. et al., 2011. Breaking the rules: understanding non-compliance with policies and guidelines. *BMJ,* 343(d5283). doi: https://doi.org/10.1136/bmj.d5283.

Dekker, S., 2022. *Restorative Just Culture Checklist.* [Online]
Available at: https://sidneydekker.com/wp-content/uploads/2022/04/RestorativeJustCultureChecklist.pdf
(Accessed 06 March 2024).

Dekker, S., Oates, A. & Rafferty, J., 2022. *Restorative Just Culture in Practice Implementation and Evaluation.* 1st ed. New York: Routledge. doi: https://doi.org/10.4324/9781003162582.

Department of Health, 2005. *The Blood Safety and Quality Regulations 2005.* [Online]
Available at: https://www.legislation.gov.uk/uksi/2005/50/introduction/made
(Accessed 11 April 2024).

Healthcare Improvement Scotland, 2019. *Learning from adverse events through reporting and review. A national framework for Scotland,* Scotland: Healthcare Improvement Scotland. Available at: https://www.healthcareimprovementscotland.scot/wp-content/uploads/2024/03/20191216-AE-framework-4th-Edition.pdf (Accessed 03 May 2024).

Health Services Safety Investigations Body (HSSIB), 2024. *Workforce and patient safety.* [Online]
Available at: https://www.hssib.org.uk/patient-safety-investigations/workforce-and-patient-safety/
(Accessed 25 May 2024).

Improvement Academy, 2022. *Yorkshire Contributory Factors Framework.* [Online]
Available at: https://improvementacademy.org/resource/yorkshire-contributory-factors-framework/
(Accessed March 27 2024).

Johnstone, R., 2017. Glut of anesthesia guidelines a disservice, except for lawyers. [Online] *Anesthesiology News,* 43(1), pp.1-6. Available at: https://www.researchgate.net/publication/315754396_Glut_of_anesthesia_guidelines_a_disservice_except_for_lawyers (Accessed 08 April 2024).

Lounsbury, O. & Sujan, M., 2023. Achieving a restorative Just Culture through the patient safety incident response framework. *Journal of Patient Safety and Risk Management,* 28(4), pp. 153-155. doi: https://doi.org/10.1177/25160435231194397.

Mersey Care NHS Foundation Trust, 2024. *Restorative Just and Learning Culture.* [Online]
Available at: https://www.merseycare.nhs.uk/restorative-just-learning-culture (Accessed 06 March 2024).

Narayan, S. et al., 2023. *The 2022 Annual SHOT Report,* Manchester: Serious Hazards of Transfusion (SHOT) Steering Group. doi: https://doi.org/10.57911/WZ85-3885.

NHS Wales Executive, 2023. *National Policy on Patient Safety Incident Reporting & Management,* Wales: NHS Wales. Available at: https://du.nhs.wales/files/incidents/national-policy-on-patient-safety-incident-reporting-2-0-pdf/ (Accessed 03 May 2024).

NHS England (NHSE), 2023. *Patient Safety Incident Response Framework.* [Online]
Available at: https://www.england.nhs.uk/patient-safety/patient-safety-insight/incident-response-framework/ (Accessed 31 January 2024).

NHS England (NHSE), 2024. *NHS leadership competency framework for board members.* [Online]
Available at: https://www.england.nhs.uk/long-read/nhs-leadership-competency-framework-for-board-members/
(Accessed 03 March 2024).

Peerally, M. F., Carr, S., Waring, J. & Dixon-Woods, M., 2017. The problem with root cause analysis. *BMJ Quality & Safety,* Volume 26, pp. 417-422. doi: https://doi.org/10.1136/bmjqs-2016-005511.

Adverse Events Related to Anti-D Immunoglobulin (Ig) n=425

9

Authors: Jennifer Davies, Simon Carter-Graham and Vera Rosa

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	**NICE**	National Institute for Health and Care Excellence
cffDNA	Cell-free fetal deoxyribonucleic acid	**NIPT**	Non-invasive prenatal testing
FMH	Fetomaternal haemorrhage	**PSE**	Potentially sensitising event
IBGRL	International Blood Group Reference Laboratory	**RAADP**	Routine antenatal anti-D Ig prophylaxis
Ig	Immunoglobulin	**SOP**	Standard operating procedure
IT	Information technology	**SOT**	Solid organ transplant
LIMS	Laboratory information management system		

Key SHOT messages

- High numbers of anti-D Ig errors continue to be reported. Delays and omissions in administration of anti-D Ig (following PSE and RAADP) account for the majority of errors. Previous SHOT recommendations remain relevant to reduce risk of these errors
- NIPT using cffDNA can predict the D-type of the fetus supporting targeted use of anti-D Ig/ RAADP. Challenges remain with access to results, misinterpretation of results and false-positive/ negative results

Recommendations

- Interoperability between LIMS, including reference laboratory, and maternity systems reduces risk of transcription errors and should be implemented
- Organisations should review current processes to identify gaps where improvements could be implemented to support safe practice
- Processes should be in place that support recognition of the need for anti-D Ig in non-gynaecology and maternity settings

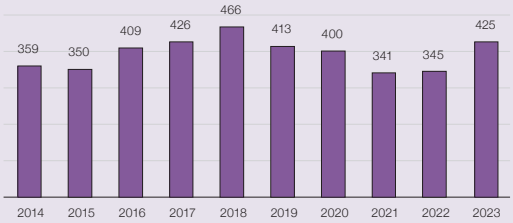
Action: Laboratory management, IT departments, maternity services, reference laboratories

SHOT
Serious Hazards of Transfusion

Headline data 2023

Number of reports n=425
Deaths n=0
Major morbidity n=1

Anti-D Ig reports by year



Demographic data

Male n=0
Female n=425
Adults n=412
Paediatric n=1
Unknown n=12

Potential for major morbidity n=284

Late/omitted RAADP n=98
Late/omitted anti-D Ig following a PSE (including delivery) n=186

Introduction

Guidelines for safe and appropriate administration of anti-D Ig post sensitising events and RAADP have now been in place for many years (Qureshi, et al., 2014; NICE, 2008; NICE, 2019; NICE, 2023). 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 and D-mismatch SOT (Qureshi, et al., 2014). In this chapter, 425 cases have been analysed, mainly related to anti-D Ig management during pregnancy. In addition, 41 near miss cases were reported.

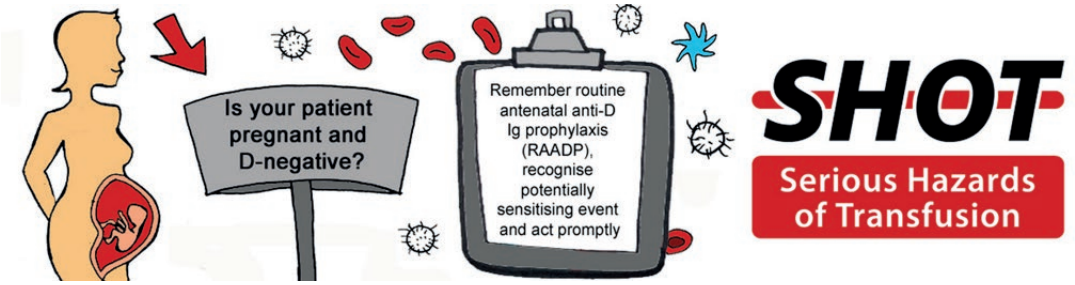
SHOT data continue to demonstrate that errors in anti-D Ig and RAADP management occur in both clinical and laboratory settings. The management of patients requiring anti-D Ig and RAADP is multifaceted, errors can occur at all stages of the process.

Deaths related to transfusion n=0

There were no deaths reported in the cases analysed for 2023 related to anti-D Ig errors.

Major morbidity n=1

A mother developed immune anti-D following omission of anti-D Ig during pregnancy, this is detailed in Chapter 27, Immune Anti-D in Pregnancy. 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. The impact of anti-D Ig and RAADP errors should not be underestimated.



Overview of cases n=425

Omission or late administration of anti-D Ig/RAADP continue to account for the majority of errors, 284/425 (66.8%) (Table 9.1). These were mainly related to discharge prior to administration, 81/284 (28.5%), failure to order, 60/284 (21.1%), failure to check relevant results, 44/284 (15.5%) and incorrect decision to omit, 36/284 (12.7%). Where incorrect decisions resulted in omission, the majority were for PSE (30/36), notably where mothers were seen outside of maternity and gynaecology settings. Formal investigation following the error had been performed in 282/425 (66.4%) cases. Failures in team function, poor written or verbal communication, gaps in knowledge and mismatch between workload and staff provision were the most common contributory factors identified in errors.

Anti-D Ig category	Number of reports
Omission or late administration of anti-D Ig	284
Anti-D Ig given to the mother of a D-negative infant	59
Wrong dose of anti-D Ig given	16
Anti-D Ig given to a woman with immune anti-D	15
Anti-D Ig handling and storage errors	14
Anti-D Ig given to a D-positive woman	11
Anti-D Ig given to the wrong woman	10
Right product right patient	8
Miscellaneous	8
Total	**425**

Table 9.1: Distribution of anti-D Ig related error reports in 2023 (n=425)

Case 9.1: Incorrect decision to omit anti-D Ig

During a major haemorrhage protocol activation, an adult therapeutic dose of D-positive platelets was transfused to a D-negative mother. The baby's sample tested D-negative at delivery. The clinical team returned the anti-D Ig because the baby was D-negative, failing to recognise the need for anti-D Ig following the transfusion of D-positive platelets.

It is important to remember that anti-D Ig may be required where D-positive blood components are given to D-negative patients of childbearing potential (Qureshi, et al., 2014). This can occur within, or outside the maternity setting and is unrelated to the infant D-type.

Case 9.2: Incorrect dose of anti-D Ig following cell salvage

A dose of 500IU anti-D Ig was given to a mother post delivery. The laboratory was not informed that cell salvage products had been re-infused and that a 1500IU dose should have been provided.

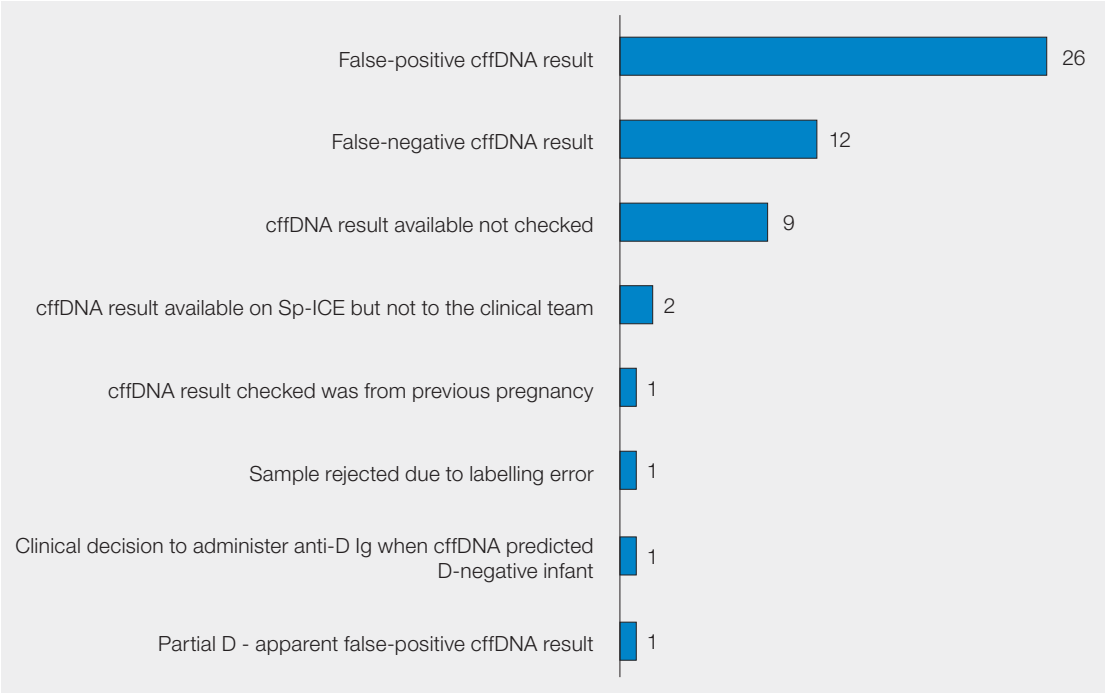
Where 500IU anti-D Ig is used for PSE and post delivery, effective communication with the laboratory where cell salvage has been re-infused helps ensure an appropriate dose (1500IU) is provided in accordance with BSH guidelines (Qureshi, et al., 2014).

Non-invasive prenatal screening n=53

Since 2016, high-throughput NIPT for fetal *RHD* (cffDNA) screening has been available across the UK for non-immunised D-negative pregnant women (NICE, 2016). Prediction of the fetal D-type enables targeted administration of anti-D Ig. 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 screening results. False-positive and false-negative results must be reported

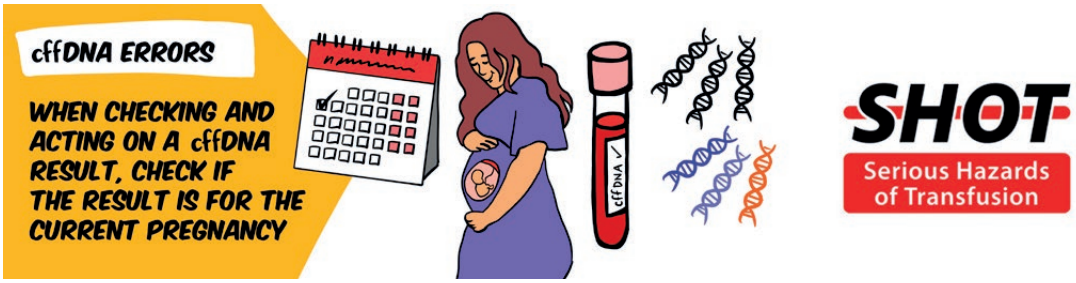
to SHOT and to the test provider. A checklist for investigation of discrepant results is available on the SHOT website and can be used for local investigation (see 'Recommended resources'). The screening assay should not be confused with the diagnostic assay for fetal D-typing, provided by IBGRL, which provides a higher level of specificity and sensitivity and is performed where the mother has immune anti-D. SHOT only collect data relating to errors with the screening assay.

Figure 9.1: Number and breakdown of cases related to non-invasive prenatal screening for RHD (n=53)



cffDNA=cell free fetal deoxyribonucleic acid; Ig=immunoglobulin; Sp-ICE=Specialist Services Integrated Clinical Environment

In total, 53 reports were analysed by SHOT in 2023. From those 26/53 were false-positive cffDNA results and 12/53 false-negative (Figure 9.1). Cases where cffDNA results were available to both laboratory and clinical areas but not checked prior to anti-D Ig issuing or administration accounted for 9/53 cases.



Involvement of information technology n=68

IT was noted as being involved in errors in 68/425 (16.0%) of cases, the majority of these related to omission or delay, 26/68 (38.2%) and anti-D Ig administered to a mother with a D-negative infant, 20/68 (29.4%).

The involvement of IT was varied but the main themes included:

- IT in place but not used, used incorrectly or not working
- Lack of interoperability between different IT systems (reference laboratory, local laboratory, and clinical systems)
- Flags in laboratory IT systems not heeded
- HSE cases where anti-D Ig was stored in devices outside laboratory control and without electronic temperature excursion alerts

Near miss cases n=41

There were 41 near miss cases analysed in 2023. Omission or late administration (8/41) and wrong dose (8/41) were the most common categories, followed by anti-D Ig issued but not administered to a woman carrying/delivering a D-negative infant (7/41) (Table 9.2). Laboratory errors accounted for over half of the total cases, 28/41 (68.3%) with 12 errors occurring during component selection where baby's blood group, mother antibody status or cffDNA results for current pregnancy were not checked prior to issue of anti-D Ig (8/12).

In most cases, 28/41, (68.3%) the NM occurred due to a failure to follow SOP or policy. This highlights the importance of ensuring that SOP and policies are clear and comprehensive to allow easy and unambiguous practice embedded within a system that supports safe practice.

Checks at pre-administration were the point of error detection in 16/41 cases, with a pre-administration checklist used in 10/16 cases. Other stages of detection included during testing, at authorisation of results, at collection and during routine equipment checking.

Anti-D Ig category	Number of reports
Omission or late administration of anti-D Ig	8
Wrong dose of anti-D Ig given	8
Anti-D Ig given to the mother of a D-negative infant	7
Anti-D Ig handling and storage errors	4
Right product right patient	4
Anti-D Ig given to a D-positive woman	3
Anti-D Ig given to a woman with immune anti-D	3
Anti-D Ig given to the wrong woman	2
Miscellaneous	2
Total	**41**

Table 9.2: Distribution of anti-D Ig related near miss events in 2023 (n=41)

A formal investigation was performed in 30/41 (73.2%) cases. The NM event was reviewed in 32/41 (78.0%) cases and in 6/32 changes were made to transfusion procedures or policy. These changes included implementation of checklists and additional checking steps. In 1 case, a distraction-free area in the blood transfusion laboratory was created where critical tasks are performed. Learning from NM events is acknowledged as a process to improve patient safety where patient harm has occurred (Woodier, et al., 2023; Jung, et al., 2021). It is important to recognise the valuable learning from NM and apply the same investigation tools to NM as for actual incidents. SHOT has been promoting the learning from NM as 'free lessons' and organisations should embed the NM investigation as part of their policies.

Learning point

- Management of anti-D Ig requires laboratory and clinical involvement. There are multiple steps to safe and appropriate administration. Formal investigation of errors and review of systems enables identification of potential gaps in processes and effective preventive measures that can be implemented

Conclusion

Safe and appropriate management of anti-D Ig requires a collaborative approach between the laboratory and other services, including maternity and gynaecology. Application of a systems-thinking approach, including consideration of human factors and ergonomics, enables implementation of barriers to error at each step in the process. It is encouraging to note that more organisations are looking to IT systems to support safe practice. IT systems, laboratory and clinical, can support safe practice but it is important to remember that these provide a safety net, they do not replace staff knowledge, and they need to be configured, maintained, and used correctly to optimise benefit. Staff training is a keystone in safe practice, induction training is critical as processes may be different across organisations. D-negative mothers, or their carers, should be provided with clear information about anti-D Ig, including the risks of missing routine appointments, and considered partners in antenatal care. Errors related to anti-D Ig consistently account for the highest proportion of errors reported to SHOT. Organisations where effective processes have been implemented, and where low error rates are seen, are encouraged to share their excellent practice via SHOT ACE reporting.

Recommended resources

Anti-D Immunoglobulin (Ig) Administration to avoid sensitisation in pregnancy - an aide memoire SHOT 2023
cffDNA discrepancy investigation form
IT supports anti-D Ig management in pregnancy
https://www.shotuk.org/resources/current-resources/

SHOT Bite No 2: Anti-D Ig Administration
SHOT Bite No 28: cffDNA screening errors
https://www.shotuk.org/resources/current-resources/shot-bites/

SHOT Videos Anti-D Immunoglobulin errors and immunisation in pregnancy: insights from SHOT (Part 1 and Part 2)
https://www.shotuk.org/resources/current-resources/videos/

References

Jung, O. S. et al., 2021. Resilience vs. Vulnerability: Psychological Safety and Reporting of Near Misses with Varying Proximity to Harm in Radiation Oncology. *The Joint Comission Journal on Quality and Patient Safety*, 47(1), pp. 15-22. doi: 10.1016/j.jcjq.2020.09.005.

Mackie, F. L. et al., 2017. The accuracy of cell-free fetal DNA-based non-invasive prenatal testing in singleton pregnancies: a systematic review and bivariate meta-analysis. *An International Journal of Obstetrics and Gynaecology*, 124(1), pp. 32-4. doi: https://doi.org/10.1111/1471-0528.14050.

National Institute for Health and Care Excellence (NICE), 2008. *Routine antenatal anti-D prophylaxis for women who are rhesus D negative TA156*. [Online] Available at: https://www.nice.org.uk/guidance/ta156 (Accessed 12 February 2024).

National Institute for Health and Care Excellence (NICE), 2016. *High-throughput non-invasive prenatal testing for fetal RHD genotype [DG25]*. [Online] Available at: https://www.nice.org.uk/guidance/dg25 (Accessed 12 February 2024).

National Institute for Health and Care Excellence (NICE), 2019. *Abortion care [NG140].* [Online] Available at: https://www.nice.org.uk/guidance/ng140/chapter/Recommendations#anti-d-prophylaxis (Accessed 12 February 2024).

National Institute for Health and Care Excellence (NICE), 2023. *Ectopic pregnancy and miscarriage: diagnosis and initial management [NG126]*. [Online] Available at: https://www.nice.org.uk/guidance/ng126/chapter/Recommendations#anti-d-rhesus-prophylaxis (Accessed 12 February 2024).

Qureshi, H. et al., 2014. BCSH guideline for the use of anti-D immunoglobulin for the prevention of haemolytic disease of the fetus and newborn. *Transfusion Medicine*, 24(1), pp. 1-66. doi: https://doi.org/10.1111/tme.12091.

Woodier, N., Burnett, C., Sampson, P. & Moppett, I., 2023. Patient safety near misses – Still missing opportunities to learn. *Journal of Patient Safety and Risk Management*, 0(0), pp. 1-7. doi: 10.1177/25160435231220430.

Incorrect Blood Component Transfused (IBCT) n=356

10

Authors: Nicola Swarbrick, Simon Carter-Graham and Victoria Tuckley with input from Caryn Hughes 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).

Abbreviations used in this chapter

ABOi	ABO-incompatible
AIHA	Autoimmune haemolytic anaemia
BMS	Biomedical scientist
CMV	Cytomegalovirus
FFP	Fresh frozen plasma
Hb	Haemoglobin
HSCT	Haematopoietic stem cell transplant
HSSIB	Health Service Safety Investigations Body
IBCT	Incorrect blood component transfused
ID	Identification
IT	Information technology
LIMS	Laboratory information management system
MHP	Major haemorrhage protocol
NM	Near miss
PID	Patient identification
PPID	Positive patient identification
SRNM	Specific requirements not met
UK	United Kingdom
UKTLC	UK Transfusion Laboratory Collaborative
WBIT	Wrong blood in tube
WCT	Wrong component transfused

Key SHOT messages

- Laboratory IBCT errors, both WCT and SRNM, have increased substantially (356 in 2023 compared to 296 in 2022)
- There were 10 ABOi transfusions in 2023, 7 red cell and 3 FFP
- There has been a dramatic rise in the number of component selection errors, particularly to HSCT patients, resulting in the wrong ABO group being transfused to patients
- Many errors involve patient identification, particularly at sample taking, blood collection and administration

Recommendations

- Accurate and complete PID is fundamental to transfusion safety. Training in correct PID procedures must be provided to all staff

Action: All staff in transfusion, ward managers

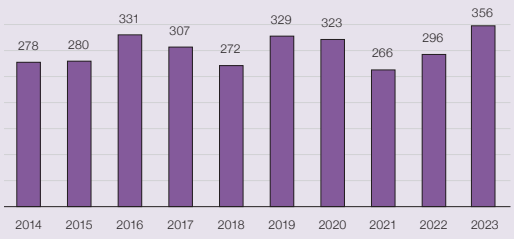
- Transfusion competency training and assessment should be audited for effectiveness, particularly following errors. Competency-assessment should not just be a tick-box exercise
- Access to specialist transfusion advice should be available to all transfusion staff at all times (SHOT, 2024)

Action: Transfusion laboratory managers, ward managers

Headline data 2023

Number of reports n=356
Deaths n=0
Major morbidity n=6

IBCT reports by year



Demographic data

Male n=160
Female n=177
Unknown n=19

Adults n=290
Paediatric n=45
Unknown n=21

Blood component data

Red cells n=304
Platelets n=35
Plasma n=12
Multiple components n=1
Granulocytes n=0
Cryoprecipitate n=1
Unknown n=3

Introduction

IBCT events have the potential to lead to patient harm including major morbidity and death, as seen in serial Annual SHOT Reports. These errors accounted for 356/3833 (9.3%) of reports in 2023, which is an increase on previous year's data. A reduction in clinical errors but a striking increase in laboratory errors was noted. The total number of IBCT-WCT reports has increased in 2023 to 121 from 87 in 2022, and an increase in the number of IBCT-SRNM reports to 235 from 209 in 2022. Figure 10.1 provides an overview of reports submitted to SHOT in 2023 where an incorrect blood component was transfused. This category includes instances where wrong components were transfused, and/or specific requirements were not met.

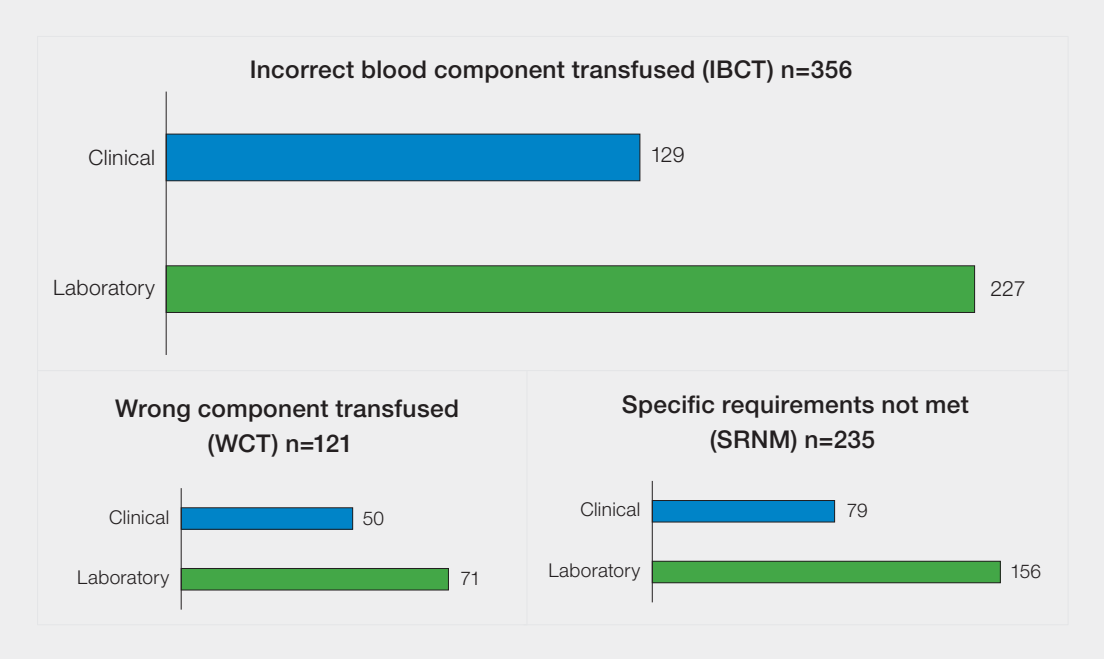


Figure 10.1: Overview of reports where an incorrect blood component was transfused in 2023 (n=356)

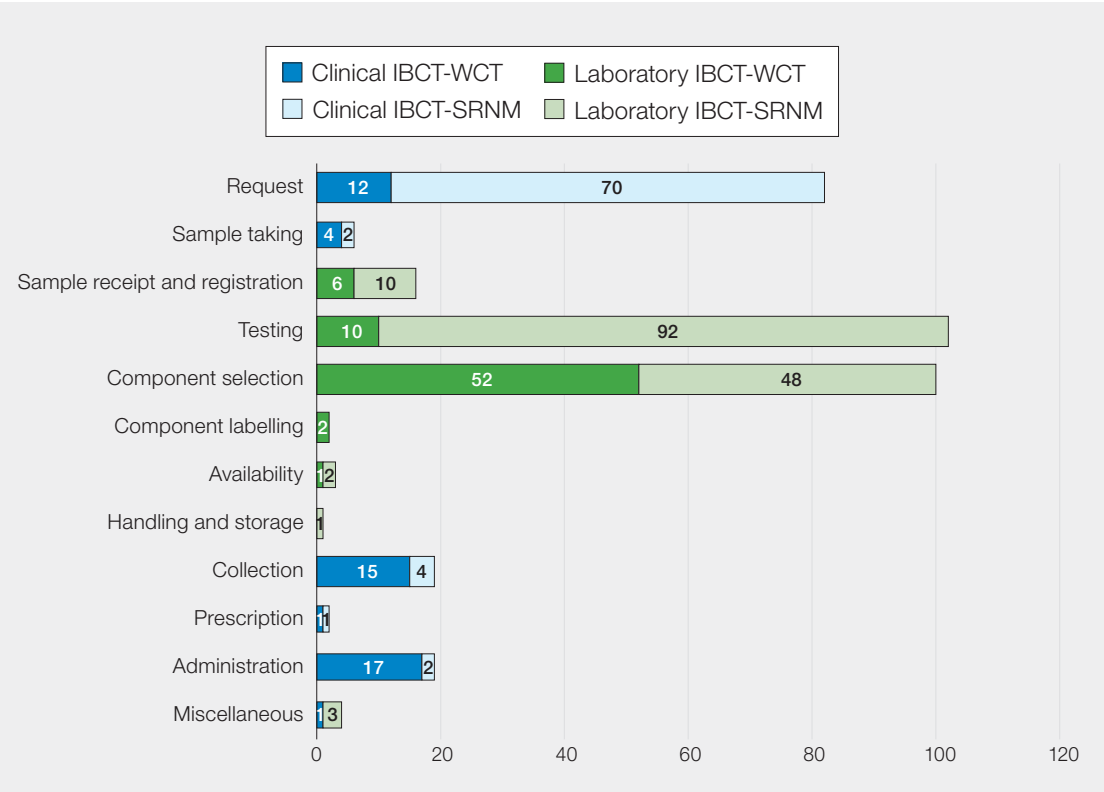


Figure 10.2: Total IBCT errors categorised by the step in the transfusion process where the error occurred (n=356)

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, 82/129 (63.6%), followed by collection, 19/129 (14.7%) and administration, 19/129 (14.7%) stages. In the laboratory, most errors occurred at testing, 102/227 (44.9%) and component selection, 100/227 (44.1%) stages.

Deaths related to transfusion n=0

There were no patient deaths in 2023 due to IBCT errors.

Major morbidity n=6

There were 6 cases of major morbidity related to IBCT errors: 4 laboratory and 2 clinical. The 2 clinical cases are detailed below in Table 10.1. In 1 case, the safety checks were not performed correctly at the collection stage and in the other, there was a failure to perform PPID at the administration stage.

The 4 laboratory cases of major morbidity resulted in sensitisation to the K antigen in patients of childbearing potential due to component selection errors. One patient developed an anti-K antibody with a titre of 1 in 256. In 3 cases there were LIMS alerts to prevent the error, but these were overridden by BMS staff. These cases are discussed further in Chapter 15, Laboratory Errors.

ABO-incompatible (ABOi) transfusions n=10

There were 7 red cell and 3 FFP ABOi transfusions included in 2023. All the red cell ABOi transfusions were because of clinical errors (collection and administration errors), with 2 resulting in major morbidity. Two component selection errors in the laboratory resulted in group O FFP being issued to non-group O patients. The third FFP case involved a historical WBIT sample which occurred in 2011 and was reported in 2023. Salient points of these are covered in Table 10.1, and detailed case descriptions can be found in the supplementary information on the SHOT website (https://www.shotuk.org/shot-reports/report-summary-and-supplement-2023/).

Table 10.1: ABOi transfusions reported in 2023 (n=10)

Case number	Case 1	Case 2	Case 3
Component transfused	Red cells group A 	Red cells group B 	Red cells group A 
Patient group	Group O	Group O	Group O
Volume transfused	>50mL	<50mL	>50mL
Primary error	**Administration** Ineffective patient ID checks	**Administration** Ineffective patient ID checks	**Collection** Wrong pickup slip used. Ineffective patient ID checks
Error detection	When patient became unwell after 100mL transfused	When 15 minute observations were being carried out	When patient became unwell after whole unit transfused
Patient impact	**Major morbidity**	**Minor morbidity**	**Death (unrelated)**
Imputability	3	2	0
Urgency	Routine	Routine	Emergency
MHP	No	No	No
Department	Ward	Ward	Ward
Adult/paediatric	Adult	Adult	Adult
Administration checklist used. Patient ID	Yes (paper) 2-person independent check	Yes (paper) 2-person independent check	No 2-person check
ID band in place	Yes	Yes	Yes

Case number	Case 4	Case 5	Case 6
Component transfused	Red cells group A 	Red cells group A 	Red cells group A 
Patient group	Group O	Group O	Group O
Volume transfused	>50mL	>50mL	1 unit
Primary error	**Collection** Wrong unit collected Ineffective patient ID checks	**Collection** Wrong unit collected Ineffective pre-transfusion checks	**Collection** Ineffective patient ID checks
Error detection	Within 3 minutes of start of transfusion	When patient became unwell after at least 50mL transfused	Six days later when patient had repeat group and save
Patient impact	**Death (unrelated)**	**Major morbidity**	**No clinical reaction**
Imputability	0	3	N/A
Urgency	Emergency	Routine	Routine
MHP	No	No	No
Department	Intensive care unit	Hamatology OPD	Ward
Adult/paediatric	Adult	Adult	Adult
Administration checklist used. Patient ID	No 2-person check	No 2-person dependent check	Yes (paper) 1-person check
ID band in place	Yes	Yes	Yes

Case number	Case 7	Case 8	Case 9	Case 10
Component transfused	Red cells group B 	FFP group O 	FFP group O 	FFP group O 
Patient group	Group O	Group B	Group B	Group B
Volume transfused	<50mL	2 units	<50mL	<50mL
Primary error	**Administration** Incomplete patient ID checks carried out	**Component selection** Group O red cells issued due to limited B stock, which prompted laboratory to issue group O FFP in error. LIMS did not prevent issue of group O to non-O patients	**Component selection** Issued group O FFP when only one previous sample. Infant transfused O red cells at other organisation, therefore grouping as group O	**Sample taking** Historical (2011) WBIT
Error detection	Identified by ward staff when there was an issue with IV line	When laboratory staff realised their error	Communication from transferring hospital	Lookback investigation following subsequent sample issue
Patient impact	**No clinical reaction**	**No clinical reaction**	**Death (unrelated)**	**No clinical reaction**
Imputability	N/A	N/A	0	N/A
Urgency	Routine	Emergency	Urgent	Emergency
MHP	No	Yes	No	Not known
Department	Ward	Theatre	NICU	ED
Adult/paediatric	Adult	Adult	Neonate	Adult

Case number	Case 7	Case 8	Case 9	Case 10
Administration checklist used. Patient ID	Yes (paper) 2-person independent check	Yes (paper) 2-person independent check. Exit checklist used by laboratory	Not known	Not known
ID band in place	Yes	Yes	Yes	Not known

It is concerning to note the upward trend in ABOi red cell transfusions (see Chapter 3, Headline Data, Figure 3.8). Sample taking, collection and administration stages of the transfusion pathway remain weak points for accurate patient identification leading to IBCT errors. Staffing shortages with steep increases in workload, resource constraints, administrative burdens, and complexity of healthcare delivery all contribute to these errors. The recently published HSSIB report, detailing issues relating to patient misidentification, outlines that these concerns impact on patient safety in all areas of healthcare including blood transfusion (HSSIB, 2024). Urgent actions are needed to address these issues and improve patient safety.

Clinical IBCT errors n=129

There were 129/356 (36.2%) cases reported in 2023 which is a decrease from the 144/296 (48.6%) in the 2022 Annual SHOT Report.

Clinical IBCT-WCT errors n=50

This was a slight increase in cases from 44 in the 2022 Annual SHOT Report.

There was a total of 15/50 (30.0%) transfusions of the wrong component type, 17/50 (34.0%) of the wrong group and 18/50 (36.0%) to the wrong patient.

More than a third of the IBCT-WCT errors, 17/50 (34.0%) occurred at the point of administration and resulted in 1 transfusion of the wrong component type, 3 wrong group transfusions and 13 cases where blood components were transfused to the wrong patient (Figure 10.3). This included 3 ABOi red cell transfusions.

There were 15/50 (30.0%) errors at collection of the component from the storage area which resulted in 9 wrong component types transfused, 3 wrong blood group transfused and 3 where components were administered to the wrong patient (Figure 10.3). This included 4 ABOi red cell transfusions.

Case 10.1: Red cells administered in error instead of platelets

A patient was due to undergo spinal surgery. As they had been taking clopidogrel, two adult therapeutic units of platelets were prescribed to be given pre surgery. The patient's Hb was 152g/L. A nurse asked the porter to collect 'one unit of blood' from a remote issue refrigerator. The red cells were issued to the patient for use during surgery if required but had not been prescribed. The nurse administering the transfusion reported that pre-transfusion safety checks were completed, but this failed to pick up that the wrong blood component was about to be administered. The unit of red cells was transfused uneventfully. When another nurse requested platelets to be collected, a second unit of red cells was brought to the ward. When the nurse realised the wrong component had been delivered, the previous transfusion was checked, and the earlier error was identified. The

patient suffered no ill effects from the red cell transfusion and surgery went ahead as planned with the prescribed platelets being administered during the surgery.

The transfusion laboratory was reported to have been very busy so the platelets had not been issued to the patient when the first collection was requested and would not have appeared on the IT system.

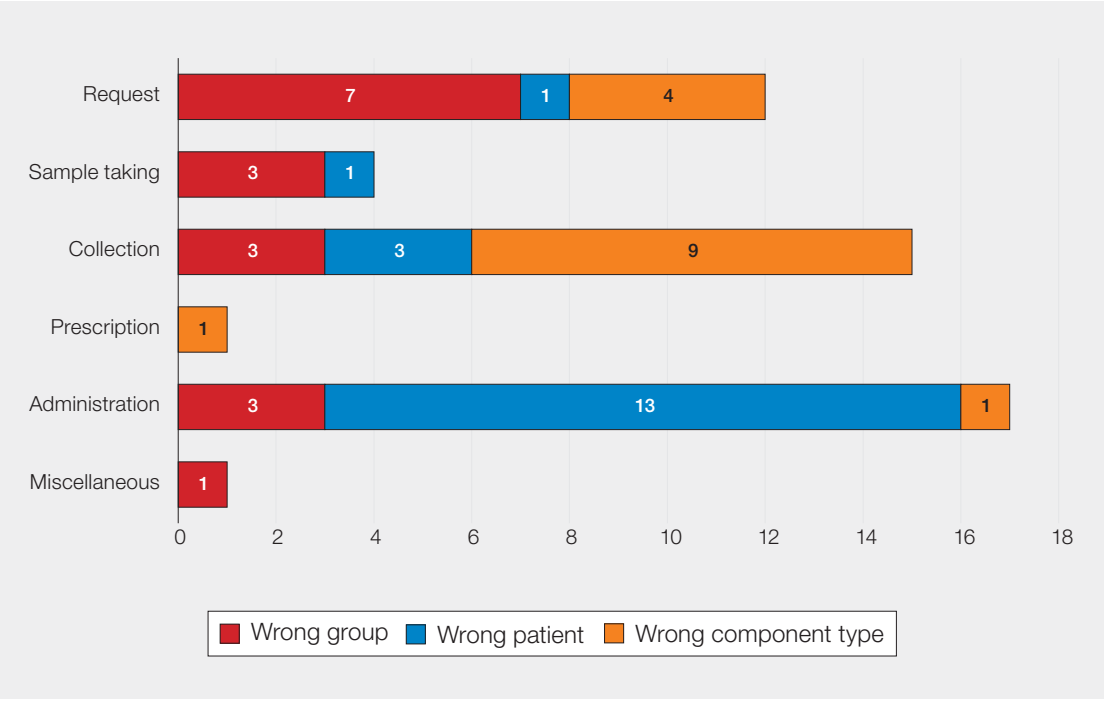


Figure 10.3: Categorisation of clinical IBCT-WCT errors by step where the primary error occurred (n=50)

Of the clinical IBCT-WCT errors, 20/50 (40.0%) were routine transfusions and 10/50 (20.0%) were emergency. Most transfusions 36/50 (72.0%) occurred between 08:00-20:00.

IT was involved in 20/50 (40.0%) which included lack of functionality of some systems, lack of interoperability and systems being available but not being used.

Learning points

- Collection and administration of blood components are critical steps in the transfusion process and effective procedures should be in place to ensure that necessary checks are performed
- It is vital to conduct positive patient identification and complete all the final checks next to the patient immediately prior to administration of the component
- When completing final administration checks it is important to ensure the correct component type is being given

Clinical IBCT-SRNM errors n=79

The number of clinical IBCT-SRNM 79/356 (22.2%) has decreased from 100/296 (33.8%) in the 2022 Annual SHOT Report.

There were 54/79 (68.4%) cases where the requirement for irradiated components was not met. In 18/54 (33.3%) of reports the patient had a diagnosis of Hodgkin lymphoma. A further 20/54 (37.0%) patients had received purine analogues. Reasons for these failures included poor communication through shared care, clinical electronic systems not being updated and lack of knowledge of the requirement.

Errors mostly occurred at the request stage 70/79 (88.6%), with further errors at the collection stage 4/79 (5.1%), 2/79 (2.5%) each at sample taking and administration and 1/79 (1.3%) at the prescription/ authorisation stage.

Case 10.2: Shared care communication failure leads to transfusion of a non-irradiated blood component

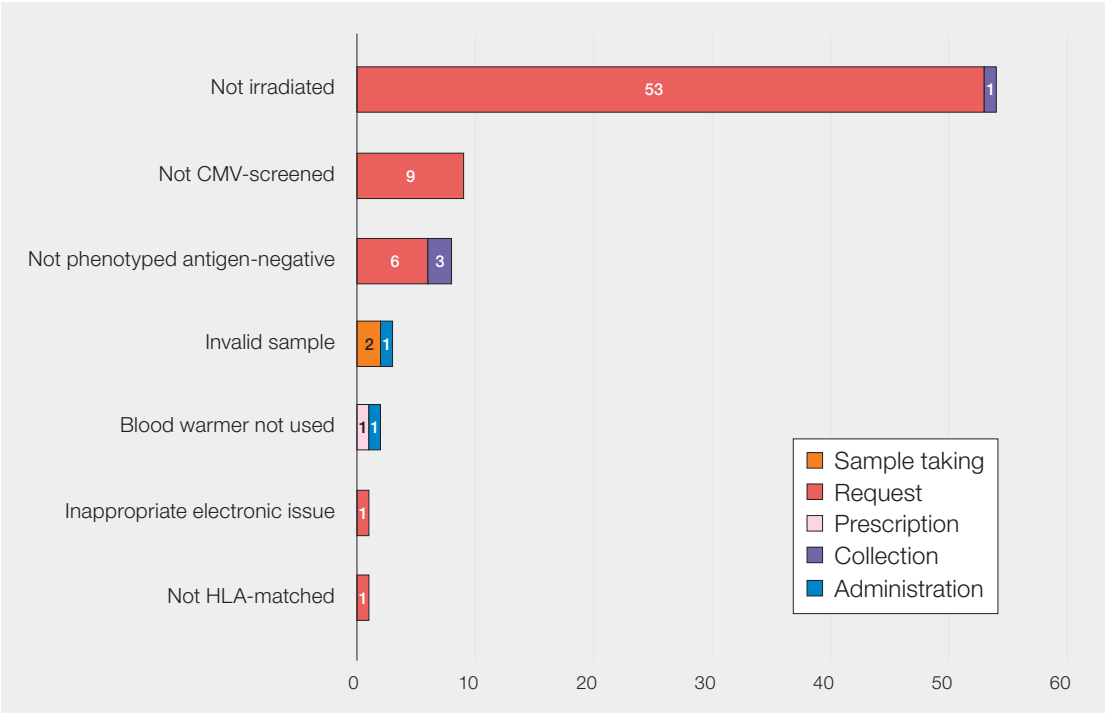
A patient with a history of Hodgkin lymphoma did not receive an irradiated red cell unit for an elective transfusion. The laboratory had not been informed of the patient's diagnosis by the clinician when the request was made therefore no alert was in place on the LIMS. Neither the request form nor the prescription/authorisation record stated the specific requirements, and no relevant clinical history was provided.

The patient was diagnosed several years previously, and their current care was shared by two hospitals, with no common electronic patient records or LIMS access. Lack of adequate patient information and access to appropriate records from the other hospital prevented any further questioning of the patients' specific requirements. At the time of writing, there was work being done to resolve this issue. The patient had no ill effects from this omission.

Adults and children with Hodgkin lymphoma are to receive irradiated blood components for life (Foukaneli, et al., 2020), yet data has shown that often the irradiation requirements for these patients is missed (Elliot, et al., 2021). In 2022 SHOT published a safety notice to highlight the importance of meeting transfusion specific requirements for all elective transfusions.

As with many reports in this category effective communication is key to preventing such errors. Highlighted in the ACE chapter is a case where staff made the specific requirements section of the request form mandatory (Chapter 6, Acknowledging Continuing Excellence in Transfusion (ACE), Case 11).

Figure 10.4: Clinical IBCT-SRNM errors and transfusion step where the error occurred (n=79)

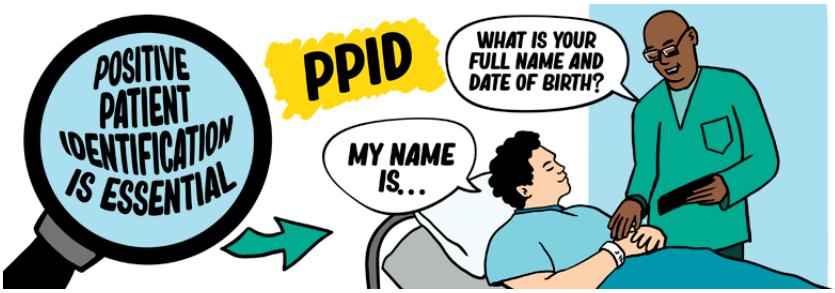


CMV=cytomegalovirus; HLA=human leucocyte antigen

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 relevant
- Specific requirements for transfusions must be documented in patient records (manual and/or electronic) and be easily accessible
- Effective processes for communication of specific requirements between the clinical area and laboratory increase the likelihood of safe transfusions occurring

- There are opportunities to identify the correct specific requirements at several steps in the transfusion process. Staff in both clinical and laboratory areas should remain vigilant and raise any suspected omission with requesting clinicians
- Where failures to meet specific requirements occur, these incidents should be thoroughly investigated, and appropriate improvement actions taken
- Healthcare professionals should comply with duty of candour to ensure transparency and partnership with patients



Laboratory IBCT errors n=227

In 2023 there has been a striking increase in reports of incorrect blood components transfused due to laboratory errors from 152/296 (51.4%) in 2022 to 227/356 (63.8%) in 2023. There has been an increase of laboratory errors resulting in IBCT-WCT from last year from 43 to 71, and an increase in IBCT-SRNM errors from 109 to 156 in 2023.

Laboratory IBCT-WCT errors n=71

Error subcategory	Sample receipt and registration	Testing	Component selection	Component labelling	Component availability
					
Number of error reports	6	10	52	2	1

Table 10.2: Laboratory IBCT-WCT errors in 2023 (n=71)

There were 71 laboratory errors which led to the wrong component being transfused, most of which were due to component selection errors, 52/71 (73.2%) and testing errors, 10/71 (14.1%) (Figure 10.5).

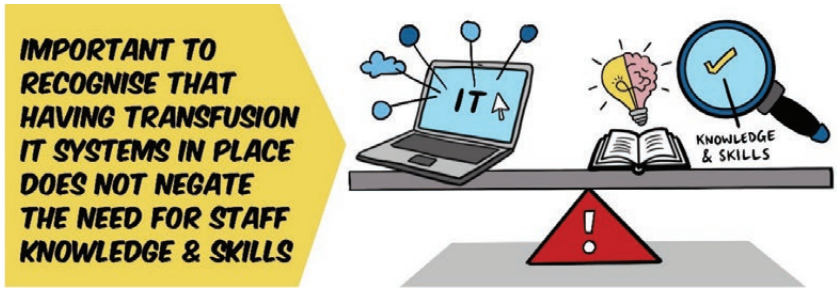
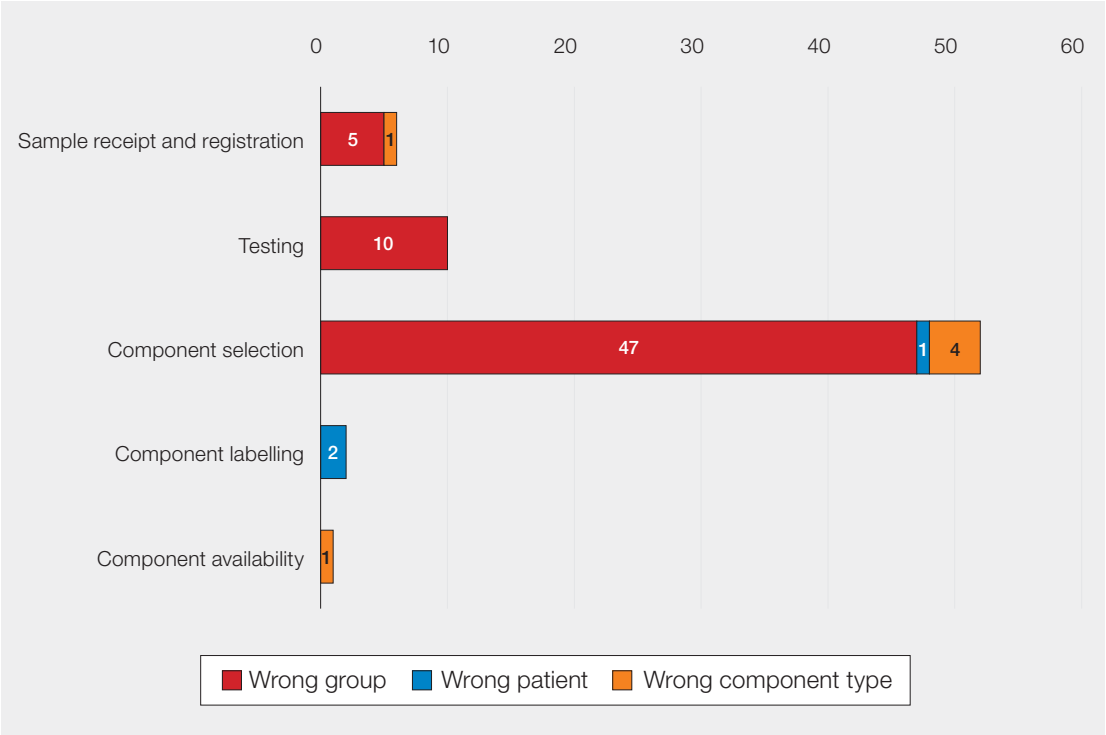


Figure 10.5: Laboratory IBCT-WCT errors by transfusion step (n=71)

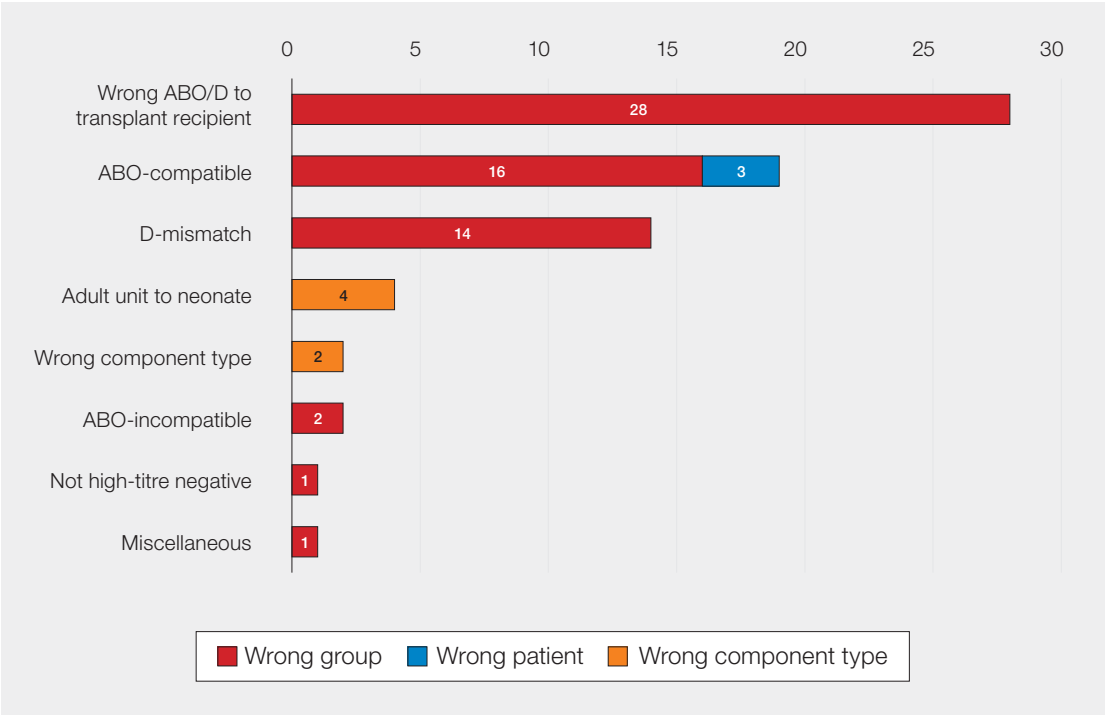


There were 28 laboratory errors which led to the wrong ABO/D group being transfused to transplant patients (Figure 10.6). Errors of incorrect group to transplant patients has more than doubled from last year's number of 13. IT was stated as an influencing factor in 27/28 cases and included lack of functionality in LIMS for transplant patients (16/28), LIMS flags not heeded (6/28), alerts not added or added incorrectly to LIMS (4/28) and failure to consult the historic record (1/28).

There were 14 laboratory errors which led to D-negative individuals receiving D-positive blood components, of which 4 were to children and 4 to females of childbearing potential.

Of the 19 laboratory IBCT-WCT errors which resulted in an ABO-compatible transfusion, 7 were due to group specific components being issued in the absence of a confirmatory group result.

Figure 10.6: Laboratory IBCT-WCT error by category (n=71)



Case 10.3: Incorrect ABO red cells transfused to a post-HSCT patient due to not heeding IT alerts

A group A D-positive patient received a group O D-positive HSCT. The patient grouped as O D-positive and seemed to be fully converted but further investigations were required to see if the patient had been transfused elsewhere to confirm this. A request for two units of red cells was received, and two A D-positive red cell units were issued, of which the patient received one unit. The patient's clinical notes clearly stated that O D-positive red cells should be given, and a 'specific group needed' flag previously added to the LIMS. The flag appeared when issuing the components but was misread and cleared using a comment designed for use on a 'phenotype required' flag. Secondary LIMS checks were also bypassed as the group and screen results were not validated before the blood was issued. Outstanding results were discovered and validated 12 hours later when checking the outstanding work. Unfortunately, the error was not noticed at this point and the second unit remained available for collection but was not required. The error was only detected during a subsequent request for red cell transfusion when BMS staff looked through recent transfusion history.

The BMS involved stated that they had been called in to cover the shift at short notice and were rushing to clear the workload. The laboratory has plans to install a new LIMS system which has rules for HSCT patient grouping requirements.

Please see 'Recommended resources' for guidance on safe transfusions in HSCT patients.

Learning points

- Where possible LIMS alerts and algorithms should be used to their full potential for transplant patients, both solid organ and HSCT
- Laboratory staff require sufficient knowledge of transplant ABO requirements to not rely on IT alerts alone
- Policies and processes must be in place to ensure specific transfusion requirements are met for all patients especially those with complex requirements

Laboratory IBCT-SRNM errors n=156

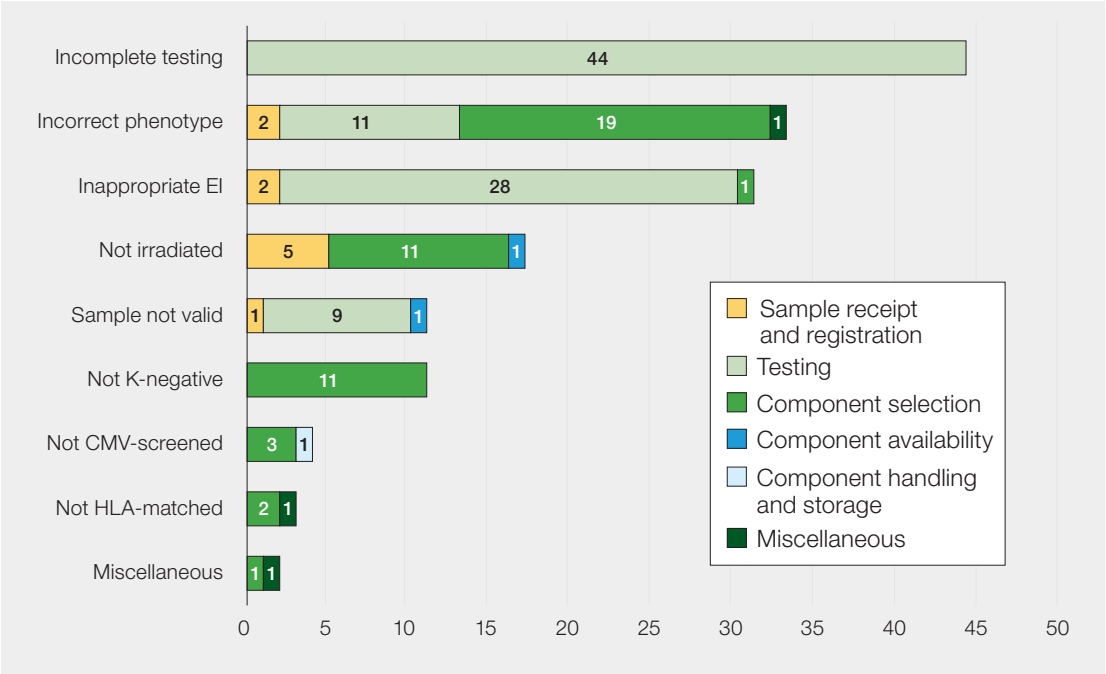
There were 156 laboratory errors which led to patients receiving blood components which did not meet their specific requirements, with the majority due to testing errors, 92/156 (59.0%) and component selection errors, 48/156 (30.8%), as illustrated in Table 10.3 and Figure 10.7.

Error subcategory	Sample receipt and registration	Testing	Component selection	Component handling and storage	Component availability
					
Number of error reports	**10**	**92**	**48**	**1**	**2**

Table 10.3: Laboratory IBCT-SRNM errors in 2023 (n=156)

Miscellaneous n=3

Figure 10.7: Laboratory IBCT-SRNM errors by transfusion step (n=156)



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

Testing errors n=92

Laboratory testing errors were due to issuing of components where testing was incomplete (44/92), inappropriate use of electronic issue (28/92), issue of red cells which were not phenotype/antigen-matched (11/92), and testing performed on invalid sample (exceeding validity timing) (9/92).

Where testing was incomplete, this was mainly due to:

- Failure to complete antibody identification (21/44) including incorrect antibody identification
- Failure to complete internal quality control prior to transfusion (6/44)
- Failure to validate test results prior to issue (5/44)

In 23/44 of the incomplete testing cases, there were issues related to LIMS, with alerts overridden, LIMS not used correctly, or LIMS not set up appropriately allowing issue of units prior to completion of tests.

Case 10.4: Red cells transfused to patient not meeting antigen requirements and without serological crossmatch

Red cell units were electronically issued to a patient with AIHA and detected autoantibodies for an urgent transfusion. This was based on a report from the reference laboratory using samples that had exceeded the 72-hour sample expiry rule. The current sample had not been tested in-house and no further samples had been sent to the reference laboratory for antibody investigations. Furthermore, the unit selection recommended by previous reference laboratory reports suggested issuing C-, K- ABO D-compatible units, but C+, K- units were selected instead. The reporter stated this error occurred out-of-hours and that the BMS involved was not fully competent in this task. They were asked to cover the shift at short notice due to illness, as no other sufficiently trained staff were available. The BMS did not seek transfusion advice for this complex patient.

Learning points

- LIMS rules and algorithms should be used to full advantage to ensure blood components are not issued prior to completion of laboratory tests and meet all specific requirements
- Electronic issue rules on LIMS should be robust, and consider all national requirements (Staves, et al., 2024; MHRA, 2010)
- LIMS have the potential to reduce laboratory errors, but lack of functionality impacts on detection of errors prior to issue of units. LIMS suppliers must review the capability of LIMS rules and algorithms to ensure they are meeting patient and laboratory requirements
- Laboratory staff should adhere to UKTLC recommendations (Dowling, et al., 2024) in relation to staff knowledge and skills, particularly where they have a requirement to provide training to other staff to minimise the potential for compounding knowledge gaps

Contributory factors for IBCT-WCT and IBCT-SRNM

Many similar contributory factors have been found within both clinical and laboratory IBCT reports, and impact upon patient safety (Figure 10.8).

Figure 10.8: Contributory factors for IBCT errors in 2023

Learning points

- A laboratory exit check, used correctly, should identify most laboratory errors prior to release of blood components. The implementation and effective use of the PAUSE checklist or equivalent is recommended for all transfusion laboratories (Narayan, et al., 2022)
- Errors continue to occur when staff are deemed competent. Competency documentation should be reviewed for effectiveness and potential gaps. Competency assessments should reflect changing demands and current standards
- Mismatches between staffing levels and workloads continue to impact on transfusion safety. During incident investigation, potential impact of staffing levels and skill mix, particularly out-of-hours, should be addressed and issues escalated

Near miss IBCT cases n=152 (87 clinical, 65 laboratory)

In 2023 there were 152 NM IBCT events due to 87 clinical and 65 laboratory errors. Most NM IBCT-WCT involved potential transfusion to the wrong patient, 75/107 (70.1%) and most NM IBCT-SRNM involved potential transfusion of non-irradiated components when these were required, 32/45 (71.1%). These themes match those observed in transfused errors for clinical incidents, but differ to the themes seen in laboratory transfused errors (the majority being wrong group to transplant patient and incomplete testing). NM IBCT cases are discussed further in the supplementary chapter which can be found in the supplementary information on the SHOT website (https://www.shotuk.org/shot-reports/report-summary-and-supplement-2023/).

Conclusion

Ineffective safety checks at various steps in the transfusion process continue to lead to IBCT errors. This includes patient misidentification, which remains a safety issue throughout all of healthcare, as outlined in the HSSIB patient safety report (HSSIB, 2024). For blood transfusion, misidentifying patients may result in patients receiving blood intended for another patient, or not receiving blood when required, both of which can result in serious patient harm. Patient identification can be challenging and often repetitive, and the critical importance of accurate PID can be overlooked. SHOT data indicates that PID weaknesses lie at sample taking, collection and administration stages of the transfusion pathway. As recommended, the use of a pre-administration transfusion checklist should now be embedded into healthcare settings (Davies & Cummings, 2017), but significant numbers of errors continue to be reported. Where these errors occur within organisations, checklists must be reviewed for their effectiveness and improved. This point is mirrored in the laboratory IBCT errors reported, where over 65% of reporters stated their organisation used a laboratory exit check for components.

Safety checks are not merely check boxes to be marked off. They are critical actions designed to ensure integrity of the process and patient safety. Safety checks require careful attention, thoroughness and understanding of the underlying principles to be effective. Treating them as mere formalities undermines their purpose and can lead to serious consequences.

Laboratory IBCT errors, both WCT and SRNM, have increased substantially. There has been a dramatic rise in the number of component selection errors, particularly to HSCT patients, resulting in the wrong ABO group being transfused to patients. Errors where blood components were issued before laboratory testing was completed and errors where blood was issued inappropriately using electronic issue have also increased significantly. LIMS rules should provide assistance and prompts in these circumstances, yet these errors continue to increase. LIMS rules and algorithms must identify these errors and alert staff prior to the release of blood components.

Suboptimal training is still evident as indicated by the large number of staff who are deemed competent for the task undertaken. Competency assessments are limited in developing the higher-level knowledge and skills in problem-solving, decision-making and critical thinking. Persistent recruitment and retention issues impact hugely on the ability to train new staff and maintain competency in existing staff. SHOT reports suggest gaps in staffing numbers have required some staff to join out-of-hours and lone working situations before they are trained.

IT continues to be a contributory factor in IBCT errors. Increasing numbers of organisations are implementing new hospital-wide electronic patient record systems, thus adding an additional burden to staff. New systems can resolve some existing problems but do introduce new issues. The Judiciary Preventable Future Deaths have detailed cases which include concerns relating to hospital IT systems, including poor interoperability between IT systems, and sufficient alerts and flags in line with UK guidance and recommendations (Courts and Tribunals Judiciary, 2024).

Recommended resources

Pre-transfusion administration checklist
Laboratory and clinical PAUSE checklists
https://www.shotuk.org/resources/current-resources/

SHOT Safety Notice 02: SRNM 2022
https://www.shotuk.org/resources/current-resources/safety-notices/

Safe transfusions in haemopoietic stem cell transplant recipients
https://www.shotuk.org/resources/current-resources/

Shared care - Blood transfusion shared care form
https://nationalbloodtransfusion.co.uk/rtc/east-england/documents-and-resources/

References

Courts and Tribunals Judiciary, 2024. *Prevention of Future Death Reports.* [Online] Available at: https://www.judiciary.uk/?s=&pfd_report_type=&post_type=pfd&order=relevance (Accessed 01 May 2024).

Davies, D. S. & Cummings, J., 2017. *Safe transfusion practice: use a bedside checklist,* UK: Medicines and Healthcare products Regulatory Agency (MHRA). Available at: https://www.cas.mhra.gov.uk/Home.aspx (Accessed 08 April 2024).

Dowling, K. et al., 2024. UK Transfusion Laboratory Collaborative: Minimum standards for staff qualifications, training, competency and the use of information technology in hospital transfusion laboratories 2023. *Transfusion Medicine,* 34(1), pp. 3-10. doi: https://doi.org/10.1111/tme.13029.

Elliot, J. et al., 2021. Missed irradiation of cellular blood components for vulnerable patients: Insights from 10 years of SHOT data. *Transfusion Medicine,* 61(2), pp. 385-392. doi: https://doi.org/10.1111/trf.16189.

Foukaneli, T. et al., 2020. Guidelines on the use of irradiated blood components. *British Journal of Haematology,* 191(5), pp. 704-724. doi: https://doi.org/10.1111/bjh.17015.

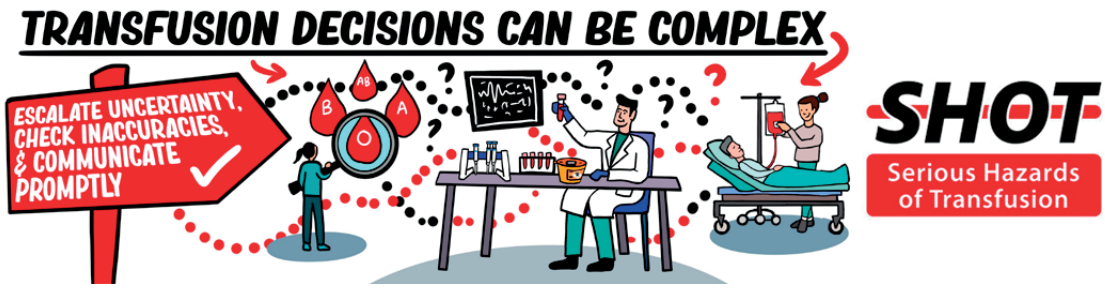
Health Services Safety Investigations Body (HSSIB), 2024. *National learning report: Positive patient identification.* [Online] Available at: https://www.hssib.org.uk/patient-safety-investigations/positive-patient-identification/national-learning-report/ (Accessed 08 April 2024).

Medicines and Healthcare products Regulatory Agency (MHRA), 2010. *Guidance: Electronic issue of blood components.* [Online] Available at: https://www.gov.uk/government/publications/electronic-issue-of-blood-components (Accessed 01 May 2024).

Narayan, S. et al., 2022. *The 2021 Annual SHOT Report,* Manchester: Serious Hazards of Transfusion (SHOT) Steering Group. doi: https://doi.org/10.57911/QZF9-XE84.

Serious Hazards of Transfusion (SHOT), 2024. *UKTLC.* [Online] Available at: https://www.shotuk.org/resources/current-resources/uktlc/ (Accessed 02 May 2024).

Staves, J. et al., 2024. Guidelines for the specification, implementation and management of IT systems in hospital transfusion laboratories: A British Society for Haematology Guideline. *Transfusion Medicine,* 34(2), pp. 81-166. doi: https://doi.org/10.1111/tme.13027.



11 Handling and Storage Errors (HSE) n=342

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	**NM**	Near miss

Key SHOT messages

- Clinical errors contribute to 259/342 (75.7%) of HSE errors reported in 2023, with excessive time to transfuse, pump and giving set errors accounting for most of these errors, 193/259 (74.5%)
- Of the laboratory errors, cold chain errors including inappropriate return to stock and refrigerator failure accounted for most errors, 54/83 (65.1%)

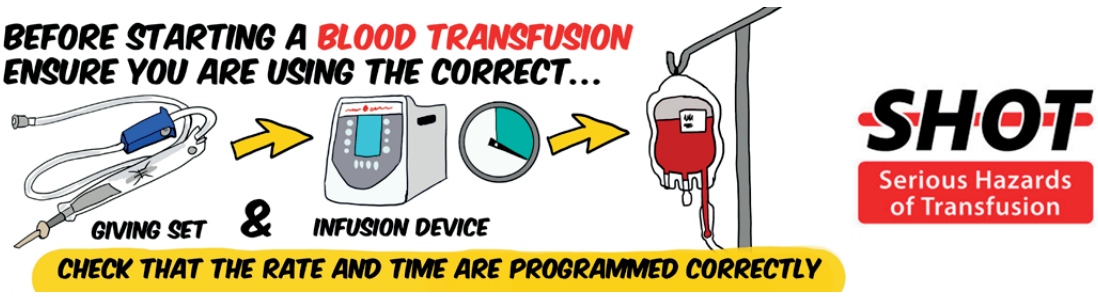
Recommendations

- Laboratories should have an effective procedure in place to periodically test the functionality and alarm settings of their temperature-monitoring systems

Action: Transfusion laboratory managers

- A structured handover in clinical areas is needed when patients are receiving a transfusion that continues into the next shift. This should be audited regularly to inform local improvement actions
- Any gaps in staff knowledge need to be identified and addressed in transfusion training

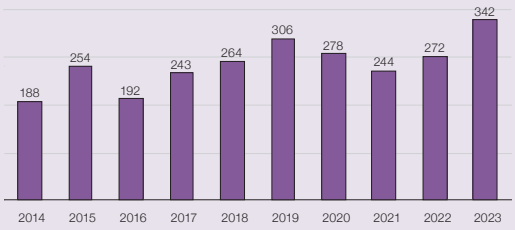
Action: Education leads, ward managers, audit leads



Headline data 2023

Number of reports n=342
Deaths n=0
Major morbidity n=0

HSE reports by year



Demographic data

Male n=170
Female n=147
Unknown n=25

Adults n=282
Paediatric n=32
Unknown n=28

Blood component data

Red cells n=289
Platelets n=29
Plasma n=16
Cryoprecipitate n=4
Granulocytes n=1
Multiple components n=3

Introduction

There was an increase of errors reported from 272 in 2022 to 342 in 2023. HSE errors accounted for 342/3833 (8.9%) errors in 2023 compared with 272/3499 (7.8%) in 2022 (Narayan, et al., 2023). Clinical errors accounted for 259/342 (75.7%), which is a smaller percentage than 2022, 218/272 (80.1%), and laboratory errors for 83/342 (24.3%), which is an increase from 2022, 54/272 (19.9%). The variation between clinical and laboratory errors are illustrated in Figure 11.1.

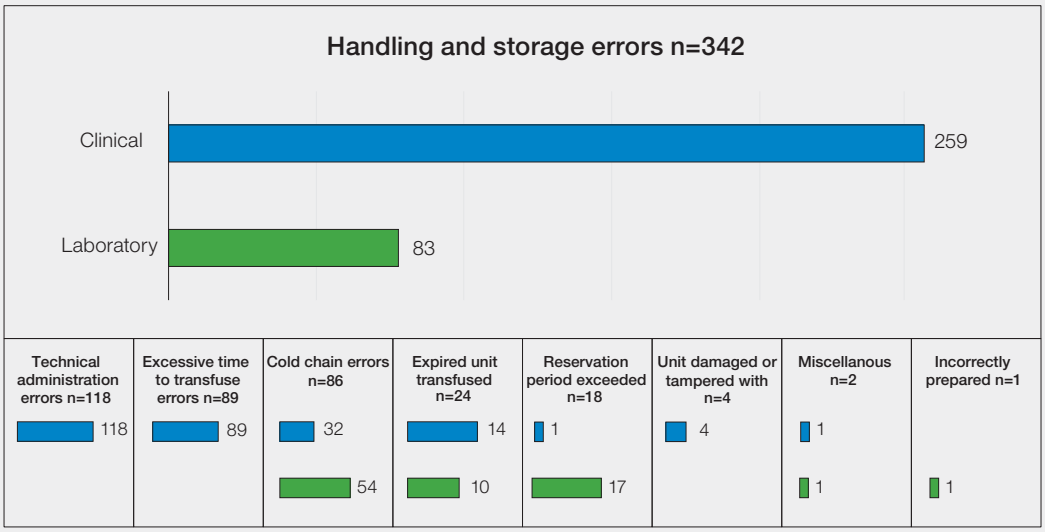


Figure 11.1: Breakdown of 2023 handling and storage error (HSE) reports (n=342)

Deaths related to transfusion n=0

There were no deaths that were related to errors associated with HSE in 2023.

Major morbidity n=0

There was 1 case of major morbidity related to a HSE error in 2023, but as an uncommon reaction, this has been included in the numbers for the UCT category. A patient developed chest pains and desaturation soon after the start of a blood transfusion. The clinical deterioration was due to venous air

embolism following inappropriate preparation of the line prior to transfusion. This highlights the potential complications following HSE errors. Proper handling and storage of blood products are crucial for ensuring patient safety and effectiveness of transfusions. See Chapter 20, Uncommon Complications of Transfusion (UCT), Case 20.3 for more details.

Clinical HSE errors n=259

The number of clinical errors has increased (from 218 reported in 2022 to 259 in 2023) and a similar rise in technical administration errors was noted,118/259 (45.6%) in 2023 and 94/218 (43.1%) in 2022. Technical administration errors have been further categorised in Table 11.1.

Table 11.1: Clinical technical administration errors (n=118)

Technical administration error	Total
Pump programming error	62
Incorrect giving set	39
Same venous access used	7
Manual drip rate incorrect	4
Miscellaneous	3
Prescribed too fast	2
Recalled but given in error	1
Total	**118**

Of the 62 administration pump errors, 51 incidents related to the pump being set incorrectly despite a correct prescription. There were 39 errors related to giving sets, of which 2 also had additional errors (excessive time to transfuse and incorrect preparation).

Excessive time to transfuse errors occur equally within routine hours and out of routine hours. These are reported more frequently following routine requests (46/89) than during emergency/urgent requests (31/89). When asked, 42/89 reporters felt that handover had impacted on the error but only 23/42 had a structured handover in place between shifts and staff changes. Examples of structured handover process were initially outlined by the NHS Institute for Innovation and Improvement (2010) Situation, Background, Assessment and Recommendation (SBAR) implementation and training guide. Laboratory areas can also benefit from good quality structured handovers (Tuckley, et al., 2022).

Case 11.1: Excessive time to transfuse using the wrong giving set

When receiving a non-urgent transfusion, the patient reported that the transfusion they were receiving had run for an extended period (approximately 6 hours). It was found to have been administered through the incorrect giving set. Upon investigation, the documentation was found to be sub-optimal. No stop time and no end observations were recorded. There were no medical or nursing notes pertaining to the transfusion. The patient was in the day surgery unit which after hours was covered by agency staff supervised by a single substantive nurse not familiar with this area.

Non-urgent transfusion should be avoided outside of routine hours, where at all possible and not detrimental to patient safety. Providing comprehensive orientation and support to agency staff can help address challenges they face when working in unfamiliar surroundings. It is important that transfusions are given in settings which support safe practice and have appropriately trained staff.

Laboratory HSE errors n=83

The number of laboratory errors have increased to 83 in 2023 from 54 in 2022, with the majority being cold chain errors, 54/83 (65.1%), which have been further categorised in Table 11.2.

Table 11.2: Laboratory cold chain errors (n=54)

Cold chain error	Number of cases
Inappropriate return to stock	27
Refrigerator/equipment failure	17
Incomplete cold chain	7
Transport and delivery	2
Inappropriate storage	1
Total	**54**

Of the 17 refrigerator/equipment failure errors, 9 involved a temperature-monitoring system and of the 27 inappropriate returns to stock errors, 7 involved a blood-tracking system.

Case 11.2: Temperature-monitoring system alarm limits set incorrectly

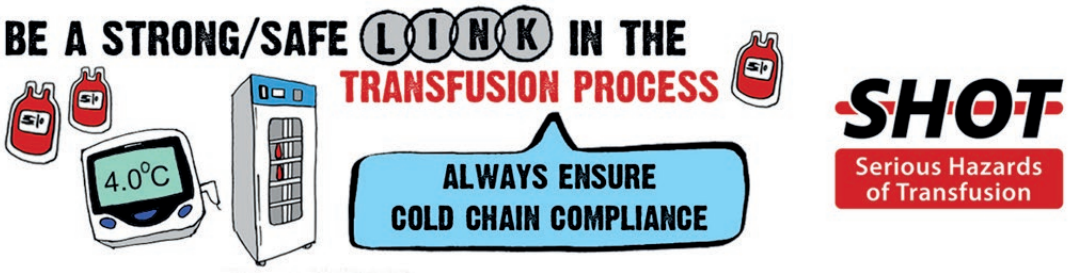
During a training session the transfusion practitioner noted that the issue refrigerator door was slightly ajar, and closed the door, but did not inform the laboratory staff at the time of the event. Later, when laboratory staff reviewed the temperature logs on the temperature-monitoring system and the paper chart on the refrigerator, it was noted that the temperature had been above 6°C for approximately 2 hours. The lead biomedical scientist immediately initiated a recall of all red cell components that had been stored in the refrigerator during the time that it had been outside the acceptable temperature.

It emerged that one patient had been transfused with a unit of red cells implicated in the temperature excursion. The consultant haematologist was made aware and there was no obvious adverse reaction in the patient. Five other red cell units were disposed of. The blood refrigerator temperature-monitoring system usually triggers an audible and visual alarm in the laboratory, but this did not occur. The alarm settings were reviewed, and it was noted that the air temperature alarm was set to trigger at 7.7°C with a 5-minute delay. No justification could be provided for the air alarm setting and so it was immediately adjusted to meet requirements. The blood refrigerator temperature probes were connected to a third-party alarm escalation service, but did not trigger an alarm to switchboard as expected.

The blood refrigerator was also fitted with a door open alarm. The settings for this were checked and found to be on 3-minute delay, this has since been adjusted to a 1-minute delay. It is not clear whether the door alarm did sound on the day of the event but, during testing, it was observed that the alarm was not very loud.

Learning points

- Blood giving sets should be stored in clearly labelled containers and distinguishable from other giving sets to prevent selection of the wrong type
- Staff should be trained to use pumps appropriately, verify pump settings regularly and minimise interruptions to focus on critical tasks
- To prevent excessive time to transfuse incidents, clinical areas need to have a system in place to alert staff and the patient when a transfusion should stop, and the unit be taken down. An example of an innovative solution can be found in Chapter 10, Handling and Storage Errors (HSE) of the 2022 Annual SHOT Report (Narayan, et al., 2023)



Near miss HSE errors n=138

There were 138 handling and storage near miss events in 2023, including 104 clinical errors and 34 laboratory errors. Of the clinical NM-errors, 93 were cold chain errors where blood components were stored in inappropriate conditions in the clinical area, and in 11 cases expired blood components were collected. Of the laboratory NM-errors these were mainly due to 23 expired units issued, and 6 cold chain errors. Insufficient handover impacted upon 37/138 (26.8%) NM-HSE errors, and mostly affected clinical cold chain errors, 25/93 (26.9%).

Conclusion

The overall findings remain consistent with previous Annual SHOT Reports with an increasing trend in reported errors especially in the laboratory. There continues to be a mismatch between workload and staffing in both the clinical and laboratory areas. It also highlights that even though staff are trained and competency-assessed the same errors keep happening. SHOT reiterates that all staff who participate in the handling and storage of blood components throughout the transfusion process should be aware of and adhere to the correct procedures that are outlined in guidelines and their local transfusion policy. Transfusion policies should be easy to access and contain useful information based on the most current published guidance available (Robinson, et al., 2018). By embedding these policies in working practice, safe patient care overall can be achieved.

Recommended resources

Patient Blood Management - Blood assist app

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

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

References

Narayan, S. et al., 2023. *The 2022 Annual SHOT Report*, Manchester: Serious Hazards of Transfusion (SHOT) Steering Group. doi: https://doi.org/10.57911/WZ85-3885.

NHS Institute for Innovation and Improvement, 2010. *Safer care SBAR, Situation, Background, Assessment and Recommendation implementation and training guide,* UK : NHS England (NHSE). Available at: https://www.england.nhs.uk/improvement-hub/wp-content/uploads/sites/44/2017/11/SBAR-Implementation-and-Training-Guide.pdf (Accessed 08 April 2024).

Robinson, S. et al., 2018. The administration of blood components: a British Society for Haematology Guideline. *Transfusion Medicine,* 28(1), pp. 3-21. doi: https://doi.org/10.1111/tme.12481.

Tuckley, V. et al., 2022. Safe handovers: Safe patients-why good quality structured handovers in the transfusion laboratory are important. *Transfusion Medicine,* 32(2), pp. 135-140. doi: https://doi.org/10.1111/tme.12853.

Avoidable, Delayed or Under/ Overtransfusion (ADU) and Incidents Related to Prothrombin Complex Concentrate (PCC) n=382

12

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

Abbreviations used in this chapter

AAGBI	Association of Anaesthetists of Great Britain and Ireland	**ICH**	Intracranial haemorrhage
ADU	Avoidable, delayed or under/overtransfusion	**ICU**	Intensive care unit
BMS	Biomedical scientist	**INR**	International normalised ratio
BSH	British Society for Haematology	**IR**	Interventional radiology
CAS	Central alerting system	**IT**	Information technology
CT	Computed tomography	**MHP**	Major haemorrhage protocol
DOAC	Direct acting oral anticoagulant	**NHSE**	National Health Service England
ED	Emergency department	**PCC**	Prothrombin complex concentrate
FBC	Full blood count	**4F-PCC**	Four factor PCC
FFP	Fresh frozen plasma	**TACO**	Transfusion-associated circulatory overload
GI	Gastrointestinal	**TRALI**	Transfusion-related acute lung injury
Hb	Haemoglobin	**UK**	United Kingdom
		WBIT	Wrong blood in tube

Key SHOT messages

- Delays in blood component transfusion and PCC administration are often multifactorial and impact on patient safety
- Avoidable and overtransfusions could be reduced by improved management of haematinic deficiency
- Mistakes continue to be made with paediatric prescribing and administration
- Common contributory factors to reported incidents include suboptimal staffing levels, mismatched with workload, gaps in staff knowledge, poor staff training, failure to communicate effectively

Specific chapter-related recommendations are covered in the individual chapters. Only those applicable to all categories are covered here.

Recommendations

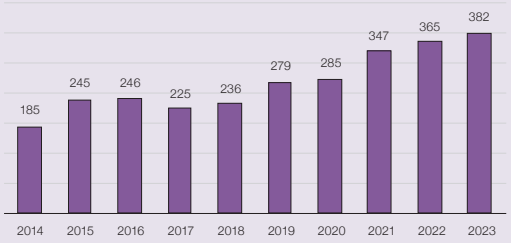
- Clear guidelines for patients being transferred between hospital departments, or between hospitals must be available and followed to ensure patient safety. This should include the need for adequately trained and skilled staff to supervise the transfer
- Major haemorrhage protocols should be reviewed and practiced end-to-end with drills to ensure that they are workable, and that staff are familiar with them

Action: Hospital chief executive officers, transfusion laboratory managers, hospital transfusion committees

Headline data 2023

Number of reports n=382
Deaths n=14
Major morbidity n=14

ADU reports by year



Demographic data

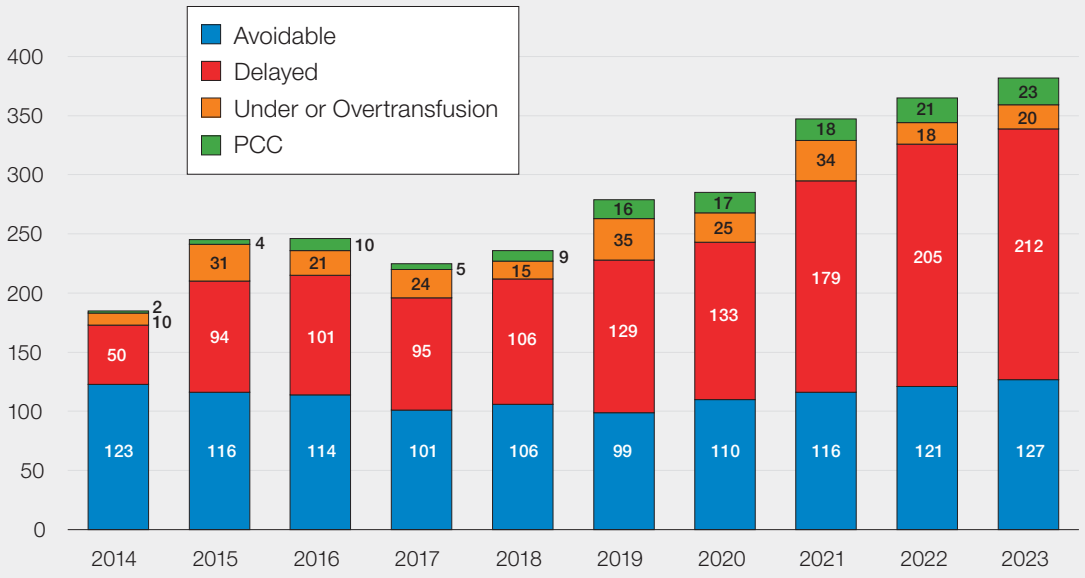
Male n=162
Female n=215
Unknown n=5

Adults n=331
Paediatric n=40
Unknown n=11

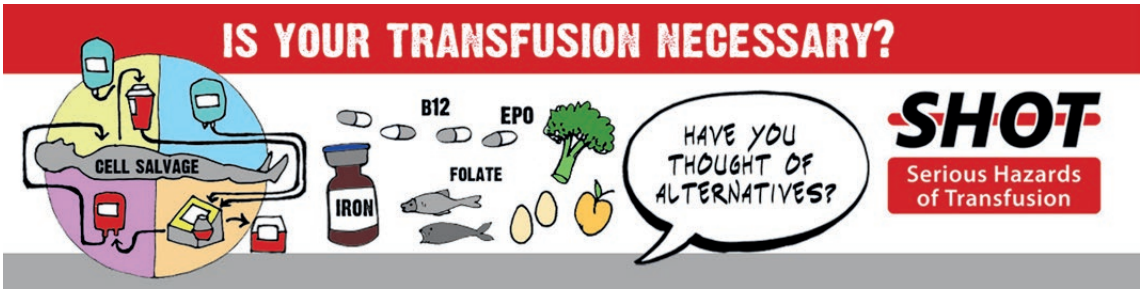
Blood component data

Red cells n=274
Platelets n=33
Plasma n=11
Multiple components n=25
PCC n=23
Granulocytes n=3
Cryoprecipitate n=1
Unknown n=12

Figure 12.1: ADU reports by category 2014-2023



PCC=prothrombin complex concentrates



Overview of ADU cases

Cases submitted to SHOT in the ADU categories have been increasing steadily in the recent years. The cases from 2023 are summarised in Table 12.1.

ADU category	Total cases	Deaths related to transfusion*	Major morbidity	Paediatric cases	Near miss cases
Delayed transfusions	212	9	12	23	0
Avoidable transfusions	127	0	0	8	3
Under or overtransfusion	20	1	2	9	1
Incidents related to PCC	23	4	0	0	0
Total	**382**	**14**	**14**	**40**	**4**

**There was 1 death that was definitely related to delayed PCC (imputability 3), and 3 deaths due to delays that were probably related (imputability 2). The remaining 10 deaths were possibly related to transfusion (imputability 1)*

Table 12.1: Overview of ADU cases in 2023 (n=382)

Problems with MHP activations n=65

In 65 cases, errors related to activation of the MHP were reported (28 of these occurred out-of-hours):

- 50 delays (2 deaths possibly related)
- 12 avoidable including 10 instances with use of O D-negative red cells
- 1 undertransfusion
- 2 overtransfusion (1 death possibly related)

For more information, analysis, and case studies on problems with MHP activations, please see the supplementary information on the SHOT website (https://www.shotuk.org/shot-reports/report-summary-and-supplement-2023/).

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/

12a Delayed Transfusions n=212

Authors: Paula Bolton-Maggs, Josephine McCullagh, 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

- Poor communication at multiple points during the patient's care is common and exacerbates delays
- 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 issues contribute to delayed transfusions
- Lack of knowledge and awareness of correct procedures contributes to delays in transfusion

Recommendations

- Activation of MHP should be simple and standardised to avoid issues with hospital-specific procedures
- Hospitals should review their MHP and test them with drills and simulation to ensure they are fit for purpose. This should cover all the steps in the process from end-to-end and must include all staff groups involved
- MHP activations should be followed by a debrief with everyone involved to identify what went well and what could be improved
- Transfusion professionals should work closely with higher education institutes to ensure that the courses they are offering are fit for purpose and ensure all staff are equipped with the skills and knowledge they require to deliver safe transfusions

Action: Hospital transfusion committees, higher education institutes

Introduction

The number of delays in transfusion reported to SHOT has increased (n=212) when compared to the previous year (n=205) see Figure 12a.1. Incorrect activation of the MHP remains a key issue contributing to delays in transfusion, and this is consistent over the past 5 years. Increasing reports of delays prompted the publication of a CAS alert, with actions for hospitals (SHOT, 2022). A recent survey evaluating the effectiveness of the CAS national alert noted that 42% of responders did not have adequate resources to action the recommendations, and 71% identified staffing issues as the main barrier to implementing any actions. Inadequate staffing and poor skills mix in transfusion laboratories has increased over the last decade. See the 'Recommended resources' for a link to the survey report.

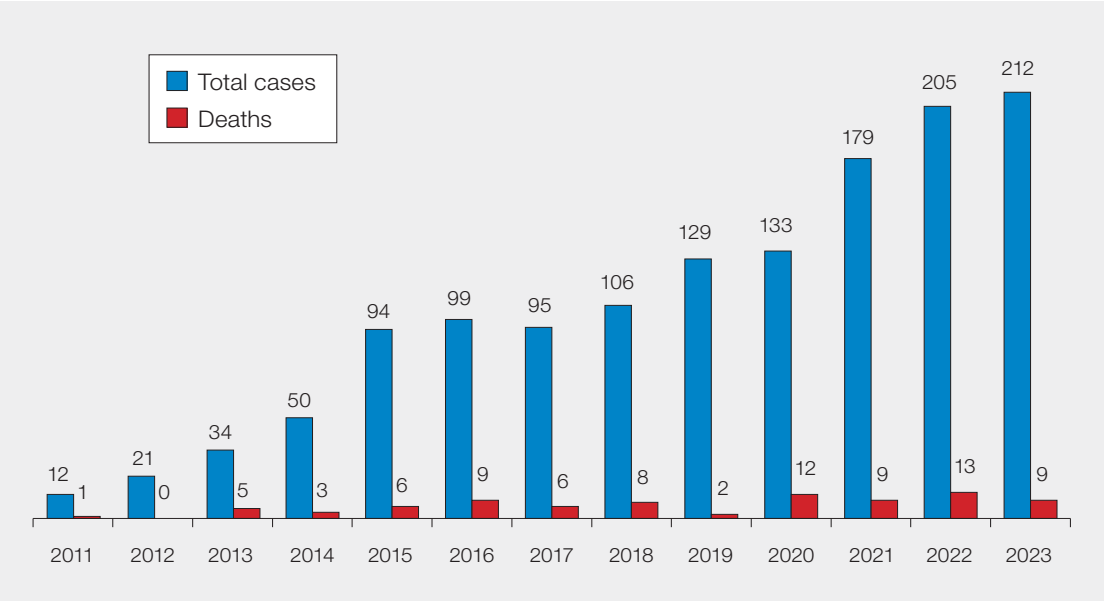


Figure 12a.1: Delayed transfusions by year 2011-2023

Deaths related to transfusion n=9

There were 9 deaths reported due to delays. This compares with 13 deaths in 2022 and 9 in 2021. More than half of all deaths were associated with delays in urgent or emergency transfusions for patients in the ED. Common themes were delays in decision-making and missing vital steps in the transfusion process due to lack of knowledge, training, and poor staffing levels. In 4 cases, there were transfusion delays in patients with acute bleeding. Three deaths were probably related (imputability 2) and 6 were possibly related (imputability 1) to the transfusion delay.

Case 12a.1: Delay in red cell transfusion in patient with a GI bleed awaiting a hospital bed contributes to death

An elderly patient with haematemesis, dark stool and shortness of breath was attended at home by a paramedic crew. The patient had tachycardia and was pale with low blood pressure. The patient was taken as an emergency to the ED. On arrival there were delays offloading from the ambulance due to lack of available space. Whilst still in the ambulance, the patient began to deteriorate and despite escalating care from the paramedics and a haemoglobin of 38g/L, treatment was delayed by more than 2 hours and the patient passed away from a cardiac arrest.

Case 12a.2: Lack of understanding on how to activate the MHP contributes to patient death

A patient with a perforated duodenal ulcer was being managed as an outlier in a COVID-19 bay. The clinical team caring for the patient identified that the patient was bleeding and there was a requirement for urgent blood components. Due to unfamiliarity with the management of MH, staff failed to correctly activate the MHP. Instead, a doctor instructed a nurse, not directly involved in this patient's care, to 'get blood' without conveying the urgency. Lack of vital information caused confusion between the laboratory staff and the nurse as to what was expected. The communication difficulties were compounded by lack of understanding among staff about how to activate the MHP. The patient was in a COVID-19 bay and the rarity of major bleeding in a ward environment caused delay in blood transfusion which contributed to the death of this patient.

One case resulted in the death of a patient due to incorrect laboratory procedures with delay in recognition and subsequent treatment. This involved a patient who presented with cytopenia with a delay in the diagnosis of acute promyelocytic leukaemia and died of bleeding. This case is described in detail in Chapter 15, Laboratory Errors (Case 15.1).

Learning points

- Failure to communicate urgency of requests leads to delays in blood component provision. Ensure that requests for samples and blood components are clear and that the urgency is stated
- Good handover is essential especially when serious bleeding occurs out-of-hours
- Recognition of bleeding is crucial for timely and appropriate treatment
- Laboratory staff working in transfusion must be adequately trained and competency-assessed, especially in identifying urgent cases when 'lone working' out-of-hours

Major morbidity n=12

Seven of 12 reports that resulted in major morbidity were associated with MHP and 10/12 were due to delays in urgent (2) or emergency (8) transfusion.

Delays associated with MHP n=50

There has been a general increase in the number of delays associated with MHP over the last few years of SHOT reporting, see Figure 12a.2.

Figure 12a.2: Number of delayed transfusions associated with MHP 2016-2023

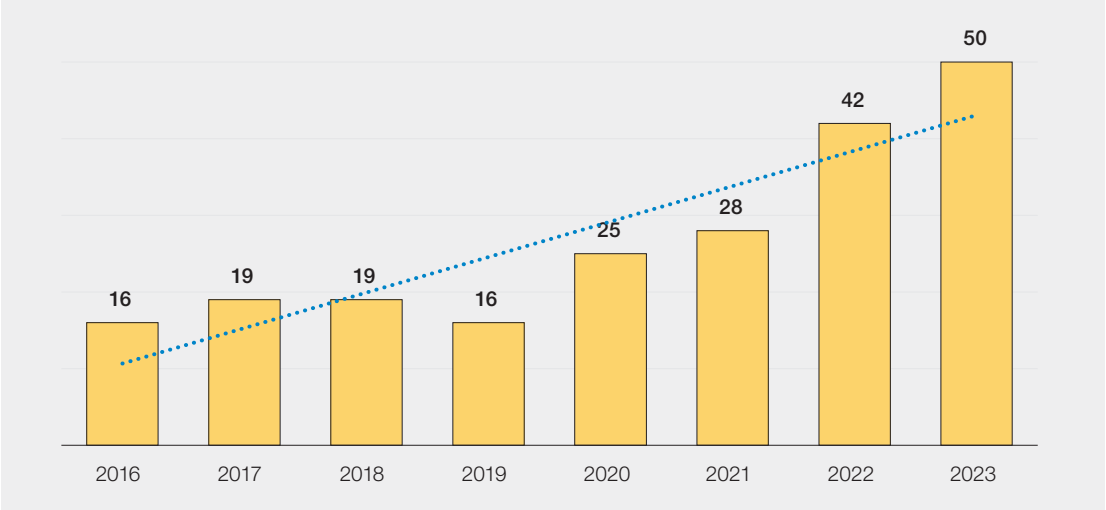


Figure 12a.3 illustrates the key factors contributing to delayed transfusion in major haemorrhage situations reported to SHOT in 2023.

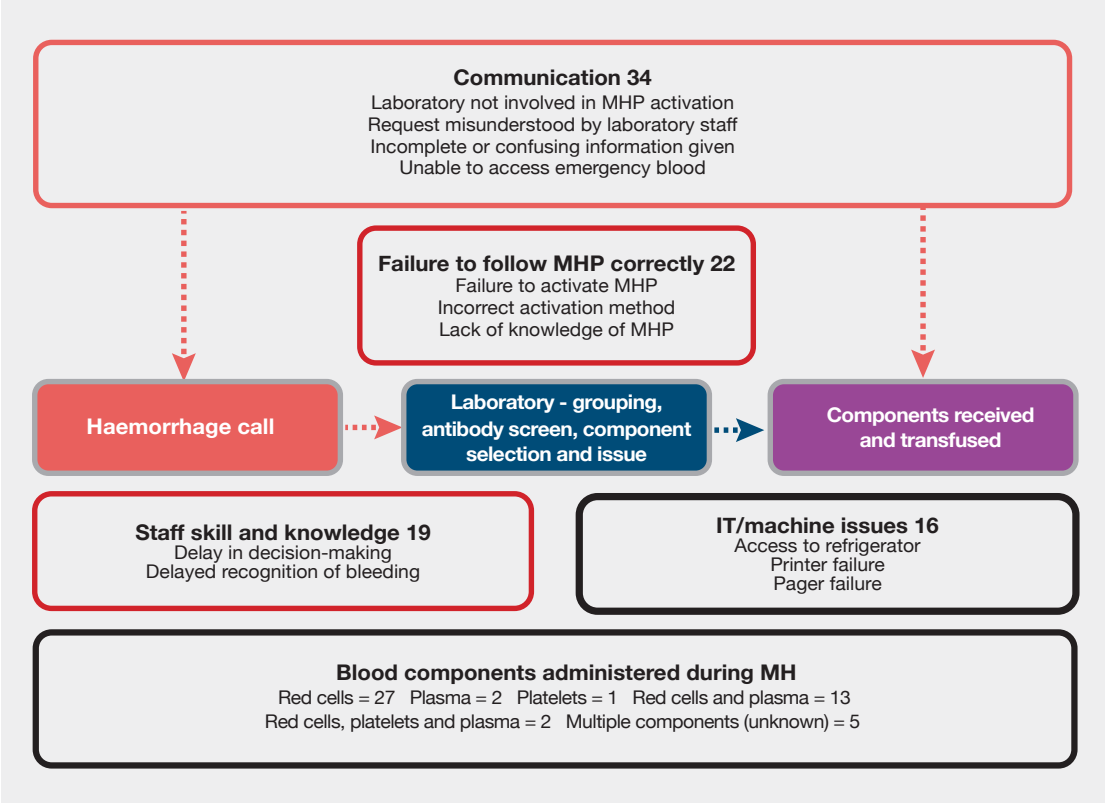


Figure 12a.3: Key factors contributing to delayed transfusions in major haemorrhage in 2023 (n=50)

MHP=major haemorrhage protocol; IT=information technology

Learning points

- Failure to communicate effectively in urgent situations causes unnecessary delays in transfusion
- MHP are either not activated when indicated or not followed correctly. Emergency procedures such as MHP should be simple and easy to follow

SHOT
Serious Hazards of Transfusion

Laboratory errors n=56

Laboratory errors discussed here cover both hospital transfusion laboratories and Blood Services. Key themes identified in laboratory errors resulting in delays were lack of knowledge and training of staff (n=17) and failure in effective communication (n=18).

Case 12a.3: A sample that did not meet acceptance criteria was sent to the Blood Service resulting in unnecessary delay in transfusion

An elderly person requiring transfusion for the treatment of chronic anaemia had a blood sample taken for group and screen. The sample was accepted by the hospital transfusion laboratory and referred to the laboratory in the Blood Service for further testing. The Blood Service staff telephoned the hospital laboratory to inform them that the surname on the sample did not match the surname on the request form and therefore the sample had been rejected. This required a repeat sample and caused a delay in the provision of red cells for the patient.

The labelling error should have been detected earlier in the process which would have avoided the delay.

Case 12a.4: BMS decided not to thaw cryoprecipitate due to previous high levels of wastage

The MHP was activated for a patient with major bleeding post-surgery. Cryoprecipitate was ordered as part of the initial 'Pack 1'. The BMS working in the transfusion laboratory decided not to thaw the cryoprecipitate because they had encountered wastage of frozen components in a previous shift. This decision resulted in a 75-minute delay in the issue of cryoprecipitate. The patient recovered and survived.

Case 12a.5: Printer failure caused delay in transfusion

The MHP was activated for a patient suffering from a GI bleed. There was a delay in the blood components being issued as the printer failed to print labels. The BMS did not realise that the printer had run out of labels and tried to reprint. The BMS contacted senior staff at home for advice. The printer was reloaded with labels, but they were misaligned. The patient was given two units of red cells after a 15-minute delay.

Laboratory staff failed to use backup label printer/emergency unit labels to allow issue of units in a timely manner.

Learning points

- Awareness of contingency/back up plans is essential to ensure smooth processes when technical issues arise
- Worries about component wastage should not result in delays in component provision especially in emergency situations
- Timely communication can prevent additional delays

Blood Service errors n=8

There were 8 reports due to Blood Service issues that resulted in delay in transfusion, an increase compared to 1 in the 2022 Annual SHOT Report (Narayan, et al., 2023).

Case 12a.6: Incorrect red cell units sent to the hospital results in delayed transfusion

Samples were sent from a hospital transfusion laboratory to a Blood Service reference laboratory for further testing and crossmatching of red cell units. The reference laboratory completed the testing but sent the blood components to the wrong hospital. This error resulted in a 2-hour delay in treatment.

Learning points

- Clear and adequate communication between Blood Service staff and hospital laboratory staff is essential to prevent miscommunication and to avoid delays in testing and supply of urgent blood components
- The risk of blood components being sent to the wrong location can be reduced by ensuring there are sufficient checks in place before sending blood components to hospitals transfusion laboratories

Conclusion

Patients should not die or suffer harm from transfusion delays. Poor communication, lack of staff knowledge and skills contributes to many cases of delay especially during major haemorrhage. The recommended actions in the SHOT CAS alert will help address preventable transfusion delays and improve patient safety (SHOT, 2022). Staffing levels and skill mix have been identified as barriers for effective implementation of the recommendations and must be addressed.

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/

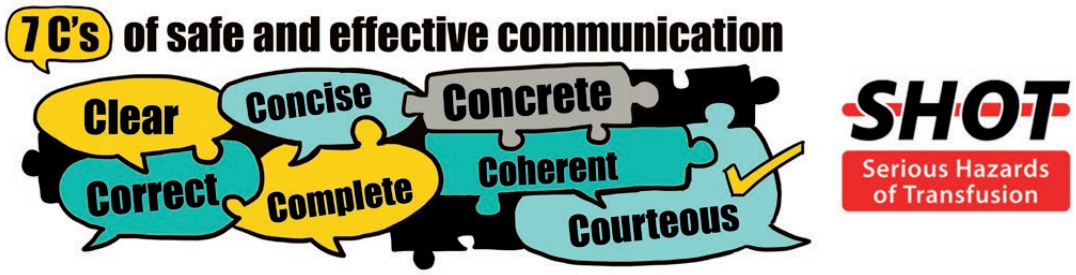
15s30m stands for 15 seconds, 30 minutes – taking a few extra seconds at the start of a process can save someone a lot of time further along, reducing frustration and increasing joy at work.
https://fabnhsstuff.net/fab-stuff/15-seconds-30-minutes

Transfusion 2024 – A 5-year Plan for Clinical and Laboratory Transfusion
https://www.nationalbloodtransfusion.co.uk/sites/default/files/documents/2023-03/Transfusion%202024%20Brochure%20FINAL%20%2811.12.2020%29.pdf

References

Narayan, S. et al., 2023. *The 2022 Annual SHOT Report,* Manchester: Serious Hazards of Transfusion (SHOT) Steering Group. doi: https://doi.org/10.57911/WZ85-3885.

Serious Hazards of Transfusion (SHOT), 2022. *Central Alerting System: Preventing transfusion delays in bleeding and critically anaemic.* [Online] Available at: https://www.cas.mhra.gov.uk/ViewandAcknowledgment/ViewAlert.aspx?AlertID=103190 (Accessed 08 April 2024).



12b Avoidable Transfusions n=127

Authors: Catherine Booth, Paula Bolton-Maggs 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

- It is essential to establish the cause of thrombocytopenia before transfusing platelets. A blood film should be examined to confirm a low platelet result even in patients who might be expected to have thrombocytopenia
- Accurate patient identification is fundamental in all healthcare interactions. This involves positive patient identification at the time of taking any blood sample. It is also important when carrying out tasks such as writing in notes or on a prescription chart

Recommendations

- Training in major haemorrhage protocols should be multidisciplinary and include all staff involved when MHP is activated
- Training should emphasise that group O red cells are only used when group-specific or crossmatched red cells are not readily available

Action: Hospital transfusion teams

Introduction

There were 127 reports of avoidable transfusions, similar to the 121 reported in 2022. Components involved were 109 red cells, 15 platelets, 2 FFP and 1 cryoprecipitate.

Note that where avoidable transfusions cause a reaction in a patient, such as a febrile, allergic or hypotensive reaction or TACO, these are included in the corresponding reaction chapter rather than here. The total number of transfusions reported to SHOT which were felt to be avoidable is therefore greater.

Deaths related to transfusion n=0

There were no deaths related to avoidable transfusions in 2023.

Major morbidity n=0

There were no patients suffering major morbidity because of an avoidable transfusion in 2023.

Classification of avoidable transfusions n=127

Group	Red cells	Platelets	Plasma components	Total reports
Flawed decision	32	7	2	**41**
Appropriate decision, inappropriate component	37	0	0	**37**
Decision based on inaccurate results	25	5	1	**31**
Failure to respond to change in circumstances	7	2	0	**9**
Transfusion without decision	7	1	0	**8**
Transfusion necessitated by equipment failure	1	0	0	**1**
Total	**109**	**15**	**3**	**127**

Table 12b.1: Classification of avoidable transfusions by error type and blood component (n=127)

SHOT
Serious Hazards of Transfusion

Flawed decision n=41

Cases of flawed decision included: transfusion for haematinic deficiency (n=15), transfusion of multiple units without reassessment (n=4), transfusion outside of guidelines without clinical justification (n=12: 6 of which were platelets), overestimation of blood loss (n=5), transfusion of someone who had withheld consent (n=3), misinterpretation of thromboelastography (n=1).

Case 12b.1: Unnecessary empirical transfusion given for upper gastrointestinal bleeding

A patient with alcoholic liver disease presented after vomiting blood at home. They were haemodynamically stable, but two units of red cells were transfused without any Hb check. The post-transfusion Hb was 125g/L.

The results suggest this patient had not lost a volume of blood sufficient to require transfusion. The 2022 National Comparative Audit of upper gastrointestinal bleeding, which is expected to be released later in 2024, has highlighted that overtransfusion is common in this patient group and is associated with adverse patient outcomes (Booth 2024, personal communication. 13 March).

Learning point

- Not all patients presenting with bleeding require transfusion. Unless there is haemodynamic instability, a Hb check should be performed first, and restrictive thresholds applied outside of major haemorrhage

Appropriate decision, inappropriate component n=37

These were all avoidable use of group O red cells.

In 7 patients there was delay in sending a group and screen sample, and in 4 there were laboratory delays in sample processing.

In 15 cases, crossmatched blood was available, in 5 of these the laboratory was not told that the patient needed blood urgently, and in 10 the clinical team collected group O units in error. There is a misconception that group O is the correct component to be given in all emergencies.

Case 12b.2: Lack of understanding of appropriate use of O D-negative red cells

The doctor caring for a trauma patient was not aware that crossmatched red cells were available and requested O D-negative emergency units. The porter delivered named patient units from the laboratory, but the nurse rejected these twice as she was expecting emergency O D-negative units rather than named patient units (D-positive). The nurse did not check the compatibility label which confirmed the units supplied were for that patient.

Learning point

- The whole multidisciplinary team need to understand the role of group O emergency units, in particular that these are to use only to preserve life until crossmatched units are available

In 5 cases there were problems with collection of crossmatched units, though this also highlights resilience in the system protecting the patient from delays to transfusion. Two reports described errors in IT systems preventing access to crossmatched units and 3 patients were given emergency group O units when transfusion was not urgent.

Decision based on inaccurate result n=31

Cases where decisions were based on inaccurate results included: FBC sample taken from a drip arm (n=9), inaccurate point-of-care sample (n=6), use of previous results (n=4), platelet clumping (n=4), WBIT in FBC sample (n=3), wrong patient's result used (n=2), analyser error (n=3).

Learning point

- Wrong blood in tube is not only significant for transfusion samples. WBIT in FBC or biochemistry samples can result in inappropriate patient treatment. Positive patient identification is essential before taking any sample

Case 12b.3: Platelet clumping in an oncology patient results in two unnecessary platelet transfusions

A FBC from a patient with leukaemia showed a significant drop in platelets compared to the previous day. The analyser flagged possible platelet aggregates, but the result was released. A blood film was made but only examined routinely the next day. This showed platelet clumping, and the count was visually normal. By this time the patient had been transfused with platelets. Another sample sent the next day again reported low platelets. No blood film was made, and a further platelet transfusion was given. The post-transfusion platelet count was 232x10^9/L.

Learning points

- Thrombocytopenia should be confirmed on a blood film even when a patient has a condition compatible with a low platelet count. Marked fluctuations in the platelet count should raise suspicion of a spurious result
- Review of blood film to confirm laboratory results in a timely manner can avoid unnecessary or incorrect treatment

Case 12b.4: Failure to correctly identify the patient at the time of authorising the transfusion leads to transfusion of the wrong patient

A doctor had reviewed the FBC for patient A and a red cell transfusion was indicated. The doctor mixed up two patients' names and results and authorised transfusion for patient B in error. Patient B's Hb was 100g/L and they received a red cell unit they did not require.

Learning point

- Patient identification errors resulting in inappropriate treatment can occur without the patient being present. It is essential to correctly identify the patient during any interaction

Failure to respond to a change in circumstances n=9

Cases where there was a failure to respond to change in circumstances included: transfusion given before a procedure which was cancelled (n=3), units authorised 'just in case' for surgery transfused routinely (n=1), authorisation written in advance and recent results not checked (n=1), transfusion already given (n=2), change in decision not communicated (n=1).

One patient was given a transfusion as part of a trial protocol but was subsequently found to be ineligible for the trial.

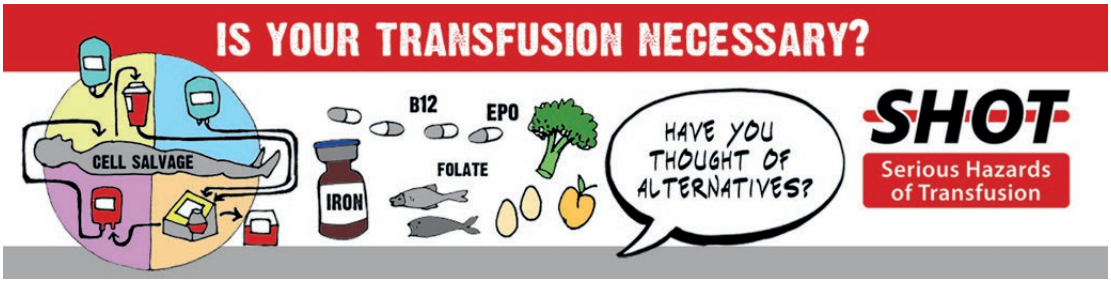
Transfusion without decision n=8

Seven patients received a transfusion without any completed authorisation. Three of those were patients regularly attending a day unit, and it is notable that one reporter cited staff shortage due to the junior doctors strikes as a contributory factor.

One patient had a red cell transfusion authorised rather than albumin as a result of a verbal request.

Transfusion necessitated by equipment failure n=1

Malfunction of a haemodialysis machine resulted in a patient losing 200-300mL of blood into the circuit and a red cell transfusion was then required.



Near miss avoidable transfusions n=3

These included 1 drip arm sample, detected due to abnormal biochemistry results taken at the same time, 1 multiple unit transfusion stopped when a family raised concerns and 1 inappropriate use of group O serendipitously blocked due to incorrect use of the remote issue refrigerator.

Conclusion

Avoidable transfusions constitute a diverse group, but lack of knowledge, failure to question unusual results and failure of correct patient identification emerge as recurring themes. Creating additional opportunities for checks and challenge, for example use of computerised decision support and empowering laboratory and nursing staff to question inappropriate or unusual requests can increase the chance of errors being corrected before transfusion proceeds.

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/

SHOT
Serious Hazards of Transfusion

Under or Overtransfusion n=20

12c

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 a handling and storage error).

Key SHOT message

- As in previous years, more than half the cases of overtransfusion were in children (8/14)

Recommendations

- Paediatric transfusion protocols should be readily accessible to all clinical staff
- Hospitals should have clear guidelines for patients being transferred between hospitals to reduce the risk of adverse outcomes

Action: Hospital transfusion teams

Introduction

The number of reports (20) is similar to last year (18). In 2023, there were 14 reports of overtransfusion and 6 of undertransfusion. The majority were clinical incidents (19/20).

Many cases were reported in children, 9/20. Eight of these were overtransfused and 1 was undertransfused.

Deaths related to transfusion n=1

Case 12c.1: A patient died following surgery where overtransfusion was justified

Shortly after an uneventful elective surgery (exchange of ureteric stents), the patient developed hypotension and tachycardia and was only minimally responsive to intervention (including intravenous fluids and vasopressors). The abdomen appeared distended, and the patient began complaining of back pain. The patient was thought to have major haemorrhage and was transfused three units of red blood cells and two units of FFP (emergency MHP). CT showed no evidence of bleeding, but there was evidence of pulmonary oedema. The patient was transferred to critical care and remained extremely unstable. TACO was considered but not supported by bedside echocardiography. Sadly, the patient died. Subsequently blood cultures from the patient grew E. coli. This death was referred to the coroner who concluded multi-organ failure, E Coli urosepsis with chronic ureteric obstruction caused the patient's death. The blood transfusion could have contributed to the patient's deterioration, but the relationship to the patient's outcome was not certain.

Initial investigation by hospital transfusion team felt this was unlikely to be TACO/TRALI or anaphylaxis to blood components. However, in the absence of an identifiable source of bleeding and rise in Hb from

114 to 184g/L, it was concluded that this was a clinically justified overtransfusion where the anaesthetist had substantial grounds to believe the patient was experiencing major haemorrhage.

Major morbidity n=2

A child received a full adult unit of red cells (300mL) when the correct volume would have been 150mL. The post-transfusion Hb was 190g/L. As a result, the child was admitted to ICU overnight and required venesection.

An adult with a platelet count of $27x10^9$/L who presented with haematuria received four platelet pools inappropriately prescribed by a junior doctor without adequate knowledge; only one was indicated. There was misunderstanding following discussion between the doctor and haematologist. The patient, already with pulmonary oedema, developed shortness of breath and required admission to ICU for 3 days. The patient later died but this was unrelated to the transfusion.

Overtransfusion n=14

More than half of the reported cases (8/14) were in paediatric patients. These are discussed in more detail in Chapter 24, Paediatric Cases.

Six adults received excess transfusion, 1 caused by a WBIT.

Case 12c.2: WBIT in FBC sample impacts two patients

A patient was transfused based on a wrong FBC result involving incorrectly labelled blood samples. Labels for Patient 1 were printed, but the phlebotomist was unable to get a sample from the patient. At the same time, there was a request for bloods to be taken from Patient 2 but the IT system defaulted to the Patient 1's record following an incorrect hospital number data entry. This resulted in labels belonging to Patient 1 being printed. PPID was not undertaken correctly at the time of phlebotomy, and the incorrect labels were attached to the FBC sample which contained Patient 2's blood.

The FBC results were issued against Patient 1. The laboratory staff noticed the discrepant Hb result in relation to the previous results from this patient but attributed this to surgery because the request had originated from a surgical ward. The junior medical and nursing staff had also discussed the discrepancy of both Hb and mean cell volume but the possibility of WBIT was not considered. Patient 1 was unnecessarily transfused a unit of red cells resulting in a post-transfusion Hb of 151g/L with no adverse symptoms. Patient 2, whose Hb had been 91g/L fell to 71 then 69g/L resulting in a delay before they were transfused. A mismatch between workload, staff provision, an ineffective IT system and communication factors were noted to be contributory factors in this incident.

Case 12c.3: Hypotension attributed to GI bleeding results in overtransfusion

An elderly woman with pre-existing cardiac failure and poor renal function suffered a major GI bleed requiring a red cell transfusion and endoscopy which confirmed arterial bleeding from a duodenal ulcer. She was stabilised but the following morning had hypotension. No formal laboratory sample was taken between the first transfusion and the second the day after. An urgent Hb was recorded mistakenly as 49g/L but on the venous gas was 119g/L. Based on the erroneous result, she received six units of red cells; her Hb rose to 198g/L and she required venesection. CT angiogram showed no evidence of bleeding. She was admitted to ICU following IR treatment with gastroduodenal artery coil. Four days later she returned to the ward, Hb 152g/L. Although she subsequently died this was not related to the overtransfusion.

Learning point

- Hypotension can have different causes and is not always due to bleeding. Thorough evaluation of the patient is crucial for guiding appropriate management. This will ensure the patient receives the care they need promptly and effectively

Haematinic deficiency n=1

A child with a Hb of 35g/L due to iron deficiency was intentionally transfused to Hb 96g/L and at a rate (6.13mL/kg/hr) greater than recommended (3-5mL/kg/hr). Iron deficiency is very well tolerated in young children. A smaller volume at a slower rate would have been more appropriate, but not every child, even with such a low Hb, requires transfusion as they are often very chronically anaemic.

There were a further 16 avoidable transfusions in patients with haematinic deficiencies, see Chapter 12b, Avoidable Transfusions.

Undertransfusion n=6

Of the 6 reports of undertransfusion, 2 involved FFP. In 1 case, two bags were given instead of three and in the other case one bag with 250mL of FFP was issued by the laboratory instead of the 1L requested resulting in delay of a planned procedure.

There were 3 reports of red cell undertransfusion, 1 in a child. A sample was run as a neonatal one, but the child was over a year of age and a paedipack was issued instead of a full unit. Another was in a patient whose target Hb was >100g/L because of radiotherapy. The patient received only one of five units of red cells resulting in failure to achieve the target. The 3rd case is described in Case 12c.4.

A patient with leukaemia failed to receive granulocytes as they had not been prescribed and were therefore wasted. There was no harm to the patient.

Case 12c.4: Splenic rupture with major haemorrhage requiring interhospital transfer

An elderly man on oral anticoagulants developed abdominal pain found to be caused by splenic rupture. He required emergency transfer to another hospital site for IR. Transfusion of red cells was started and planned to continue throughout the transfer. He also received PCC and tranexamic acid. There was no nurse available to accompany the patient, and the paramedics did not know how to manage the infusion pump when it stopped working and the transfusion was not completed. The transfusion laboratory at the transferring hospital had not been informed of the transfer, so the available crossmatched red cell units and patient sample were not sent with him. During the IR procedure he was peri-arrest and received emergency group O D-negative units and FFP. The splenic embolisation was successful and he was transferred to a ward.

The report noted that there was a lack of clarity on inter-site transfer for patients who require intervention. There were multiple handovers and unclear information among teams. Such transfers are known to be associated with risks of adverse events (Haji-Michael, 2005). The laboratory protocol for transfer of red cell units with patients was not followed. Guidelines are available for interhospital transfer noting the importance of appropriate equipment and personnel (AAGBI, 2006; Ahmed & Majeed, 2008; Warren, et al., 2004).

Learning points

- Transfer of seriously ill patients between sites carries additional risks; ideally patients should be accompanied by medical or nursing staff
- Handovers concerning seriously ill patients are essential and should be concise and accurate

Near miss n=1

A child avoided an excessive transfusion because an error in the prescription was detected by the staff member undertaking the pre-administration check.

Conclusions

Errors in paediatric transfusion continue to be a cause for concern. Transfusion training should ensure that clinicians authorising transfusions understand the use of all blood components including indications, monitoring, recognising, and managing adverse reactions.

Ensuring safety when transferring patients between hospitals involves careful coordination and communication between clinical teams, verifying patient information, transport with appropriate staff accompanying to monitor and manage patients during transfer. Clear protocols for communication and continuity of care are essential to minimise risks and ensure a smooth transition for the patient.

Finally, all transfusion decisions must be made after carefully assessing the risks and benefits of transfusion therapy. Clinical and laboratory staff must work collaboratively and in a co-ordinated fashion to be able to deliver individualised, holistic, patient-centred care.

Recommended resources

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

BSH guidelines for paediatric transfusion
https://b-s-h.org.uk/guidelines/guidelines/transfusion-for-fetuses-neonates-and-older-children

Guidance on: Transfer of the critically ill adult
https://ics.ac.uk/resource/transfer-critically-adult.html

References

Ahmed, I. & Majeed, A., 2008. Risk management during inter-hospital transfer of critically ill patients: making the journey safe. *Emergency Medicine Journal*, 25(8), pp. 502-505. doi: 10.1136/emj.2007.054361.

Association of Anaesthetists of Great Britain and Ireland (AAGBI), 2006. *Inter-hospital transfer of the critically-ill patient in the Republic of Ireland*, London: AAGBI. doi: http://dx.doi.org/10.21466/g.I-HTOTC.2006.

Haji-Michael, P., 2005. Critical care transfers – a danger foreseen is half avoided. *Critical Care*, 9(4), pp. 343-344. doi: https://doi.org/10.1186/cc3773.

Warren, J. et al., 2004. Guidelines for the inter- and intrahospital transport of critically ill patients. *Critical Care Medicine*, 32(1), pp. 256-262. doi: 10.1097/01.CCM.0000104917.39204.0A.

Incidents Related to Prothrombin Complex Concentrates n=23

12d

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

- 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 suspected ICH are at high risk of death or serious sequelae and require urgent anticoagulant reversal

Recommendations

- The ED should ensure they have a protocol with clear instructions for dose and administration of PCC. Staff should be appropriately trained in their use
- A standardised single first dose for emergency use should be adopted to reduce PCC administration delays in urgent situations
- Use of PCC should be regularly audited for timeliness and appropriateness

Action: Medical directors, hospital transfusion teams, audit leads

Introduction

A total of 23 cases were reported in this category. Most PCC incidents were reported in the elderly population, median age 85 years. Only 1 patient was under 70 years of age. There were 17/23 (73.9%) reports of delayed PCC infusion. Other errors included inappropriate doses, either under or over recommended units, infusion pumps set at the wrong rate and lack of trained staff to administer the PCC.

All patients were taking anticoagulants, either warfarin or apixaban/edoxaban. Nine patients had ICH, 5/9 following falls. Six patients had GI bleeding.

Deaths related to transfusion n=4

Four patients died (all on warfarin) possibly (n=3) or definitely (n=1) related to the delay in administration of PCC. This case has been described in Case 12d.1.

Case 12d.1: Failure to reverse warfarin and inadequate red cell transfusion

An elderly person was admitted with a suspected cerebrovascular accident which was not confirmed on CT. However, they were found to have a Hb of 44g/L and very high INR (confirmed on repeat testing). The patient received a single unit of red cells but no reversal of the high INR. They had

epistaxis earlier in the day but no other bleeding. No bleeding source was sought. The patient collapsed and died 15 hours after admission. The patient was on an acute ward which was very short staffed and usually relied on bank and agency staff.

Of the 3 deaths with possible imputability, 1 was a patient with ICH where the long delay in receiving PCC (8 hours) was associated with expansion of the haematoma. An elderly patient fell downstairs sustaining a head injury with confirmed ICH, and the PCC administration was delayed for 5 hours. Another elderly patient on warfarin was admitted with GI bleeding where PCC was delayed by 3.5 hours due to a delay in decision-making and incorrect use of the recently implemented electronic prescribing system.

Learning point

- The finding of a high INR should prompt urgent communication to the clinical team and appropriate actions taken especially when patients are on anticoagulants. If a decision has been made for anticoagulant reversal with PCC, this should be administered without delay

Major morbidity n=0

There were no patients that suffered major morbidity in 2023 as a result of the PCC administration.

Fixed dose PCC for emergencies

Delay can be reduced by using a fixed emergency dose avoiding both the need for finding the weight and use of calculations. Patients on warfarin should also receive vitamin K and follow up of the INR to ensure reversal and to determine if further PCC is required.

Continued confusion about dose and rate of infusion suggest that a fixed dose regimen might be safer. The literature demonstrates good correction of the INR in most (Bizzell, et al., 2021) including patients with ICH with a fixed dose of 2000IU (Dietrich, et al., 2021). A recent systematic review comparing fixed- versus variable-dose 4F-PCC included three randomised trials and 16 cohort studies with extracranial haemorrhage as the main indication. The authors concluded that fixed dose provides benefits in terms of dose reduction, more rapid administration, better haemostasis with reduced mortality and fewer thromboembolic events (Alwakeal, et al., 2024).

One UK centre has used a fixed dose of 1000IU for both warfarin and DOAC reversal since 2017 with clear benefit (Davies, et al., 2019). Their protocol provides for PCC removal from the refrigerator without laboratory or haematology clinical staff approval. A significant reduction in time from request to administration was demonstrated (for warfarin, mean 48 compared with 126 minutes). No significant difference was noted in mortality for standard dose (13%) and fixed dose (3%) (p=0.2117), although the data suggest that a fixed-dose regime may reduce mortality risk. Dose reduction resulted in significant financial savings. No inappropriate use occurred.

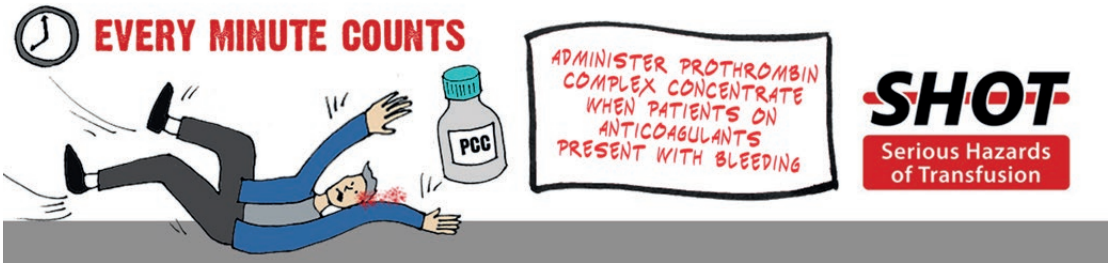
Further evidence is presented in Chapter 6, Acknowledging Continuing Excellence in Transfusion (ACE), Case 16, where a fixed-dose regimen (1000IU) was introduced to improve management of patients with ICH and GI bleeding. Subsequent local audit results identified that 67% of patients received PCC within 1 hour of the decision being made compared with 36% pre implementation of the project. Patient survival rate has increased to 86% from 53% pre implementation. In 43% of cases, the initial dose of 1000IU of PCC was sufficient to reverse the INR without need for further PCC.

Previous publications have also supported a fixed-dose approach. Haemostatic efficiency was shown in an open-label, multicentre, randomised clinical trial. Patients with non-intracranial bleeds requiring vitamin K reversal with 4F-PCC were allocated to either a 1000IU fixed-dose of 4F-PCC or a variable dose based on weight and INR. Effective haemostasis was achieved in 87.3% (n=69 of 79) in fixed and 89.9% (n=71 of 79) in the variable dosing cohort. Median door-to-needle times were reduced to 109 minutes (range 16 to 796) in fixed compared with 142 (17 to 1076) for the variable dose (P=.027). An INR < 2.0 at 60 minutes after 4F-PCC infusion was reached in 91.2% versus 91.7% (P=1.0) (Abdoellakhan, et al., 2022). Another meta-analysis of fixed-dose versus variable-dose of PCC reviewed data from 10 studies

including 988 patients. Fixed-dose PCC was associated with reduced mortality and a shorter order-to-needle time. These authors advocated further studies focusing on clinical outcomes (Mohammadi, et al., 2022). 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.

Conclusion

Delayed administration is the most frequent cause for PCC incident reports (73.9%). 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, and certainly within an hour (NHSE, n.d.). All medical 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 patient death.



Recommended resource

CAS Alert - Preventing transfusion delays in bleeding and critically anaemic patients
https://www.cas.mhra.gov.uk/ViewandAcknowledgment/ViewAlert.aspx?AlertID=103190

References

Abdoellakhan, R. A. et al., 2022. Fixed Versus Variable Dosing of Prothrombin Complex Concentrate for Bleeding Complications of Vitamin K Antagonists—The PROPER3 Randomized Clinical Trial. *Annals of Emergency Medicine*, 79(1), pp. 20-30. doi: https://doi.org/10.1016/j.annemergmed.2021.06.016.

Alwakeal, A. et al., 2024. Fixed- Versus Variable-Dose Prothrombin Complex Concentrate for the Emergent Reversal of Vitamin K Antagonists: A Systematic Review and Meta-Analysis. *Critical Care Medicine.* doi: 10.1097/CCM.0000000000006212.

Bizzell, A. C., Mousavi, M. K. & Yin, E., 2021. Fixed- versus variable-dose prothrombin complex concentrate protocol for vitamin K antagonist reversal. *International Journal of Haematology,* 114(3), pp. 334-341. doi: 10.1007/s12185-021-03176-w.

Davies, J. et al., 2019. *Fixed Dose Prothrombin Complex Concentrate for Direct Oral Anticoagulant and Low Molecular Weight Heparin Reversal: A Rapid and Effective Solution.* Harrogate, British Blood Transfusion Society (BBTS).

Dietrich, S. K., Mixon, M. A. & Rech, M. A., 2021. Fixed-dose prothrombin complex concentrate for emergent warfarin reversal among patients with intracranial hemorrhage. *The American Journal of Emergency Medicine,* Volume 49, pp. 326-330. doi: 10.1016/j.ajem.2021.06.032.

Mohammadi, K., Yaribash, S., Sani, M. A. & Talasaz, A. H., 2022. Efficacy and Safety of the Fixed-Dose Versus Variable-Dose of 4-PCC for Vitamin K Antagonist Reversal: A Comprehensive Systematic Review and Meta-Analysis. *Cardiovascular Drugs and Therapy,* 36(3), pp. 533-546. doi: 10.1007/s10557-021-07192-0.

NHS England (NHSE), n.d. *Delay in treatment with prothrombin complex concentrate (PCC).* [Online] Available at: https://www.england.nhs.uk/patient-safety/patient-safety-insight/learning-from-patient-safety-events/how-we-acted-on-patient-safety-issues-you-recorded/delay-in-treatment-with-prothrombin-complex-concentrate-pcc/#:~:text=PCC%20are%20human%20blood%20produc (Accessed 26 April 2024).

13 Near Miss (NM) Reporting n=1420

Author: Vera Rosa

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

ADU	Avoidable, delayed or under/overtransfusion	**SAE**	Serious adverse event
HSE	Handling and storage error	**SOP**	Standard operating procedure
IBCT	Incorrect blood component transfused	**SRNM**	Specific requirements not met
Ig	Immunoglobulin	**UKTLC**	United Kingdom Transfusion Laboratory Collaborative
NM	Near miss		
NPSA	National Patient Safety Agency	**WBIT**	Wrong blood in tube
RBRP	Right blood right patient	**WCT**	Wrong component transfused
RCA	Root cause analysis		

Introduction

Near miss events account for the largest category of cases reported to SHOT in 2023, 1420/3833 (37.0%). This is an increase from the previous two years, 54 more NM cases compared to 2022 (n=1366) and 265 compared to 2021 (n=1155) (Figure 13.1). Near miss events cover all SHOT categories which could have resulted in a SAE if the error had not been identified prior to transfusion or blood product administration. In 2023, in each SHOT category, there was a slight decrease in the number of NM. However, there was an increase of errors where a component was transfused in the equivalent categories.

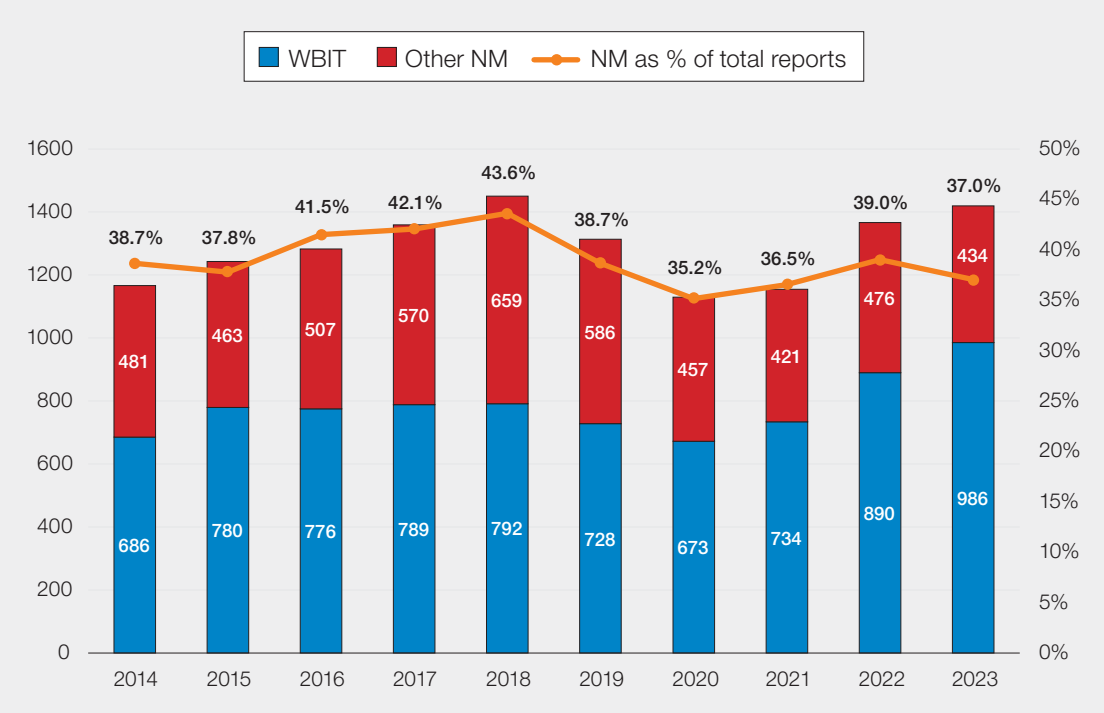


Figure 13.1: A decade of NM and WBIT reports 2014-2023

NM=near miss; WBIT=wrong blood in tube

The largest number of NM in a single category continues to be WBIT events accounting for 986/1420 (69.4%). This is an increase from 2022 (n=890/1366, 65.2%). There was also an increase in NM anti-D Ig errors with 41/1420 (2.9%) cases. In the remaining SHOT categories, there was a slight decrease in the number of NM reports as shown in Table 13.1.

Table 13.1: Comparison of the NM per SHOT category reported to SHOT in 2022 and 2023

SHOT category	Number of cases in 2022	Number of cases in 2023	Variance
WBIT	890	986	+96
HSE	140	138	-2
IBCT-WCT	115	106	-9
RBRP	118	99	-19
IBCT-SRNM	52	46	-6
Anti-D Ig	37	41	+4
ADU	14	4	-10
Total	**1366**	**1420**	**+54**

NM events are often overlooked as they do not cause patient harm. However, the risk of error occurring is present, and recognising, reporting, and investigating NM are vital to identify gaps in processes and risk factors. Understanding the conditions when NM occur allows implementation of corrective and preventative actions to improve patient safety. NM should be investigated effectively similar to how adverse events and reactions are investigated.

In 2023, there were 1027/1420 (72.3%) NM where RCA or other equivalent formal investigations were carried out and 1215/1420 (85.6%) where the NM had been reviewed. Of the NM cases reviewed, in 120/1215 (9.9%) events resulted in changes in transfusion procedures and policies. These were clarification of and designing comprehensive SOP as well as implementation of checklists or additional checking steps. Of the 393 cases where RCA or equivalent was not carried out, 11/393 (2.8%) stated *'not performed as there wasn't patient harm involved'* as the reason. Including additional answers such as '*not required*', '*not appropriate*', or *'not part of Trust policy'* increased this number to 45/393 (11.5%). In 1 case, the incident had not been investigated as the poor practice was accepted to be the norm and as such, an investigation was deemed as not necessary.

SHOT has been promoting and encouraging the learning from NM which are considered as 'free lessons', giving the opportunity to learn and share the learning without patient harm. The learning from NM should not be under-valued but acknowledged as a preventative warning of risks for patient harm. Case 13.1 illustrates how investigating a NM event supported improvements in the transfusion electronic system.

Case 13.1: Near miss helps to identify safety issues with requesting electronic system

A unit of red cells was collected by a porter using the porter electronic system. The unit collected was for a different patient. Both patients had the same surname, however no other patient details matched the blood request. When the blood component arrived at the ward and the details were checked, the error was identified and reported to the laboratory. The red cell unit was returned to the laboratory.

Investigation of this incident identified safety concerns with the porter's electronic system which was found to be unfit for purpose. The request using the electronic system could be sent without patient-specific information from the ward which led to the error. Poor compliance and different practices between sites within the organisation were also identified. The case was reviewed by the hospital transfusion team, hospital transfusion committee and facilities management forum. Safety issues were cascaded via huddles, strategic clinical networks were created, and a scoping exercise was undertaken to establish required improvements. A new SOP and flow chart was developed outlining details of the new processes to be followed. A communications package was developed to inform all parties of the new system in place. Porters were advised not to collect any blood components without complete patient information. A new escalation system is to be implemented to deal with these issues as well as an audit schedule to highlight ongoing issues and address them at ward level.

It is encouraging to see how meticulously this NM event was investigated and improvement actions implemented. The team's commitment to excellence and collaboration resulted in valuable lessons learned contributing to continuous improvement efforts.

Learning point

- Investigation of NM helps identify causes of errors and contributory factors before patient harm occurs. A thorough and complete investigation can lead to changes in processes, systems and policies to improve transfusion safety

Discussion of near miss errors per SHOT category

NM cases have been reviewed and discussed in each relevant chapter for this Annual SHOT Report and Table 13.2 shows the chapter that include NM events according to the current SHOT definitions.

Table 13.2: Categorisation of all NM according to SHOT definitions in 2023 (n=1420)

Category	Discussed in chapter	Number of reports	Percentage of cases
WBIT	Chapter 13a	986	69.4%
HSE	Chapter 11	138	9.7%
IBCT-WCT	Chapter 10	106	7.5%
RBRP	Chapter 14	99	7.0%
IBCT-SRNM	Chapter 10	46	3.2%
Anti-D Ig	Chapter 9	41	2.9%
ADU	Chapter 12	4	0.3%
Total		**1420**	**100%**

Conclusion

It is important to recognise that learning from NM is as useful as learning from incidents without the psychological and physical impact of an incident (Woodier, et al., 2023; Jung, et al., 2021). The lessons learnt from NM can lead to improvements within healthcare organisations, increasing patient safety by allowing sharing of the lessons learnt as well as the actions implemented to mitigate the risks (NPSA, 2004). Each organisation should facilitate and encourage a reporting culture, where staff feel psychologically safe to report these incidents without fear of blame or negative consequences (Woodier, et al., 2023; NPSA, 2004; Caspi, et al., 2023; Jung, et al., 2021). This involves a proactive approach of investigating incidents focused on systems rather than on individuals (NPSA, 2004; Woodier, et al., 2023). The results from the 2023 SHOT and UKTLC transfusion laboratory culture survey demonstrated that laboratory staff are still being a target of incivility and disciplinary action upon raising safety concerns or following incident reporting (SHOT, 2024). Recommendations have been published within the report to help organisations create a psychological safety culture for staff. Organisations must implement and embed investigation of NM events as part of their policies and facilitate resources for staff to understand the potential for improving patient safety when investigating NM.

Recommended resources

Wrong Blood In Tube (WBIT) investigation template
https://www.shotuk.org/resources/current-resources/

SHOT Bite No. 17: Learning from Near Misses (NM)
SHOT Bite No. 23: Civility in Healthcare
SHOT Bite No. 24: Speaking up for safety
SHOT Bite No. 25: Safety-I and Safety-II
https://www.shotuk.org/resources/current-resources/shot-bites/

References

Caspi, H., Perlman, Y. & Westreich, S., 2023. Managing near-miss reporting in hospitals: The dynamics between staff members' willingness to report and management's handling of near-miss events. *Safety Science,* 164(4), p. 106147. doi: https://doi.org/10.1016/j.ssci.2023.106147.

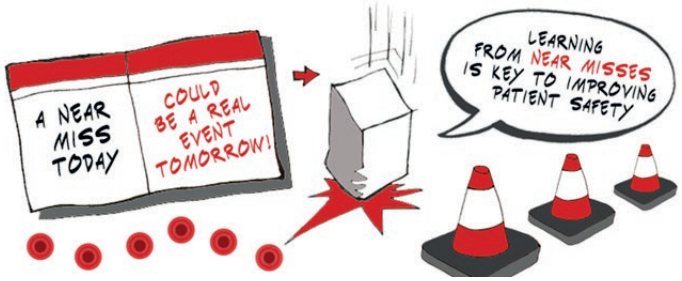
Jung, O. S. et al., 2021. Resilience vs. Vulnerability: Psychological Safety and Reporting of Near Misses with Varying Proximity to Harm in Radiation Oncology. *The Joint Comission Journal on Quality and Patient Safety,* 47(1), pp. 15-22. https://doi.org/10.1016/j.jcjq.2020.09.005.

National Patient Safety Agency (NPSA), 2004. *Seven steps to patient safety - The full reference guide.* [Online] Available at: https://www.publichealth.hscni.net/sites/default/files/directorates/files/Seven%20steps%20to%20safety.pdf (Accessed 12 February 2024).

Serious Hazards of Transfusion (SHOT), 2024 *SHOT Surveys.* [Online] Available at: https://www.shotuk.org/resources/current-resources/shot-surveys/ (Accessed 26 April 2024).

Woodier, N., Burnett, C. & Moppett, I., 2023. The Value of Learning From Near Misses to Improve Patient Safety: A Scoping Review. *Journal of Patient Safety,* 19(1), pp. 42-47. doi: https://doi.org/10.1097/pts.0000000000001078.

Woodier, N., Burnett, C., Sampson, P. & Moppett, I., 2023. Patient safety near misses – Still missing opportunites to learn. *Journal of Patient Safety and Risk Management,* 0(0), pp. 1-7. doi: https://doi.org/10.1177/25160435231220430.



SHOT
Serious Hazards of Transfusion

13a Near Miss - Wrong Blood in Tube (WBIT) n=986

Authors: April Molloy, Paula Bolton-Maggs, Vera Rosa 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.

Abbreviations used in this chapter

cffDNA	Cell-free fetal deoxyribonucleic acid	**PPID**	Positive patient identification
HSSIB	Health Services Safety Investigations Body	**WBIT**	Wrong blood in tube
ID	Identification	**Wi-Fi**	Wireless fidelity

Key SHOT messages

- Correct patient identification remains a key safety measure and patients should be encouraged to participate in critical identification steps
- Identification bands are an essential safety precaution. These must be applied carefully and correctly
- 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
- A high proportion of WBIT continue to be reported from maternity areas, this could be due to multiple factors which need to be investigated locally and addressed to improve patient safety

Recommendations

- Training about patient identification bands should be reviewed and their importance emphasised

Action: Education teams, hospital transfusion teams and maternity leads

- In line with the HSSIB recommendations, local organisations should review and identify system-wide requirements for scanning in positive patient identification since the use of scanning technology can help to reduce misidentification incidents

Action: Hospital chief executives and medical directors

Introduction

For the third consecutive year, there has been an increase in WBIT near miss incident reports, 986 cases in 2023 (890 cases in 2022, 734 cases in 2021) see Figure 13.1 in Chapter 13, Near Miss (NM) Reporting. The majority were routine samples, 810/986 (82.2%) and 78/986 (7.9%) were classed as urgent or emergency. Cases from maternity departments account for 388/986 (39.4%) reports. WBIT continues to represent the largest proportion of near miss events, 986/1420 (69.4%).

What errors lead to WBIT?

WBIT errors continue to result from the same two leading causes: failure to identify the patient correctly at phlebotomy, 434/986 (44.0%) and labelling the blood samples away from the patient, 285/986 (28.9%). These two errors continue to be reported every year. Of concern, both errors occurred together in 170/719 (23.6%) of the reports.

Where reported, routine group and screen samples, 856/961 (89.1%) were most commonly implicated. The overall number for crossmatch samples was 105/961 (10.9%) with a small number, 21/105 (20.0%), required for an emergency transfusion.

Patient ID bands, when used accurately, should help to prevent errors. Ten incidents were reported with ID band errors: failure to apply ID bands (3), wrong band attached to patient (2), patient not correctly identified when band applied (3), patient wrongly identified at admission (1) and 1 case where case records had been merged with another patient of the same name but different date of birth and ID number. Care must be taken to avoid patient misidentification. Forty-four incidents were reported involving patients with identical or similar names. PPID using first name, surname, date of birth and a unique patient identification number is key to safe practice. Case 13a.1 illustrates the importance of PPID. Patient ID bands are crucial to prevent errors in healthcare settings by ensuring accurate patient identification during procedures, treatments including transfusions and administration of medication.

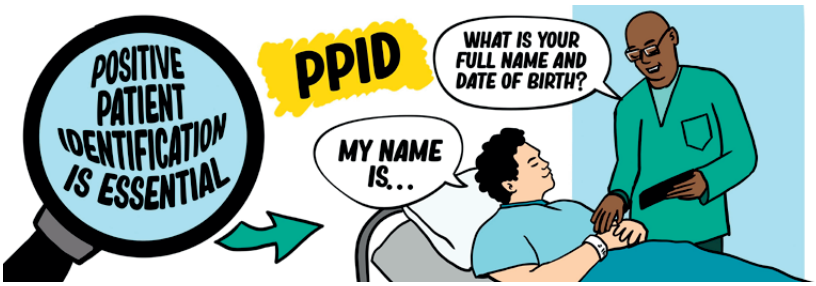
Venepuncture requires concentration and attention to detail. In 1 case, the doctor was distressed by a toxic safety culture in the ward with bullying and interruption, which resulted in a WBIT. Civility in healthcare has been shown to have an impact on patient safety. Incivility contributes to an increased risk of incidents and negative consequences in staff wellbeing and psychological safety (Civility Saves Lives, 2022).

Case 13a.1: Patient care documented on the wrong patient record

A patient queried why they were being called by another name. The patient's pregnancy records had been uploaded incorrectly to another non-pregnant patient's notes. Previous clinical notes and booking in bloods were undertaken under incorrect patient details/records. The patient had not been positively identified at the previous appointment.

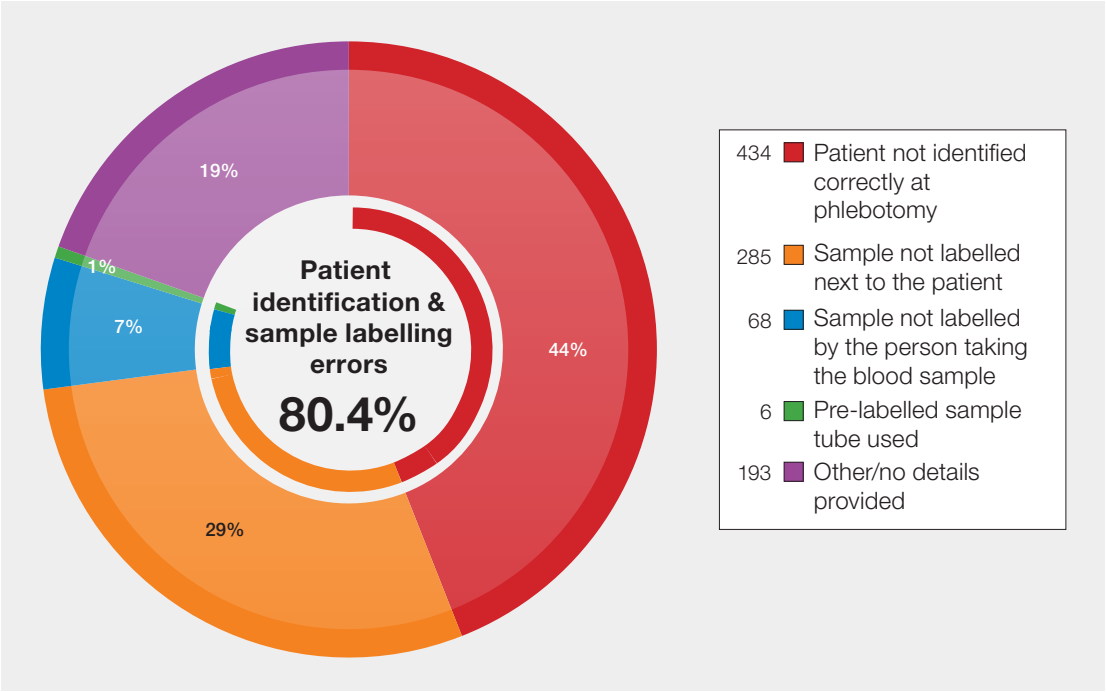
Learning points

- Care must be taken to ensure the correct ID band is applied to the right patient
- PPID, sample taking, and labelling should always be a single, continuous process carried out beside the patient
- Involving the patient in their own care by encouraging them to confirm their identity, where possible, and confirming their details on the sample will help reduce errors



SHOT
Serious Hazards of Transfusion

Figure 13a.1: Primary errors leading to WBIT in 2023 (n=986)



Detecting the primary error can be challenging in historical WBIT i.e., when the initial error occurred some years ago.

The majority of errors were detected by laboratory staff, 830/986 (84.2%), while clinical teams identified the incident in 120/986 (12.2%) cases. In the remaining 36 cases the error was identified by other healthcare professionals, or the information was not provided.

Figure 13a.2: Point in the process where the error was detected in WBIT reported in 2023 (n=986)

SHOT
Serious Hazards of Transfusion

Case 13a.2 highlights the importance of PPID.

Case 13a.2: Patient not adequately identified prior to phlebotomy

The hospital transfusion laboratory received two samples for a patient with no previous blood transfusion history. The samples and the request forms were correctly labelled and processed. However, ward staff later called the laboratory to say the samples had been taken from the wrong patient. The doctor realised the mistake when the nurse was placing the wristband on the patient. The patient had a similar name and date of birth as the intended patient and was without a wristband at the time of sample collection.

This incident highlights the importance of PPID at phlebotomy; in this instance, PPID did not occur on two occasions (two samples were sent), or two samples were taken during the same phlebotomy.

Learning point

- Sending two samples from the same venepuncture could prove to be fatal if the wrong patient is bled or the correct patient bled but another patient's details are used. The samples taken from the same venepuncture will group identically and could lead to a potential ABO-incompatible transfusion

ABO-incompatibility

In 536 cases, blood group data was provided. If these WBIT had not been detected, 256/536 (47.8%) patients could have received ABO-incompatible blood components with a risk of serious harm or death (Table 13a.1).

		Group of the blood component that might have been transfused					
		A	B	AB	O	Compatible	Incompatible
Patient blood group	A	44	30	8	119	163	38
	B	22	6	6	38	44	28
	AB	6	2	1	12	21	0
	O	131	44	15	52	52	190
	Totals	**203**	**82**	**30**	**221**	**280**	**256**

Case 13a.3 illustrates the importance of undertaking a group-check sample correctly to avoid potential ABOi transfusions.

Case 13a.3: Failure to accurately identify patients leads to NM-WBIT

A doctor planned to take two group and screen samples from a patient that did not have a blood group history recorded in the laboratory. The samples were taken 10 minutes apart, but one was taken from the correct patient and the other was inadvertently taken from a different patient. The request forms were completed prior to taking the samples and the doctor did not check the patients' identities or their ID bands. Samples were then labelled away from the patient's side.

Testing revealed that the first sample grouped as O D-positive, and the second taken 10 minutes later grouped as A D-positive. Two repeat samples had to be obtained from the right patient to ascertain their correct blood group. There was a lack of medical staff on duty and the doctor involved was the only doctor on duty at the time, with multiple competing tasks to complete. There were no delays to transfusion, or any other adverse outcome reported as a result of this WBIT.

It is crucial to recognise that WBIT errors, where the blood in the tube is not that of the patient identified on the label, may lead to catastrophic outcomes, such as death from ABO-incompatible red cell transfusion. Transfusion is a multi-step, multidisciplinary process requiring diligence, accurate ID checks and accurate documentation. Errors continue to occur despite multiple interventions (education, training, competency testing, guidelines, and use of IT systems). Although this is focusing on WBIT in relation to blood transfusion, all pathology samples should be identified and linked to the correct patient with the same degree of care. Improving staff awareness and consideration of human factors is essential.

Sampling

Consistent with previous years, midwives, nurses, and doctors, constitute the largest groups of staff involved in collecting WBIT transfusion samples as outlined in Figure 13a.3.

Figure 13a.3: Numbers of different healthcare professionals who took blood samples resulting in WBIT in 2023 (n=986)

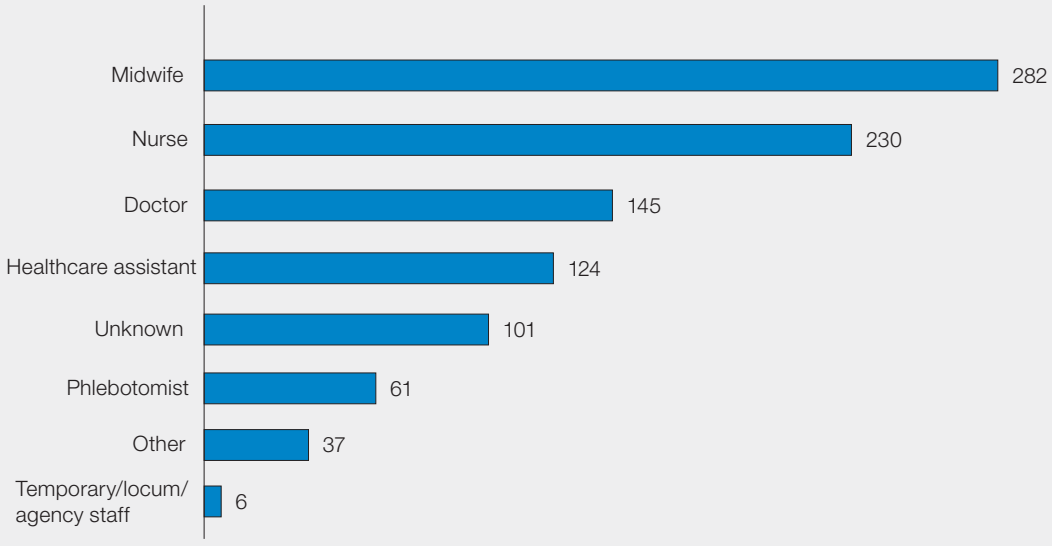


Table 13a.2 shows the primary errors in the different healthcare professional groups. It is notable that the most common error for phlebotomists (74.5%) was failure to correctly identify the patient.

Primary error	Midwife	Nurse	Doctor	Healthcare assistant	Phlebotomist
Patient not identified correctly at phlebotomy	118 (51.8%)	110 (53.4%)	59 (45.4%)	74 (65.5%)	38 (74.5%)
Sample not labelled next to the patient	88 (38.6%)	84 (40.8%)	55 (42.3%)	26 (23.0%)	10 (19.6%)
Sample not labelled by person taking the blood	19 (8.3%)	11 (5.3%)	16 (12.3%)	11 (9.7%)	3 (5.9%)
Pre-labelled sample tube used	3 (1.3%)	1 (0.5%)	0	2 (1.8%)	0
Total	**228**	**206**	**130**	**113**	**51**

Table 13a.2 Primary errors associated with WBIT in different professional groups in 2023

Maternity cases n=388

Maternity departments and antenatal clinics appear to be high-risk areas for transfusion errors. Of WBIT cases reported in 2023, 388/986 (39.4%) occurred in obstetrics/maternity. These incidents included 61 errors involving neonates:

- Mother and cord mix ups (n=52)
- Confusion in sampling twins (n=9)

Serial Annual SHOT Reports continue to highlight the need for improved processes for labelling of cord blood samples and the risk of WBIT when labelling the infant's umbilical cord sample after the placenta had been moved away from the patient's side, as reflected in Case 13a.4.

Case 13a.4: A baby's blood group not as predicted from cffDNA result

A mother noted that her baby's blood group result (D-positive) did not correspond with the cffDNA result (predicted D-negative). The placenta had been discarded into the general placenta bucket with others, placed in individual plastic bags but unlabelled. No cord bloods were taken. A second midwife retrieved what she thought was the correct placenta from the bin, took a cord sample and sent it to the hospital transfusion laboratory. Repeat bloods from the baby confirmed the sample from the retrieved placenta was a WBIT.

Case 13a.5: Cord sampling mix-up

Cord bloods were taken in the labour ward from newborn twins. Twin 1 grouped as A D-negative and Twin 2 as O D-negative. Subsequent samples were taken for Twin 1, which grouped as O D-negative. Repeat bloods confirmed WBIT from cord sampling at delivery. The staff member taking samples at delivery had not undertaken transfusion training and was unaware that they were not to use pre-labelled tubes.

Learning points

- Particular care must be taken in labelling cord blood samples. This should be done before the placenta is removed from the mother's side
- Samples from twins must be fully identified; they will have the same date of birth and surname, but the different ID numbers should be included

Human factors

Review of human factors questions showed that there was a mismatch between staffing levels and workload in 353/986 (132 did not answer) and communication issues in 186 (134 did not answer). Problems in both these areas contributed to 100 WBIT cases.

Conclusion

Misidentification of patients has been highlighted by a National Learning Report (HSSIB, 2024). PPID is seen as a routine task, but is common, complex, and critical for patient safety. The report highlights the need to improve patient safety by seeking to better understand and address the risks associated with PPID through a safety management system approach. SHOT reporting shows that this is a continuing problem in blood transfusion with significant risk to patient safety. The increasing trend and number of multiple errors is concerning. Although the HSSIB report recommends further development of scanning technology, this must be set up properly with adequate staffing to support it. In 1 case, a WBIT occurred when labels were printed for multiple patients away from the bedside due to an inadequate number of printers and issues with Wi-Fi.

Regardless of whether patient identification is manual or electronic, it is imperative that this is correctly determined. This is the simplest way of involving the patients in their own care and can prevent adverse clinical outcomes. Appropriate minimum identification criteria should be established and adhered to. WBIT events should be monitored, investigated using human factors principles and appropriate mitigating actions implemented.

Recommended resources

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

SHOT Bite No. 17: Learning from Near Misses (NM)
SHOT Bite No. 23: Civility in Healthcare
https://www.shotuk.org/resources/current-resources/shot-bites/

Wrong Blood In Tube (WBIT) Investigation template
https://www.shotuk.org/resources/current-resources/

Civility saves lives
https://www.civilitysaveslives.com/

National Comparative Audit – 2022 Audit of Blood Sample Collection and Labelling
https://hospital.blood.co.uk/audits/national-comparative-audit/

References

Civility Saves Lives, 2022. *Civility Saves Lives.* [Online] Available at: https://www.civilitysaveslives.com/ (Accessed 29 February 2024).

Health Services Safety Investigations Body (HSSIB), 2024. *National learning report: Positive patient identification.* [Online] Available at: https://www.hssib.org.uk/patient-safety-investigations/positive-patient-identification/national-learning-report/ (Accessed 08 April 2024).

Right Blood Right Patient (RBRP) n=259 14

Authors: Caryn Hughes, 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

BMS	Biomedical scientist	**PTR**	Patient transfusion record
EBMS	Electronic blood management system	**RBRP**	Right blood right patient
EPR	Electronic patient record	**RCA**	Root cause analysis
LIMS	Laboratory information management system	**TACO**	Transfusion-associated circulatory overload
PID	Patient identification		

Key SHOT messages

- Effective use of pre-administration checklists play an important role in detecting PID errors prior to transfusion. Where noncompliance is detected, appropriate actions must be taken to ensure accurate and complete PID prior to commencing the transfusion
- Most laboratory errors could have been prevented by using a laboratory exit check highlighting the importance of safety checks at critical steps in the transfusion pathway
- RBRP errors have the potential to result in incorrect component transfusion in other circumstances

Recommendations

- The key recommendations from the 2021 Annual SHOT Report remain pertinent: importance of PID, laboratory exit checks, collection checks, and pre-administration checklist (Narayan, et al., 2022)
- RBRP errors should be investigated with the same rigour as incidents where patient harm occurred, as they highlight deficiencies in the process where harm was narrowly avoided

Action: All staff in transfusion, hospital risk departments, all staff investigating transfusion incidents

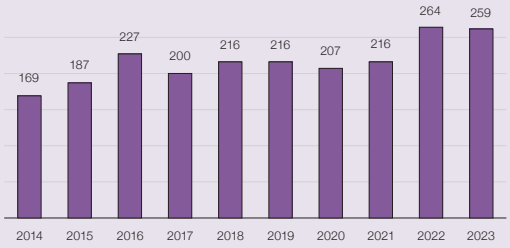
- Electronic systems should be used to their full potential to prevent RBRP errors

Action: Senior hospital managers, hospital transfusion committees, hospital transfusion teams

Headline data 2023

Number of reports n=259
Deaths n=0
Major morbidity n=0

RBRP reports by year



Demographic data

Male n=137
Female n=109
Unknown n=13

Adults n=234
Paediatric n=11
Unknown n=14

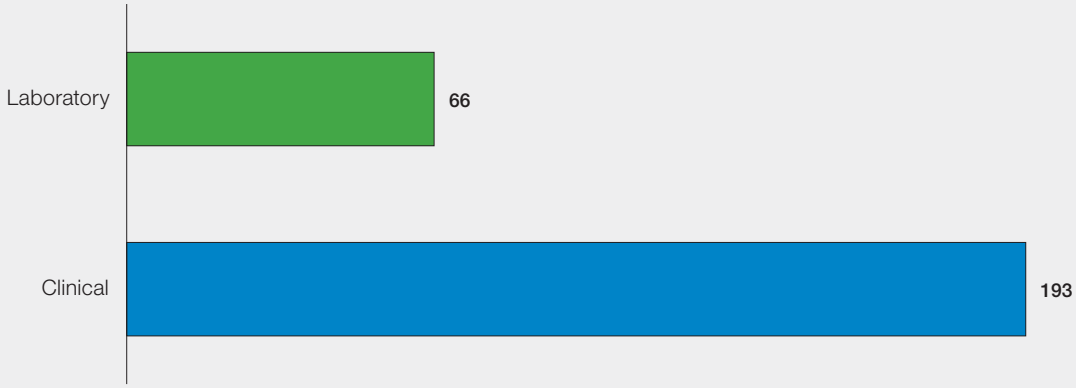
Blood component data

Red cells n=231
Platelets n=14
Plasma n=9
Multiple components n=4
Cryoprecipitate n=1

Introduction

There were 259 cases reported in 2023, a slight decrease from 2022 (n=264). Clinical cases accounted for 193/259 (74.5%) and laboratory cases 66/259 (25.5%). Clinical cases increased from 73.1% in 2022 and laboratory cases decreased from 26.9%.

Figure 14.1: Breakdown of RBRP reports in 2023 (n=259)



Overview of RBRP errors

Most laboratory reports were due to component labelling, 36/66 (54.5%) and errors with patient demographic details, 17/66 (25.8%). Of the labelling errors, 25/36 (69.4%) were due to transposed labels between units intended for the same patient. Sample receipt and registration errors accounted for 27/66 (40.9%) laboratory reports, with 17 demographic data entry errors and 7 cases where available information was not heeded. Most laboratory errors, 61/66 (92.4%) could have been detected by using a laboratory exit check such as PAUSE (Narayan, et al., 2022).

Clinical RBRP reports were mainly due to PID errors at sample taking, 75/193 (38.9%) and 17/193 (8.8%) errors at administration which included 9 patients who were transfused without a wristband. In 53/193 (27.5%) cases, the primary error was in the prescription and 23/193 (11.9%) related to incorrect details on the transfusion request. Collection errors accounted for 12/193 (6.2%) cases and of these 6/12 (50.0%) were because of PID errors.

The largest number of errors in RBRP occurred at sampling, 75/259 (29.0%) followed by prescription errors, 56/259 (21.6%) and component labelling errors accounted for 37/259 (14.3%) (Figure 14.2).

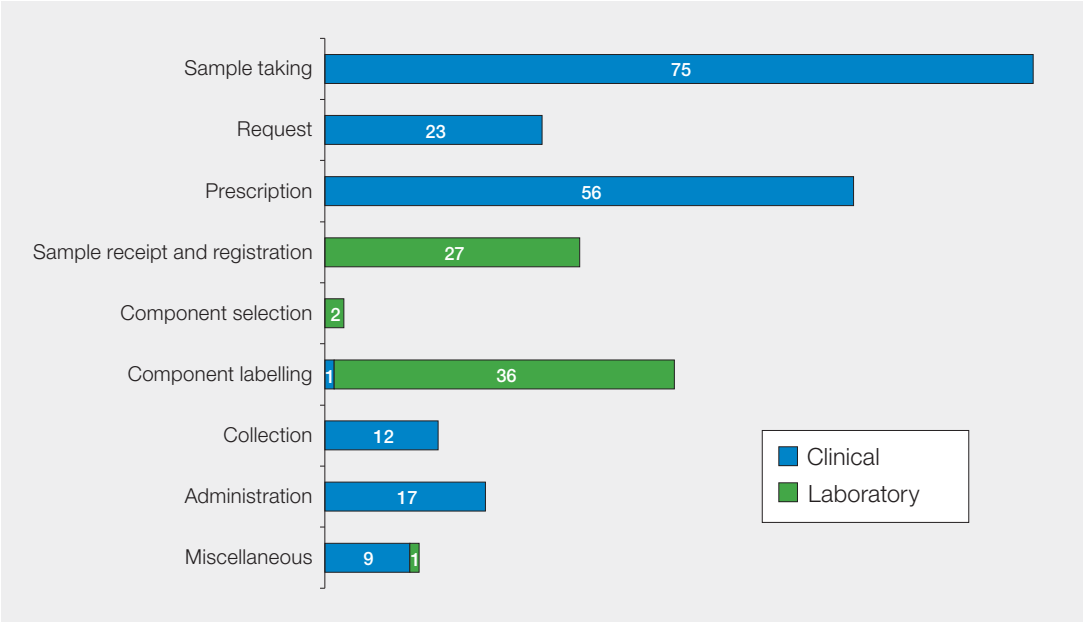


Figure 14.2: RBRP classified by the step in the transfusion process where the primary error occurred in 2023 (n=259)

Patient identification (PID) errors n=150

Errors with patient demographic details, in the laboratory and clinical settings, accounted for 150/259 (57.9%) of all RBRP errors. PID errors occurred throughout all steps of the transfusion process, with 92/150 (61.3%) due to sample and request form transcription errors in the clinical area. Laboratory errors accounted for 25/150 (16.7%) where the patient identification information was not heeded, or data was incorrectly entered into LIMS.

Case 14.1: Blood component transfused despite PID/compatibility label mismatch

A group and screen sample was incorrectly labelled for the intended patient and a unit of red cells was issued and transfused with incomplete details. The clinical staff contacted the transfusion laboratory and queried the name discrepancy. The BMS said the blood component was safe to transfuse and incorrectly told the clinical team it was a middle name instead of the second part of the forename. The sample should have been rejected and the blood component recalled. The RCA concluded that the patient details on the sample were taken from the EPR not the patient's ID band. The two-part forename was assumed to be a middle name and not included on the sample. A contributing factor was that the discrepancy between the request form and sample was not detected.

This demonstrates how inaccurate PID at the sampling step impacts on the safe administration of a blood component. It highlights the importance of labelling samples directly from the patient's ID band which must be attached to the patient. Assumptions were made by the BMS with regards the patient's name and there was no check against the request form and sample label, which would have detected the error.

Clinical RBRP errors n=193

Prescription errors n=56

Of the 193 clinical errors, 56/193 (29.0%) were related to prescription errors, where 8 errors had incorrect patient details on the prescription. A pre-administration checklist had been used in 38/56 (67.9%) cases but failed to detect the error.

Case 14.2: No patient identifiers on the prescription

Due to an incomplete record of traceability, a copy of the PTR was requested as evidence of transfusion. Only the actual prescription section of the PTR had been completed without patient details on either the front or the back of the PTR to indicate which patient the prescription was for. The prescriber had not completed the patient details on the consent section, TACO pre-transfusion risk assessment, indication for transfusion and pre-transfusion results. Despite the prescription being incomplete, both units of red cells were administered to the patient by an external agency nurse who was not trained to administer transfusions in the hospital.

There were multiple cumulative errors in this case, any of which could have resulted in an IBCT. RBRP cases provide free learning opportunities to rectify patient safety issues before harm occurs and should be investigated to the same extent as patient harm incidents.

Pre-administration checklists

Total clinical RBRP errors:

- 121/193 of errors used a pre-administration checklist, but failed to detect the error
- 4/193 had a checklist available but did not use it
- 27/193 did not have a pre-administration checklist implemented in their organisation
- 41/193 stated a checklist was not applicable, or did not answer the question

Laboratory RBRP errors n=66

There were 66 laboratory errors, most of which were due to component labelling errors (36/66) and sample receipt and registration errors (27/66).

Component labelling errors n=36

Labelling errors were mainly due to transposition of labels between units for the same patient (25/36).

Sample receipt and registration errors n=27

Sample receipt and registration errors were mainly due to patient identification errors at the booking in stage leading to errors on the compatibility label (26/27). These errors were mostly due to demographic data entry errors (17/26) and available information on the sample or request form not heeded (7/26). Case 14.3 illustrates a data entry error resulting in incorrectly labelled red cells being transfused.

Case 14.3: PID amended in error by laboratory and assumptions by clinical area led to unit of red cells being transfused

A BMS erroneously amended a patient's forename in LIMS in error to the name of the patient's ward. The forename field was adjacent to location field in LIMS on the patient registration page. This led to the unit being issued with the compatibility tag stating the incorrect forename and resulted in a compatibility tag and ID band mismatch at the bedside. A new ID band with the patient's name as the name of the ward was then printed (EPR had automatically been updated by LIMS) and used to transfuse the patient. Using the new ID band would not have alerted the staff to a mismatch on the EBMS which was then used to confirm patient identification.

The ward nurse noticed the patient's forename read as the ward name on EPR and the compatibility tag. This patient had restrictions on family members being aware they were in hospital and information being passed on to them. The nurse mistakenly attributed the change in name was to protect their identity. The staff nurse therefore printed a new ID band which was then used to transfuse the patient. As all other identifiers matched, they reported being confident that this was the correct patient.

Whilst it is encouraging to see interoperability between LIMS and EPR systems, proper process and restrictions should be in place for how and who can make amendments to patient identifiers.

Contributory factors to RBRP errors

Considering the human contribution to system failures and investigating the reasoning and behaviour of individuals, rather than attributing the error itself, facilitates change for reducing the potential for errors (Woods, et al., 1994). These identified that causative factors can be addressed through changes in practice and local working environments (Improvement Academy, 2022).

Analysis of the contributory factors in RBRP errors identified several commonalties between the clinical and laboratory settings (Figure 14.3).

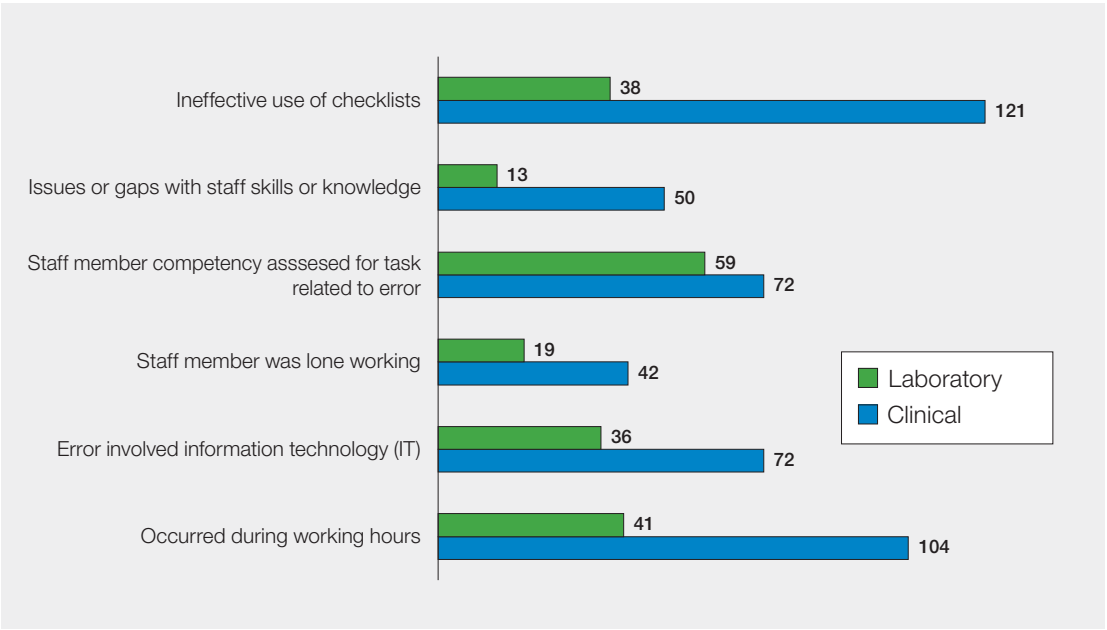
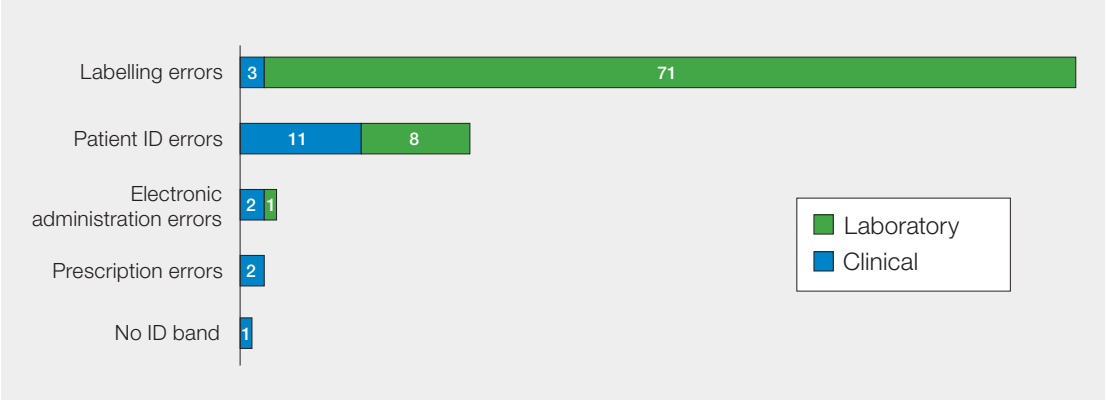


Figure 14.3: Contributory factors in RBRP errors reported in 2023 (n=259)

Near miss RBRP cases n=99

There were 99 near miss RBRP incidents, 19/99 (19.2%) originated in the clinical area and 80/99 (80.8%) in the laboratory. Component labelling errors, 71/80 (88.8%) accounted for the majority of cases in the laboratory. In the clinical area, sampling errors, 10/19 (52.6%) were the most reported. A high number of cases, 71/99 (71.7%), were detected at pre-administration checks, with 57/99 (57.6%) using a formal pre-administration checklist.

Figure 14.4: RBRP near miss events in 2023 by subcategory for clinical and laboratory errors (n=99)



ID=identification

Learning points

- All staff involved in the transfusion process should be aware of how to undertake accurate and complete PID checks
- Sample labelling must be undertaken at the patient's side using the ID band attached to the patient
- Pre-administration processes must include checking the patient's identity against the prescription and the blood component compatibility label

Conclusion

Patient identification is complex but remains fundamental to ensuring patient safety (HSSIB, 2024). Inaccurate and incomplete PID processes throughout the transfusion process can result in significant harm. Despite the use of pre-transfusion checklists errors continue to occur. Sampling and labelling errors remain undetected prior to transfusion, highlighting many deficiencies in clinical and laboratory processes. The lack of appropriate checks at the collection and administration (including prescription) steps resulted in missed opportunities to detect some RBRP errors. While transfusion procedures may differ between establishments, there are essential common checks that must be undertaken which could reduce the number of RBRP (and incorrect blood component transfused) incidents. Sampling, collection, and pre-administration checks should follow British Society for Haematology guidelines (Robinson, et al., 2018). The use of correctly configured information technology can act as an additional safety barrier to help detect and reduce RBRP errors.

Recommended resources

SHOT Video: The Pre-administration Blood Component Transfusion Bedside Check 2020
https://www.shotuk.org/resources/current-resources/videos/

SHOT PAUSE checklist
SHOT Safe Transfusion Practice: Transfusion Checklist
https://www.shotuk.org/resources/current-resources/

SCRIPT Using Information Technology for Safe Transfusion
https://www.shotuk.org/resources/current-resources/script/

References

Improvement Academy, 2022. *Yorkshire Contributory Factors Framework.* [Online]
Available at: https://improvementacademy.org/resource/yorkshire-contributory-factors-framework/ (Accessed 01 March 2024).

Narayan, S. et al., 2022. *The 2021 Annual SHOT Report,* Manchester: Serious Hazards of Transfusion (SHOT) Steering Group. doi: https://doi.org/10.57911/QZF9-XE84.

National Services Safety Investigations Body (HSSIB), 2024. *National learning report: Positive patient identification.* [Online] Available at: https://www.hssib.org.uk/patient-safety-investigations/positive-patient-identification/national-learning-report/ (Accessed 08 April 2024).

Robinson, S. et al., 2018. The administration of blood components: a British Society for Haematology Guideline. *Transfusion Medicine,* 28(1), pp. 3-21. doi: https://doi.org/10.1111/tme.12481.

Woods, D. D., Johannesen, L. J., Cook, R. & Starter, N. B., 1994. *Behind human error: cognitive systems, computers, and hindsight.* Ohio: Crew Systems Ergonomics Information Analysis Center.

15 Laboratory Errors n=742 (535 transfused errors and 207 near miss)

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

Abbreviations used in this chapter

ABOi	ABO-incompatible
APML	Acute promyelocytic leukaemia
BMS	Biomedical scientist
cffDNA	Cell-free fetal deoxyribonucleic acid
EBMS	Electronic blood-management system
ED	Emergency department
EI	Electronic issue
EQA	External quality assessment
FBC	Full blood count
FFP	Fresh frozen plasma
Hb	Haemoglobin
HCPC	Health and Care Professions Council
HDU	High dependency unit
HSE	Handling and storage errors
IBCT	Incorrect blood component transfused
IBGRL	International Blood Group Reference Laboratory
ICU	Intensive care unit
Ig	Immunoglobulin
LIMS	Laboratory information management system
MHRA	Medicines and Healthcare products Regulatory Agency
PCC	Prothrombin complex concentrate
PTT	Pre-transfusion testing
RBRP	Right blood right patient
SCD	Sickle cell disease
SOP	Standard operating procedure
SRNM	Specific requirements not met
UK	United Kingdom
UK NEQAS	UK National External Quality Assurance Scheme
UKTLC	UK Transfusion Laboratory Collaborative
WCT	Wrong component transfused

Key SHOT messages

- IBCT-SRNM events were the most common category of transfused laboratory errors accounting for 156/535 (29.2%) in 2023
- The most common category of transfused laboratory errors occurred at the testing step, 192/535 (35.9%)
- Major morbidity due to sensitisation to the K antigen continues to occur (n=4 in 2023)
- Laboratory delays contributed to 1 patient death (imputability-probable), and 3 cases of major morbidity in 2023
- Many incidents were related to insufficient staff knowledge in non-routine situations
- Common contributory factors include staff shortages, poor skill mix, lone working, education, ineffective IT, communication issues and poor safety culture

Recommendations

- Patients should not die or suffer harm from avoidable delays in transfusion. Where transfusion needs are complex, laboratory staff should have access to and follow specialist advice to provide the most suitable component available. Hospital policies and processes must reflect this
- Staff must have protected time for training and education to provide a safe service

- Bespoke operational roles should be considered for project/change implementation to ease the pressure on routine staff
- Policies for lone working should be reviewed to identify when extra support or reallocation of tasks are required
- A just and learning safety culture should be implemented to improve the safety of patients and staff members, and to ease the existing recruitment and retention pressures in the laboratory

Action: Transfusion laboratory managers

Introduction

There has been an increase in laboratory errors which resulted in transfusion, 535/1764 (30.3%) of total errors in 2023 compared to 431/1542 (28.0%) in 2022. Laboratory near misses were 207 in 2023 compared to 220 in 2022. The largest category of laboratory errors were IBCT-SRNM events, 156/535 (29.2%), which remains a consistent theme within laboratory errors (Figure 15.1). There was also an increasing trend in giving the incorrect blood group to patients undergoing haematopoietic stem cell transplants. Please see further information in Chapter 10, Incorrect Blood Component Transfused (IBCT) and 'Recommended resources'. Human factors related to laboratory errors are discussed in the supplementary information on the SHOT website (https://www.shotuk.org/shot-reports/report-summary-and-supplement-2023/).

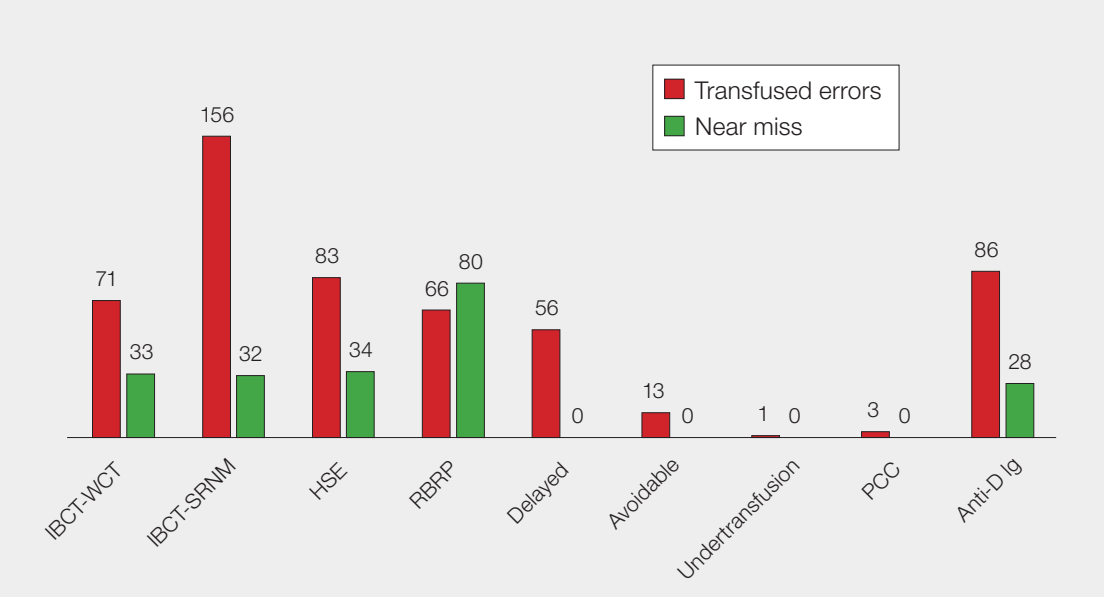
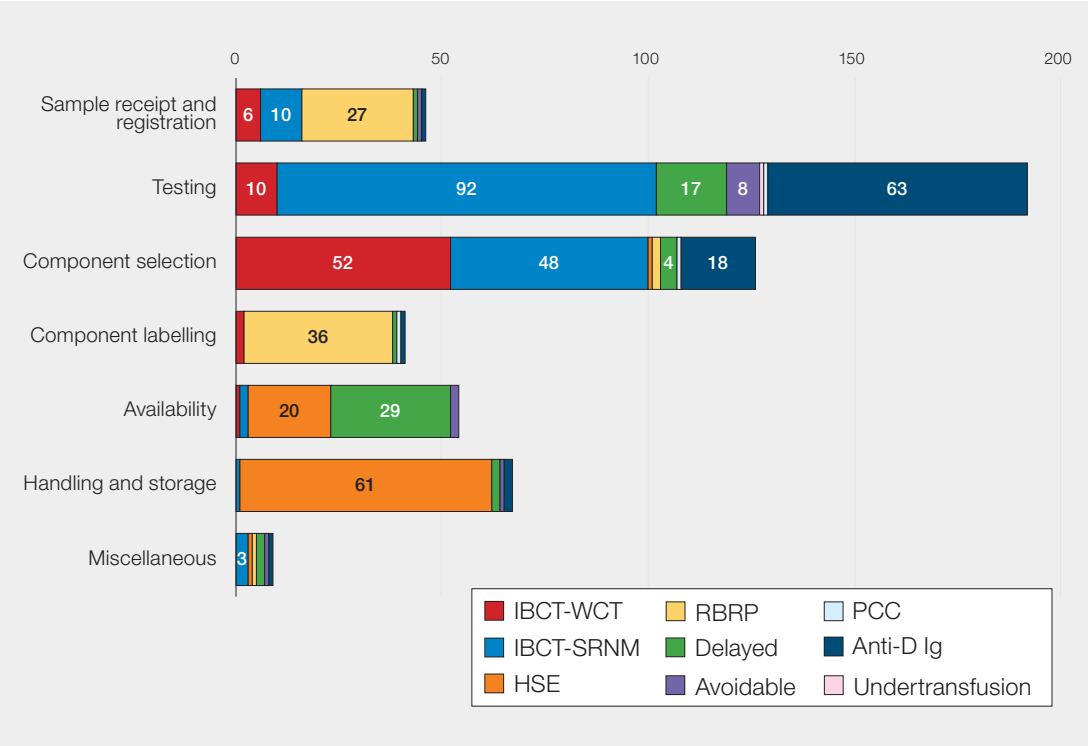


Figure 15.1: Laboratory errors and near misses by reporting category in 2023 (n=742)

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

In 2023, categorisation of errors at the component labelling, availability and handling and storage transfusion step, have been separated into three constituent steps to gain focused learning. These are now categorised as component labelling errors, availability errors, and handling and storage errors. Errors occurring at the testing step are, as in previous years, the highest source of error within the laboratory 192/535 (35.9%) (Figure 15.2).

Figure 15.2: SHOT laboratory data across all categories showing the stage in the transfusion process where the primary error occurred (n=535)



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

Deaths related to transfusion n=1

There was 1 death in 2023 where there was a delayed transfusion caused by an error during haematology testing (imputability 2).

Case 15.1: Death probably related to delay in platelet transfusion, due to laboratory results being suppressed pending film review

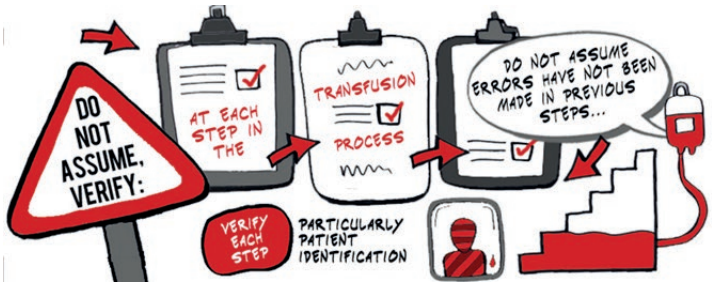
A patient with undiagnosed APML presented in the ED at 9pm on day 1. An FBC sample showed a Hb of 39g/L, white cell count of 86x10^9/L and platelet count of 15x10^9/L. Results were reviewed by BMS 1 who had not been signed off on FBC validation whilst BMS 2 was taking a break. A routine blood film was requested, and an urgent review was not flagged. The platelet count was not visible to clinical staff, as reporting parameters required it to be confirmed by blood film. The FBC result was not phoned through to the clinical area. Red cell transfusion commenced around 03:00 on day 2. The high white cell count was referred by the ED to the clinical haematology department using the routine referral system, and was not flagged as urgent, therefore it was not viewed by the haematology team until 11:00 on day 2. After seeing this result the blood film was reviewed urgently, and the diagnosis of an acute leukaemia was made. The critically low platelet count and diagnosis was available to the clinical teams at around 11:20 on day 2. There was over a 12-hour delay in the diagnosis of an acute leukaemia and commencement of urgent chemotherapy. This also caused a delay in coagulation testing, which was requested around 12:30 on day 2 and the fibrinogen result was 1.8g/L. However, when the fibrinogen level dropped to 1.2g/L on day 3 this was not escalated as an urgent referral as it was above the local threshold for telephoning results. Cryoprecipitate was not administered for another 7.5 hours after the result was available on day 4. Treatment was initiated urgently with blood component support, but the patient developed a subdural haemorrhage and died.

Upon investigation, there was a communication failure between the BMS staff. BMS 2 originally requested that BMS 1 looked at the FBC results and make any blood films that were needed. This was interpreted as being asked to validate the results. Local action was to remind BMS 1 to act within their scope of responsibility. Within the laboratory, inadequate staffing levels and skill mix had already been raised within the organisational risk register and has subsequently been escalated to the divisional director.

APML is a specific form of acute leukaemia characterised by severe coagulopathy which can rapidly lead to death through haemorrhage. The provisional diagnosis can be made based on the appearance of the blasts on the blood film. If suspected, specific APML therapy will be given immediately. For this reason, all patients newly presenting with suspected leukaemia in the ED require a coagulation screen and discussion with haematology urgently, so that appropriate treatment can be initiated.

Learning points

- Staff should never be expected to perform tasks they do not feel they have sufficient knowledge or expertise to do
- Clinicians who order blood tests have a responsibility to follow up and review test results so as to initiate appropriate management
- Provision of essential blood components for patients may depend on timely availability of relevant haematology/coagulation test results, necessitating prompt release of these results



SHOT
Serious Hazards of Transfusion

Major morbidity n=7

There were 7 cases where laboratory errors contributed to major morbidity, 4 cases of IBCT-SRNM causing sensitisation to the K antigen in patients of childbearing potential, and 3 cases of delays, 2 of which caused admission to the ICU or HDU, and 1 case where a patient went into peri-arrest before being given red cells (Case 15.2).

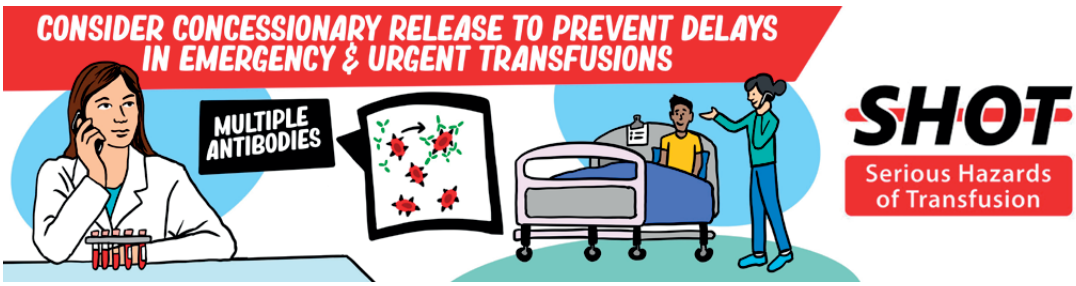
Case 15.2: Communication failure causes delay and major morbidity

A patient with SCD and a Hb of 45g/L was admitted in crisis. The patient had a progressive anaemia with multiple antibodies therefore frozen red cells were ordered from the Blood Service. The following morning, the patient deteriorated with peri-arrest, hypoxia and acidosis. One red cell unit was transfused at 08:00. The transfusion consultant advised to administer further red cell units although fully compatible units would not be available for some hours. The laboratory was advised by the consultant haematologist to select ABO, Rh, K matched red cells at 09:00. The laboratory was contacted at 11:30 to ask about availability of the blood. The patient was finally transfused after midday and recovered from this episode. The transfusion delay was caused by communication failure, poor venous access for sampling and staff inexperience with issuing the best available red cells due to the presence of multiple red cell antibodies. The staff are now aware that if blood is required urgently the clinical team can request red cells to be issued using concessionary release before testing is complete.

Learning point

- Guidance for concessionary release should be detailed within an SOP and should form part of competency-assessments or scenario-based training drills within the laboratory (Milkins, et al.,2013; Stanworth, et al., 2022)

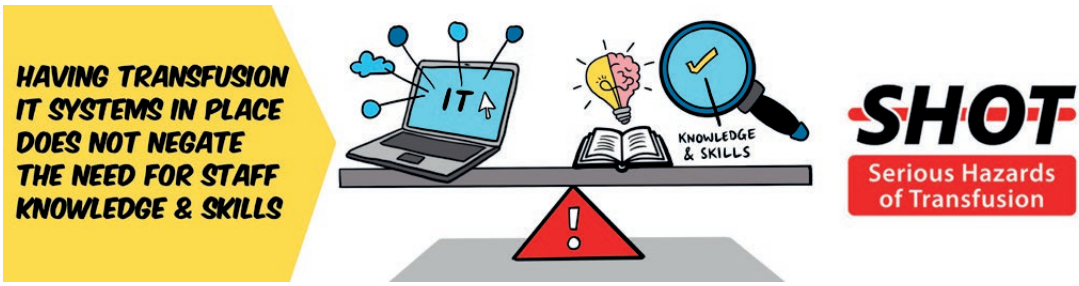
Further cases of laboratory errors impacting upon delays can be found in Chapter 12a, Delayed Transfusions.



ABO-incompatible transfusions n=2

Two laboratory errors resulted in ABOi FFP transfusions, one to an adult and the other to a child. Both errors occurred at the component selection step.

The 1st case involved transfusion of four group O FFP to a group B patient during a major haemorrhage protocol activation. The patient suffered no adverse effects. In the 2nd case, 5mL of group O high-titre negative FFP was transfused to a neonate who was group A. They appeared to be group O upon testing of one sample only (policy stipulates two groups required for this action); however, the laboratory was subsequently informed that the patient had been transferred and had received one unit of group O emergency red cells at a previous site. These cases are discussed in more detail in Chapter 10, Incorrect Blood Component Transfused (IBCT).



Laboratory themes 2023: Laboratories under increasing pressure

Many complex and interacting themes were observed within the laboratory data in 2023. These are similar to those observed in 2022, with additional pressures being observed, presenting an increasingly complicated picture (Figure 15.3).

Figure 15.3: Additional pressures on transfusion laboratories evident in 2023 SHOT data

Errors by step in the transfusion process

Transfusion step		Pressure points	Learning points
Sample receipt and registration n=64		Data entry and information not being inputted into the LIMS from the request form	The use of end-to-end electronic systems should prevent most transcription errors and allow pertinent clinical information to be automatically transmitted to LIMS
46 errors↑	**18 NM↔**		
Testing n=206		Errors mostly due to failure to follow procedure 101/192 (52.6%)	LIMS should have appropriate controls to prevent issue of blood components without appropriate testing, in the absence of a clinical concession All incorrect cffDNA results should be reported to SHOT
192 errors↑	**14 NM↓**		
Component selection n=197		Incomplete knowledge of several transfusion principles including • Group changes in transplant patients • Patient groups requiring phenotype-matched components • Anti-D and anti-K	Laboratories should have clear procedures for blood grouping requirements in transplant patients Laboratories should have a clear procedure for concessionary release and be aware of when to escalate potential delays in obtaining blood components to clinical teams
126 errors↑↑	**71 NM↑↑**		
Component labelling n=115*		Component labelling errors were mostly detected by a formal bedside checklist, 51/74 (68.9%) Many incidents stated label verification software could have detected the error earlier, or that it was in place but not used	Label verification software can detect many component labelling errors before the component is released to the clinical area The use of a laboratory exit checklist or pre-administration checklist can assist in identifying component labelling errors
41 errors	**74 NM**		
Component availability n=66*		Communication in emergencies Lack of clear procedures to return blood components which no longer meet requirements (e.g., expired component or expired sample) Please also see Case 15.5 in the supplementary information	Laboratories should have a clear procedure for concessionary release and be aware of when to escalate potential delays in obtaining blood components to clinical teams Clear communication between laboratory staff and clinical teams is vital to prevent transfusion errors. Policies, procedures, and advice from experts should be easily accessible Patients should never be transfused unnecessarily when not clinically indicated to avoid wastage of blood stocks
54 errors	**12 NM**		
Component handling and storage n=78*		Timely response to temperature-monitoring software	Laboratories should have clear procedures regarding component quarantine and return to stock parameters
67 errors	**11 NM**		

Table 15.1: Laboratory errors by step in the transfusion process (n=742)

There were an additional 9 errors and 7 NM classed as 'miscellaneous' which are discussed in the supplementary information on the SHOT website (https://www.shotuk.org/shot-reports/report-summary-and-supplement-2023/)

**These transfusion steps are new for 2023 therefore comparison with previous data is not available*

Sample receipt and registration errors resulted in:

- Compatibility labels with incorrect patient information due to data entry errors
- Patients receiving components which were not irradiated, or were of the incorrect blood group due to not identifying information on the request form and/or LIMS

Testing errors resulted in:

- Patients receiving blood components prior to testing being completed
- Incorrect management of anti-D Ig due to incorrect cffDNA screening predictions
- Delays in provision of blood components
- NM errors mostly resulted in potential incorrect management of anti-D Ig

Component selection errors resulted in:

- Incorrect group components being transfused to transplant patients
- Provision or potential provision of components which were; incorrect phenotype/not antigen-negative, K-positive to patients of childbearing potential and not irradiated
- Incorrect provision of anti-D Ig to patients with immune anti-D or to those with a D-negative infant

Component labelling errors resulted in:

- Transposition of labels on blood components intended for the same patient
- NM errors mostly resulted in potential RBRP errors

Component availability errors resulted in:

- Delays in provision of blood components, or expired blood components being available when they should have been discarded

Component handling and storage errors resulted in:

- Transfusion or potential transfusion of components with incomplete cold chain or reservation period exceeded

Abbreviated and accelerated training

The results of the UKTLC survey 2022 showed increasing recruitment and retention issues within the transfusion laboratory workforce, with concerns raised relating to the number, suitability, and calibre of applicants for HCPC registered roles. Most respondents felt that newly qualified HCPC registered BMS had a poor level of transfusion education. These recruitment and retention issues are occurring alongside an increase in workload (60.8% saw an increase in workload). A concerning trend of 'abbreviated and accelerated training' has been observed within reports submitted to SHOT, in which staff are being allowed to work alone and outside of routine hours with only selected competency-assessments completed. In these circumstances there may also be a delay in receiving additional training required, as once a staff member is 'signed off' for lone working they are traditionally compliant with all training requirements. In environments when staffing provision is already at critically low levels any further training may 'slip through the net'. This compounds the initial risk of working without adequate knowledge for all tasks. Similar concerns have been noted with approved abbreviated training programmes for junior doctors (Chivers, 2023).

Cases 15.6 and 15.7 in the supplementary information for this chapter highlights errors where staff were allowed to participate in lone working before they were fully trained.

Lone working

Laboratory data in 2023 showed that errors occur at a disproportionate rate when individuals were lone working. A total of 431 reports provided an answer to the question 'Was the member of staff lone-working at the time of the incident', with 160/431 (37.1%) staff lone-working. Lone working is usually instigated outside of core hours when the workload is anticipated to be lower than in the routine working day. The UKTLC standards 2024 state that staff should have access to specialist transfusion laboratory advice outside of routine working hours (Dowling, et al., 2024), however in the UKTLC survey 2022, 45.9% had no formal arrangement for support. Lone working may be considered a risk factor for transfusion errors, and laboratories may wish to evaluate when lone working is necessary, or other methods to alleviate pressures when a member of staff is working by themselves. Case 15.3 describes how many different laboratory pressures may be influencing inadequate testing and substandard patient care.

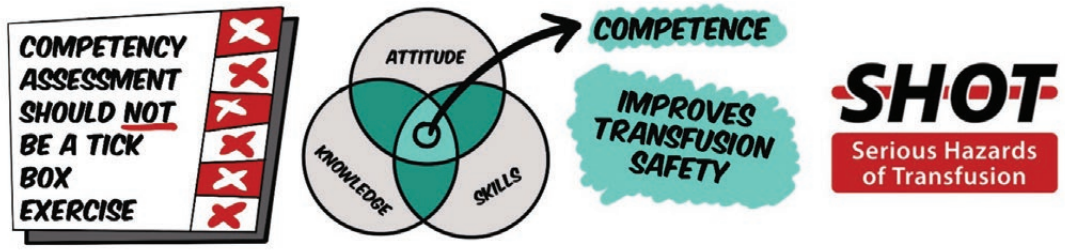
Case 15.3: Lack of staff knowledge leads to inappropriate editing of results and incomplete testing when lone working

A sample was received from a patient requiring red cell transfusion postoperatively when the BMS was lone working in the laboratory. The analyser flagged the sample as haemolysed, and the results were validated and accepted by the BMS rather than being rejected, as the BMS did not know how to reject a haemolysed sample. There was no result in the patient reverse group (B cells) and the BMS inappropriately amended the result to a 3+. The LIMS excluded the patient from EI and highlighted the requirement for a serological crossmatch due to the group amendment. The BMS was unaware that a modification would de-select EI and entered a negative reaction (compatible) into the crossmatch result, even though no test had been performed, due to the patient not having any antibodies or alert flags.

Although the BMS was deemed competent, they were bank staff who did not routinely work core hours and were previously employed as a transfusion BMS within the organisation. This incident happened over a weekend where there was no second checker available. The reporter identified that samples prior and after this incident were suitable for EI suggesting there was a primary issue with the sample being tested at the time.

This case illustrates the importance of laboratory staff having regular knowledge updates and practical time within the laboratory. The UKTLC standards 2024 state that all staff should have a minimum of 10 routine working days within the laboratory, so that they can be informed of changes in practice and receive appropriate support from senior staff (Dowling, et al., 2024).

It also illustrates that competency-assessment can often be a point of weakness if it is completed as a one-off tick box exercise. Scenarios and questions within competency-assessments should also be regularly updated in light of changes in practice or following learning from patient safety incidents. The 2019 UPTAKE model of competency-assessment can be found in the 'Recommended resources' for this chapter.



IT implementation

In 2023, 287/535 (53.6%) of all laboratory error reports were assessed to have an IT component, with the most common reason for this being cited as a lack of functionality to support safe practice.

Many laboratories in the UK are undergoing IT implementation projects – either through the introduction of electronic blood-management systems, integration with new electronic patient record or new LIMS systems. Introduction of new IT systems can temporarily increase the workload pressures within the laboratory along with challenges relating to migrating data and changes in functionality from older systems. These factors may temporarily increase the risk of errors occurring when there is no extra staffing provision or expertise made available to manage such projects. New guidelines relating to IT within the transfusion laboratory have recently been published and can be used as a source of information for any laboratories implementing new IT systems (Staves, et al., 2024).

Safety culture in the transfusion laboratory

In November 2023 a survey was undertaken by SHOT and the UKTLC, with input from the MHRA haemovigilance team, to examine safety culture within transfusion laboratories in the UK. Many of the results were concerning. The recommendations from the survey report should be implemented to improve safety culture within laboratories. A link to the survey summary can be found in the 'Recommended resources' for this chapter.

Case 15.4 below illustrates the impact of a poor safety culture on staff decision-making and the potential to generate error.

Case 15.4: Laboratory safety culture and leadership issues influence a component selection error

A patient with thalassaemia received red cells which did not match their Rh and K phenotype. The requirement for phenotype-matched components was recorded in the LIMS (despite an initial mistaken diagnosis of sickle cell disease being communicated). An additional step to highlight this requirement in the patient notes field on the LIMS was not completed which resulted in the BMS

not selecting phenotype-matched red cells.

During investigation the BMS stated they were multi-tasking and rushing, and the event happened at a weekend when there were less staff available than normal. The report stated that staff do not have the correct amount of protected time to develop their knowledge and are less prepared to deal with complex cases. Additionally, the BMS stated they felt they were 'being watched' and there was a blame culture within the laboratory. Leadership and staffing issues within the laboratory had been identified during a recent inspection. Corrective actions included updating SOP for issuing phenotype-specific blood and potential changes to LIMS but did not mention culture issues identified.

It is encouraging to see that systemic problems were identified and specific actions were put in place, however the impact of poor leadership and culture cannot be underestimated.

Conclusion

Transfusion laboratories are under escalating pressures, and this is reflected in the steep increase in laboratory errors in 2023. It is evident that many of these events were preventable and would potentially not have occurred in periods of proper staffing and resource allocation. There has been a reduction in staffing availability, change in education of newly qualified staff and increased workload alongside many necessary improvement projects. Transfusion laboratory professionals need to be appropriately supported so they may continue to provide high-quality patient-centred services.

Concerning results observed in the 2023 laboratory culture survey may be a direct result of this increased pressure and a service approaching breaking point. It is essential that staff members are able to acknowledge and escalate when patient and professional safety concerns arise. In the face of a challenging working environment, staff members should feel valued for the lifesaving work they do every day.

Despite these challenges, laboratory staff are working tirelessly to provide support to patients. There are 4 cases within Chapter 6, Acknowledging Continuing Excellence in Transfusion (ACE) which illustrate excellent communication, collaboration and focus on patient safety by transfusion laboratory staff.

SHOT would like to acknowledge the unwavering commitment, dedication, and tireless efforts by all staff in transfusion especially in the laboratories, who work under immensely stressful situations to save and improve lives.

UK Transfusion Laboratory Collaborative update

Authors: Kerry Dowling and Jennifer Davies

The UKTLC continues to work in partnership with key stakeholders in the transfusion process aiming to improve transfusion safety. This year the 2023 UKTLC standards have been published in Transfusion

Medicine and have been welcomed by the laboratory community. The standards aim to help laboratories in four main areas (staffing, education, IT and a just culture). The standards are evidence based to reduce errors occurring in the transfusion laboratory and were updated to reflect changes in practice and support transfusion laboratories with current challenges.

The 2022 UKTLC survey highlighted staffing, workload, and education challenges, this is reflected in the laboratory errors reported to SHOT. Gaps in transfusion knowledge, lack of specialised staffing resource and inability to meet staffing levels required in capacity plans impacts the laboratories' ability to provide a safe and stable service. Positively, 86.5% of the survey respondents had a capacity plan in place, however respondents noted a lack of compliance with the plan and highlighted deficiencies in both staffing numbers and skill mix. Where capacity plans are not met escalation to Trust/Health Board management is required detailing the risks and impacts with reference to the requirements of BSQR 2005.

The 2023 culture survey has highlighted further concerns with a theme of incivility in the working place, a lack of psychological safety and a pressure to present an inaccurate assessment of the severity of incidents. This coupled with the staffing and workload pressures is a cause for concern for transfusion safety. Recommendations have been released in response to this survey and the UKTLC is working with partners to highlight these issues.

The implementation of IT systems such as 'electronic blood-management systems' remains a challenge for hospitals as demonstrated by the UKTLC survey where a third of respondents had no EBMS in place. The 2023 UKTLC standards recommend implementation of these systems to their full functionality to support safe transfusion practices.

In May 2023, the UKTLC survey findings and new standards were publicised in two webinars. A joint UKTLC, SHOT and MHRA webinar in June 2023 explored key aspects of incident investigations, regulatory framework, the use of human factors and ergonomics, and the importance of effective interventions. Recordings of these webinars can be accessed on the UKTLC page of the SHOT website (https://www.shotuk.org/resources/current-resources/uktlc/), along with other resources, including survey results and tools for compliance with the standards.

This year, the UKTLC will continue to work with key partner organisations to help laboratories improve transfusion safety including staff education and IT strands of work.

SHOT
Serious Hazards of Transfusion

UK NEQAS update

Authors: Richard Haggas 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 2023. On this occasion, there were ABO grouping errors made, when during a PTT 'R' exercise, one laboratory labelled the samples and recorded the results in a non-standard order, and this was not noticed during data entry. Compounding this grouping error, the laboratory also reported two incorrect phenotypes and the theoretical deselection of a donor unit due to the blood group being incorrect. Three other

laboratories, across more than one exercise, recorded correct grouping reactions but reported an incorrect blood group interpretation. Since ABO/D grouping and antibody screening tests are largely automated, with automatic transmission of results to the laboratory information management systems (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.

'Procedural' errors also account for a high proportion of missed compatibility and missed incompatibility during crossmatching. During the PTT 'R' exercises, several laboratories made errors in crossmatching due to various factors; these include incorrectly labelling the samples when booking into the LIMS, making data entry errors, and transposing samples during testing. 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. Although most LIMS will prevent the issue of ABO-incompatible units, when IT systems fail this safeguard is not available and manual checking of groups on donations is required. This is also the situation with EQA samples, and it is important to check the group of donors prior to making decisions on theoretical compatibility. 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. As in 2022, there was a repeat occurrence of a laboratory obtaining negative reactions during the initial screen for a plasma sample containing an antibody. Repeat testing after the closing date showed expected results; an investigation showed the original result had a low liquid level flag which had not been actioned as per the local policy. 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.

Interestingly, this year there have been a small number of examples of donor unit deselection, on grounds that are out with the BSH guidance (Milkins, et al., 2013). Two laboratories deselected two group O D-negative r"r (cdE/cde) donors for a 92-year-old male with a blood group of A D-negative and no alloantibodies. Both laboratories indicated they did not want to select E positive red cells for a D-negative patient; this deselection went against their laboratory policy. Additionally, one further laboratory reported two group O D-negative K-positive donors as incompatible with a male patient with blood group B D-positive and no alloantibodies. According to this BSH guideline, there is no requirement to deselect r"r donor units for issuing to D-negative male patients, or K-positive donor units to male patients, when no alloantibodies are detected, unless the clinical details indicate a specific requirement to do so. Doing this may reduce the availability of rr (cde/cde) units, and K-negative units respectively, for patients who require them to prevent potential sensitisation.

Recommended resources

UKTLC standards
https://onlinelibrary.wiley.com/doi/10.1111/tme.13029

SCRIPT Using Information Technology for Safe Transfusion
https://www.shotuk.org/resources/current-resources/script/

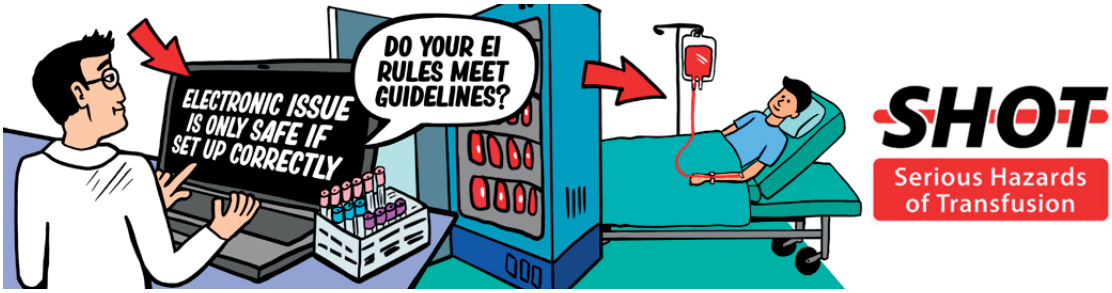
2023 SHOT, MHRA and UKTLC laboratory culture survey summary
https://www.shotuk.org/resources/current-resources/shot-surveys/

UPTAKE model of competency-assessment (page 107, 2019 Annual SHOT Report)
https://www.shotuk.org/shot-reports/report-summary-and-supplement-2019/

SHOT Bite 24: Speaking up for patient safety
https://www.shotuk.org/resources/current-resources/shot-bites/

PAUSE checklist
The laboratory component labelling and exit check
https://www.shotuk.org/resources/current-resources/

Concessionary release example template (Appendix 9)
https://onlinelibrary.wiley.com/doi/epdf/10.1111/j.1365-3148.2012.01199.x



References

Chivers, D. J., 2023. Rapid Response: Shortened undergraduate training will put more pressure on already overworked Junior Doctors. *BMJ,* Volume 381, p. 1422. Available at: https://www.bmj.com/content/381/bmj.p1422/rr-1 (Accessed 27 June 2024)

Dowling, K. et al., 2024. UK Transfusion Laboratory Collaborative: Minimum standards for staff qualifications, training, competency and the use of information technology in hospital transfusion laboratories 2023. *Transfusion Medicine,* 34(1), pp. 3-10. doi: https://doi.org/10.1111/tme.13029.

Milkins, C. et al., 2013. Guidelines for pre-transfusion compatibility procedures in blood transfusion laboratories. *Transfusion Medicine,* 23(1), pp. 3-35. doi: https://doi.org/10.1111/j.1365-3148.2012.01199.x.

Narayan, S. et al., 2020. *The 2019 Annual SHOT Report,* Manchester: Serious Hazards of Transfusion (SHOT) Steering Group. doi: https://doi.org/10.57911/5NG7-MJ28.

Stanworth, S. J. et al., 2022. Haematological management of major haemorrhage: a British Society for Haematology Guideline. *British Journal of Haematology,* 198(4), pp. 654-667. doi: https://doi.org/10.1111/bjh.18275.

Staves, J. et al., 2024. Guidelines for the specification, implementation and management of IT systems in hospital transfusion laboratories. *Transfusion Medicine,* 34(2), pp. 81-166. doi: https://doi.org/10.1111/tme.13027.

Errors Related to Information Technology (IT) n=541

16

Authors: Megan Rowley and Jennifer Davies

Definition:

This chapter includes transfusion adverse events that relate to laboratory information management systems as well as other information technology 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. Where the corrective and preventive action suggested by hospitals in response to errors included IT solutions, these have been included.

Abbreviations used in this chapter

BSH	British Society for Haematology
CAPA	Corrective and preventative action
EBMS	Electronic blood management system
EPR	Electronic patient record
HSE	Handling and storage error
IBCT	Incorrect blood component transfused
LIMS	Laboratory information management system
NHS	National Health Service
RBRP	Right blood right patient
SCRIPT	SHOT collaborative reviewing and reforming IT processes in transfusion
SRNM	Specific requirements not met
UK	United Kingdom
UK NEQAS	UK National External Quality Assurance Scheme
UKTLC	UK Transfusion Laboratory Collaborative
WBIT	Wrong blood in tube
WCT	Wrong component transfused

Key SHOT messages

- There is increasing recognition that IT systems can prevent recurrence of errors in clinical and laboratory transfusion practice thereby improving patient safety. It is important to note however for this to happen, IT should be implemented correctly, or existing systems modified appropriately
- The learning from the implementation of new transfusion-related IT systems should be shared with others through the SCRIPT group and SCRIPT resources can be used to support and educate all those involved in procurement, implementation and operation of these IT systems

Recommendations

- Undertake a gap analysis for all existing transfusion-related IT systems and automation against the updated UKTLC standards (standard 3) (Dowling, et al., 2024) and the updated BSH guidelines for the specification, implementation, and management of IT systems in hospital transfusion laboratories (Staves, et al., 2024). A gap analysis tool has been provided by BSH
- The specification of new IT systems and upgrade of existing systems should be undertaken with reference to updated BSH guidelines for the specification, implementation, and management of IT systems in hospital transfusion laboratories (Staves, et al., 2024)

- When introducing new IT systems across any part of the transfusion pathway, human factors and ergonomics should be considered to gain all the possible benefits of technology for staff, as well as for patient safety

Action: Laboratory managers, IT professionals, hospital transfusion teams

SHOT Collaborative Reviewing and reforming IT Processes in Transfusion

The SHOT SCRIPT group formed in 2019, continues to work to improve transfusion safety through improved IT systems and practices. Many resources have been added to the webpage to support organisations with purchasing, validating, and implementing IT systems that support safe transfusion practice, including LIMS, EBMS and EPR systems. The interactive document 'Using Information Technology for Safe Transfusion' has been designed to support organisations in identifying how IT could be used across all SHOT 10 steps. SCRIPT resources now include educational cases relating to IT, and a short IT video is available on the webpage. In 2023 the SCRIPT group published the SCRIPT survey focussing on LIMS: Laboratory information management systems: Are we ready for digital transformation? (Davies, et al., 2023). The BSH IT guidelines have now been published, including a gap analysis tool for local compliance monitoring (Staves, et al., 2024). SCRIPT continue to work with key stakeholders to improve uptake and use of IT systems in transfusion, including UK NEQAS, IT suppliers and the NHS England (Transfusion Transformation project).

Introduction

The number of IT errors in 2023 have increased by 39.8% (2023 n=541, 2022 n=387). Of the cases included in the IT chapter the question 'Did IT contribute to this error?' was answered by the majority of reporters. Only 156/541 (28.8%) said 'YES', IT *did* contribute which means that 71.2% of IT cases were not identified by the reporters themselves. The question 'Could the error have been prevented by using IT?' was answered by 463 reporters, of whom 222 (47.9% of respondents) said 'YES' therefore identifying need for greater use of technology. Not only did the expanded IT questions provide additional information about the type and providers of IT systems in use, and the nature of the IT contribution to errors, but there was greater reflection on *possible* IT solutions. Further information can be found in supplementary Table 16.4 on the supplementary information on the SHOT website (https://www.shotuk.org/shot-reports/report-summary-and-supplement-2023/).

Table 16.1: Categories containing errors related to IT in 2023 (n=541)

Primary reporting category	Laboratory errors	Clinical errors	Total cases 2023
Incorrect blood component transfused laboratory (IBCT-WCT)	58	20	**78**
Special requirements not met (IBCT-SRNM)	112	51	**163**
Right blood right patient (RBRP)	30	56	**86**
Avoidable, delayed and under/overtransfusion (ADU)	19	50	**69**
Handling and storage errors (HSE)	45	100	**145**
Total	**264**	**277**	**541**

Other cases with IT errors	
Anti-D immunoglobulin errors	68
Near miss	148
WBIT	224
Total	**440**

Table 16.2: Other categories containing errors related to IT in 2023 (n=440)

Flags, alerts, and warnings n=194

The largest group of clinical and laboratory errors related to IT systems are due to flags, alerts, and warnings as well as the use of logic rules and algorithms within the software. In 66 cases, alerts and warnings were in place but not heeded; in 56 cases, flags were not updated or were removed in error; in 72 cases, the available flags or logic rules were not used. Cases related to the LIMS are addressed within Chapter 15, Laboratory Errors.

In the clinical area, at the point of blood collection and at patient's side, EBMS are used to identify the right component for the right patient. The lack of clarity of alerts can cause messages to be overlooked or misunderstood by clinical operators. Also, staff in the laboratory are not always able to support clinical staff who contact them with queries about error messages. This may sometimes be due to lack of familiarity or inadequate training but also, particularly with lone workers, be due to competing priorities.

Case 16.1: Alert on EBMS overridden twice

The wrong platelet pack from a two-unit donation was issued electronically and the discrepancy between codes was highlighted by the EBMS at the point of collection. The laboratory re-issued the same unit, but the discrepancy remained, so the alert was overridden without identifying or resolving the source of the error. The same discrepancy was highlighted at the pre-administration check and again was overridden, and the unit transfused. This error came to light when the second pack from this donation could not be issued because it had already been fated as 'transfused'. This highlights the importance of understanding the exact nature of the error message and effective troubleshooting before proceeding with transfusion.

Learning points

- Error messages should be both clear and specific. It is important that both clinical and laboratory staff understand what action to take in response to an error message so that patient safety is maintained, and delays are minimised
- Training in the use of clinical and laboratory IT systems must include troubleshooting advice. When a problem has been identified, this should be investigated and resolved appropriately. The learning from the incident should be disseminated widely and added to any future training resources

Interoperable IT systems n=55

The recently updated UKTLC standards and BSH guidelines highlight the importance of interoperable IT systems to reduce the risk of transcription errors and to ensure that all clinical and laboratory information to support a patient's transfusion is available (Dowling, et al., 2024; Staves, et al., 2024). It is also important that data on previous LIMS or a merged/networked LIMS is accessible. There were 23 reports of patient ID discrepancies between the LIMS and the EPR which resulted from an IT error although blood components were issued to the right patient; 24 reports where there was failure to link, merge or

reconcile computer records on different systems; 8 reports of WCT or SRNM where historical data was available on an IT system, but the record was not accessed.

Errors arising from use of IT systems including EBMS n=98

These errors related to the functionality of computer systems, both LIMS (n=23) and EBMS (n=44) as well as errors arising from manual processes such as selecting the wrong record (n=7) or entering data incorrectly into an IT system (n=24). It is advisable when implementing or updating IT systems to ensure that there is appropriate validation to ensure the systems work as intended. With updated BSH guidance available, checking existing systems against the guidance using the gap analysis tool provided will highlight any lack of functionality that may need addressing. Where any unexpected errors occur or IT systems do not function as specified, contact with the manufacturer is essential to highlight the faults so that all users of the system can benefit from any improvements.

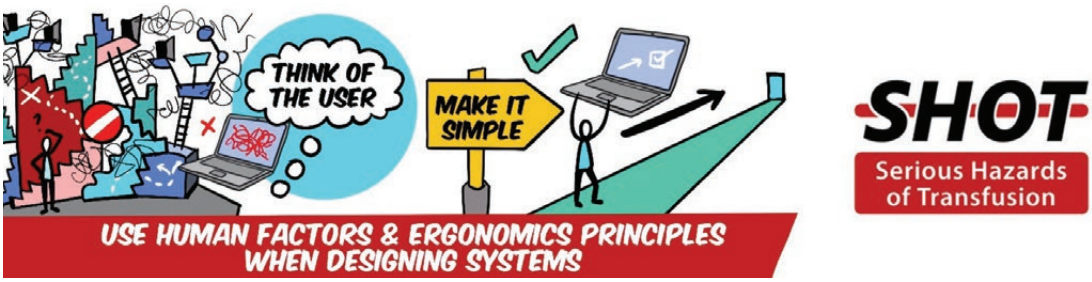
IT system and other equipment failure n=130

BSH guidelines highlight the importance of having a documented contingency plan for planned or unplanned IT downtimes, which may be isolated to one system or may affect whole networks (Staves, et al., 2024). The UKTLC standards recommend that the plan must be 'accessible and easy to implement and be included in staff training and competency assessments' (Dowling, et al., 2024). There were 23 reports of errors due to failure of IT systems during both planned and unplanned downtime and one notable feature was the potential for failure of communication before, during and after such incidents. Good downtime processes can always be improved by incorporating learning from errors and incidents. Having a short script, action list or aide memoire to support staff through unfamiliar downtime processes has been implemented with some success.

Other equipment failure (n=107) is included in this category, and this includes infusion pumps, refrigerators, and temperature-monitoring systems. These are discussed further in Chapter 11, Handling and Storage Errors (HSE).

Learning point

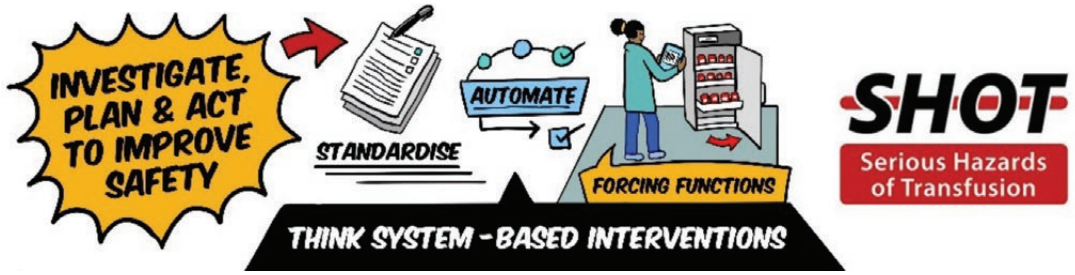
- Action cards, scripts or aide memoires can be rapidly and consistently deployed to support processes in planned and unplanned downtime



IT systems as CAPA n=64

It is encouraging to see new clinical and laboratory IT systems in place, or in advanced stages of implementation, although some of the errors reported relate to these new systems. When analysing the

2023 reports we have identified where a new or upgraded IT system has been suggested as CAPA. This includes systems that have been specified, procured and are at various stages of implementation and cases where additional IT functionality is identified as necessary to reduce the likelihood of an error occurring. Some CAPA were clearly aspirational with no specific funding identified or capacity to implement systems that have the potential to prevent the errors reported. This has always been part of the definition for inclusion, but it is notable that more consideration is being given to the safety benefits of IT systems. Approximately half of these were systems that had already been specified, procured, or implemented and would have prevented the errors, had they been fully operational. The other systems were identified with the comment that there was either no funding or no capacity to implement systems that may have prevented the errors reported.



IT errors relating to Anti-D Ig n=68

These are discussed further in Chapter 9, Adverse Events Related to Anti-D Immunoglobulin (Ig).

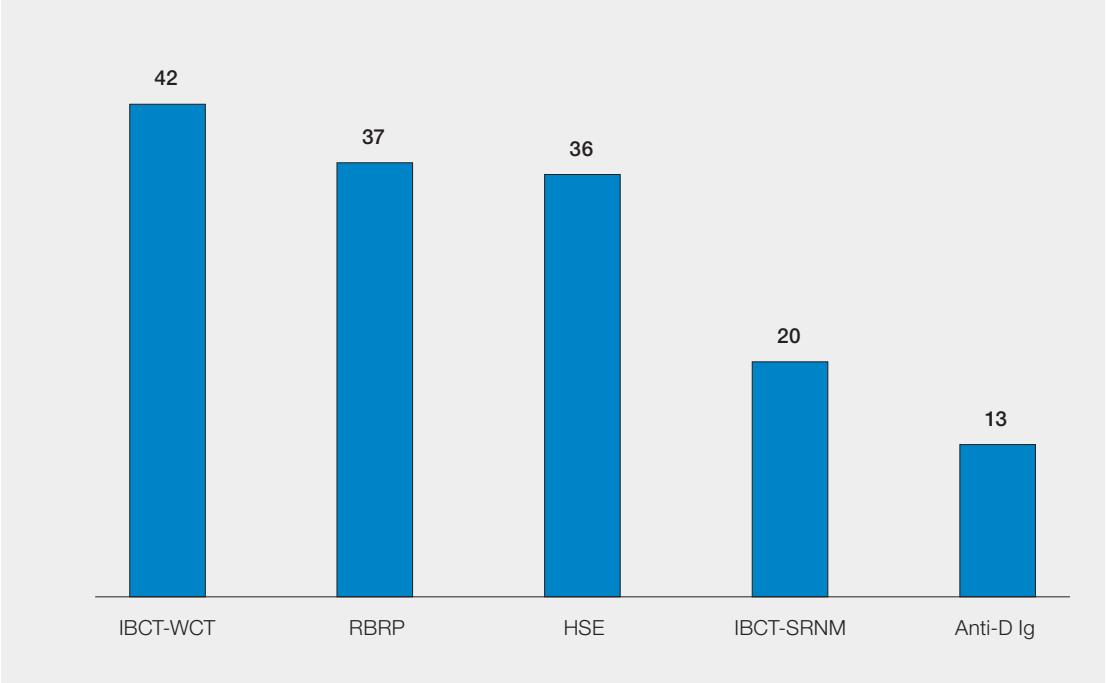
Near miss WBIT n=224

A total of 224 near miss WBIT were IT related, and a further 148 near miss events in other categories also involved IT. IT was recognised as being a method to reduce errors in 124/224 (55.4%) of WBIT cases, with many reporters noting lack of funding and resource capacity being a barrier to obtaining electronic sample labelling systems. IT was in place but not used correctly in 49/224 (21.9%) cases, IT was in place but not used in 29/224 (12.9%) cases. Where patient blood groups were reported (n=122), 70/122 (57.4%) had the potential to result in an ABO-incompatible transfusion. A formal incident investigation, where this question was answered, was performed in 163/224 (72.8%) cases.

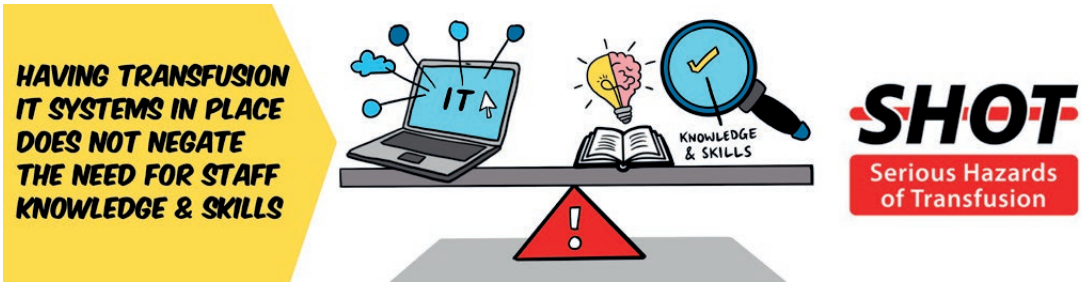
Other near miss IT-related events n=148

The majority of IT-related near miss events were seen in the IBCT-WCT, RBRP and HSE reporting categories (Figure 16.1). For IBCT-WCT errors, where the blood group of the component and recipient were reported (n=30), 6 of these cases would have led to an ABO-incompatible transfusion. Errors originated in the laboratory, 84/148 (56.8%) and the clinical setting, 64/148 (43.2%). In 94/148 cases, the reporter stated that IT did not contribute to the error. In 23/94, the reporter did not consider that IT could have prevented the errors. Review of the 23 cases noted that IT was implicated, with common themes including failures to heed IT warnings, IT systems not being updated and staff over-reliance on IT. It is encouraging to note that a formal incident investigation was carried out in 117/148 (79.1%) of cases where this question was answered.

Figure 16.1: Near miss events related to IT by SHOT reporting category in 2023 (n=148)



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



Recommended resources

UKTLC Standards (2023) Standard 3 - Information Technology
https://www.shotuk.org/resources/current-resources/uktlc

Using Information Technology for Safe Transfusion
https://www.shotuk.org/resources/current-resources/script/

References

Davies, J. et al., 2023. SHOT UK Collaborative Reviewing and Reforming IT Processes in Transfusion (SCRIPT) survey: Laboratory information management systems: Are we ready for digital transformation?. *Transfusion Medicine,* 33(6), pp. 433-439. doi: https://doi.org/10.1111/tme.13010.

Dowling, K. et al., 2024. UK Transfusion Laboratory Collaborative: Minimum standards for staff qualifications, training, competency and the use of information technology in hospital transfusion laboratories 2023. *Transfusion Medicine,* 34(1), pp. 3-10. doi: https://doi.org/10.1111/tme.13029.

Staves, J. et al., 2024. Guidelines for the specification, implementation and management of IT systems in hospital transfusion laboratories: A British Society for Haematology Guideline. *Transfusion Medicine,* 34(2), pp. 81-166. doi: https://doi.org/10.1111/tme.13027.

REACTIONS IN PATIENTS

17 Febrile, Allergic and Hypotensive Reactions (FAHR) n=336

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	**HLA**	Human leucocyte antigen
EASL	European Association for the Study of the Liver	**IgA**	Immunoglobulin A
FAHR	Febrile, allergic and hypotensive reactions	**IHN**	International Haemovigilance Network
FFP	Fresh frozen plasma	**ISBT**	International Society for Blood Transfusion

Key SHOT messages

- The number of FAHR cases reported to SHOT is increasing, with a higher proportion of severe cases
- 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
- Repeat compatibility testing is often carried out unnecessarily following allergic reactions or reactions to platelets or plasma components

Recommendations

- Give appropriate targeted treatment and if needed, preventative cover for future transfusion (Soutar, et al., 2023), as indicated below:

Table 17.1: 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

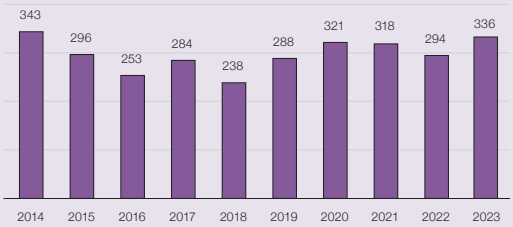
- Haematology registrars should receive training in classification, appropriate investigation and management of transfusion reactions in the laboratory induction at the start of their programme

Action: Hospital transfusion team, Haematology training programme directors

Headline data 2023

Number of reports n=336
Deaths n=0
Major morbidity n=119

FAHR reports by year



Demographic data

Male n=175
Female n=161
Unknown n=0

Adults n=300
Paediatric n=36
Unknown n=0

Blood component data

Red cells n=192
Platelets n=99
Plasma n=28
Cryoprecipitate n=1
Multiple components n=14
Granullocytes n=2

Introduction

Reactions are classified according to the ISBT/IHN definitions, which are summarised below in Table 17.2, and have been adopted by BSH (Soutar, et al., 2023). Mild reactions are not reportable to SHOT.

Table 17.2: 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*

Total number of FAHR reactions n=336

The total number of reports submitted in 2023 was the highest in the last 5 years. This was due to an increase in reported febrile reactions to red cells in adults. There was no change in the total number of allergic reactions, or in reactions in children.

While there has been an increase in the absolute number of cases reported in 2023, no significant difference was noted in the proportion of FAHR cases to the total reports received (336/3833, 8.8% in 2023 as compared to 294/3499, 8.4% in 2022).

Deaths related to transfusion n=0

There were no transfusion-related deaths reported in 2023.

Major morbidity n=119

The ISBT/IHN classification of a severe reaction has been used to define major morbidity.

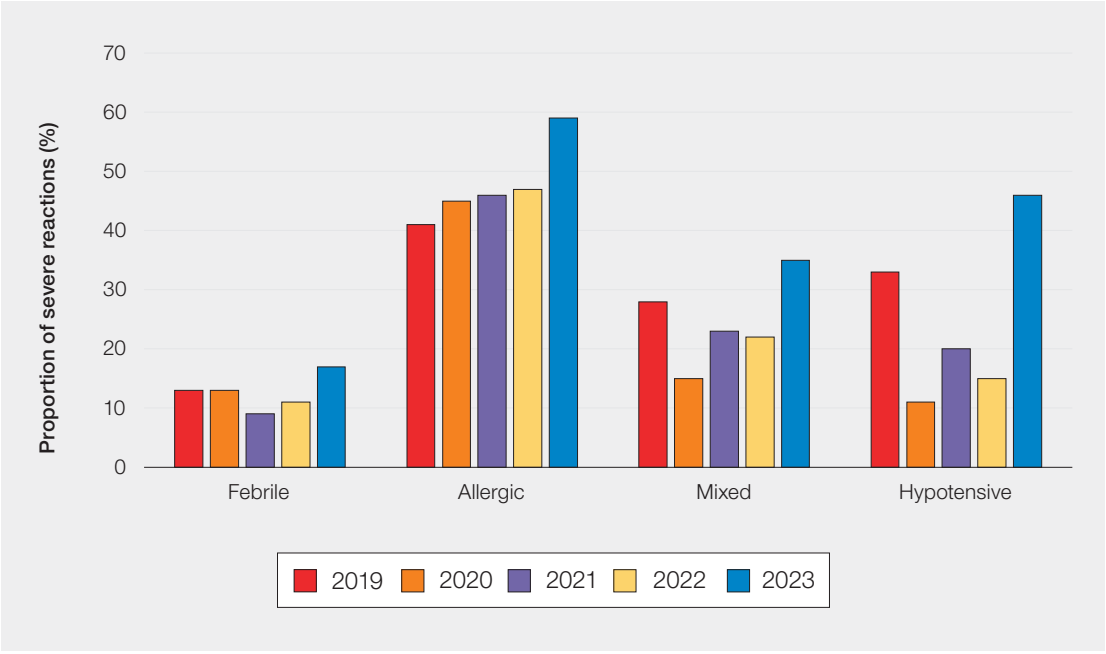
Reactions are categorised in Table 17.3.

Table 17.3: Classification of FAHR in 2023

	Moderate	Severe	Total
Febrile	136	27	**163**
Allergic	50	73	**123**
Mixed allergic/febrile	24	13	**37**
Hypotensive	7	6	**13**
Total	**217**	**119**	**336**

In all reaction types, there has been an increase in the number and proportion of reactions classified as severe. The overall proportion of severe reactions rose from 77/294 (26.2%) in 2022 to 119/336 (35.4%) in 2023.

Figure 17.1: Proportion of reactions classified as severe 2019-2023



Of note, in 24 of the 119 reactions classified as severe in 2023, this was primarily because the patient was admitted, or hospital stay was prolonged. This proportion is similar to 2022.

Reactions in IgA deficient patients n=4

There were 4 reactions, all to red cells, reported in 3 patients who were subsequently discovered to have severe IgA deficiency. Two were confirmed to have anti-IgA antibodies; the 3rd patient had not

been tested. All 3 patients suffered febrile-type reactions with marked systemic upset. Two were classic hyperacute reactions which presented within 10 minutes of starting transfusion. One of these patients gave a history of reaction to transfusion 6 years previously. The 3rd patient developed fever, rigors, tachycardia, hypotension, and a drop in oxygen saturations after 100mL had been transfused. They developed an identical reaction when a second transfusion was attempted 24 hours later.

It is recommended that these patients receive washed components for future red cell or platelet transfusions, provided this does not risk delaying an urgent transfusion (Latham, 2019).

Anaphylactic reactions n=50

Fifty severe allergic reactions were reported which required the use of adrenaline, compared to 36 in 2022. Of these, 22 were routine transfusions; 24 occurred on general wards, 2 in outpatients and 1 in a community setting. Children were disproportionately represented: 12/50 (24.0%) cases were in patients under 18 years.

Case 17.1: Inappropriate use of FFP prior to liver biopsy results in an anaphylactic reaction

A patient was given FFP prophylactically prior to liver biopsy due to prolonged international normalised ratio. They developed itching, wheeze, angioedema, and a drop in oxygen saturations requiring the anaphylaxis pathway.

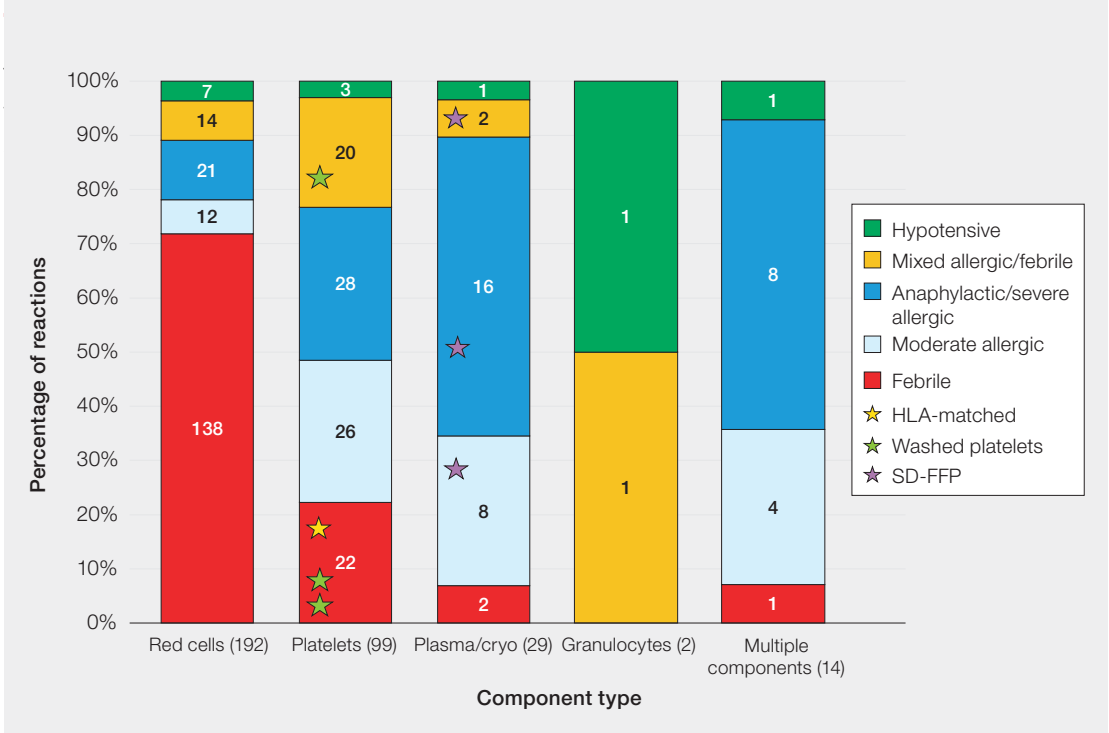
Learning points

- All areas administering blood components need to be appropriately equipped and staff trained to manage a severe acute reaction. This includes settings where transfusion is given in the community
- FFP should not be given in patients with chronic liver disease and deranged clotting tests prior to invasive procedures, as these tests do not correlate well with bleeding risk (Bent & Das, 2023; EASL, 2022)

One patient was reported to have suffered life-threatening reactions to multiple transfusions. In response, the Blood Service worked to develop a series of non-standard components to systematically reduce exposure to potential allergens, including triple-washed, mannitol free units. Eventually it was established that the reactions were unrelated to transfusion and were in fact felt to be self-induced.

This highly unusual case demonstrates the importance of careful consideration of the categorisation and pathogenesis of transfusion reactions, and of sometimes unexpected diagnoses. It also demonstrates the potential to develop and transfuse non-standard components if required in extreme situations.

Figure 17.2: Reactions by component type in 2023 (n=336)

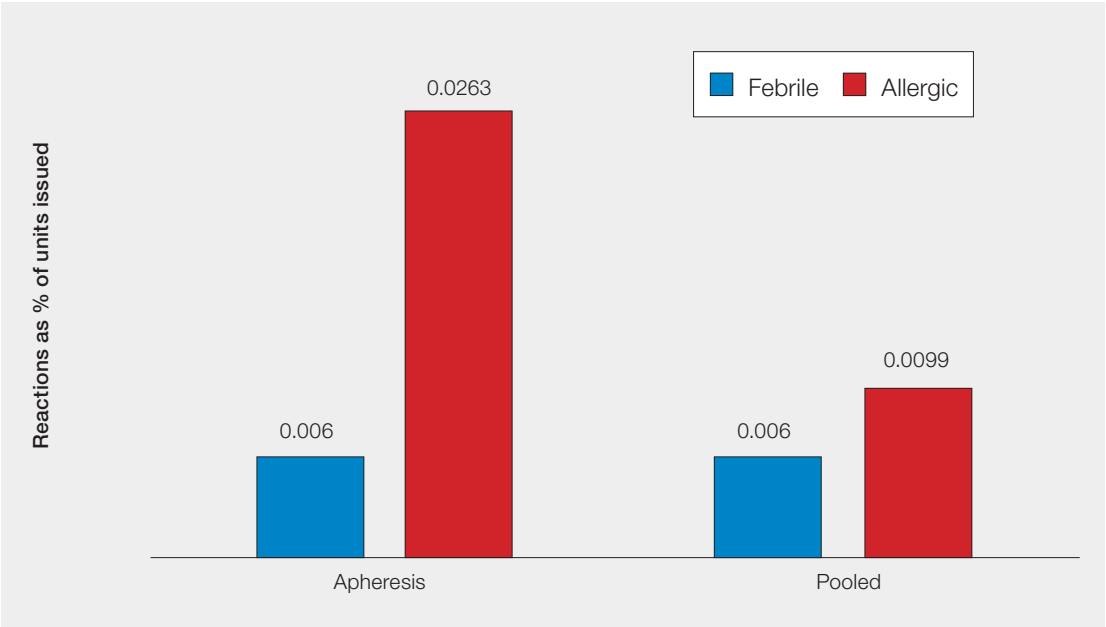


HLA=human leucocyte antigen; cryo=cryoprecipitate; SD-FFP=solvent detergent treated fresh frozen plasma

The incidence of allergic reactions was 2.7 times higher in apheresis platelets compared to pooled platelets, which relates to their higher plasma content (Estcourt, et al., 2017). The incidence of febrile reactions was identical in the two component types (Figure 17.3).

The first step for subsequent transfusions for a patient experiencing a mild to moderate allergic reaction to apheresis platelets should be to switch to a pooled component.

Figure 17.3: Incidence of reactions as a percentage of platelet units issued in 2023



Analysis of reactions remains comparable to previous years in the following characteristics (Table 17.4).

Recipient or transfusion characteristic	Percentage
Age distribution	89% of patients were aged 18 years or over
Sex	52% were male
Urgency of transfusion	58% were given routinely
Timing of transfusion	68% occurred within standard hours
Location	60% were on wards and 12% in outpatient/day case units

Table 17.4: Characteristics of FAHR

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. The proportion of patients mismanaged in this way was the lowest for the last 5 years; see Table 17.5.

Year	Number of febrile reactions	Medication stated	Antihistamine and/or steroid
2023	163	163/163 (100%)	61/163 (37.4%)
2022	132	130/132 (98.5%)	61/130 (46.9%)
2021	174	155/174 (89.1%)	61/155 (39.3%)
2020	166	140/166 (84.3%)	58/140 (41.4%)
2019	146	130/146 (89.0%)	62/130 (47.7%)

Table 17.5: Reported treatment of febrile reactions 2019-2023

Subsequent management

In 20 cases, a plan was made to give antihistamine and steroid prior to future transfusions, and in a further 7 cases, the report suggested use of 'pre-medication'. Three of these patients had experienced febrile reactions.

Learning points

- Steroids are not recommended for the prevention of allergic reactions, and neither steroids nor antihistamine have any role in preventing febrile reactions
- Repeated doses of steroids can cause immunosuppression and other complications such as diabetes (Yeates & Charlton, 2023)

Investigation

Laboratory investigations should be tailored to the reaction type.

Of the 123 reactions with purely allergic features, 51 (41.5%) were unnecessarily investigated with repeat compatibility testing and in 31 (25.2%) blood cultures were taken from the patient. The blood component was sent for culture in 10 cases, all of which were negative.

Inappropriate red cell serological testing was performed in 46/135 (34.1%) patients having reactions to platelets or plasma components.

Case 17.2: Inappropriate investigation and management of a febrile platelet reaction

A patient with lymphoma developed fever and rigors on their way home after an outpatient platelet transfusion. They returned to hospital and were treated with hydrocortisone and chlorphenamine. Repeat group and screen was sent but no blood cultures were performed.

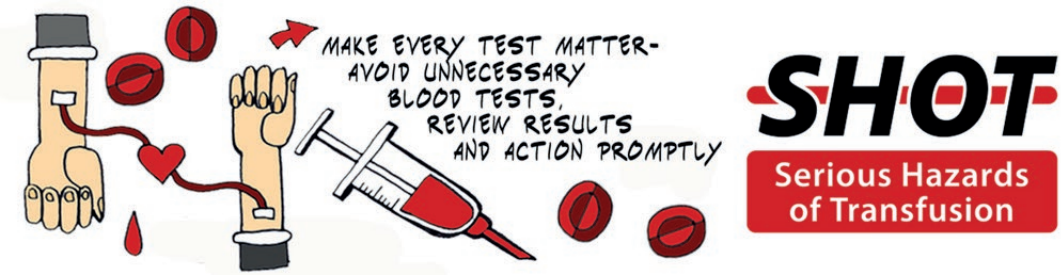
The treatment given for this febrile platelet reaction was directed against an allergic reaction, while investigation was for a febrile reaction to red cells. In a febrile potentially immunocompromised patient, blood cultures to exclude an intercurrent infection would have been appropriate.

Case 17.3: Inappropriate investigation and follow-up plans for a patient after an allergic reaction to FFP

A patient developed itching and eye swelling during transfusion of FFP in the context of major haemorrhage. They were appropriately treated with an antihistamine and their symptoms settled. They were investigated with a repeat group and screen and because of this reaction, a flag was placed on their record to require a serological crossmatch (rather than electronic issue) for future transfusions.

Learning points

- Red cell antibodies do not cause allergic transfusion reactions or reactions to platelets or plasma components. Repeat compatibility testing is not required in these scenarios
- Unnecessary investigations add to the demand on the laboratory at a time when staffing is almost universally stretched and cause avoidable delays in provision of blood components for future transfusions



Conclusion

Febrile, allergic, and hypotensive reactions are an unavoidable and unpredictable risk of transfusion. Although all patients recovered fully from the acute episode, 2023 saw a higher proportion of clinically severe reactions. Clinicians have a duty not to cause additional harm by giving inappropriate treatment. Haematology teams need to be well educated so they are confident to advise on appropriate, immediate, and subsequent management and relevant investigations. A survey of UK haematology registrars in 2023 found that only 53% felt that their training equipped them to give safe clinical transfusion advice to colleagues in other specialties (Booth 2024, personal communication. 13 March).

It is encouraging that the proportion of febrile reactions treated inappropriately with antihistamine and/or steroids has reduced in 2023, and it is hoped this improvement will be maintained in future years. There remains overuse of hydrocortisone for prevention of reactions, contrary to guidelines, and unnecessary

repeat compatibility testing for allergic and non-red cell 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 FAHR video
https://www.shotuk.org/resources/current-resources/videos/

Haematology Curriculum for Higher Medical Training Blood Transfusion Training Guidance
https://www.thefederation.uk/training/specialties/haematology

References

Bent, C. & Das, R., 2023. *Joint guidance from the British Societies of Interventional Radiology and Haematology on managing Bleeding Risk during Procedures in Interventional Radiology,* UK: British Society for Haematology (BSH). Available at: https://b-s-h.org.uk/media/udvdcvhh/bsir-bsh-ir-bleeding-risk-guidance-2022.pdf?cf=638107532702030000 (Accessed 4 February 2024).

Estcourt, L. J. et al., 2017. Guidelines for the use of platelet transfusions. *British Journal of Haematology,* 176(3), pp. 365-394. doi: https://doi.org/10.1111/bjh.14423.

European Association for the Study of the Liver (EASL), 2022. EASL Clinical Practice Guidelines on prevention and management of bleeding and thrombosis in patients with cirrhosis. *Journal of Hepatology,* 76(5), pp. 1151-1184. doi: https://www.journal-of-hepatology.eu/article/S0168-8278(21)02033-X/fulltext.

Latham, T., 2019. *Investigation and clinical management of suspected reactions to immunoglobulin A (IgA),* England: NHSBT clinical guideline. Available at: https://hospital.blood.co.uk/clinical-guidelines/nhsbt-clinical-guidelines/ (Accessed 4 February 2024).

Soutar, R. et al., 2023. Guideline on the investigation and management of acute transfusion reactions. *British Journal of Haematology,* 201(5), pp. 832-844. doi: https://doi.org/10.1111/bjh.18789.

Yeates, L. & Charlton, A., 2023. Management of platelet transfusion reactions within the northern centre for cancer care (abstract). *Transfusion Medicine,* 33(S1), pp. 52-53. doi: https://doi.org/10.1111/tme.13005.

18 Pulmonary Complications n=205

Authors: Oliver Firth and Sharran Grey with input from other members of the Pulmonary Working Expert Group

Abbreviations used in this chapter

ISBT	International Society of Blood Transfusion
IV	Intravenous
MHRA	Medicines and Healthcare products Regulatory Agency
TACO	Transfusion-associated circulatory overload

Key SHOT messages

- Pulmonary complications of transfusion remain a leading cause of transfusion-related mortality and morbidity, contributing to 20/38 (52.6%) transfusion-related deaths reported to SHOT in 2023
- TACO-related deaths rarely occur in the absence of risk factors, with a median of four TACO risk-assessment criteria present in each case
- Management of TACO risk is hindered by underutilisation of the risk-assessment tool, low rates of risk identification, and frequent failure to translate risk assessments into proactive management plans
- Utilisation of the SHOT TACO incident investigation tool is high and steadily increasing

The recommendations from previous years continue to be relevant and specific recommendations are also covered in the individual chapters.

Recommendations

- 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, national blood transfusion committees, hospital transfusion teams

- TACO 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
- A structured review and incident investigation should be undertaken for every case of TACO to optimise organisational and individual patient-safety measures

Action: All staff involved in transfusion

Headline data 2023

Number of reports n=205
Deaths n=20
Major morbidity n=30

Pulmonary reports by year

Demographic data

Male n=81
Female n=124
Adults n=199
Paediatric n=4
Unknown n=2

Blood component data

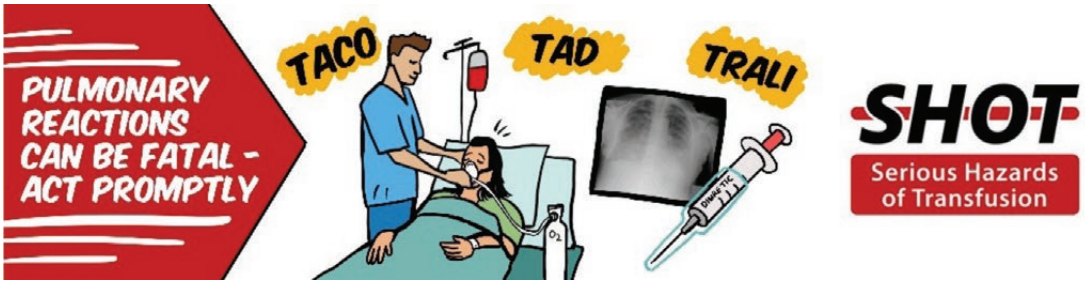
Red cells n=160
Platelets n=10
Plasma n=8
Granulocytes n=2
Cryoprecipitate n=1
Multiple components n=24

Introduction

Transfusion-related pulmonary complications contribute significantly to death and major morbidity. Patients with respiratory complications are often elderly with multiple comorbidities which could all contribute. Pulmonary complications present diagnostic and therapeutic challenges with mainly supportive measures available and paucity of specific therapies. Like in the recent years, the pulmonary cases which do not meet ISBT TACO criteria (Wiersum-Osselton, et al., 2019) have been consolidated into a single chapter. The approach acknowledges that multiple factors could have contributed to the reaction, and this has been explored further in the non-TACO chapter.

TACO is the leading cause of transfusion-related deaths over the past decade. In addition, SHOT data also suggests that fluid overload contributes to most pulmonary reactions which do not meet TACO criteria. A national patient safety alert to address the rising deaths from TACO has been released (MHRA and SHOT, 2024).

The analysis below evaluates 10 years of data from 2014-2023 provided to SHOT regarding TACO-related deaths. The data has been used to evaluate the presence of TACO risk factors, recognition of risk by clinicians, the use of TACO mitigation strategies, the use of risk assessment and incident investigation tools, and institutional learning following TACO-related deaths.



Prevalence of pre-transfusion TACO risk factors

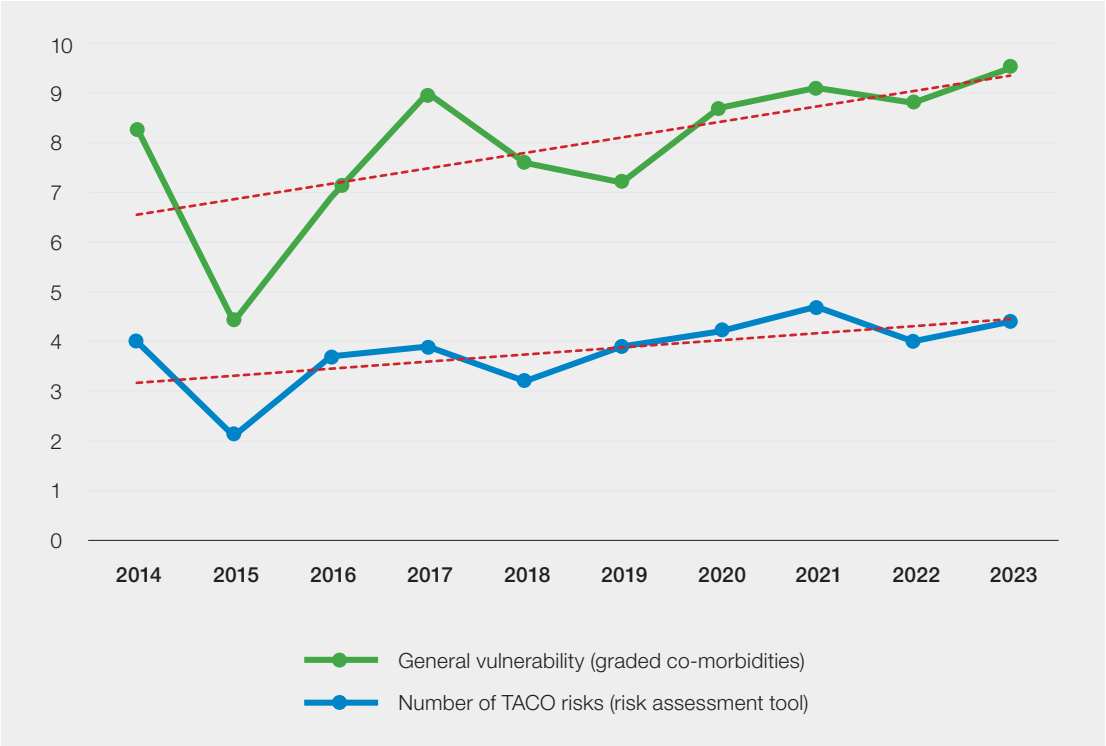
Retrospective application of the TACO risk assessment tool showed that 88/93 (94.6%) cases had identifiable TACO risk factors pre transfusion. Among the 5 cases where none could be identified, 2 lacked data, 2 likely had undocumented cardiac risk factors, leaving 1 case where no formal risk factors could be identified despite comprehensive data. Having a single TACO risk factor was uncommon and seen in only 8/93 (8.6%) of patients, with a median of four TACO risk factors present per patient. Table

18.1 illustrates the unadjusted prevalence of TACO risk factors. A scoring system was applied: where the risk factor was absent (0), present but incidental (1), or an active contributor to admission (2). This highlighted positive fluid balance as being both the most prevalent and clinically significant risk factor. Scoring made one further change to the overall ranking of the TACO risk factors, elevating severe anaemia in significance from 6th to 3rd. A yearly average of the number of TACO risks and comorbidities per patient, is shown in Figure 18.1, which demonstrates an increasing trend in general comorbidities and TACO risk over the period.

Table 18.1: The prevalence of each 'TACO risk' as outlined in the SHOT risk-assessment tool among TACO-related deaths over the past decade

SHOT TACO risk-assessment category	Frequency
IV fluids in the past 24 hours	59/93 – 63%
Clinically significant positive fluid balance	55/93 – 59%
Heart failure or related cardiac disease	42/93 – 45%
Renal impairment	39/93 – 42%
Hypoalbuminaemia	37/93 – 40%
Severe anaemia	36/93 – 39%
Peripheral oedema	30/93 – 32%
Regular diuretic use	29/93 – 31%
Undiagnosed respiratory symptoms	20/93 – 22%
Pre-existing pulmonary oedema	15/93 – 16%

Figure 18.1: The number of TACO risk factors and graded TACO vulnerability among TACO-related deaths reported to SHOT 2014-2023



TACO=transfusion-associated circulatory overload

Utilisation of the TACO risk-assessment tool

The TACO risk assessment was introduced in 2016, and data collected on its use since 2019. Analysis of the use of the TACO risk-assessment tool was possible in 54 of the 93 cases. Adoption of the risk assessment was initially slow, and rates of use have plateaued, with it being used in 35-40% of the most recent cases of TACO-related death (Figure 18.2). Where the tool was used, clinicians identified TACO risks in 11/20 (55.0%) patients, while retrospective application of the tool to these cases identified risks in 18/20 (90.0%). Reporting through the SHOT questionnaire on TACO risk factors has two questions, first whether the clinician identified TACO risks, and second which risks were identified. Due to a paucity

in data submission for this second question, it was not possible to assess the correlation between the risks identified through retrospective application of the risk assessment, and those recognised by the clinicians.

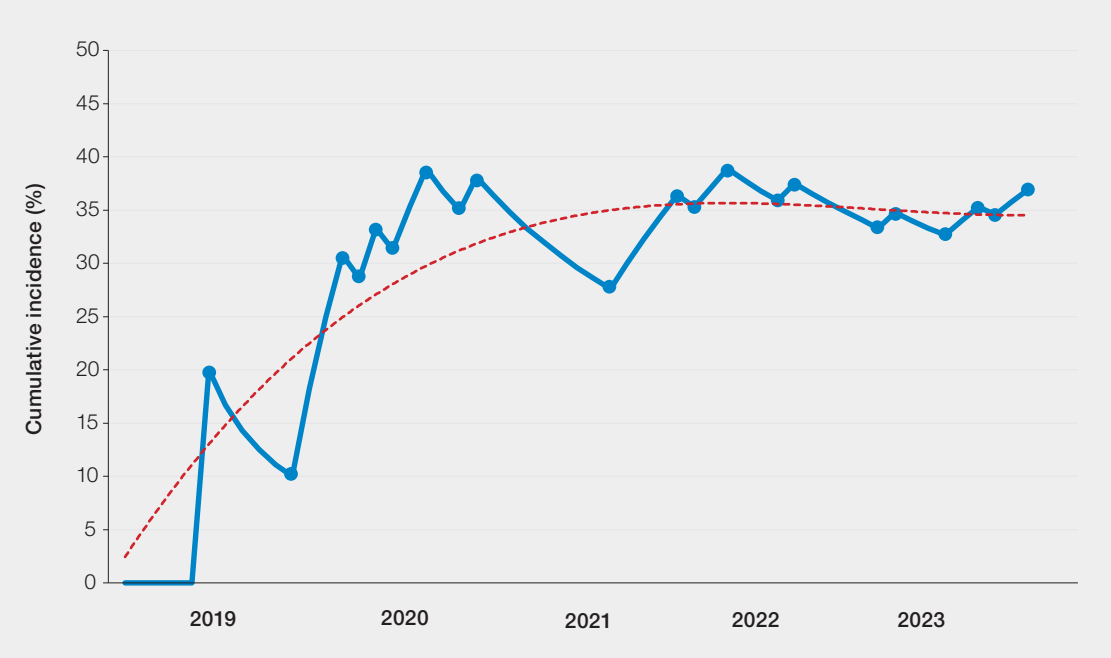


Figure 18.2: Cumulative incidence of usage of the SHOT TACO risk-assessment tool in TACO-related deaths 2019-2023

Preventability and TACO mitigation strategies

The data set was reviewed to assess potential preventability of TACO. In 84/93 (90.3%) cases potential mitigating actions were not undertaken, and in 64/84 (76.2%) cases there was more than one mitigation possible. Table 18.2 illustrates the frequency of the potential recommended mitigation strategies. Of the 9 cases where no additional mitigations could be recommended, 2 were transfusions in the context of major haemorrhage, where assigning mitigations is challenging, and 2 were transfusions in patients approaching the end of their life, where transfusion-related imputability was low. The final 5 cases consisted of four examples where use of the TACO risk assessment led to optimal mitigation strategies being employed, and 1 case with no reported TACO risk factors. While the data suggested a lower average preventability rating in cases where the TACO risk assessment had been used (1.15 versus 1.38), this did not reach statistical significance (p=0.35 by Welch's T-test).

Recommended unused mitigation	Frequency
Prophylactic diuretic	57/93 – 61%
Fluid balance measurement	53/93 – 57%
Single unit transfusion and review	36/93 – 39%
Body weight dosing	16/93 – 17%
Vital sign monitoring	13/93 – 14%
Other e.g., alternatives to transfusion	20/93 – 22%

Table 18.2: Frequency of unused TACO mitigation strategies in TACO-related deaths 2014-2023

Review and institutional learning

Over the 10-year period, 58/93 (62.4%) of TACO-related deaths were reviewed formally, 26/93 (27.9%) informally, and in 9/93 (9.7%) cases there was no evidence of review. The SHOT TACO incident investigation tool was introduced in 2021 to aid the review process by providing a framework from which

to work. Since its introduction there have been 20 TACO-related deaths. Initial uptake was slow, but its usage has increased, with 60% of recent case reviews utilising the SHOT TACO incident investigation tool to structure the review process (Figure 18.3). Institutional learning following review was demonstrated in 20/93 (21.5%) cases with the learning objectives presented in Table 18.3.

Figure 18.3: Rolling cumulative incidence of use of the SHOT TACO incident investigation tool for the previous 5 cases of TACO-related deaths 2021-2023

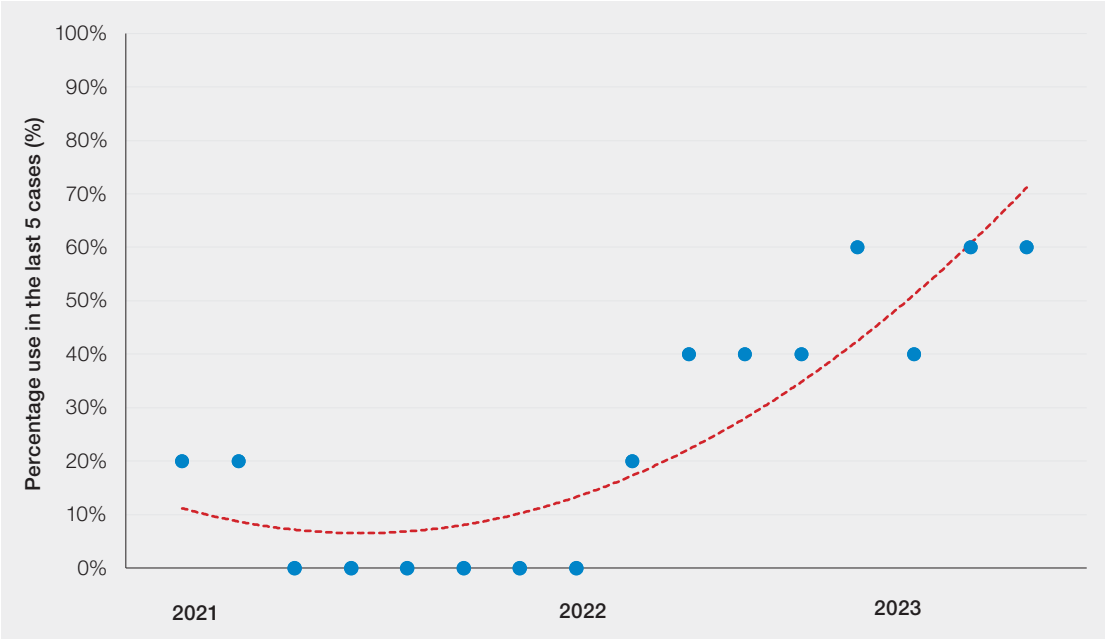
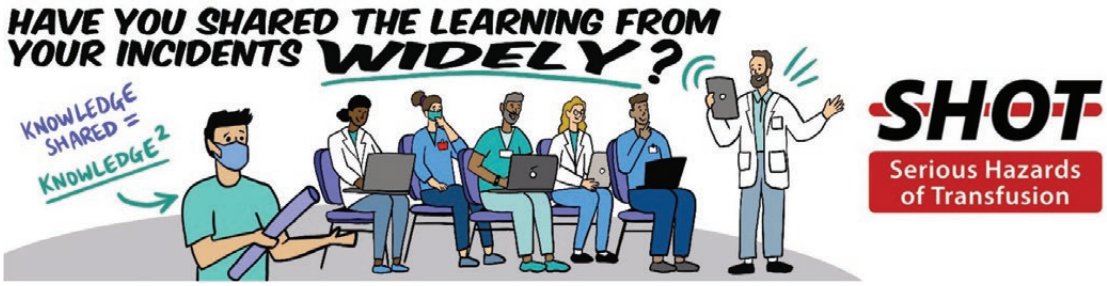


Table 18.3: Reported self-identified institutional learning objectives following TACO-related deaths

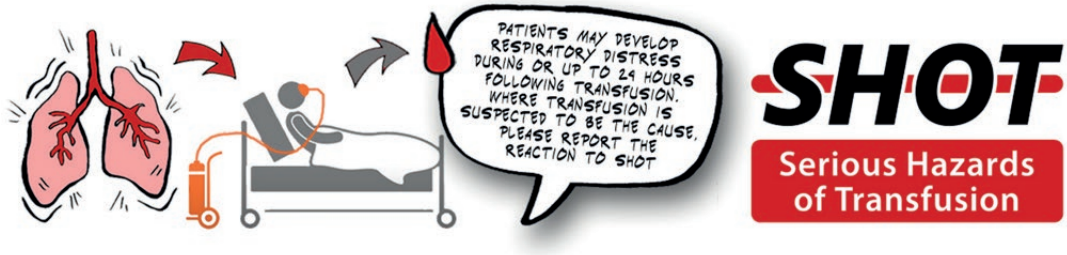
Category of improvement	Frequency
TACO pre-transfusion risk assessment related	11/20 – 55%
Education for prescribers	7/20 – 35%
Change in protocols/policies	6/20 – 30%



Conclusion

This data set supports current understanding that TACO seldom occurs in the absence of risk factors, and, in most instances multiple risk factors are present. Intravenous fluids, positive fluid balance, and congestive cardiac failure are the most prevalent risk factors, and therefore nearly every case of TACO-related death in the past 10 years had potential mitigation strategies that might have been suitable for application. Mitigation strategies appear to be underutilised, and while this is partly due to low use of the risk-assessment tool to guide practice, risks and potential mitigation strategies are commonly missed even when it is used. The rising number of TACO-related deaths raise concerns around our ability to recognise and manage patients at risk of TACO, but this data set may provide additional clarity. It shows that in cases of TACO-related death, patients in 2023 have more pre-transfusion risk factors and a higher vulnerability to TACO than 10 years ago. Possible explanations for this might include improvements in our reporting of patient risks, or that our ability to prevent TACO-related deaths in lower risk patients is improving. The increase in TACO-related deaths, therefore, may at least in part be due to increasing numbers of transfusions in patients with greater complexity and higher comorbidity burdens. A similar

pattern is seen in non-TACO pulmonary complications, and it is likely that wider adoption of TACO risk-reduction measures will also prevent or mitigate many of these. Positive practice was evident from the analysis, with a robust culture of review emerging, marked by increasing use of the SHOT TACO incident investigation tool. It was notable that conclusions drawn following formal review of TACO cases in hospitals mirror the deficiencies identified in this report, and the institutional learning it fosters appears to recommend suitable corrective measures.



References

Medicines & Healthcare products Regulatory Agency (MHRA) and Serious Hazards of Transfusion (SHOT), 2024. *Central Alerting System: Reducing risks for transfusion-associated circulatory overload.* [Online] Available at: https://www.cas.mhra.gov.uk/ViewandAcknowledgment/ViewAlert.aspx?AlertID=103249 (Accessed 08 April 2024).

Wiersum-Osselton, J. C. et al., 2019. Revised international surveillance case definition of transfusion-associated circulatory overload: a classification agreement validation study. *The Lancet,* 6(7), pp. e350-e358. doi: https://doi.org/10.1016/s2352-3026(19)30080-8.

18a Transfusion-Associated Circulatory Overload (TACO) n=172

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† after transfusion, with additional features including cardiovascular system changes not explained by the patient's underlying medical condition; evidence of fluid overload and a relevant biomarker¥.

† SHOT accepts cases up to 24 hours

¥ see Table 18a.1 for details of required and additional criteria for a surveillance diagnosis

Abbreviations used in this chapter

Hb	Haemoglobin	**NBTC**	National Blood Transfusion Committee
HFIT	Human factors investigation tool	**NPSA**	National Patient Safety Agency
ICU	Intensive care unit	**NT-pro BNP**	N-terminal-pro brain natriuretic peptide
IDA	Iron deficiency anaemia	**TACO**	Transfusion-associated circulatory overload

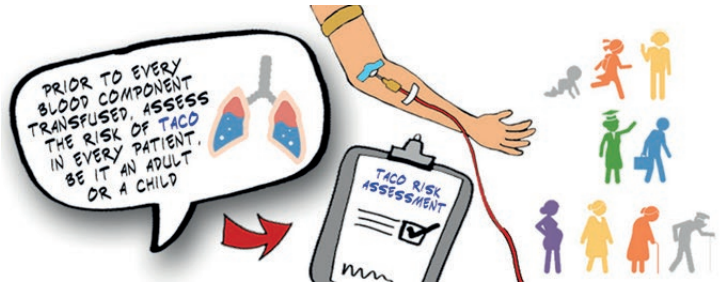
Key SHOT messages

- The number of TACO cases reported in 2023 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 risk assessment 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
- Severe chronic anaemia (asymptomatic or minimally symptomatic) requires only minimal transfusion (usually a single unit) followed by pharmacological treatment where appropriate. Non-bleeding adult patients with severe chronic anaemia are particularly vulnerable to TACO even in the absence of comorbidities that predispose to TACO

Recommendation

- Perform a gap analysis and implement the recommendations of the NPSA alert on TACO (MHRA and SHOT, 2024). This incorporates ongoing SHOT recommendations and access to further guidance and supporting resources

Action: Hospital Trusts/Health Boards



SHOT
Serious Hazards of Transfusion

Introduction

The TACO pre-transfusion risk assessment infographic (Figure 18a.1) was updated in the 2020 Annual SHOT Report to make it suitable for incorporation into clinical documents. Following feedback from reporters, a clarification has been added regarding the use of a prophylactic diuretic. The word 'checklist' has also been standardised to 'risk assessment'.

TACO Risk Assessment		YES	NO
	Does the patient have any of the following: 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 is 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 (where appropriate/not contraindicated)	
Monitor vital signs closely, including oxygen saturation	

Name (PRINT):		**Due to the differences in adult and neonatal physiology, babies may have a different risk for TACO. Calculate the dose by weight and observe the notes above.**
Role:		
Date:	**Time (24hr):**	
Signature:		

TACO=transfusion-associated circulatory overload

Figure 18a.1: TACO pre-transfusion risk assessment

Table 18a.1: TACO surveillance definition (adapted from Wiersum-Osselton, et al., 2019)

TACO surveillance definition
Patients classified with TACO (surveillance diagnosis) should exhibit at least one required criterion* with onset during or up to 12 hours after transfusion (SHOT continues to accept cases up to 24 hours), and a total of 3 or more criteria i.e., *A and/or B, and total of at least 3 (A to E)
*** Required criteria (A and/or B)**
A. Acute or worsening respiratory compromise and/or
B. Evidence of acute or worsening pulmonary oedema based on: • clinical physical examination, and/or • radiographic chest imaging and/or other non-invasive assessment of cardiac function
Additional criteria
C. Evidence for cardiovascular system changes not explained by the patient's underlying medical condition, including development of tachycardia, hypertension, jugular venous distension, enlarged cardiac silhouette and/or peripheral oedema
D. Evidence of fluid overload including any of the following: a positive fluid balance; clinical improvement following diuresis
E. Supportive result of a relevant biomarker, e.g., an increase of BNP levels or NT-pro BNP to greater than 1.5 times the pre-transfusion value

The number of cases reported in 2023 is the highest to date and is an increase of 12 cases from 2022 (n=160). 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=15

There were 15 deaths related to TACO in 2023, 2 of which were probably related (imputability 2), and 13 were possibly related (imputability 1). In 2022 there was 1 case that was definitely related to transfusion (imputability 3). Although there are no cases that were evaluated as definitely related to transfusion reported in 2023, the number of deaths has almost doubled compared to 2022 when there were 8, which is a concerning signal in the data (Table 18a.2).

Major morbidity n=20

There were 20 cases of major morbidity in 2023 which is a slight reduction but broadly similar compared to recent years.

Table 18a.2: Demographic overview of TACO cases in 2023

Demographic	Number of reports
Deaths (imputability 3)	0
Deaths (imputability 2)	2
Deaths (imputability 1)	13
Major morbidity	20
Age	Range: 2 months – 96 years (2 age under 18 years) Median: 75.5 years
Gender	104 female, 68 male
Body weight (adults)	Female (n=45): average 64.7kg (range 42-95.5kg) Male (n=36): average 71.1kg (range 50.9-122kg)
Top 4 medical specialties	Acute medicine=34, haematology=30, general medicine=14, emergency medicine=13
Bleeding patients (NBTC indication code R1 or 'massive bleeding' indicated) (NBTC, 2020)	21
Non-bleeding patients (other NBTC indication codes or not stated)	151

TACO is more commonly reported in elderly, non-bleeding patients but is seen across all age groups. These data are consistent with previous years. There were 2 cases in the under-18 age group (age 2 and 3 months). TACO was reported more frequently in female patients and appears to be a consistent characteristic compared to data from previous years. Weight was provided in 45 adult female cases, with an average of 64.7kg (42-95.5kg). Weight was provided in 36 adult male cases, with an average of 71.1kg (50.9-122kg). The apparent higher incidence of TACO in female patient may be attributed to the lower average weight of female patients compared to male, and increased risk of TACO in patients with lower body weight. This underlines the importance of weight-adjusted red cell dosing and single unit transfusion, particularly in patients with lower body weight. Adult medical specialties, including emergency medicine and haematology continue to be the most common specialties where TACO is reported. This should be considered when targeting TACO education and mitigation plans.

Case 18a.1: TACO risks failed to be identified leading to missed opportunities and death

A female patient weighing 52kg with a Hb level of 68g/L was prescribed two units of red cells. She had liver disease and sepsis with peripheral oedema. The cause of the anaemia was not clear, but she was not actively bleeding, and the NBTC indication code assigned to the transfusion was R2 (acute anaemia). A TACO pre-transfusion risk assessment was completed, and the clinician did not identify any risks, therefore no actions were assigned to mitigate TACO. The first unit of red cells was given without issue and the second unit was commenced 4 hours later without a clinical review. She became acutely unwell after the first hour, and an emergency call was made. She developed dyspnoea and tachypnoea with oxygen desaturation to 90% from a previously normal level and had tachycardia and systolic hypertension. The post-transfusion chest X-ray showed significant pulmonary oedema. The NT-pro BNP was significantly raised however there was no pre-transfusion value. An echocardiogram showed moderate left ventricular systolic dysfunction which had not been previously reported. A fluid balance was not reported but there had been a 5kg increase in weight post transfusion. Multiple doses of furosemide were given resulting in some diuresis, but respiratory symptoms remained unchanged. ICU admission was required, and continuous infusion of diuretic was administered, with morphine and antibiotics. The patient unfortunately died. Sepsis was clearly a major factor however the transfusion was assessed as contributory to the death.

A local structured review was performed in the form of an audit of the TACO pre-transfusion risk assessment completion, transfusions out-of-hours, and the single unit red cell policy.

Recommendations following the audit were broadly as follows:

- Education and training on single unit policy, transfusion triggers and Hb targets
- Review the operational use of the TACO risk-assessment tool
- Education on the TACO risk-assessment process
- Ensure the TACO risk assessment is applied to platelets and cryoprecipitate
- Additional education on stable patients with anaemia, overnight transfusion and adopting transfusion reaction e-learning

This is an example of the TACO risk assessment being completed incorrectly resulting in missed opportunities to prevent or mitigate TACO. The patient had peripheral oedema due to liver disease, sepsis, and hypoalbuminemia: therefore, there were clear signs of pre-transfusion fluid overload. The patient may have had previously undiagnosed heart failure which was uncovered by this episode of TACO. Had

this been correctly identified as a risk, several mitigation options could have been considered assuming deferral of the transfusion to manage the pre-transfusion overload was not clinically appropriate. A single unit policy or weight-adjusted red cell dosing would have prevented the transfusion of excessive and unnecessary volume of red cells. The patient had not developed signs of TACO after the first red cell unit. The patient was on a regular diuretic, and it may have been possible to give an additional prophylactic dose. Fluid balance monitoring was not in place, and it was only apparent after the transfusion that there was significant overload due to the increase in body weight when recorded post transfusion. The SHOT structured TACO incident investigation tool does not appear to have been used in this case, however actions concerning most of the preventable factors appear to have been identified.

Excessive red cell transfusion in non-bleeding adult patients with both chronic and acute anaemia continues to be a significant feature in TACO cases, particularly in patients with lower body weight. The team reporting this case should be commended for focussing education and training on transfusion triggers and the use of single unit transfusions. Organisations are encouraged to consider system changes such as embedding in electronic or other controlled processes to avoid the over-reliance on staff knowledge alone.

Potentially preventable factors in cases of mortality n=15

Table 18a.3 and Table 18a.4 below describe the use of the TACO risk assessment in 2023 and a review of potentially preventable factors following case review, with a summary of trends and themes which are similar findings compared to data from previous years.

Table 18a.3: Use of TACO risk assessment in TACO-related deaths in 2023

TACO risk assessment performed	9/15
Risk(s) identified on TACO risk assessment	8/9
Risk(s) NOT identified on TACO risk assessment when present on case review	1/9
Risks(s) identified on TACO risk assessment fully agree with risks present on case review	0/9
Instances of risks missed in the 6 cases where a TACO assessment was NOT performed:	Hypoalbuminaemia (2); renal impairment (2); fluids (3); cardiac impairment (1); peripheral oedema (2); positive fluid balance (1)
Instances of risks missed in the 9 cases where a TACO risk assessment WAS performed:	Positive fluid balance (3); fluids (2), pulmonary oedema (2); likely fluids involved (1); cardiac impairment (1); renal impairment (2); hypoalbuminaemia (3); peripheral oedema (1)
TACO mitigations assigned	7/15
Mitigation measures performed as assigned/planned	5/7

Key themes include:

- Failure to perform TACO risk assessment in a significant number of cases, and risks missed in all cases where the risk assessment was not performed. This is not limited to specific risks for TACO
- Risks not comprehensively identified in individual patients (additional risks were identified on case review). This is not limited to specific risks for TACO
- Missed opportunities to assign TACO mitigation measures
- Failure to perform TACO mitigation measures as assigned/planned

Transfusion NOT indicated	3/15 (includes 1 case of iron deficiency anaemia that could have been potentially treated with intravenous iron)
Indicated transfusions (n=12) that could have been deferred	1/12 (pre-transfusion overload with no clear urgency for transfusion)
Appropriate volume transfused	9/15 (clear evidence of overtransfusion in 2 cases)
Appropriate/close monitoring	14/15 (TACO not immediately recognised in 1 case)
Fluid balance monitoring	8/15
No prophylactic diuretic given	8/15
On regular diuretic (no additional prophylactic dose given)	4/15
Diuretic identified as required but unable to ascertain if given	1/15
No prophylactic diuretic and regular dose withheld	1/15
On regular diuretic and additional prophylactic dose given	1/15
Structured case review	6/15

Table 18a.4: Preventable factors for TACO-related deaths in 2023

Key themes include:

- Some transfusions were inappropriate and could have been avoided altogether, including a case of IDA that could have been treated with iron replacement
- One case could potentially have been deferred to address the pre-transfusion overload
- Inappropriate volume of red cells transfused with clear cases of overtransfusion. Evidence for lack of application of weight-adjusted red cell dosing and single unit and review policy
- Fluid balance monitoring not performed in some cases. Unclear whether it was due to practical reasons or an oversight
- No prophylactic diuretic was administered in most cases. It is not possible to ascertain whether this was an oversight or that a diuretic was contraindicated. It is noted that there was some degree of renal impairment in 9/15 cases which may have influenced the decision not to give a prophylactic diuretic
- The transfusion contributed to death to some extent in all 15 cases. There was evidence of a structured review in only 6 cases, potentially leading to missed opportunities to improve practice and patient safety

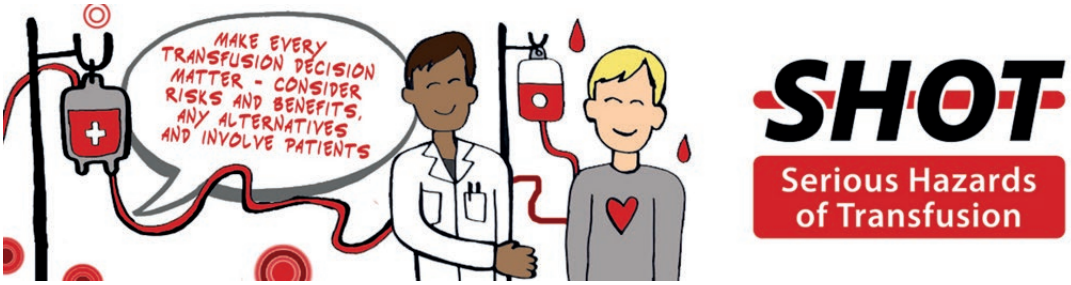
A recent 10-year review of the TACO deaths, as reported to SHOT highlighted that TACO is rarely seen in the absence of risk factors identified on the pre-transfusion TACO risk assessment. This safety check appears to be under-utilised and often inaccurately completed, leading to inadequate mitigation strategies. Organisations are urged to implement SHOT recommendations to enhance patient safety (Firth, et al., 2024).

Transfusion management approach in non-bleeding adult patients: avoiding the risks of mismanagement in severe chronic anaemia

Accurate identification of the cause of anaemia is a critical step in safe and appropriate transfusion management. Acute anaemia is defined as anaemia of recent onset which is caused by bleeding, surgery, or critical illness in a haemodynamically stable patient. It corresponds to NBTC indication codes R2 and R3, the latter in the context of acute coronary syndrome. This contrasts with transfusion-dependent anaemia (R4) which may be caused by bone marrow failure or haemoglobinopathy, and severe chronic anaemia (e.g., caused by haematinic deficiency, or anaemia of chronic disease) (NBTC, 2020). There is no

universal Hb trigger or target for severe chronic anaemia. Physiological compensation means transfusion is not likely to be required if the Hb is >70g/L. The transfusion of a single unit may be indicated to alleviate symptoms in severe anaemia (Hb <70g/L) or prevent the acute complications of severe anaemia while the underlying cause is treated e.g., iron replacement in iron deficiency anaemia.

SHOT data have shown that severe anaemia is an independent risk factor for TACO (Narayan, et al., 2019) and these patients are vulnerable to overtransfusion leading to TACO-related deaths and major morbidity. It is important that clinicians authorising transfusion understand the rationale for different approaches to transfusion management, and the risks of not recognising acute versus chronic anaemia. The presence of acute coronary syndrome and cardiac ischaemia in acute and chronic anaemia present additional challenges and risks. The decision to transfuse further units to achieve a higher Hb target in a patient with acute coronary syndrome/cardiac ischaemia should be balanced against the increased risk of TACO and exacerbation of heart failure. Strategies that support this such as education, training and process-embedded guidelines are key components of safe decision-making in transfusion. Figure 18a.2 describes the transfusion management approach for non-bleeding adult patients and details the specific approach that should be adopted for patients with severe chronic anaemia.



Conclusion

There has been slow adoption of the TACO pre-transfusion risk assessment tool since it was launched but this is increasing steadily. While encouraging, the analysis of the data shows it is still under-used or used ineffectively. Although there has been some uptake of the TACO structured incident investigation tool, there are still missed opportunities to enhance patient safety. The SHOT HFIT questions, and the analyses in the main chapter, are only included for reports in established error categories, but it can be demonstrated that some reaction cases may also be error-based. For the first time this year, a TACO case has been examined in the Human Factors and Ergonomics (HFE) supplementary information using the HFIT main headings to examine the significance of HFE involved (https://www.shotuk.org/shot-reports/report-summary-and-supplement-2023/).

Overtransfusion of red cells 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 continues to contribute to patient deaths due to excessive transfusion. There are several strategies 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 National Patient Safety Alert has been released UK-wide by SHOT through the MHRA (MHRA and SHOT, 2024). This is intended to support and provide a structure for organisations to implement 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 in due course. Identifying risk-factors for TACO in vulnerable patients prior to transfusion helps initiate appropriate mitigating measures. TACO deaths are potentially preventable.

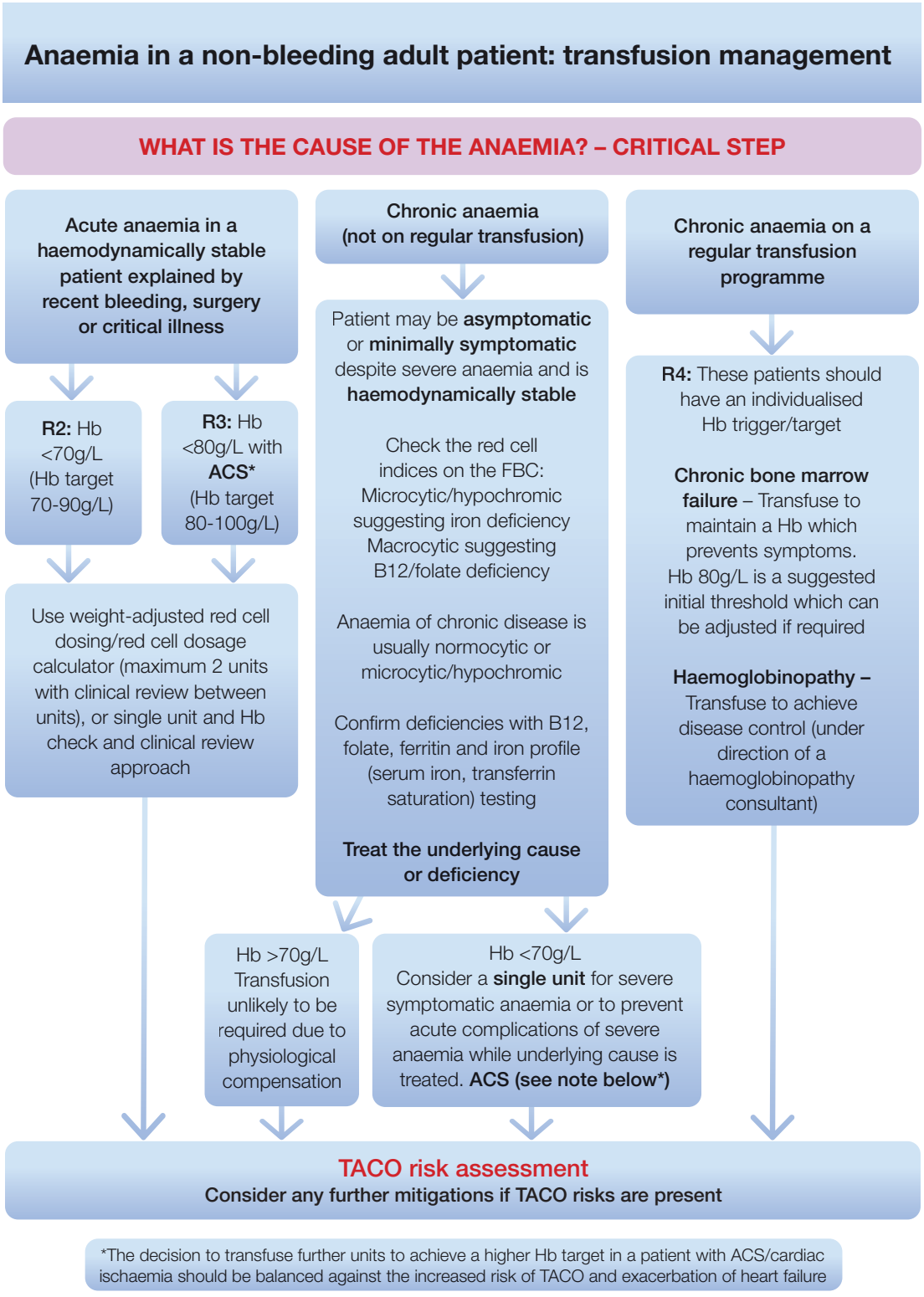


Figure 18a.2: Transfusion management approach in non-bleeding adult patients

ACS=acute coronary syndrome; FBC=full blood count; Hb=haemoglobin; TACO=transfusion-associated circulatory overload

Recommended resources

Example of weight-adjusted red cell dosing implemented in clinical practice
NHS MHRA and UKCA Marked blood transfusion Red Cell Dosage Calculator Software App (rcdcalculator.co.uk)

TACO Incident Investigation Guidance Tool
TACO Risk assessment in 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 – Transfusion-Associated Circulatory Overload
https://www.shotuk.org/resources/current-resources/videos/

NPSA Alert (2024): TACO
National Patient Safety Alert: Reducing risks for transfusion-associated circulatory overload (NatPSA/2024/004/MHRA) - GOV.UK (www.gov.uk)

Transfusion-Associated Circulatory Overload (TACO) Cumulative Data
https://www.shotuk.org/resources/current-resources/data-drawers/transfusion-associated-circulatory-overload-taco-data-drawer/

National Comparative Audit of TACO
https://hospital.blood.co.uk/audits/national-comparative-audit/reports-grouped-by-year/transfusion-associated-circulatory-overload-audit-2017/

References

Firth, O., Grey, S., Narayan, S. & Poles, D., 2024. Deaths attributable to transfusion- associated circulatory overload: 10-year review of serious hazards of transfusion (SHOT) data. *British Journal of Haematology,* 204(S1), pp. 63-64. doi: https://doi.org/10.1111/bjh.19398.

Medicines & Healthcare products Regulatory Agency (MHRA) and Serious Hazards of Transfusion (SHOT), 2024. *Central Alerting System: Reducing risks for transfusion-associated circulatory overload.* [Online]
Available at: https://www.cas.mhra.gov.uk/ViewandAcknowledgment/ViewAlert.aspx?AlertID=103249
(Accessed 08 April 2024).

Narayan, S., Grey, S., Bolton-Maggs, P. & Poles, D., 2019. Is severe anaemia an independent risk factor for TACO? Case based discussions based on TACO reports to SHOT, the United Kingdom haemovigilance scheme (abstract). *Vox Sanguinis,* 114(S1), p. 231. doi: https://doi.org/10.1111/vox.12792.

National Blood Transfusion Committee (NBTC), 2020. *Indication Codes for Transfusion in Adults - An Audit Tool,* England: National Blood Transfusion Committee. Available at: https://nationalbloodtransfusion.co.uk/sites/default/files/documents/2023-02/NBTC%20indication%20codes%20-%20Final%20-%20Jan%2020%20%28004%29.pdf
(Accessed 03 May 2024).

Wiersum-Osselton, J. C. et al., 2019. Revised international surveillance case definition of transfusion-associated circulatory overload: a classification agreement validation study. *The Lancet,* 6(7), pp. e350-e358. doi: https://doi.org/10.1016/s2352-3026(19)30080-8.

Pulmonary Complications of Transfusion: Non-TACO n=33

18b

Authors: Tom Latham and Oliver Firth

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.

Abbreviations used in this chapter

ARDS	Acute respiratory distress
CRP	C reactive protein
CT	Computed tomography
CXR	Chest X-ray
FFP	Fresh frozen plasma
FiO2	Inhaled oxygen fraction
Hb	Haemoglobin
HLA	Human leucocyte antigen
HNA	Human neutrophil antigen
HR	Heart rate
ICU	Intensive care unit
IRC	International Revised Consensus (TRALI definition)
RR	Respiratory rate
SaO2	Oxygen saturation
SD-FFP	Solvent detergent FFP
TACO	Transfusion-associated circulatory overload
TAD	Transfusion-associated dyspnoea
TRALI	Transfusion-related acute lung injury

Key SHOT messages

- Pulmonary complications are often multifactorial
- 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 blood donor
- The risk-benefit balance of transfusion should be carefully considered particularly in patients with multiple risk factors for fluid overload and/or acute lung injury

Recommendation

- A structured TACO investigation tool should be used for all pulmonary complications

Action: All staff involved in investigating transfusion reactions

Introduction

In 2023, a total of 33 cases were included in the non-TACO category. Fifty-five cases were originally submitted or transferred from other categories. Of these, 11 were withdrawn as they were either of insufficient severity or due to the underlying condition, 10 cases were transferred to TACO and 1 was deferred pending investigation results. For more details, see the supplementary data tables and information on the SHOT website (https://www.shotuk.org/shot-reports/report-summary-and-supplement-2023/).

Cases were classified using the IRC definitions of TRALI (Table 18b.1). Cases satisfying both TRALI and TACO criteria (Wiersum-Osselton, et al., 2019) were categorised as 'TRALI-TACO' and cases satisfying neither as 'TAD'. The TAD category is subclassified into TAD-IC (cases which could not be classified because of incomplete information reported) and TAD-C (cases where there was sufficient information to judge that the case did not meet either TACO or TRALI criteria).

The final classification of cases with imputability is presented in Table 18b.2 and major morbidity and mortality in Table 18b.3.

Table 18b.1: International revised consensus classification of TRALI (Vlaar, et al., 2019)

TRALI type I - Patients who have no risk factors for ARDS and meet the following criteria:	
a.	i. Acute onset
	ii. Hypoxemia (P/F ≤300 or SpO2 < 90% on room air)
	iii. Clear evidence of bilateral pulmonary edema on imaging (e.g. chest radiograph, chest CT, or ultrasound)
	iv. No evidence of left atrial hypertension (LAH), or, if LAH is present, it if judged to not be the main contributor to the hypoxemia
b.	Onset during or within 6 hours of transfusion
c.	No temporal relationship to an alternative risk factor for ARDS
TRALI type II - Patients who have risk factors for ARDS (but who have not been diagnosed with ARDS) or who have existing mild ARDS (P/F of 200-300), but whose respiratory status deteriorates and is judged to be due to transfusion based on:	
a.	Findings as described in categories a and b of TRALI type I and
b.	Stable respiratory status in the 12 hours before transfusion

Table 18b.2: Final classification of non-TACO cases

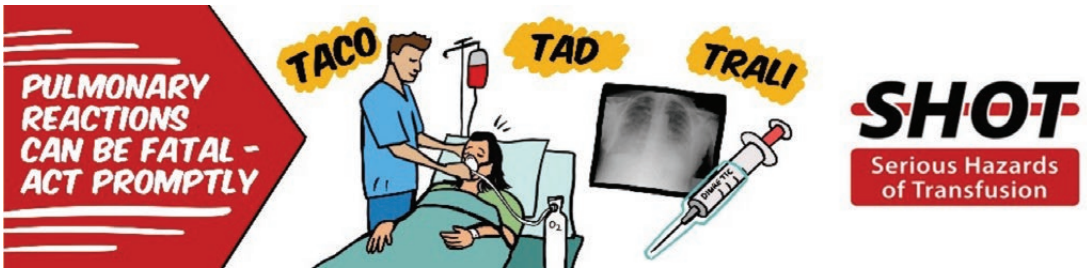
		Imputability			
		1-possible	**2-probable**	**3-definite**	**Total**
Category	TAD-C	7	8	1	**16**
	TAD-IC	7	4	0	**11**
	TRALI-TACO	0	0	1	**1**
	TRALI type II	4	1	0	**5**
Total		**18**	**13**	**2**	**33**

Table 18b.3: Non-TACO major morbidity and mortality

		Major morbidity and mortality		
		Major morbidity	**Death**	**Total**
Category	TAD-C	6	2	**8**
	TAD-IC	0	3	**3**
	TRALI type II	4	0	**4**
Total		**10**	**5**	**15**

Deaths related to transfusion n=5

There were 5 deaths reported, all in the TAD category. All patients were severely unwell prior to transfusion. Death was possibly (imputability 1) related to TAD in 3 cases and probably related (imputability 2) in 2 cases. In both imputability 2 cases, extensive investigation was not considered appropriate because the patient was terminally ill. Fluid overload was clinically thought to have contributed to the deterioration in all 5 cases, but they did not satisfy sufficient criteria to be classified as TACO. For more details and a narrative summary of the deaths, see the supplementary information on the SHOT website (https://www.shotuk.org/shot-reports/report-summary-and-supplement-2023/).



Major morbidity n=10

There were 10 cases of major morbidity (defined as requiring ventilation or ICU admission). Six were classified as TAD-C and 4 as TRALI type II.

Case 18b.1: TAD-C - High suspicion of fluid overload not satisfying TACO criteria

A patient with decompensated liver disease, impaired left ventricular function, aortic stenosis, and low albumin, was receiving diuretics for fluid overload. They developed respiratory distress and crepitations during a two-unit FFP transfusion given to correct clotting abnormalities during an endoscopy for bleeding varices. The CXR showed increased consolidation in the left lower lobe. The risk of fluid overload was noted prior to transfusion. There was no immediate response to diuretic at the time of the reaction, but the patient was given further diuretics in ICU. The patient was ventilated overnight and improved by morning.

This case is included as it is emblematic of the challenges of transfusing unwell patients and of classifying reactions in such cases. The patient was identified as being at high risk of tolerating fluid poorly but there were also high risks of leaving clotting uncorrected during major bleeding. Appropriate treatment was rapidly provided. The case was classified as TAD-C since insufficient criteria were present to classify as TACO; the TACO criteria do not take account of pre-existing risk.

FFP transfusion to correct clotting in patients already fluid overloaded is a recurrent feature in cases reported to SHOT; the balance of risk and benefit must be carefully considered. The use of alternatives such as prothrombin complex concentrate is not recommended for routine correction of coagulation abnormalities in liver disease but could have a favourable risk/benefit ratio in this situation.

TRALI and leucocyte antibody cases

Cases have been classified as TRALI using the IRC definition. 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.

Cases meeting TRALI criteria n=6

Of the cases which met TRALI criteria, 5 were classified as TRALI type II. One case was classified as 'TRALI and TACO cannot be distinguished' and was positive for leucocyte antibodies, see Case 18b.3. Most patients were unwell prior to transfusion and the transfusion reactions were of low imputability. A summary of all cases meeting TRALI criteria is given in the supplementary data, Table 18b.5 (https://www.shotuk.org/shot-reports/report-summary-and-supplement-2023/).

Case 18b.2: TRALI type II - Recurrent pulmonary reactions with SD-FFP

A patient was undergoing plasma exchange for suspected thrombotic thrombocytopenic purpura (eventually confirmed as haemolytic uraemic syndrome). Respiratory deterioration occurred on three successive occasions during exchange. CXR showed worsening bilateral changes and there was a rising CRP, but the patient was not thought to have pneumonia. Renal function was normal and there was a negative fluid balance and no features of fluid overload.

The case meets criteria for TRALI and the recurrent deterioration during successive procedures does suggest a causative role for the transfusion. Investigation of the product for leucocyte antibodies is not within the scope of the Blood Services and would have to be arranged by the manufacturer. SD-FFP is a pooled product and pooling is generally considered to reduce the risk of antibody-mediated TRALI through dilution of antibodies from any given donor (Sachs, et al., 2005). Product information does include respiratory adverse events following SD-FFP, though acknowledges the difficulty in assigning imputability. A recent study from the Netherlands suggested the incidence of cases meeting TRALI criteria was reduced in critical care patients after changing to routine use of SD-FFP, although the difference was not statistically significant (Klandermann, et al., 2022). SD-FFP is regulated as a medicine not a blood component and is reported to the MHRA via the Yellow Card system but SHOT will accept cases for review.

Cases with leucocyte antibodies n=1

Case 18b.3: TRALI/TACO with HLA class I antibody

A patient with pre-eclampsia but normotensive, low albumin, and peripheral oedema was transfused one unit of red cells for postpartum haemorrhage following caesarean section. Dyspnoea developed 2-6 hours after transfusion, and oxygen saturation was 95% on oxygen (FiO2 not recorded). CXR showed upper lobe diversion and a CT scan the following day confirmed pulmonary oedema. There was no response to diuretic or haemodynamic change. Donor antibody testing showed HLA B45 antibodies cognate with the recipient. The patient made a complete recovery.

The case has been classified as TRALI/TACO since the case satisfies both TRALI and TACO criteria. The finding of cognate antibody in the sole donor supports the idea that antibody has caused or contributed to the reaction, although the association of HLA class I antibodies with TRALI is less strong than for class II or granulocyte specificities.

Clinical features of reactions

Many recipients had pre-existing factors which could cause acute lung injury or difficulty tolerating additional fluid ('risk factors' Figure 18b.1a) or had features reported at the time of transfusion indicating fluid overload or cardiorespiratory strain ('state factors' Figure 18b.1b). Notably, over half of cases had pre-existing risk factors for fluid overload and inflammatory conditions. Multiple risk factors were present in many cases, with a median of 4 risk factors per case (Table 18b.4). It is not possible to investigate whether individual risk factors entail a higher risk of pulmonary complications from this data in the absence of a control group. Figure 18b.2 however shows that certain pairs of risk factors occurred more commonly than expected statistically, suggesting the coexistence of multiple risk factors may have a more than additive risk of transfusion reaction. Liver disease and inflammation particularly appear to interact with other risk factors, consistent with an observation that sepsis and alcohol abuse were noted as risk factors for acute lung injury in transfused critical care patients in a prospective study (Gajic, et al., 2007).

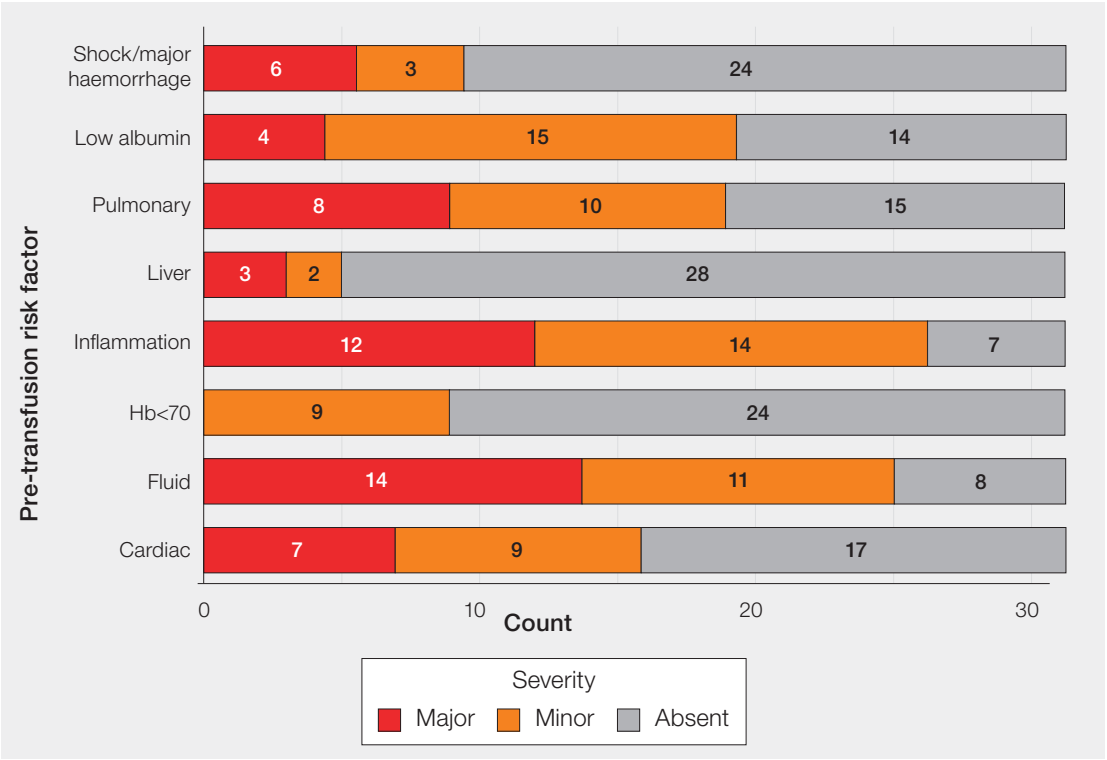


Figure 18b.1: Pre-transfusion features of pulmonary cases

Figure 18b.1a: Risk factors

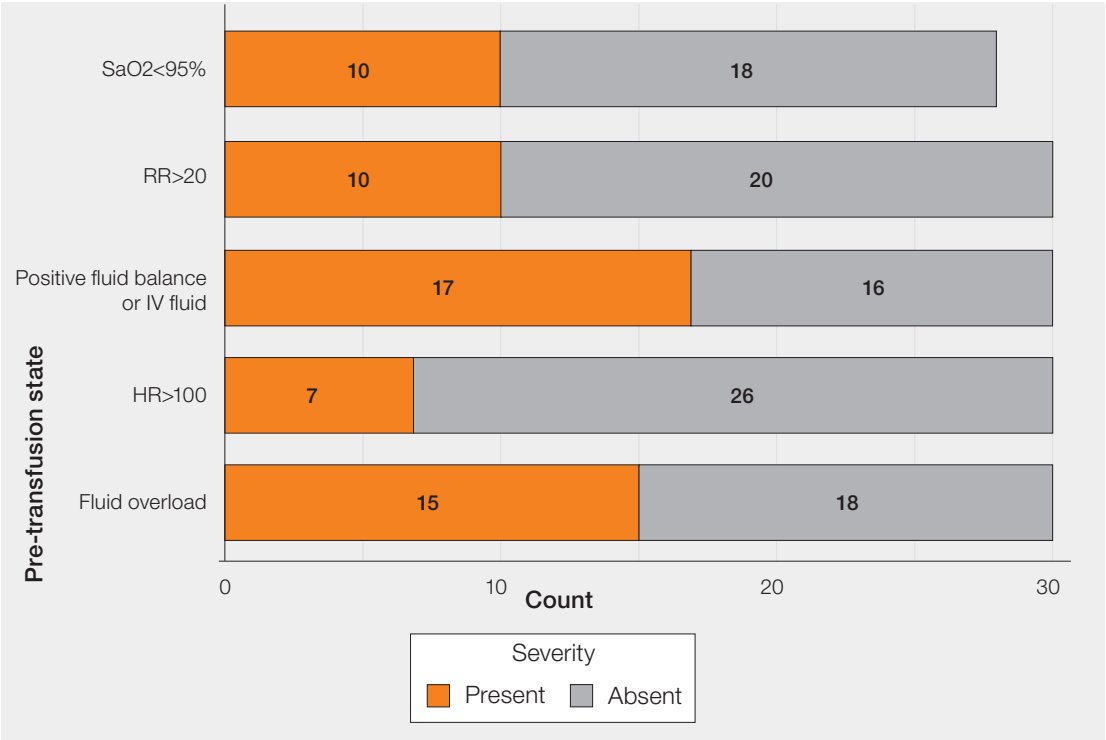
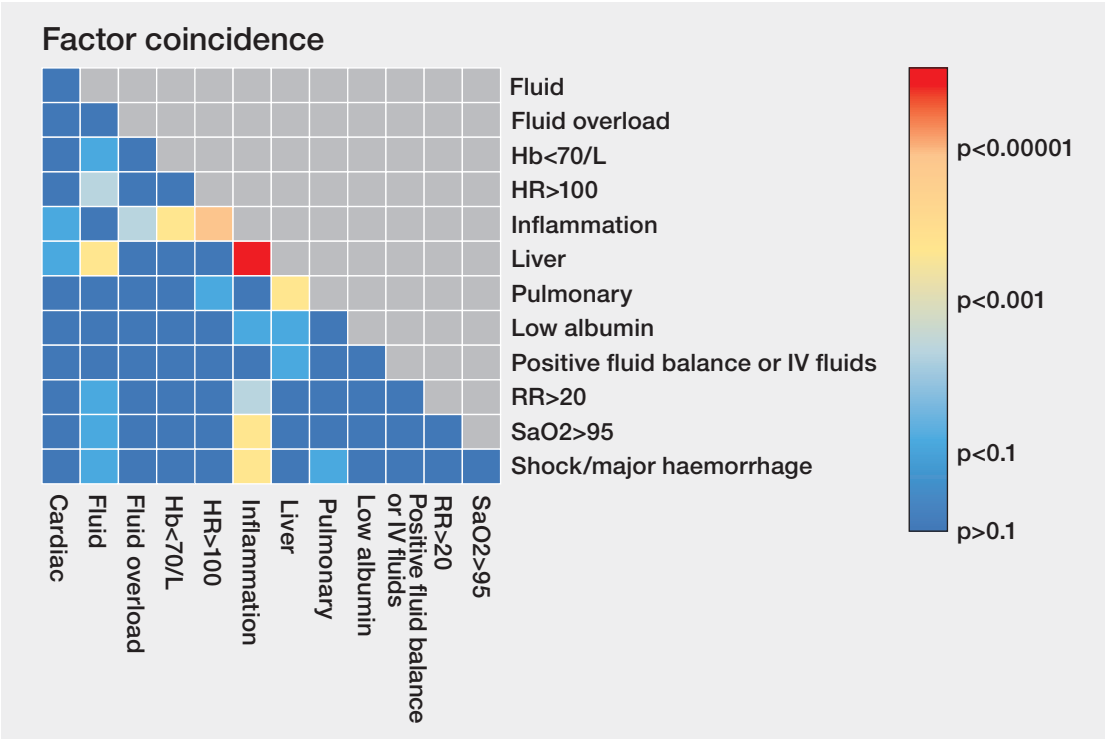


Figure 18b.1b: State factors

		Number of pre-transfusion state factors present					
Number of pre-transfusion risk factors present		**0**	**1**	**2**	**3**	**4**	**Total**
	1	0	1	1	0	0	**2**
	2	1	2	0	2	0	**5**
	3	1	1	1	1	1	**5**
	4	1	4	2	2	0	**9**
	5	1	3	1	1	2	**8**
	6	0	1	2	1	0	**4**
	Total	**4**	**12**	**7**	**7**	**3**	**33**

Table 18b.4: Number of factors present per pulmonary case

Figure 18b.2: Statistical significance of factor coincidence (Fisher exact test with multiple testing correction)



Hb=haemoglobin; HR=heart rate; RR=respiratory rate; SaO2=oxygen saturation

Data completeness and concordance with SHOT recommendations

The proportion of cases classified as TAD-IC because there was insufficient information to apply the TACO or TRALI criteria remains unsatisfying. This is not meant as a criticism of reporters or treating clinicians, but an observation that the data needed to classify reactions using formal international criteria seem to be challenging to provide in practice. This has been illustrated in the supplementary chapter. More generally, only about 2/3 of reports were able to supply a full set of the recommended transfusion observations and 9% were not able to supply any observations. These are long-established recommendations. Only about a third of submissions reported the use of a TACO pre-transfusion risk assessment or a structured investigation, as has been recommended by SHOT for several years. These figures are similar to the 2022 Annual SHOT Report (Narayan, et al., 2023).

Conclusion

As in previous years, transfusion recipients suffering pulmonary complications are often complex with multiple comorbidities across all reporting categories, with little to distinguish cases in different categories. Antibody-associated cases and cases where the transfusion appears the sole contributor are rare. Fluid overload is suspected as a contributory factor even in cases which do not meet TACO criteria; it is important to remember that TRALI and TACO are haemovigilance reporting categories not pathological diagnoses and examine all possibly preventable factors regardless of classification. The suggestion that comorbidities, particularly liver disease, and inflammation, may interact synergistically to create increased risk of tolerating transfusion poorly is worthy of further study.

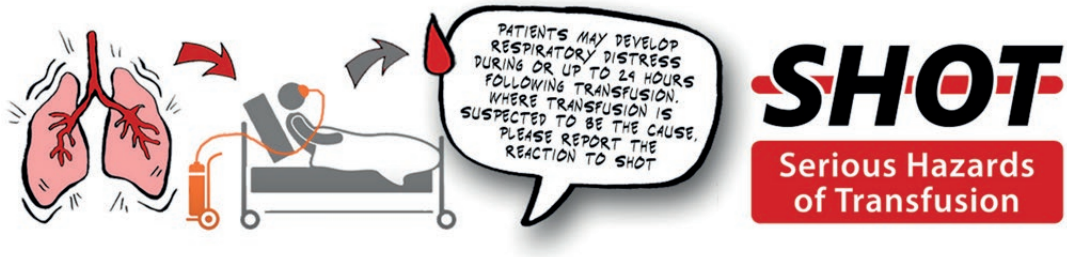
Avoiding fluid overload and minimising transfusion remain the only approaches available to clinicians to prevent pulmonary complications. The risk/benefit balance of transfusion should be carefully considered in unwell patients, particularly those with multiple comorbidities.

Recommended resources

TACO Incident Investigation Guidance Tool
TACO Checklist: in risk assessment/checklist alternative format for incorporation into clinical documents
https://www.shotuk.org/resources/current-resources/

SHOT Video: TACO
https://www.shotuk.org/resources/current-resources/videos/

SHOT Bite No. 11: Respiratory Symptoms During Transfusion
https://www.shotuk.org/resources/current-resources/shot-bites/



References

Gajic, O. et al., 2007. Transfusion-related acute lung injury in the critically ill: prospective nested case-control study. *American Journal of Respiratory and Critical Care Medicine,* 176(9), pp. 886-891. doi: https://doi.org/10.1164/rccm.200702-271oc.

Klanderman, R. B. et al., 2022. Incidence of transfusion-related acute lung injury temporally associated with solvent/detergent plasma use in the ICU: A retrospective before and after implementation study. *Transfusion,* 62(9), pp. 1752-1762. doi: https://doi.org/10.1111/trf.17049.

Narayan, S. et al., 2023. *The 2022 Annual SHOT Report,* Manchester: Serious Hazards of Transfusion (SHOT) Steering Group. doi: https://doi.org/10.57911/WZ85-3885.

Sachs, U. J., Kauschat, D. & Bein, G., 2005. White blood cell-reactive antibodies are undetectable in solvent/detergent plasma. *Transfusion,* 45(10), pp. 1628-1631. doi: https://doi.org/10.1111/j.1537-2995.2005.00587.x.

Vlaar, A. P. et al., 2019. A consensus redefinition of transfusion-related acute lung injury. *Transfusion,* 59(7), pp. 2465-2476. doi: https://doi.org/10.1111/trf.15311.

Wiersum-Osselton, J. C. et al., 2019. Revised international surveillance case definition of transfusion-associated circulatory overload: a classification agreement validation study. *The Lancet,* 6(7), pp. e350-e358.doi: https://doi.org/10.1016/s2352-3026(19)30080-8.

19 Haemolytic Transfusion Reactions (HTR) n=53

Authors: Tracey Tomlinson and Anicee Danaee

Definition:

Acute haemolytic transfusion reactions (AHTR) are characterised by fever, a fall in haemoglobin (Hb), rise in bilirubin and lactate dehydrogenase (LDH) and a positive direct antiglobulin test (DAT). They generally present within 24 hours of transfusion.

Delayed haemolytic transfusion reactions (DHTR), occur more than 24 hours following a transfusion and are associated with a fall in Hb or failure to increment, rise in bilirubin and LDH and an incompatible crossmatch not detectable pre transfusion.

Hyperhaemolysis is characterised by more severe haemolysis than DHTR, with haemolysis affecting the transfused red cells and the patient's own red cells; there is a decrease in Hb to below pre-transfusion levels, which is often associated with a reticulocytopenia. It may be triggered by a new red cell alloantibody, but frequently no new red cell antibody is identified. Hyperhaemolysis can be divided into acute and delayed hyperhaemolysis.

Abbreviations used in this chapter

AHTR	Acute haemolytic transfusion reaction
DAT	Direct antiglobulin test
DHTR	Delayed haemolytic transfusion reaction
ED	Emergency department
EPO	Erythropoietin
Hb	Haemoglobin
HTR	Haemolytic transfusion reaction
ICU	Intensive care unit
IV	Intravenous
IVIg	Intravenous immunoglobulin
LDH	Lactate dehydrogenase
SCD	Sickle cell disease
Sp-ICE	Specialist Services Integrated Clinical Environment

Key SHOT messages

- Avoidable transfusion/s continue to be reported resulting in patient death and major morbidity
- Poor communication contributes to incidents
- While there has been an increase in the number of cases of hyperhaemolysis reported in 2023, it remains under-recognised and under-reported

Recommendations

- Effective communication is vital to maintain transfusion safety, this includes communicating the reasons for, and risks of transfusion to the patient, communication between clinical areas and communication between hospitals

Action: All staff involved in transfusion

- Provide as much information as possible to SHOT when reporting, including the investigations performed, treatment modality and patient outcome

Action: Haemovigilance reporters

- Do not withhold lifesaving transfusion, even if the patient has a history of alloantibodies, and carefully monitor the patient for signs and symptoms of a haemolytic transfusion reaction

Action: Clinical staff involved in transfusion

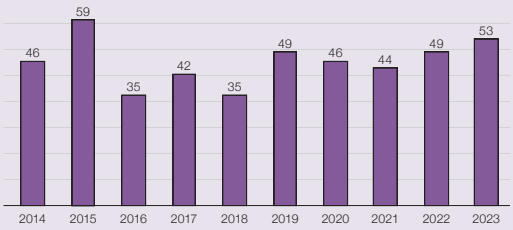
- Laboratory protocols should include a full investigation for HTR which might include referring samples when resources for testing are not available locally

Action: Laboratory staff involved in transfusion

Headline data 2023

Number of reports n=53
Deaths n=2
Major morbidity n=18

HTR reports by year



Demographic data

Male n=22
Female n=31
Adults n=49
Paediatric n=2
Unknown n=2

Blood component data

Red cells n=53
Platelets n=0
Plasma n=0
Multiple components n=0

Introduction

A total of 53 cases have been included, 9 acute, 31 delayed reactions and 13 cases of hyperhaemolysis. The total number of reactions reported is comparable to 2022 (49 cases), 2021 (44 cases) and 2020 (46 cases) but demonstrates a small increasing trend.

All reported cases occurred following red cell transfusions.

Age range and median

The patient's age was not provided in 2 reports (1 male patient and 1 female patient). The age range in the remaining cases was 12 to 95, with a median age of 47. This is shown in Figure 19.1, broken down further by gender. HTR were reported in 2 paediatric patients. In 31/53 (58.5%) of the reactions the patients were female.

Figure 19.1: Age range in males and females experiencing a HTR in 2023

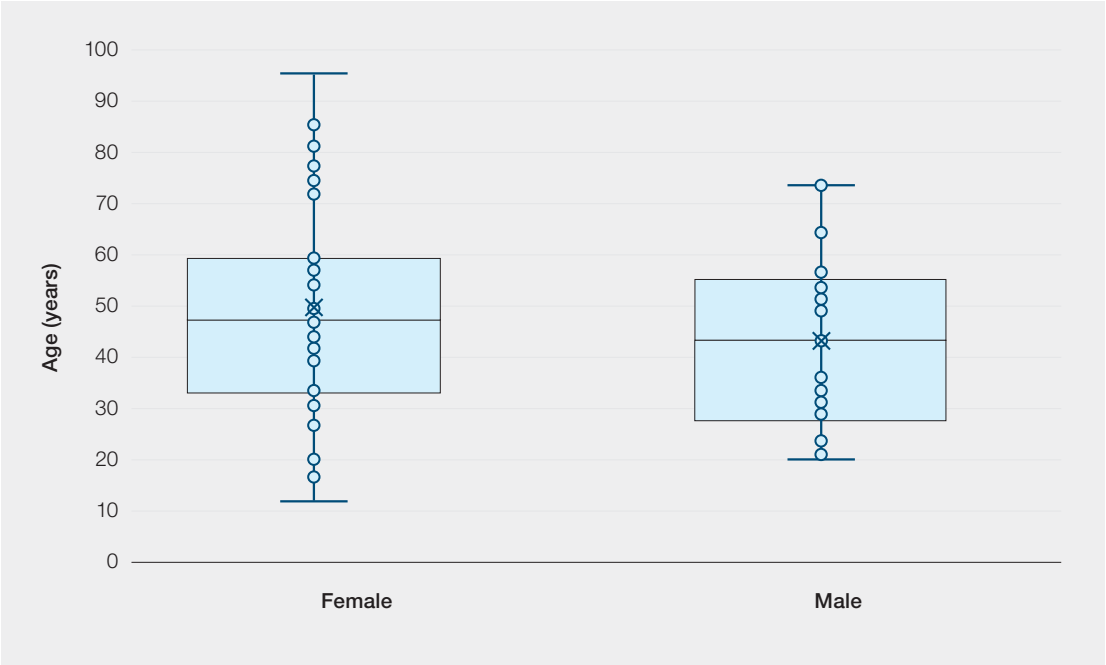


Figure 19.1 is a box and whisker diagram showing the median age and the age range of patients experiencing a HTR reported to SHOT separated by gender. The middle bar in the shaded box indicates the median age, the outer bars of the box represent the upper and lower quartiles. The lines extending from the boxes (whiskers) indicate the lowest and highest values.

Deaths related to transfusion n=2

Two deaths related to the transfusion reactions were reported (imputability 2). Both reactions occurred in patients with SCD.

Case 19.1: Fatal haemolytic transfusion reaction following unnecessary elective exchange transfusion

A patient with SCD was scheduled for an exchange transfusion in advance of elective surgery. The patient was informed that the surgery had been cancelled and despite this being communicated to the patient in advance of the transfusion, this information was not communicated to the haematology team and the exchange transfusion went ahead. Five days later the patient presented at the ED with severe pain and symptoms consistent with a delayed HTR. The patient later collapsed and suffered a cardiac arrest.

Case 19.2: Death attributed to hyperhaemolysis with delays in treatment

A patient with SCD and an existing heart condition presented to haematology outpatients with severe pain 5 days post transfusion. The patient did not have an appointment and was told to go to ED where they were admitted for suspected hyperhaemolysis and transferred to the ICU. The patient was treated with IVIg, methylprednisolone and eculizumab and was showing signs of recovery when they suffered cardiac arrest and died.

Major morbidity n=18

There were 18 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 6 cases of hyperhaemolysis reported with 'minor morbidity' were upgraded.

Hyperhaemolysis n=13

All 13 hyperhaemolysis cases reported occurred in patients with SCD. While the majority of hyperhaemolysis cases continue to be reported in this patient group, hyperhaemolysis does occur in other patient groups as shown in Table 19.1.

Clinical condition	Acute reaction	Delayed reaction	Total
SCD	26	21	**47**
T-cell lymphoma	1	0	**1**
Dosai-Dorfman syndrome	1	0	**1**
Myelodysplastic syndrome	0	1	**1**
Diamond-Blackfan anaemia	0	1	**1**
Myelofibrosis post transplant	1	0	**1**
Non-Hodgkin lymphoma	1	0	**1**
Total	**30**	**23**	**53**

Table 19.1: Hyperhaemolysis cases reported between 2017 and 2023

While the number of hyperhaemolysis cases reported in 2023 was comparable to previous years, it is suspected that hyperhaemolysis is still under-reported. 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).

Hyperhaemolysis can be divided into acute and delayed hyperhaemolysis. Acute hyperhaemolysis occurs within 7 days of transfusion and the DAT is usually negative. Delayed hyperhaemolysis occurs more than 7 days post transfusion and the DAT is often positive. In contrast to a classical DHTR, in delayed hyperhaemolysis both patient and transfused red cells are haemolysed (Danaee, et al., 2015). Six cases reported the reactions occurred within the first 7 days post transfusion.

Treatment in hyperhaemolysis

SHOT started requesting information on the treatment used to manage patients experiencing hyperhaemolysis in 2020. The aim is to provide a better understanding of practice nationally and improve and share knowledge. Eculizumab has been licensed to treat ongoing brisk haemolysis (NHSE, 2020) and was reported as being used in 1 case. SHOT data shows that patients are generally treated with a combination of IVIg, IV steroids and EPO. A summary of the treatment methods reported is provided in Figure 19.2. This demonstrates a move towards more aggressive treatment regimens with 12/13 (92.3%) patients receiving two or more different treatments in 2023.

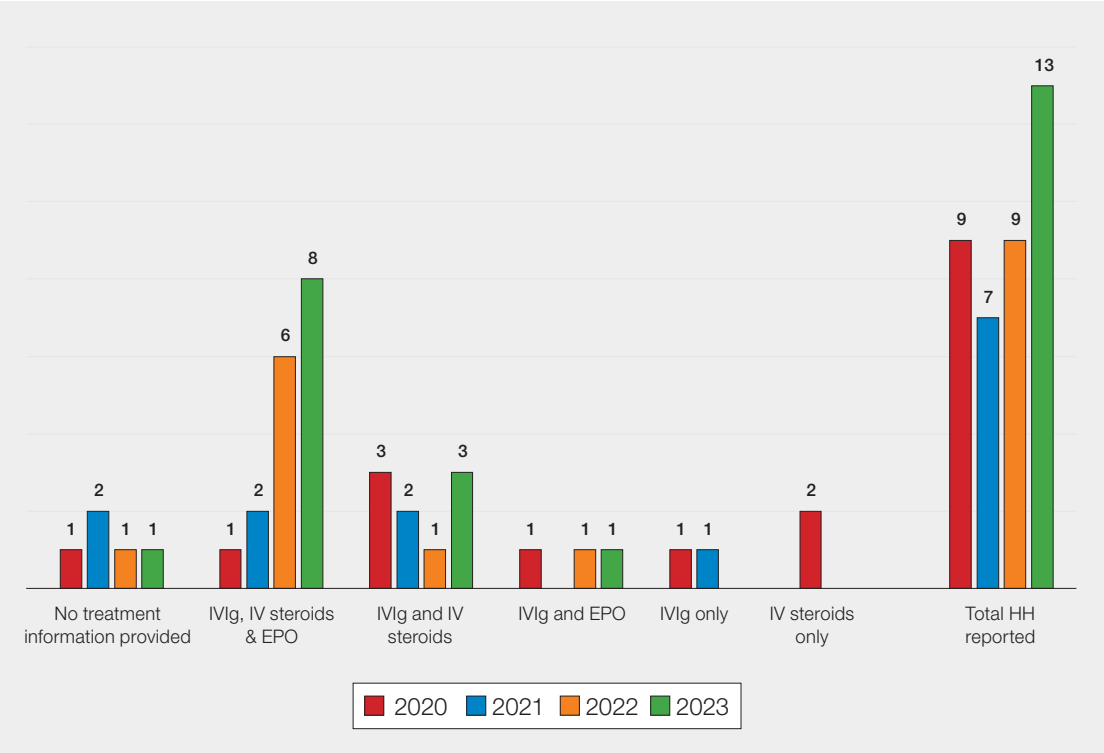


Figure 19.2: Treatments used to manage hyperhaemolysis

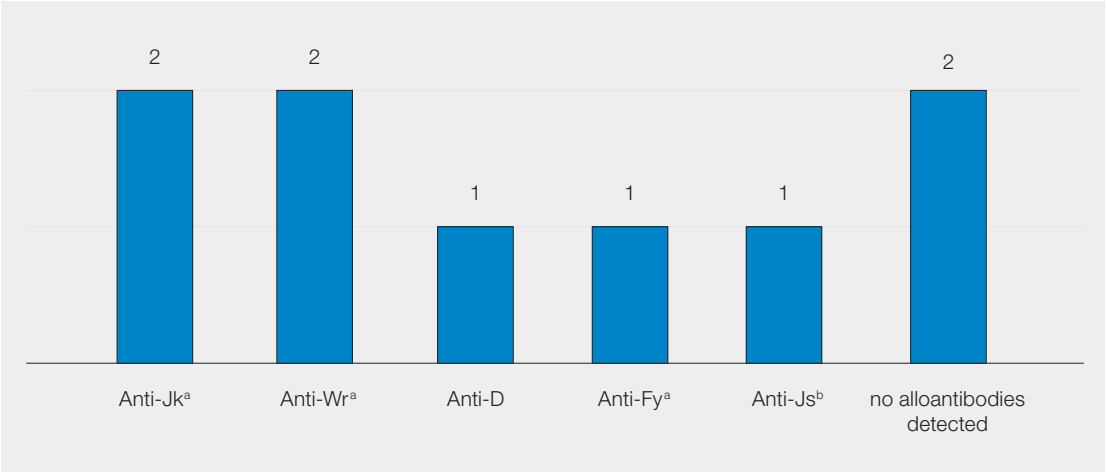
EPO=erythropoietin; HH=hyperhaemolysis; IV=intravenous; IVIg=intravenous immunoglobulin

Clinical and laboratory signs and symptoms

Acute haemolytic transfusion reactions n=9

Alloantibodies to red cell antigens were identified in 7 of the 9 AHTR cases reported. The alloantibodies implicated are shown in Figure 19.3.

Figure 19.3: Alloantibodies reported in AHTR in 2023



There were 2 cases reported in which no alloantibodies were detected. In 1 case the patient had a strongly active warm autoantibody. In the other case the antibody screen was negative in both the pre- and post-transfusion samples. The DAT was positive post transfusion but unfortunately an eluate was not performed.

In 4 cases, antigen-positive red cells were transfused urgently following advice from specialist transfusion medical staff.

The remaining case involved the presence of an anti-Js^{b} antibody.

Case 19.3: Acute haemolytic transfusion reaction in a patient with known anti-Js^{b}

A patient with a history of anti-Js^{b} was scheduled for major surgery with a high expected blood loss. Js^{b} antigen-negative blood is rare, with 100% of caucasians being Js^{b}-positive (Reid, et al., 2012) however two Js^{b}-negative units were provided from the Blood Service frozen blood bank and issued to the patient. Some additional 'best matched' Js^{b} untyped units were also crossmatched on standby in case of major blood loss which were placed in the theatre blood refrigerator in error. During the surgery a one-unit top-up transfusion was prescribed. One unit of the 'best matched' red cells was taken and transfused despite the compatible Js^{b}-negative units being available for transfusion. The patient immediately started to exhibit symptoms of an acute transfusion reaction but recovered fully following appropriate management.

Learning points

- 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 using concessionary release. An example form is outlined in the BSH 2013 guideline, appendix 9 (Milkins, et al., 2013)
- Where patients have complex blood requirements, the transfusion plan should clearly define blood availability and use

Delayed haemolytic transfusion reactions n=31

No clinical symptoms of a transfusion reaction were reported in 8/31 DHTR cases submitted to SHOT and in all 31 cases a lack of sustained Hb increment following transfusion was described.

Antibodies were detected in 28/31 of the DHTR reported and in 25 of these cases, alloantibodies were detected in the post-transfusion plasma that were not detected pre transfusion. In 5 of these cases, the antibody specificity implicated had been previously reported on Sp-ICE. One case involved the transfusion of antigen-positive emergency O D-negative red cells in an emergency.

Antibodies to the Kidd blood group system remain the most frequently implicated antibodies in DHTR however in contrast to previous years, in 2023, there were more cases due to anti-Jk^{b} than anti-Jk^{a} (Figure 19.4).

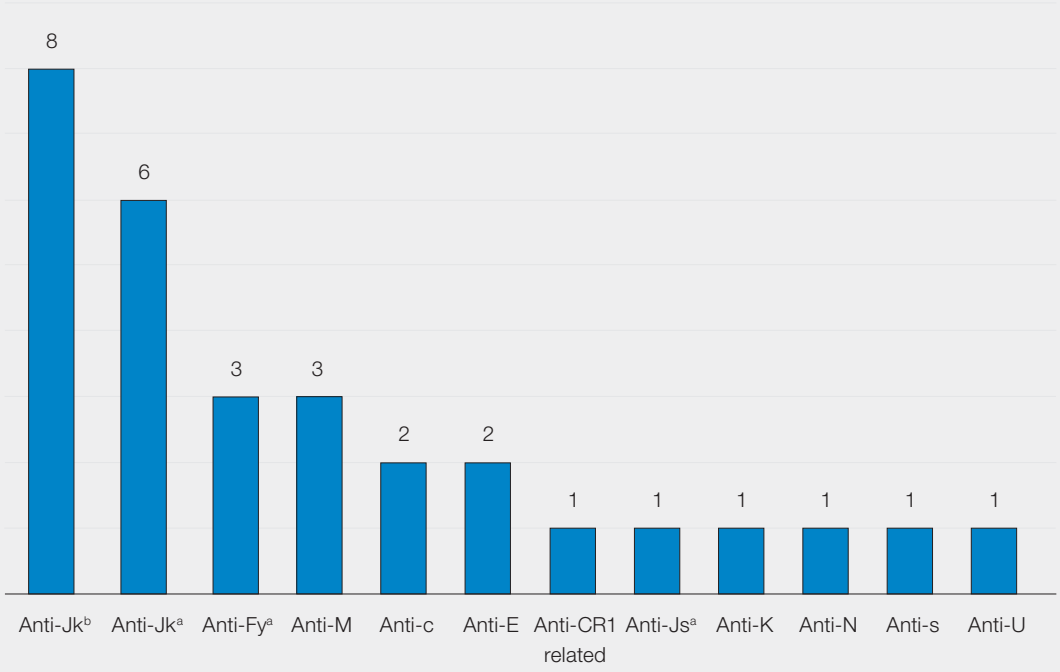
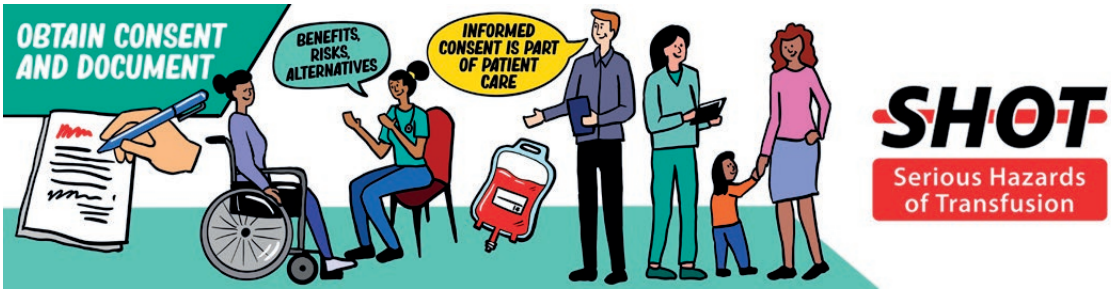


Figure 19.4: Alloantibodies implicated in DHTR in 2023

Unnecessary transfusions

There were 2 HTR reported in 2023 in patients whose transfusions were not indicated by current guidelines. One of these cases resulted in a patient death and has been described earlier in this chapter. The other transfusion was for a patient with iron deficiency.

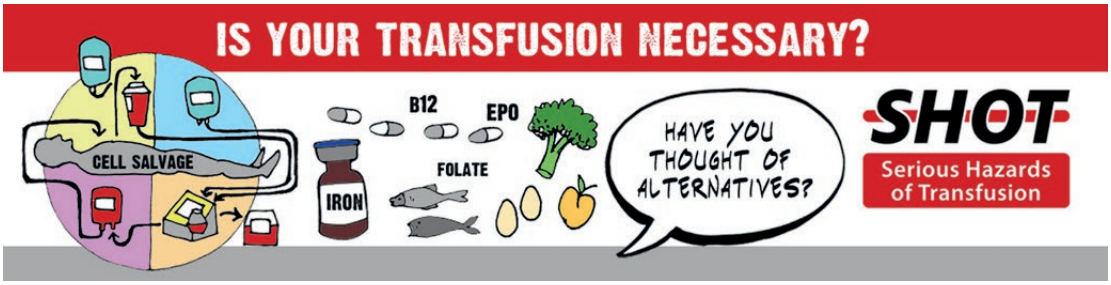
There was 1 further case reported in which the reason for transfusion and patient consent was not recorded in the patients notes and therefore the appropriateness of the transfusion cannot be assessed.



While the safety of transfusion continues to improve, it must be remembered that it is not without risks. Care should be taken to ensure that transfusions are only given where indicated and supported by published guidelines.

Learning point

- Transfusions should only be given where indicated and supported by published guidelines



Quality of data

Two potential cases had to be rejected due to insufficient information being available in the report to allow confirmation. Further cases which were included had key information missing from the report that limited the analysis of these cases. Examples of missing information included patient age, underlying clinical condition, reason for transfusion and the outcome of the laboratory investigations performed.

Conclusion

HTR continue to be a cause of transfusion-associated reactions and it is important that both clinical teams and patients are educated in the signs and symptoms of a HTR to allow their prompt management.

Many HTR, especially DHTR, are largely preventable and local protocols should be in place to reduce the risk, including the use of patient databases such as Sp-ICE, to identify historical antibody information.

All HTR should be reported to SHOT with as much information as possible provided to facilitate a better understanding of gaps in management and inform recommendations to improve safety.

Recommended resources

SHOT Bite No. 8: Massive Haemorrhage Delays
SHOT Bite No. 15: Hyperhaemolysis
SHOT Bite No. 31: Sp-ICE
https://www.shotuk.org/resources/current-resources/shot-bites/

References

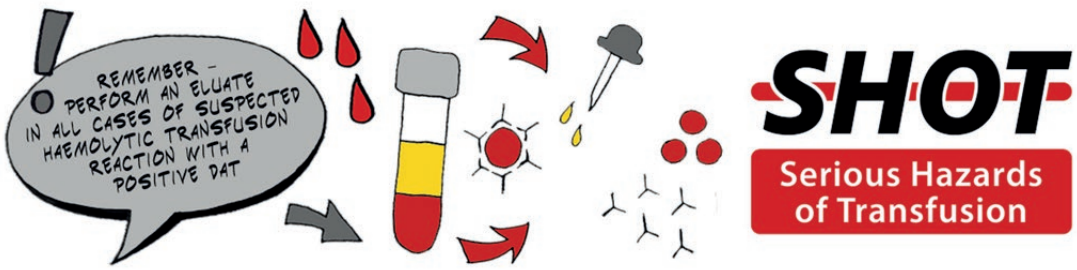
Adkins, B. D., Sharma, D. & Eichbaum, Q., 2020. Can we better predict delayed hemolytic transfusion reactions and hyperhemolysis in sickle cell disease?. *Transfusion and Apheresis Science,* 59(2), p. 102681. doi: https://doi.org/10.1016/j.transci.2019.102681.

Danaee, A., Inusa, B., Howard, J. & Robinson, S., 2015. Hyperhemolysis in Patients With Hemoglobinopathies: A Single-Center Experience and Review of the Literature. *Transfusion Medicine Reviews,* 29(4), pp. 220-230. doi: https://doi.org/10.1016/j.tmrv.2015.06.001.

Milkins, C. et al., 2013. Guidelines for pre-transfusion compatibility procedures in blood transfusion laboratories. *Transfusion Medicine,* 23(1), pp. 3-35. doi: https://doi.org/10.1111/j.1365-3148.2012.01199.x .

NHS England (NHSE), 2020. *Rituximab and eculizumab for the prevention and management of delayed haemolytic transfusion reactions and hyperhaemolysis in patients with haemoglobinopathies.* [Online] Available at: https://www.england.nhs.uk/publication/rituximab-and-eculizumab-for-the-prevention-and-management-of-delayed-haemolytic-transfusion-reactions-and-hyperhaemolysis-in-patients-with-haemoglobinopathies/ (Accessed 30 April 2024).

Reid, M. E., Lomas-Francis, C. & Olsson, M. L., 2012. Disease Association. In: *The Blood Group Antigen FactsBook.* 3rd ed. s.l.:Elsevier Ltd., p. 471.



20 Uncommon Complications of Transfusion (UCT) n=24

Authors: Caryn Hughes and Shruthi Narayan

Definition:

Pathological reaction or adverse effect in temporal association with transfusion which cannot be attributed to already defined side effects and with no risk factor other than transfusion and do not fit under any of the other reportable categories, including cases of transfusion-associated hyperkalaemia.

Abbreviations used in this chapter

BSH	British Society for Haematology	**ODP**	Operating department practitioner
Hb	Haemoglobin	**SpO2**	Oxygen saturation using pulse oximeter
IV	Intravenous	**UCT**	Uncommon complication of transfusion
NEC	Necrotising enterocolitis		

Key SHOT messages

- Atypical complications of transfusion can occasionally occur, and reporting such cases helps improve awareness and patient safety
- All relevant investigation findings, including laboratory test results are required by SHOT to enable accurate categorisation and imputability to be assigned

Recommendations

- Reporters are encouraged to continue to report cases with unusual reactions to transfusion including suspected cases of transfusion-associated neonatal NEC
- Investigations into suspected reactions should follow BSH guidelines (Soutar, et al., 2023)
- Information to raise awareness of unusual complications of transfusion should be incorporated into clinical transfusion training

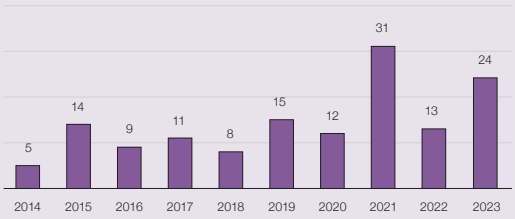
Action: Hospital transfusion committees, all staff involved in transfusion

SHOT
Serious Hazards of Transfusion

Headline data 2023

Number of reports n=24
Deaths n=2
Major morbidity n=1

UCT reports by year



Demographic data

Male n=10
Female n=13
Unknown n=1

Adults n=17
Paediatric n=6
Unknown n=1

Blood component data

Red cells n=20
Platelets n=4
Plasma n=0
Multiple components n=0
Other n=0

Introduction

This category includes cases with uncommon reactions reported in patients with a temporal relation to transfusion which cannot be classified into other categories. Patients often have multiple comorbidities which may contribute to the complication noted. Reporting and analysing these helps to facilitate our ever-evolving understanding of transfusion complications thereby improving the safety of transfused patients through the implementation of appropriate risk-reduction measures. Occasionally, uncategorisable error reports are included in UCT to ensure learning is captured and shared.

Deaths related to transfusion n=2

There were 2 deaths reported in this category, both recorded as imputability 1, possibly related to transfusion.

Case 20.1: Acute transfusion reaction resulting in patient death

An elderly patient with myelodysplastic syndrome and chronic transfusion-dependent anaemia developed sudden onset acute abdominal pain, along with associated nausea while receiving a second unit of red cells in an outpatient setting. The red cells were compatible, and all pre-administration checks had been performed as required. The transfusion was stopped immediately, all observations were within normal range with no pyrexia, hyper or hypotension, tachycardia, or bradycardia. The IV line was changed for IV saline. The patient was reviewed by the medical team and given chlorphenamine IV and hydrocortisone IV. The unused blood was returned to the transfusion laboratory along with the relevant blood samples. The unit was tested locally and was sent to the Blood Service for further testing. The patient was admitted to the ward and was treated for a transfusion reaction, further deterioration, and for suspected sepsis. The patient subsequently died, and the case was referred to the coroner.

No further details on the outcome of the coroner's investigation or laboratory findings were available to SHOT. While the clinical picture could be multifactorial, the case has been included here in view of the temporal relationship of the reaction with transfusion.

Case 20.2: Acute deterioration and death following a red cell transfusion in a neonate with pre-existing comorbidities

A premature baby required intubation in the delivery room and was transferred to the neonatal unit for respiratory support. The baby was noted to have acute respiratory distress syndrome,

hyperkalaemia, suspected sepsis, mild left pulmonary artery stenosis, anaemia of prematurity, hyperglycaemia, acute bowel, possible NEC. On day 28 post delivery, anaemia was treated with red cell transfusion based on a Hb of 84g/L. The transfusion event was uneventful but a concerning change in the infants' condition was noted later the same day with the presentation of a distended tense abdomen. The infant continued to deteriorate, requiring additional interventions and support, including re-intubation. The baby was diagnosed with a bowel perforation and worsening metabolic acidosis. Despite all efforts, the baby died.

The likelihood that the death was related to the transfusion was originally reported with an imputability of 3 (certain) however, based on the information provided, and following discussion with paediatric haemovigilance experts, the imputability was downgraded to 1 (possible). This case is also described in Chapter 24, Paediatric Cases, Case 24.1.

Major morbidity n=1

Case 20.3: Venous air embolism following inappropriate preparation of line prior to transfusion

A postoperative patient in recovery required a recheck of Hb with a decision to transfuse red cells if the Hb was <80g/L. The first Hb result was 83g/L but following repeating testing Hb was 78g/L which deemed the transfusion necessary, and a unit of red cells was requested from the transfusion laboratory. The first nurse was instructed to go on a break and a handover was given to the ODP who would take over the patient's care and initiate the transfusion. The ODP checked the blood component with the authorisation/prescription and patient's identification band and spiked the blood bag with a giving set. The giving set included a warming device and extension line distal to the warmer and attached to the patient's IV cannula. The patient quickly presented with central chest pains and a decreasing saturation - SpO2 to 50%.The transfusion was stopped, and a possible transfusion-related reaction was suspected. It was noted that approximately 10cm of wide bore extension tubing was clear and a rapid call was sent to the floor anaesthetist for medical assistance. A transfused air embolus was confirmed. A rebreathing mask was applied at 15L of oxygen which was changed to water circuit with positive end-expiratory pressure. The SpO2 increased to 96%. Crystalloids were commenced and the patient was transferred to the high-dependency unit for level 2 care for further observation. The patient was visited by the attending consultant anaesthetist and duty of candour was applied. The patient recovered and survived.

This case was initially reported as a handling and storage error, but after review, in view of adverse patient impact, this case was transferred to the UCT category.

There was a complete and thorough investigation into this case. The investigation considered several aspects including the presence of the handover documentation in the patient's notes, staffing levels at the time which were deemed to be safe and the environment, which was described as calm and free from external distractions. Consideration was given to the use of infusion pumps which may have mitigated some risk by the identification of air within part of the giving set. It was noted that the department fostered an open culture and actively encouraged all members of the team to speak up when they had concerns regarding patient safety. The surgical care pathway, anaesthetic charts, prescription, and critical care notes were clearly documented and provided an accurate account of instructions, timeline, and interventions. The ODP had attended training for blood transfusion however, this had occurred during the COVID-19 pandemic, which meant that underpinning knowledge may not have been optimal. Furthermore, the practitioner's exposure to transfusion practice was minimal and it was recognised that the gap in knowledge and skills contributed to the error.

Other UCT cases n=21

There were 3 paediatric cases, which were part of a cluster of 5 cases all from the same hospital and were unusual transfusion reactions in multiply transfused patients. These reactions had common features including rapid onset after small volume of red cells transfused, coughing, chest tightness, drowsiness in 4/5, wheeze in 2/5. Four out of 5 patients received adrenaline. These are discussed in Chapter 24,

Paediatric Cases. Two of the 5 cases met the criteria for FAHR and are therefore included in Chapter 17, Febrile, Allergic and Hypotensive Reactions (FAHR). The other 3 cases, however, were atypical and have therefore been assigned to UCT. Despite detailed review and investigation, no underlying common cause for the cluster of reactions was identified. These cases highlight the importance of local review of transfusion reactions by hospital transfusion teams as the fact that they all occurred at the same location would not have been detected by SHOT.

Several other cases were reported in this category and have been detailed in the supplementary information on the SHOT website (https://www.shotuk.org/shot-reports/report-summary-and-supplement-2023/).

Learning points

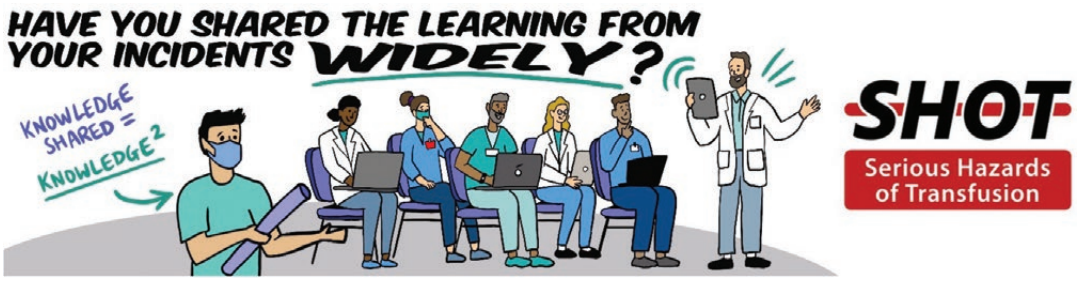
- Patients experiencing new, unusual symptoms or signs associated with a transfusion must be evaluated promptly and treated as expeditiously as possible to minimise the impact
- Clinical staff involved in transfusion must be adequately trained to recognise, and be encouraged to report, uncommon complications of transfusion
- A defined process for reporting, reviewing, and trending non-typical complications of transfusion will ensure learning from these events, inform practice, and improve transfusion safety

Conclusion

Patients receiving transfusions often have complex underlying comorbidities which may mimic or mask a transfusion reaction. This makes it challenging for healthcare staff to assign accurate imputability of the patient's reaction/complication to transfusion. All staff involved in the transfusion process have an integral part to play in the early identification, management, investigation and reporting of unusual reactions to transfusion in neonates, children, and adults. Improving knowledge on recognising transfusion reactions for all staff involved in the monitoring of transfusion recipients is vital for the early detection and treatment of these to minimise the impact of the reaction and optimise transfusion safety.

Reference

Soutar, R. et al., 2023. Guideline on the investigation and management of acute transfusion reactions. *British Journal of Haematology,* 201(5), pp. 832-844. doi: https://doi.org/10.1111/bjh.18789.



21 Transfusion-Transmitted Infections (TTI) n=4 (2 confirmed, 2 probable)

Authors: Tali Yawitch, Katy Davison, Heli Harvala, and Su Brailsford

Definition:

Included as a TTI if, following investigation, the recipient had evidence of infection post transfusion, there was no evidence of infection prior to transfusion and no evidence of an alternative source of infection.

AND

Either at least one component received by the infected recipient was donated by a donor who had evidence of the same infection.

Or at least one component received by the infected recipient was shown to contain the agent of infection. These may be identified because of infection in the recipient where transfusion is the suspected source, and a post-transfusion infection reported to the Blood Services.

Alternatively, an infection in a recipient may be identified from lookback investigations which are initiated when a donation from a repeat donor is identified as having markers of infection. Archive samples are retrieved for retrospective testing, which may find a previous donation to also be positive but with markers of infection below the detection level of routine screening. In this case further work will be carried out to identify recipients.

Note that for the purposes of the European Union legislation, serious adverse reactions (SAR) are defined as any reactions in patients that are 'life-threatening, disabling or incapacitating, or which result in, or prolongs, hospitalisation or morbidity'. These must be reported to the Medicines and Healthcare products Regulatory Agency (a legal requirement). This includes all confirmed transfusion-transmitted infections.

Abbreviations used in this chapter

AABB	Association for the Advancement of Blood and Biotherapies
ALT	Alanine aminotransferase test
anti-HBc	Antibodies to hepatitis B core antigen
anti-HBs	Antibodies to hepatitis B surface antigen
BSH	British Society for Haematology
CJD	Creutzfeldt Jakob disease
CMV	Cytomegalovirus
DNA	Deoxyribonucleic acid
EBV	Epstein-Barr virus
EIAR	Emerging Infectious Agents Report
FDA	Food and Drug Administration
FFP	Fresh frozen plasma
IU/L	International units per litre
JPAC	Joint United Kingdom (UK) Blood Transfusion and Tissue Transplantation Services
NAT	Nucleic acid testing
NHSBT	National Health Service Blood and Transplant
NIBTS	Northern Ireland Blood Transfusion Service
OBI	Occult hepatitis B virus (HBV) infection
RNA	Ribonucleic acid
SaBTO	Advisory Committee on the Safety of Blood, Tissues and Organs
SACTTI	Standing Advisory Committee on Transfusion Transmitted Infection

HAIRS	Human Animal Infections and Risk Surveillance group
HAV	Hepatitis A virus
HBV	Hepatitis B virus
HCV	Hepatitis C virus
HEV	Hepatitis E virus
HIV	Human immunodeficiency virus
HSV	Herpes simplex virus
HTLV	Human T-cell lymphotropic virus
IgG	Immunoglobulin G antibody
IgM	Immunoglobulin M antibody
SAR	Serious adverse reactions
SARS-CoV-2	Severe acute respiratory syndrome coronavirus 2
SNBTS	Scottish National Blood Transfusion Service
TMER	Transfusion Medicine Epidemiological Review
TTI	Transfusion-transmitted infections
UK	United Kingdom
UKHSA	United Kingdom Health Security Agency
vCJD	Variant Creutzfeldt Jakob disease
WBS	Welsh Blood Service
WNV	West Nile virus

Key SHOT messages

- It is important that any suspected TTI is reported to allow investigation, however, it should be noted that confirmed or probable TTI are rare
- Suspected TTI should be discussed with the consultant microbiologist, virologist and/or other infection diseases expert to confirm the diagnosis and following that, reported to the appropriate UK Blood Service for further investigations
- 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 acute HBV, HCV, and HIV infections this has been estimated to be less than 1 in 1 million donations tested and confirmed and probable transmissions remain rare with very few numbers each year
- The UK Blood Services continue to monitor rates of infection in donors to sustain a safe supply of blood components
- SHOT data is used to inform policy and change it when necessary. Additional hepatitis B anti-core testing has been introduced to reduce the risk of hepatitis B transmission from donors with occult hepatitis B where viral levels may be below the level of detection by the previous routine screening assays

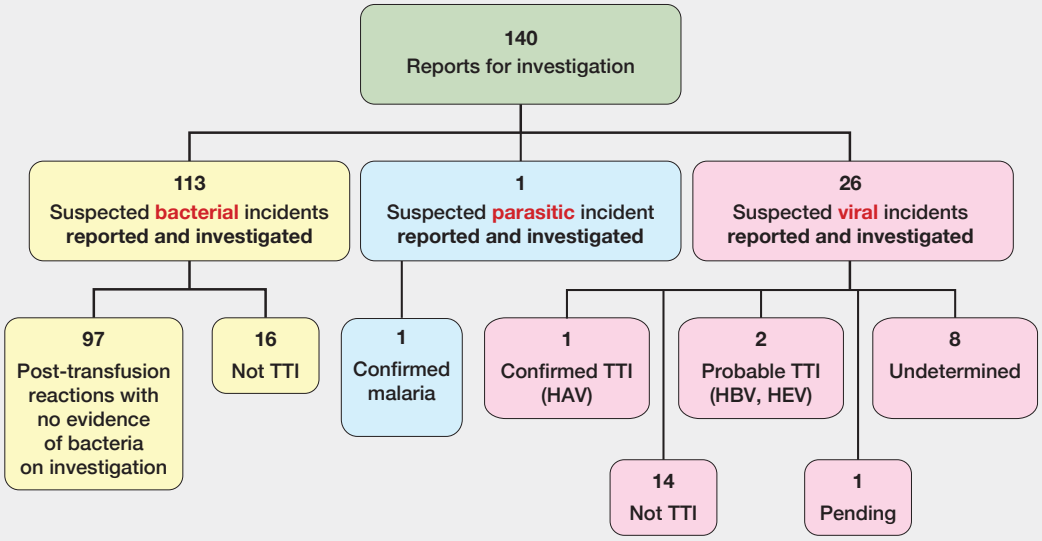
Introduction

This chapter describes suspected TTI incidents investigated by the UK Blood Services and reported to the UKHSA and NHSBT's joint Epidemiology Unit's surveillance scheme in 2023. 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.

Summary of investigations in 2023

During 2023, the UK Blood Services investigated 113 suspected bacterial incidents, 1 suspected parasitic incident and 26 suspected viral incidents (Figure 21.1).

Figure 21.1: Outcomes of suspected TTI reported to NHSBT/UKHSA Epidemiology Unit and investigated in 2023 in England, Northern Ireland, Scotland, and Wales



TTI=transfusion-transmitted infection; HBV=hepatitis B virus

Please note:

A confirmed TTI is as per the definition with evidence that the virus/bacterium is indistinguishable on molecular typing between patient and donor/donation.

- *A probable TTI is as per the definition, but where molecular typing cannot be carried out to confirm this.*
- *A possible TTI is as per the definition, but where prior infection or an alternative source could not be completely excluded.*
- *Not a TTI is defined as an investigation that concluded the infection in the recipient was NOT caused by transfusion, either as all indicated donors were traced and none of them were shown to be infected; or there was no evidence of infection in the recipient; or they were shown to be infected already prior to transfusion.*
- *A near miss is defined as either an infection was identified in the unit due to be transfused however the unit was NOT transfused (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.*
- *An undetermined conclusion is when the investigation has been completed as far as possible, however it is not possible to confirm or refute blood transfusion as cause of infection in recipient.*

Deaths related to transfusion n=0

None of the patients with confirmed TTI investigated in 2023 were reported to have died.

Major morbidity n=4

There were 4 cases with major morbidity following investigations in 2023, as detailed below.

Case 21.1 - Confirmed HAV, cleared the infection

Case 21.2 - Probable HEV, cleared the infection with treatment

Case 21.3 - Probable HBV, chronic HBV infection, likely lifelong treatment

Case 21.5 - Confirmed malaria, clearing the infection after treatment

Near misses n=0

There were no near misses reported in 2023.

Bacterial TTI reports in 2023

In 2023, no reported suspected bacterial TTI investigations were concluded to be confirmed, probable or possible.

Since 2011, all four UK Blood Services have used the BacT/ALERT system for bacterial screening which has been successful in reducing the risk of bacterial TTI, together with diversion and arm cleansing (McDonald, et al., 2017). The details are described in Table 21.1.

	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

Table 21.1: Bacterial screening methods used by the UK Blood Services

Bacterial TTI 1996-2023

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 9 such near misses, all but one in platelet components, reported between 2011 and 2023. Overall, of 37 incidents of bacterial transfusion-transmissions to individual recipients, 30 have been caused by the transfusion of platelets, 7 by red cells and 1 by FFP (Table 21.6) since reporting began in 1996. The introduction of bacterial screening of platelets, most recently by England in 2011, has had a significant impact in the numbers of bacterial TTI.

Current BSH guidance recommends that patients are advised to report any symptoms that occur within 24 hours of transfusion although patients with confirmed bacterial TTI generally become unwell very rapidly, often during transfusion (Soutar, et al., 2023). Clinical teams are reminded that any suspected bacterial TTI should be discussed with the relevant blood service so that, if appropriate, packs can be returned for culture and any other associated packs recalled.

Viral TTI reports in 2023

The number of viral TTI investigated in 2023 includes 2 reports where blood not tested for CMV was used in an emergency where normally CMV negative blood should have been requested, hence retrospective CMV testing was 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 10, Incorrect Blood Component Transfused (IBCT) of this Annual SHOT Report.

Case 21.1: Confirmed HAV transmission

Post-donation information prompted this lookback investigation. A regular donor developed symptoms of acute hepatitis within two weeks of their most recent blood donation and was subsequently diagnosed with a HAV infection. Both HAV IgM antibodies and RNA were detected in their blood sample. The recipient was identified and followed up for HAV testing. The patient was asymptomatic at the time of diagnosis of their HAV infection, they subsequently developed significant transaminitis with a peak ALT of 730 IU/L. Donor and recipient virus sequences were identical, a rare 1B subgenotype, confirming that this HAV infection was acquired via a red blood cell blood transfusion. The implicated donor was deferred from donation for 6 months, but will be eligible to donate, as HAV (like HEV) does not cause a chronic infection in healthy individuals. HAV infection is generally very rare in the UK and hence blood donations are not routinely screened for this virus. Testing for HAV (together with human parvovirus B19) will be undertaken by Blood Services in England and Scotland from Spring 2024 to facilitate collection of plasma for fractionation.

Case 21.2: Probable HEV transmission

A renal transplant recipient was diagnosed with HEV infection following abnormal liver function tests. HEV infection of the transplanted organ had been excluded, hence it was considered whether they might have acquired it via the plasma exchange or blood transfusions received during 2022. A total of 86 donor exposures (2 reds cell units and 84 FFP units) were identified for investigations. Archive samples from two of these donors tested positive for HEV RNA, but due to very low viral loads, sequencing of donor viruses was not successful. HEV genotype 3c was identified in the stored sample from the recipient. Due to a lack of sequence confirmation, this case is reported as a probable transmission. Both donors have now resolved their infection and are eligible to return to donation.

Case 21.3: Probable HBV transmission

An older person was diagnosed with acute HBV infection during their hospital admission in December 2022. Blood transfusion was considered as the most likely source of their HBV infection. They had received multiple transfusions six months prior to diagnosis of HBV; 33 donor exposures were investigated. The archive samples obtained from two donors subsequently tested positive for anti-HBc antibodies (note these donations were collected before the full implementation of anti-HBc screening in England), one donor (donor 1) had evidence of past HBV infection with high levels of anti-HBs antibodies (999 IU/ml) whereas another donor had HBV infection with low levels of anti-HBs antibodies (donor 2). HBV DNA was not detected in either donor. It is probable that the recipient acquired the hepatitis B infection via the blood transfusion from donor 2. Transmission could not be confirmed but circumstantial evidence of this donor originating from the region where recombinant genotype D/E is prevalent, the same genotype as that identified in the patient, further supports transmission. The two anti-HBc positive donors have been removed from the donor panel.

Update on Viral TTI investigation reports from 2022

There were nine additional investigations from 2022 which were not reported in the 2022 report but have since been finalised. These include 1 CMV, 2 HBV, 2 HCV, 2 HEV, 1 HSV and 1 toxoplasmosis investigation, which were concluded as possible (n=1), not TTI (n=6) or undetermined (n=2).

Case 21.4: possible HCV transmission – result pending in the 2022 Annual SHOT Report

A recipient with transfusion dependent beta thalassaemia regularly transfused in the UK was noted to have abnormal liver function tests in September 2021. Although it was initially considered to be due to transfusion related iron overload, subsequent diagnosis of past HCV infection was made. The patient had never been reported as HCV RNA positive, but antibody testing was suggestive of past HCV infection. However, it is difficult to estimate when they actually acquired HCV infection as the infection is known to remain asymptomatic for years, if not decades.

As this recipient had not been tested for HCV antibodies prior to 2021 and was not known to have ever been HCV RNA positive, it is difficult to estimate when they acquired their HCV infection. Based on their transfusion history over many decades, it is worth noting that the risk of acquiring HCV via blood transfusion in the UK was highest before the screening for HCV antibodies was introduced in 1991 and for HCV RNA in 1999. The residual risk of testing not detecting HCV has significantly reduced since the screening was implemented, and the latest (2020-2022) estimates of residual risk of HCV in the UK is approximately 1 in 64 million blood donations tested (JPAC, 2023). Testing all previous donations was not possible as the archive samples no longer existed for the donations taken prior to the implementation of screening. It is therefore possible that this individual acquired the HCV infection via blood transfusion.

Confirmed viral TTI 1996-2023

The year of transfusion may be many years before the year in which the incident is investigated and/or reported to SHOT due to the chronic nature, and possible late recognition, of some viral infections. Since 1996, 33 confirmed transfusion-transmitted viral infections have been documented in the UK. Among these, HBV (n=11) and HEV (n=12) were the most reported proven viral TTI. For HBV, this is

partly because the 'window period', 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. Since 2022, anti-core screening has been undertaken to reduce the risk of HBV transmission from donors with occult HBV.

All except two of the 12 HEV transmissions were reported before the HEV RNA testing was introduced in April 2017 in the UK (Harvala, et al., 2022), which has identified and removed 2932 HEV RNA positive blood donations from the UK blood supply to end of 2023. 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.

Parasitic TTI

In 2023, there was one parasitic TTI investigation for malaria. This was concluded to be a confirmed transmission.

Case 21.5: Confirmed malaria

A malaria diagnosis in a recipient of multiple red cell transfusions with no overseas travel or other likely risk initiated an investigation into the likely source of this infection. Testing of archive samples from donations identified between February and September 2023 were shown to be negative on routine screening for malaria antibodies. Despite negative initial screening results, samples from six donors were subjected to further testing based on their clinical history, one of whom was identified with Plasmodium malariae DNA in their blood sample and identified as the likely source of transmission. Further work is ongoing to type the malaria found in the donor and recipient, but the donor has been removed from the donor panel and appropriate medical review arranged. A lookback has been initiated into previous donations given by this donor. To date the approach of discretionary malaria antibody testing of donors based on travel history has been effective in preventing transfusion transmission of malaria, the last reported transmission in the UK was in 2003. However, following this transmission, current policies and procedures are being reviewed to see if any further mitigations are required. The patient has received treatment and is clearing their infection.

Lookback investigations

Lookback investigations are initiated in England when regular donors are found to be newly positive for a marker of infection, either seroconversion, post-donation information or introduction of a new test. In 2022 a new test for anti-HBc was introduced, and lookback investigations were initiated. During 2023, NHSBT initiated investigations prompted by 20 donors with newly detected markers of infection known to have previously donated (15 of those investigations are detailed below and shown in Table 21.2). Archive samples were available for testing for 11 donors (3 HEV [2 from TTI investigation of Case 21.2], 4 OBI and 4 syphilis) but for 4 donors the most recent negative donation had been given more than three years ago and therefore no archive was available for testing (1 EBV and 3 syphilis). Investigations involved 30 previous donations, with 40 of 45 components issued known to be transfused.

Of the 40 recipients identified, 19 were alive and 17 were tested with none found to have evidence of transmission. In lookback investigations, test results confirming negative recipient status include anti-HBc negativity 6 months post transfusion for HBV, no treponemal antibodies detected for syphilis or no RNA and IgG/IgM antibodies at 6 months post transfusion for HEV. In addition, lookback was commenced for two donors with HTLV infection with a history of donating in the 1990's, prior to leucodepletion and before anti-HTLV screening was implemented. Although NHSBT were able to identify which hospital these units had been issued to, hospitals have not been able to identify the possible recipients despite their best efforts to date (Hewitt, et al., 2013). In addition, there were two malaria and one HIV lookbacks initiated, information from these investigations is awaited.

Table 21.2: Summary of lookback investigations in England, 2023

	EBV	HEV	OBI	Syphilis	Total
Donors with a previous donation identified as positive in retrospective testing	1	3	4	7	15
Archive samples available for testing	0	3	4	4	11
Donations by these donors considered here	1	3	19	7	30
Total components from these donations	**1**	**4**	**26**	**14**	**45**
FFP	0	0	5	2	7
Plasma for medicine	0	0	1	0	1
Platelets	0	2	1	6	9
Red cells	1	2	19	6	28
Not known	0	0	0	0	0
Components reported as transfused (recipients transfused)	**1**	**4**	**24**	**11**	**40**
Recipient identified but deceased	0	3	10	7	20
Recipient identified and alive	1	1	13	4	19
Recipient status unknown	0	0	1	0	1
Recipients tested	**1**	**1**	**13**	**2**	**17**
Recipient tested positive	1*	0	0	0	1*
Recipients tested negative	0	1	12	2	15
Recipient test pending	0	0	1	0	1

** The recipient was IgG positive, which was not unexpected given their age so evidence of past EBV but unlikely due to the transfusion*

In 2023, lookback data was only reported for England.

Other reports

Not all reports proceed to a full investigation if transmission can be ruled out, as in some examples below.

- If a recipient only tests positive for antibodies to infection, it is possible that passive transfer of antibodies has occurred due to receipt of intravenous immunoglobulin. If passive transfer is suspected, repeat testing should be carried out 4-6 weeks after the transfusion date. If it is the passive transfer of antibodies, then reactivity should have resolved within this time, and the recipient will not have any evidence of infection
- In recipients where only IgM antibodies are detected, reactivity for RNA/DNA and seroconversion (e.g., IgG) would also need to be confirmed before TTI investigations commenced. This is because IgM assays are often cross-reactive and non-specific, so isolated IgM reactivity is not usually diagnostic
- In recipients with evidence of a chronic infection, previous negative results are desired. This is to evidence transfusion as being the most likely source of infection
- For older cases of possible TTI, year of transfusion should be provided for the implicated transfusions in addition to the unit numbers to enable effective investigation by the Blood Services

Residual risk of HBV, HCV, or HIV

The chance, or residual risk, of a potentially infectious HBV, HCV or HIV window period donation not being detected on testing in the UK are estimated to be very low at less than 1 per million donations

tested (Table 21.3) (JPAC, 2023). 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. The residual risk of HEV is not routinely calculated but has been previously estimated to be considerably higher than for HBV, HCV, or HIV. However, while HEV is a blood borne virus, the main route of transmission is zoonotic with humans generally exposed through diet (Harvala, et al., 2022).

	HBV	HCV	HIV
Number per million donations	0.63	0.02	0.03
95% confidence interval	*(0.46-1.61)*	*(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	34 years	17 years

Table 21.3: The estimated residual risk (and 95% confidence interval) that a donation entering the UK blood supply is a potentially infectious HBV, HCV, or HIV window period donation: 2020-2022

Far fewer TTI are observed in practice than the estimated risks in Table 21.3 indicate, partly because the estimates have wide uncertainty and the model used to calculate risk is based on the risk in all donations tested. The model does not incorporate pack non-use, recipient susceptibility to infection, or under-ascertainment/under-reporting, for example due to recipients dying from an underlying medical condition before a chronic asymptomatic viral condition is identified, or, in the case of HBV, an asymptomatic acute infection.

Blood donation testing and surveillance

Every blood donation in the UK is tested for markers of HBV, HCV, HEV, HIV, HTLV (for new donors and non-leucodepleted products for NHSBT and SNBTS and testing of all donors for NIBTS and WBS) and syphilis, with some donations also tested for malaria, *Trypanosoma cruzi* and WNV, depending on donor history. Information about donations tested and donors found positive is carefully monitored to help assure safety for recipients (NHSBT and the UKHSA Epidemiology Unit, 2023).

Anti-HBc screening for blood donations was rolled out as part of routine screening across the UK in 2022 in response to a review carried out by SaBTO (SaBTO, 2023). This has already had an impact on increased detection of potentially transmissible HBV from donors with OBI, which have been removed from the blood supply. Lookback investigations involving the testing of archive samples from donors with OBI continues and lookback investigations into the archive samples of hepatitis B core antibody positive donors began in the UK in 2023. The WBS changed to individual HEV NAT screening for apheresis donations during November 2022 and SNBTS are due to change to individual HEV NAT screening for apheresis donors from April 2024. Testing of plasma for medicine donations for HAV and B19 is anticipated to start in April 2024 in Scotland and England.

The HEV screening process is currently under review by SaBTO (SaBTO, 2024), the report is expected to be published in 2024.

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 (JPAC, 2023).

In 2023, arbovirus (dengue and WNV) outbreaks and spread, particularly within Europe continued to be monitored carefully. WNV testing for travellers returning from France and Spain had to be extended northwards to newly affected regions while blood donors returning from France and Italy are now subject to either WNV testing or a 28-day deferral for dengue depending on the areas visited, increasing complexity on donation sessions. In the UK, Usutu virus is being carefully monitored after spread in birds was detected (UKHSA on behalf of the joint HAIRS, 2023).

There were no known cases of transfusion-transmitted SARS-CoV-2 infections reported to the Blood Services in 2023 and there is still no evidence that SARS-CoV-2 is a TTI (Gates, et al., 2023).

vCJD 2023

There were no vCJD investigations in 2023.

vCJD 1996-2023

Three vCJD incidents took place prior to the introduction of leucodepletion and other measures taken by the UK Blood Services to reduce the risk of vCJD transmission by blood, plasma, and tissue products. All these measures have been reviewed and endorsed by SaBTO (Department of Health and Social Care, 2013).

Surveillance continues to look for any evidence that vCJD or CJD could still be transmitted via the blood supply with no case of vCJD being identified for investigation since 2016 and no evidence of sporadic CJD being transmitted by the blood supply (NCJDRSU, 2023). 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, 2024).

Table 21.4: Number of confirmed TTI incidents, by infection in the UK, reported to SHOT, with transfusions between October 1996 and December 2023 (Scotland included from October 1998

Year of transfusion	Bacteria	HAV	HBV	HCV	HEV	HIV	Malaria	Parvovirus (B19)	vCJD or prion	Total
1996	1	1	1	1	0	1(3)	0	0	1	6 (8)
1997	3	0	1	1	0	0	1	0	2	8
1998	3	0	1	0	0	0	0	0	0	4
1999	4	0	2 (3)	0	0	0	0	0	0 (1)	6 (8)
2000	6	1	1	0	0	0	0	0	0	8
2001	5	0	0	0	0	0	0	0	0	5
2002	1	0	1	0	0	1	0	0	0	3
2003	2	0	1	0	0	0	1	0	0	4
2004	0	0	0	0	1	0	0	0	0	1
2005	1	1	1	0	0	0	0	0	0	3
2006	2	0	0	0	0	0	0	0	0	2
2007	2	0	0	0	0	0	0	0	0	2
2008	4 (6)	0	0	0	0	0	0	0	0	4 (6)
2009	2 (3)	0	0	0	0	0	0	0	0	2 (3)
2010	0	0	0	0	0	0	0	0	0	0
2011	0	0	1 (2)	0	1 (2)	0	0	0	0	2 (4)
2012	0	0	0	0	2	0	0	1	0	3
2013	0	0	0	0	0	0	0	0	0	0
2014	0	0	0	0	1 (2)	0	0	0	0	1 (2)
2015	1	0	0	0	5 (6)	0	0	0	0	6 (7)
2016	0	0	0	0	0	0	0	0	0	0
2017	0	1	0	0	0	0	0	0	0	1
2018	0	0	0	0	1	0	0	0	0	1
2019	0	0	0	0	1	0	0	0	0	1
2020	0	0	0	0	0	0	0	0	0	0
2021	0	0	1 (2)	0	0	0	0	0	0	1 (2)
2022	0	0	0	0	0	0	0	0	0	0
2023	0	1	0	0	0	0	1	0	0	2
Total number of incidents (recipients)	**37 (40)**	**5**	**11 (14)**	**2**	**12 (15)**	**2 (4)**	**3**	**1**	**3 (4)**	**76 (88)**

Year of transfusion	Cryoprecipitate	FFP	Platelet - apheresis	Platelets - pooled	Red blood cells	Total
1996	0	0	0	4	4	**8**
1997	0	0	1	1	6	**8**
1998	0	1	2	0	2	**5**
1999	0	0	1	2	5	**8**
2000	0	0	3	4	1	**8**
2001	0	0	1	4	0	**5**
2002	0	0	0	1	2	**3**
2003	0	0	1	2	1	**4**
2004	0	0	0	0	1	**1**
2005	0	0	0	2	1	**3**
2006	0	0	1	1	0	**2**
2007	0	0	0	0	2	**2**
2008	0	0	4	2	0	**6**
2009	0	0	2	0	1	**3**
2010	0	0	0	0	0	**0**
2011	0	4	0	0	0	**4**
2012	0	1	0	1	1	**3**
2013	0	0	0	0	0	**0**
2014	0	2	0	0	0	**2**
2015	1	3	0	2	1	**7**
2016	0	0	0	0	0	**0**
2017	0	0	1	0	0	**1**
2018	0	0	1	0	0	**1**
2019	0	0	1	0	0	**1**
2020	0	0	0	0	0	**0**
2021	0	1	0	0	0	**2**
2022	0	0	0	0	0	**0**
2023	0	0	0	0	2	**2**
Total number of implicated components	**1**	**13**	**19**	**26**	**30**	**89**

Table 21.5: Number and type of implicated components from confirmed TTI recipients in the UK, reported to SHOT, with transfusions between October 1996 and December 2023 (Scotland included from October 1998)

	Bacteria	HAV	HBV	HCV	HEV	HIV	Malaria	Parvovirus (B19)	vCJD or prion	Total number of incidents (total number of recipients)
Outcomes										
Death due to, or contributed to, by TTI	7 (8)	0	0	0	2	0	1	0	3 (4)	**13 (15)**
Major morbidity	5 (6)	2	5 (6)	0	8 (11)	2 (4)	2	1	0	**25 (32)**
Minor morbidity or not reported, or unkown	25 (26)	3	6 (8)	2	2	0	0	0	0	**38 (41)**
Implicated component types										
Cryoprecipitate	0	0	0	0	1	0	0	0	0	**1 (1)**
Fresh frozen plasma	0 (1)	0	2 (4)	0	5 (8)	0	0	0	0	**7 (13)**
Platelets	30 (33)	3	1 (2)	0	4	1 (3)	0	0	0	**39 (45)**
Red blood cells	7	2	8	2	2	1	3	1	3 (4)	**29 (30)**

Table 21.6: Outcome of confirmed TTI incidents and implicated components by infection in the UK, reported to SHOT, with transfusions between October 1996 and December 2023 (Scotland included from October 1998)

Accompanying notes for Tables 21.4, 21.5 and 21.6

- *Where applicable, number of recipients are included in brackets*
- *To the end of 2023, no routine blood donation screening has ever been 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 the early malaria transmissions (1997, 2003), malaria antibody testing was not applicable at the time according to information supplied at donation*
- *HCV investigations where the transfusion was prior to screening are not included in the above table*
- *The year of transfusion may be prior to year of report to SHOT due to delay in recognition of chronic infection*
- *The 2 early HIV incidents (pre-1996 and in 1996) were associated with window period donations (anti-HIV negative/HIV RNA positive) before HIV NAT screening was in place. A third window period donation in 2002 was transfused to an elderly patient, who died soon after surgery. The recipient's HIV status was therefore not determined and not included*
- *In 2004 there was an incident involving contamination of a pooled platelet pack with Staphylococcus epidermidis, which did not meet the TTI definition because transmission to the recipient was not confirmed, but it would seem likely. This case was classified as 'not transfusion-transmitted'*
- *The vCJD case in 1999 was found to have the same blood donor as one of the 1997 transmissions and has therefore been counted as the same incident. Please note this was counted as two separate incidents in previous reports*
- *A further prion case died but transfusion was not implicated as the cause of death. The outcome was assigned to major morbidity instead because although there was post-mortem evidence of abnormal prion proteins in the spleen the patient had died of a condition unrelated to vCJD and had shown no symptoms of vCJD prior to death*
- *Data are checked regularly to ensure accuracy; however, these may be amended if new or additional information is received*

For further information or alternative breakdown of data please contact the National Coordinator for Transfusion Transmitted Infections via the NHSBT/UKHSA Epidemiology Unit at epidemiology@nhsbt.nhs.uk

Conclusion

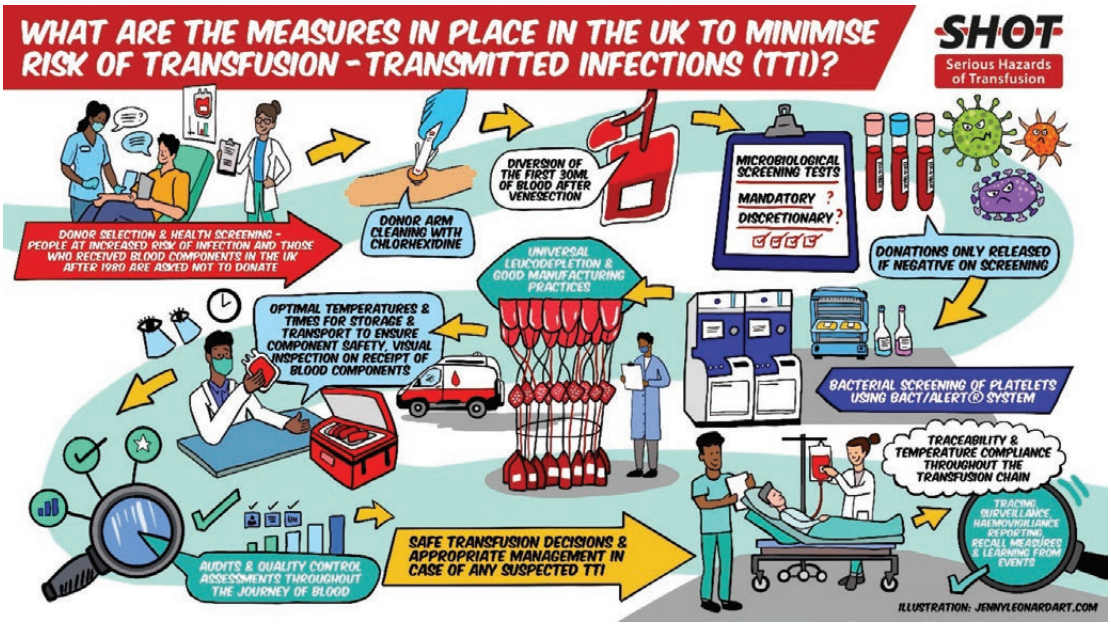
Investigations of 140 reports of possible TTI in 2023 resulted in the following: 1 confirmed malaria transmission, 1 confirmed HAV, 1 probable HBV and 1 probable HEV TTI. The last reported bacterial TTI was reported in 2015, the last HAV transmission was in 2017 and the last malaria transmission was in 2003.

These low numbers of transmissions provide assurance of the safety of the UK blood supply as a result of the effective methods and haemovigilance systems in place to reduce TTI. Policies and procedures are constantly reviewed to see if any further mitigations are required to reduce this further, most recently SaBTO have reviewed current testing for occult hepatitis B resulting in additional tests being introduced to further reduce the risk of transmission of hepatitis B (SaBTO, 2023). During 2024 HAV and B19 screening will start to be implemented by UK Blood Services to facilitate collection of plasma for fractionation.

Recommended resources

Safe supplies 2022: Monitoring safety in donors and recipients. Annual Review from the NHS Blood and Transplant and UK Health Security Agency Epidemiology Unit. London October 2023
https://hospital.blood.co.uk/diagnostic-services/microbiology-services/epidemiology/

SHOT Video: Monitoring the safety of blood supply in the UK
https://www.shotuk.org/resources/current-resources/videos/



References

Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO), 2023. *Guidance: Occult hepatitis B infection in UK blood donors.* [Online] Available at: https://www.gov.uk/government/publications/occult-hepatitis-b-infection-in-uk-blood-donors (Accessed 18 April 2024).

Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO), 2024. *SaBTO: Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO) annual report 2022 to 2023.* [Online] Available at: https://www.gov.uk/government/publications/sabto-annual-report-2022-to-2023/sabto-advisory-committee-on-the-safety-of-blood-tissues-and-organs-sabto-annual-report-2022-to-2023 (Accessed 17 April 2024).

Association for the Advancement of Blood & Biotherapies (AABB), 2022. *Australia ends donor deferral for UK residency and VCJD risk.* [Online] Available at: https://www.aabb.org/news-resources/news/article/2022/07/25/australia-ends-donor-deferral-for-uk-residency-and-vcjd-risk (Accessed 18 April 2024).

Department of Health and Social Care, 2013. *Measures currently in place in the UK to reduce the potential risk of vCJD transmission via blood.* [Online] Available at: https://www.gov.uk/government/news/measures-currently-in-place-in-the-uk-to-reduce-the-potential-risk-of-vcjd-transmission-via-blood (Accessed 18 April 2024).

Gates, S. et al., 2023. Investigating Blood Donors With Postdonation Respiratory Tract Symptoms During the Wild-Type, Delta, and Omicron Waves of the Coronavirus Disease 2019 Pandemic in England. *Open Forum Infectious Diseases,* 10(10), p. ofad499. doi: https://doi.org/10.1093/ofid/ofad499.

Harvala, H., Reynolds, C., Brailsford, S. & Davison, K., 2022. Fulminant Transfusion-Associated Hepatitis E Virus Infection Despite Screening, England, 2016-2020. *Emerging Infectious Diseases,* 28(9), pp. 1805-1813. doi: https://doi.org/10.3201/eid2809.220487.

Hewitt, P. E., Davison, K., Howell, D. R. & Taylor, G. P., 2013. Human T-lymphotropic virus lookback in NHS Blood and Transplant (England) reveals the efficacy of leukoreduction. *Transfusion,* 53(10), pp. 2168-2175. doi: https://doi.org/10.1111/trf.12105.

Joint United Kingdom Blood Transfusion and Tissue Transplantation Services Professional Advisory Committee (JPAC), 2023. *Position Statements.* [Online] Available at: https://www.transfusionguidelines.org/document-library/documents/jpac-position-statement-on-emerging-infections-may-2023/download-file/JPAC%20Position%20Statement%20on%20Emerging%20Infections%20-%20May%202023.pdf (Accessed 17 April 2024).

Joint United Kingdom Blood Transfusion and Tissue Transplantation Services Professional Advisory Committe (JPAC), 2023. *Position Statements.* [Online] Available at: https://www.transfusionguidelines.org/document-library/documents/jpac-position-statement-on-residual-risk-september-2023/download-file/JPAC%20Position%20Statement%20on%20Residual%20Risk%20-%20September%202023.pdf (Accessed 17 April 2024).

McDonald, C. et al., 2017. Bacterial screening of platelet components by National Health Service Blood and Transplant, an effective risk reduction measure. *Transfusion,* 57(5), pp. 1122-1131. doi: https://doi.org/10.1111/trf.14085.

NHS Blood and Transplant (NHSBT) and the UK Health Security Agency (UKHSA) Epidemiology Unit, 2023. *Epidemiology Unit.* [Online] Available at: https://nhsbtdbe.blob.core.windows.net/umbraco-assets-corp/32414/safe-supplies-2022_monitoring-safety-in-donors-and-recipients_accessible.pdf (Accessed 17 April 2024).

Soutar, R. et al., 2023. Guideline on the investigation and management of acute transfusion reactions. *British Journal of Haematology,* 201(5), pp. 832-844. doi: https://doi.org/10.1111/bjh.18789.

The National CJD Research & Surveillance Unit (NCJDRSU), 2023. *The Transfusion Medicine Epidemiology Review (TMER).* [Online] Available at: https://www.cjd.ed.ac.uk/projects/transfusion-medicine-epidemiology-review-tmer (Accessed 18 April 2024).

UK Health Security Agency (UKHSA) on behalf of the joint Human Animal Infectious and Risks Surveillance (HAIRS) group, 2023. *Research and analysis: HAIRS risk assessment: Usutu virus.* [Online] Available at: https://www.gov.uk/government/publications/hairs-risk-assessment-usutu-virus/hairs-risk-assessment-usutu-virus (Accessed 17 April 2024).

Post-Transfusion Purpura (PTP) n=1 22

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.

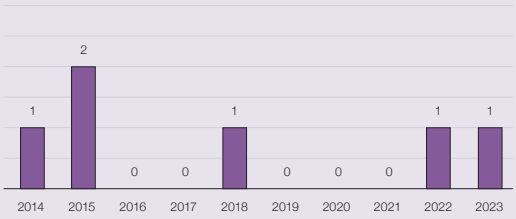
Abbreviations used in this chapter

ED	Emergency department	**IVIg**	Intravenous immunoglobulin
HPA	Human platelet antigen	**PTP**	Post-transfusion purpura

Headline data 2023

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 PTP reported in 2023.

Deaths related to transfusion n=0

There were no deaths reported in this category in 2023.

Major morbidity n=1

Case 22.1: Post-transfusion purpura with HPA-1a antibody

A patient received one unit of red cells post-delivery. She presented to the ED 18 days later with widespread petechiae and a platelet count of 3 x 10^9/L. HPA-5b antibodies were found in her plasma. IVIg was administered and she made a complete recovery.

The history and response to treatment is typical of PTP although the delay following transfusion is unusual. Most cases present around 5-7 days after transfusion. Antibody-mediated PTP remains the most likely explanation here, in the absence of any other reasons for severe thrombocytopenia. Anti-HPA antibodies often increase in the weeks following delivery and it is possible that the delayed response may represent a primary sensitisation due to the recent pregnancy rather than a pre-existing HPA antibodies.

Conclusion

PTP has become extremely rare since the introduction of universal leucodepletion. There have been 10 cases reported to SHOT over the last 11 years including this case. It remains an important diagnosis to be aware of since it is readily treatable by IVIg and has implications for avoidance of further transfusion in the recipient. Avoiding unnecessary transfusions, monitoring patients for delayed reactions and educating patients about these potential risks are vital (Narayan, et al., 2021).

Recommended resource

SHOT Bite No.30: Post-transfusion purpura
https://www.shotuk.org/resources/current-resources/shot-bites/

Reference

Narayan, S., Poles, D. & Latham, T., 2021. Post-transfusion purpura - Insights from SHOT UK. *Vox Sanguinis,* 116(S1), pp. 95-96. doi: https://doi.org/10.1111/vox.13117.

SPECIAL CLINICAL GROUPS

23 Cell Salvage (CS) n=26

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
BP	Blood pressure
CS	Cell salvage
ICS	Intraoperative cell salvage
IV	Intravenous
LDF	Leucocyte depletion filter
MHRA	Medicines and Healthcare products Regulatory Agency
NICE	National Institute for Health and Care Excellence
PCS	Postoperative cell salvage
UKCSAG	United Kingdom Cell Salvage Action Group

Key SHOT messages

- Cell salvage is a safe and effective alternative to allogeneic blood when used correctly and appropriate resources are available
- The risks associated with cell salvage are low but need to be considered and managed appropriately
- Most incidents reported to SHOT are avoidable, however, unforeseen reactions can occur, and vigilance is necessary

Recommendations

- Cell salvage policies and procedures should include information on potential risks, including cell salvage related hypotension and the simple measures that need to be taken should it occur

Action: Cell salvage leads, cell salvage practitioners and theatre teams

- Organisations should review their policies to confirm that they are up to date with current practices and guidance

Action: Cell salvage leads, hospital transfusion teams, hospital transfusion committee

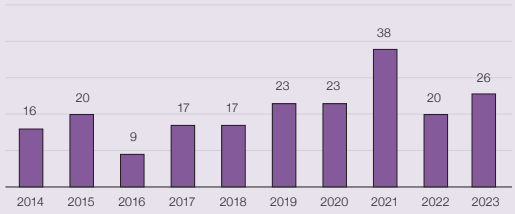
- Organisations should review local incident reporting processes to ensure cell salvage incidents can be identified as blood transfusion related and inform the hospital transfusion team who should be included in the investigation process

Action: Cell salvage leads, hospital transfusion teams, hospital transfusion committee, governance leads

Headline data 2023

Number of reports n=26
Deaths n=0
Major morbidity n=3

CS reports by year



Demographic data

Male n=7
Female n=19
Adults n=24
Paediatric n=2

Blood component data

Red cells n=26
Platelets n=0
Plasma n=0
Multiple components n=0
Other n=0

Introduction

In 2023, 26 incidents were submitted by 16 different reporting organisations. One organisation submitted 5 reports, one organisation submitted 3 reports, four organisations submitted 2 reports, and the rest submitted 1 each.

There were 2 reports related to paediatric patients, the rest were adult patients. The age range was 11-85 years, with 19 females and 7 males.

The greatest number of incidents reported were in obstetrics, vascular and orthopaedic (including spinal and trauma) surgery (Table 23.1). There was an even split between elective (n=12) and emergency (n=14) surgeries. This is in contrast with 2022 where most reports were from elective procedures.

There were 21 adverse events, of which 11 were attributable to avoidable errors, 10 machine/disposable failures, and 5 adverse reactions all of which were hypotension not related to hypovolaemia. Of these reactions, 4 occurred when using a LDF. Hypotensive reactions following reinfusion of cell salvaged blood remain the most reported reactions.

Table 23.1: Cell salvage cases by speciality in 2023 (n=26)

Specialty	Elective	Emergency	Total
Obstetrics	4	6	**10**
Vascular	2	4	**6**
Orthopaedic	3	1	**4**
Spinal	2		**2**
Trauma		1	**1**
Cardiac		1	**1**
General		**1**	**1**
Hepatobiliary	1		**1**
Total	**12**	**14**	**26**

Deaths related to transfusion n=0

There were no cases reported where a patient died because of cell salvage.

Major morbidity n=3

In 3 cases, severe hypotension following infusion of salvaged red cells contributed to the need for postoperative high-dependency care.

Types of cell salvage

All incidents related to the use of centrifugal washed cell salvage systems; 25 intraoperatively and 1 in the postoperative setting.

Cell salvage adverse events n=21

There were 11 avoidable incidents and 10 equipment-related reports.

Avoidable errors n=11

In 2 cases, both emergencies, cell salvage was not available. This resulted in a potentially avoidable transfusion of allogeneic red cells in an orthopaedic patient. In the second case, the patient died following a ruptured AAA. It was difficult to assess the benefit that cell salvage could have provided.

Three incidents related to contamination of the collected blood which was then discarded. The contraindicated substances aspirated were non-IV grade saline, chlorhexidine, and surgical glue respectively.

In an elective caesarean section, blood was collected, processed and reinfusion was started when it was realised that the set of disposables being used was a non-sterile set intended to be used for training purposes only. The reinfusion was stopped immediately, and the remaining red cells discarded. As a result of this incident, training materials are no longer kept near sterile consumables.

In another obstetric case, a new cell salvage device was being trialled for 2 weeks. The device was used in a caesarean section over a weekend by an operator with limited training. The operator failed to confirm the correct bowl size resulting in inadequate volumes of wash being used potentially affecting the quality and safety of the red cells that were reinfused. This was only discovered when the machine data was reviewed by the company representative later.

There were 2 similar incidents where the cell salvage device displayed a ‘long empty cycle’ warning, indicating that the quality of the reinfusion product may have been compromised. The usual process for dealing with this (rewashing with new disposables) was not followed, and red cell volumes of 194mL and 244mL respectively reinfused with no discernible consequence.

Incidents occurred in the final 2 cases at the time of reinfusion. In an elective caesarean section, a 1500mL blood loss was collected and processed. Unfortunately, the reinfusion exceeded the time permitted according to local protocol and the remaining red cells were discarded. It was also stated that the blood had coagulated in the bag, suggesting that inadequate anticoagulation or washing may have occurred.

In an emergency laparotomy for a ruptured spleen, massive blood loss was managed using a rapid infusion device, and 866mL of salvaged red cells were given via a device that had a 250-micron inline filter. Concern was raised that the salvaged red cells were not given back via a 40-micron filter as specified by local policy.

Rapid infusion devices allow fast infusion of warmed fluids in circumstances where large volume replacement is needed quickly. Generally, administration of salvaged red cells should meet the minimum standards required for administration of allogeneic packed red cells. If an organisation routinely uses a rapid infusion device for allogeneic red cells, then its use with salvaged red cells might also be acceptable depending on the mode of action of the infusion device. If there is no guidance from the manufacturer of the infusion device, a risk assessment should be undertaken bearing in mind that salvaged red cell infusion bags contain air and are not manufactured to withstand pressurisation. Also of note is that gravity-fed filters, such as the LDF, are not compatible with rapid infusion systems.

Learning points

- Safe cell salvage practice relies on staff involved in the process having adequate knowledge and understanding of their role. Vigilance, communication, and situational awareness is required
- Individuals must be either fully trained, or supported by someone who is, to use the cell salvage equipment safely. This is applicable to all devices, including those being trialled
- In the absence of manufacturer's guidance, a risk assessment should be performed when considering the use of infusion devices with salvaged red cells

Equipment incidents n=10

There were 3 incidents where leaks in the cell salvage disposable set prevented satisfactory processing of the collected blood and reinfusion of red cells to the patient. In 1 of these cases, a report was made to the MHRA Yellow Card scheme. In the other 2 cases, it could not be determined whether damage to the disposable set from mishandling had occurred. One of these cases involved a paediatric patient undergoing spinal surgery who received a unit of allogeneic red cells which may have been avoided.

There were 5 machine issues, including power outages, error codes and sensor failures that made the machines unusable. One of these incidents happened at setting up, allowing a replacement machine to be found. A further 3 cases failed intraoperatively, causing loss of cell salvage completely on 1 occasion and reduced contribution of cell salvage on 2 occasions. In another case, the device appeared to be giving misleading fluid volume readings in relation to postoperative bleeding in a cardiac setting. This was reported to the MHRA Yellow Card scheme.

In the final 2 cases, there were concerns over quality of the red cells for reinfusion as black particles were seen in the reinfusion bag. One of these reports came from a centre where this is an ongoing issue and a further MHRA report has been made.

Cell salvage adverse reactions n=5

There were 5 reports of adverse reactions, all of which comprised of severe hypotension on reinfusion not related to hypovolaemia. These events occurred in 3 elective procedures (obstetric, orthopaedic, and hepatobiliary surgeries) where a LDF was deployed. In 2 of these elective cases the reaction contributed to the patient needing high-dependency care postoperatively.

Case 23.1: Hypotensive reaction in a patient receiving allogeneic and salvaged red cells

A patient was undergoing invasive internal surgery and experienced significant blood loss. Cell salvage was being used and a major shock pack was requested. During transfusion of a unit of red cells from the shock pack and the cell salvaged blood, a dramatic fall in BP from 90mmHg to 45mmHg was observed. This was managed with bolus infusions of adrenaline. It is not clear whether the reaction was due to the allogeneic blood, or the salvaged red cells given through a LDF.

There were also 2 incidents of hypotension in emergency procedures, 1 in vascular surgery (without a LDF), the other in obstetrics where high-dependency postoperative care was required.

The most reported adverse reaction associated with cell salvage is hypotension. The incidents this year bring the total number of hypotensive reactions reported to SHOT since 2010 to 39. The majority of these, but not all, also feature the use of LDF.

There are two areas of application where LDF have been routinely used. In surgery involving malignancy, a LDF is used to reduce the potential risk of infusing malignant cells. In obstetrics, the theoretical risks of amniotic fluid embolus were thought to be mitigated by use of these filters. Indeed, NICE guidance on cell salvage in obstetrics stated that a LDF is nearly always used to reduce the amount of amniotic fluid contaminants in the transfused blood to levels approaching those in maternal blood (NICE, 2005). There has been no substantial revision of this guidance since publication. However, reports of hypotension have more recently called into question the risks and benefits of the continued use of LDF in the obstetric

setting. The MHRA produced a safety guidance one liner in January 2011 stating that hypotension was a rare side effect of using LDF for cell salvage reinfusion, and the use of these filters for the purpose of removing amniotic fluid contaminants was not validated (MHRA, 2011). A survey of practice published by the UK cell salvage action group in 2015 found that of 73 hospitals using cell salvage in obstetrics, 66% continued to use the LDF, 22% sometimes used it and 12% never used it routinely (UKCSAG, 2015). The most recent professional guidance, published in 2018 by the Association of Anaesthetists, did not recommend the routine use of LDF in obstetric practice (Klein, et al., 2018).

Learning points

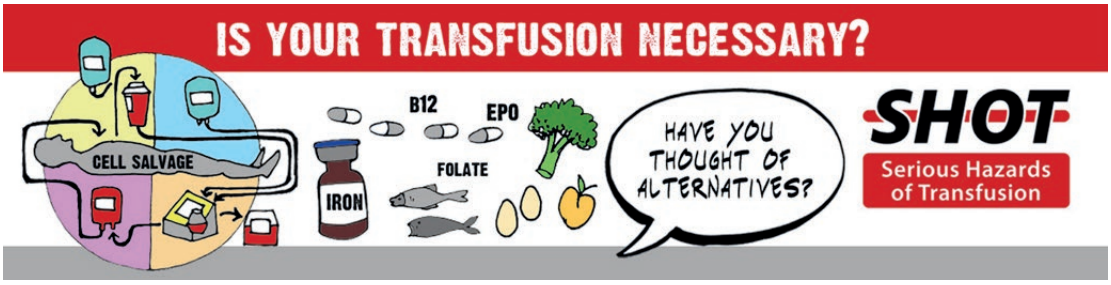
- Hypotension is the most reported adverse reaction associated with cell salvage. The use of a LDF is often (but not always) associated with this reaction
- If hypotension occurs, stop the infusion, and resuscitate with fluids and vasopressors if necessary (the reaction may be transient). Consider resuming the infusion without the LDF

Conclusion

The safe execution of cell salvage relies on everyone involved in the process understanding their role and responsibilities. The quality of the collected blood, the correct processing of that blood and the safe reinfusion of the washed red cells can be influenced by all those involved. It is imperative to provide adequate and appropriate training, including updates, to support all staff involved in the cell salvage process.

SHOT has not identified any mortality related to cell salvage in the years this reporting category has been active. This year, there were 3 cases where hypotension following infusion of salvaged red cells via a LDF contributed to the need for postoperative high-dependency care. This underlines the need for continued vigilance when using cell salvage. The adverse events relating to human errors or inexperience were preventable and again emphasise the importance of all staff within the process having sufficient knowledge and skills to perform their role safely. A few of this year's incidents relate to poor communication among staff and with laboratories. The correct labelling and prescription of autologous blood, with clear instructions to those caring for patients is vital in these situations. Consideration of any requirement for anti-D Ig is also vital in patients undergoing cell salvage especially when ICS has been used during caesarean section in D-negative, previously non-sensitised individuals and where cord blood group is confirmed as D-positive (or unknown).

Cell salvage is a valuable blood conservation method which is often under-utilised. All cell salvage operators must undertake initial and regular update training and be assessed as competent with documented training records. All hospitals where ICS and PCS are undertaken should report adverse events to SHOT. Staff should be aware that monitoring of patients is as important for the reinfusion of red cells collected by ICS or PCS as it is for allogeneic red cells and practitioners need to revisit previous Annual SHOT Reports particularly related to autologous transfusion to optimise learning from haemovigilance reports.



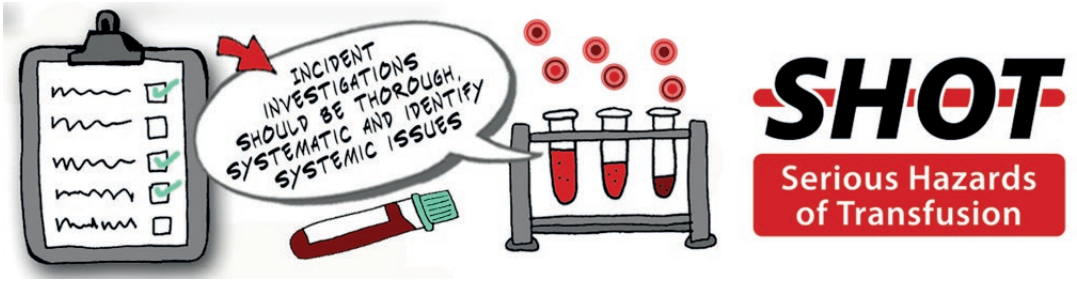
Recommended resources

SHOT Video: Haemovigilance in cell salvage
https://www.shotuk.org/resources/current-resources/videos/

UK Cell Salvage Action Group: Technical factsheets and Frequently asked questions
https://www.transfusionguidelines.org/transfusion-practice/uk-cell-salvage-action-group/technical-factsheets-and-frequently-asked-questions-faq

UK Cell Salvage Action Group
https://www.transfusionguidelines.org/transfusion-practice/uk-cell-salvage-action-group

Intraoperative cell salvage: a survey of UK practice
https://doi.org/10.1016/j.bja.2024.01.042



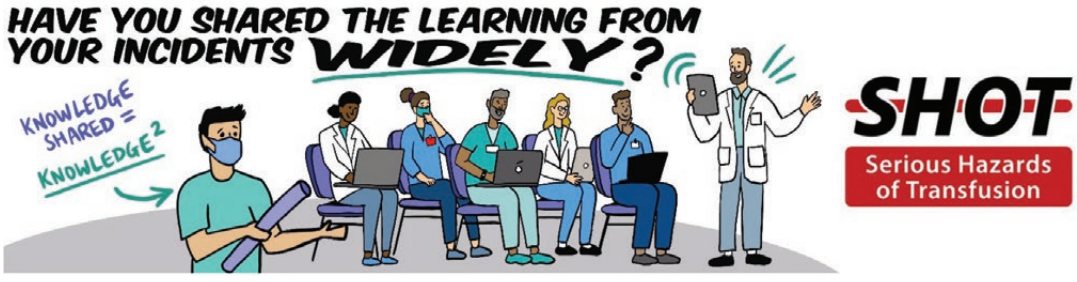
References

Klein, A. A. et al., 2018. Association of Anaesthetists guidelines: cell salvage for peri-operative blood conservation 2018. *Anaesthesia,* 73(9), pp. 1141-1150. doi: https://doi.org/10.1111/anae.14331.

Medicines and Healthcare products Regulatory Agency , 2011. *One Liners issue 82 - January 2011.* [Online] Available at: https://webarchive.nationalarchives.gov.uk/ukgwa/20110504182728/http://www.mhra.gov.uk/Publications/Safetyguidance/OneLiners/CON105973 (Accessed 10 April 2024).

National Institute for Health and Care Excellence (NICE), 2005. *Intraoperative blood cell salvage in obstetrics. Interventional procedures guidance [IPG144].* [Online] Available at: https://www.nice.org.uk/Guidance/IPG144 (Accessed 09 April 2024).

UK Cell Salvage Action Group (UKCSAG), 2015. *Intra-operative Cell Salvage: 2014. A Survey of Equipment and Practice across the UK,* s.l.: Joint UK Blood Transfusion and Tissue Transplantation Services Professional Advisory Committee. Available at: https://www.transfusionguidelines.org/document-library/documents/2014-ukcsag-survey-published-april-2015/download-file/2014%20UKCSAG%20survey%20-%20April%202015.pdf (Accessed 10 April 2024).



24 Paediatric Cases n=169

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	**IUT**	Intrauterine transfusion
BSH	British Society for Haematology	**LIMS**	Laboratory information management system
CS	Cell salvage	**NEC**	Necrotising enterocolitis
DAT	Direct antiglobulin test	**NM**	Near miss
ENT	Ear, nose and throat	**PICU**	Paediatric intensive care unit
FAHR	Febrile, allergic and hypotensive reactions	**RBRP**	Right blood right patient
FFP	Fresh frozen plasma	**SCD**	Sickle cell disease
Hb	Haemoglobin	**SRNM**	Specific requirements not met
HSCT	Haemopoeitic stem cell transplant	**TACO**	Transfusion-associated circulatory overload
HSE	Handling and storage errors	**TAD**	Transfusion-associated dyspnoea
HTR	Haemolytic transfusion reactions	**TANEC**	Transfusion-associated NEC
HTT	Hospital transfusion team	**TRALI**	Transfusion-related acute lung injury
IBCT	Incorrect blood component transfused	**TTI**	Transfusion-transmitted infection
Ig	Immunoglobulin	**UCT**	Uncommon complications of transfusion
ITP	Immune thrombocytopenic purpura	**WCT**	Wrong component transfused

Key SHOT messages

- Failure of concessionary, rapid laboratory release of components in an emergency e.g., non-neonatal specification for a child <1 year or best-matched red cells for a patient with antibodies can result in significant transfusion delays
- Inappropriate administration of adult O D-negative red cells to neonates in emergency continues to be reported
- Clear communication within teams and between clinical and laboratory areas regarding the patient's transfusion requirements is essential to ensure the timely and appropriate issue of blood components

Recommendations

- Laboratories should have clear policies for rapid, concessionary release of blood components, including roles/responsibilities
- Neonatal/infant specification emergency components should be clearly distinguished from adult components when stored together in satellite refrigerators, with staff training on correct selection in emergency
- Management of paediatric FAHR should be timely and appropriate

Action: Hospital transfusion teams

Introduction

The total number of paediatric cases reported to SHOT in 2023 has increased slightly compared to 2022 (169 vs 151, Figure 24.1). Paediatric cases account for 169/2154 (7.8%) of total reports if NM and RBRP are excluded and 274/3833 (7.1%) if NM and RBRP are included. Neonates and infants represent 1/3 of paediatric cases, 56/169 (33.1%).

Overrepresentation of paediatric reports is seen once again in FAHR, ADU (delay and overtransfusion) and IBCT-WCT. However, this year, paediatric reports are also overrepresented in HSE and in UCT (Figure 24.2).

Clinical errors remain slightly more common than laboratory errors with 63/120 clinical (52.5%) versus 57/120 (47.5%). Overall, laboratory errors have increased in paediatric as well as in adult reports, likely reflecting pressure on laboratory working. The prominence of clinical errors in ADU and HSE reflects the additional complexities of prescribing and transfusing in neonates and children.

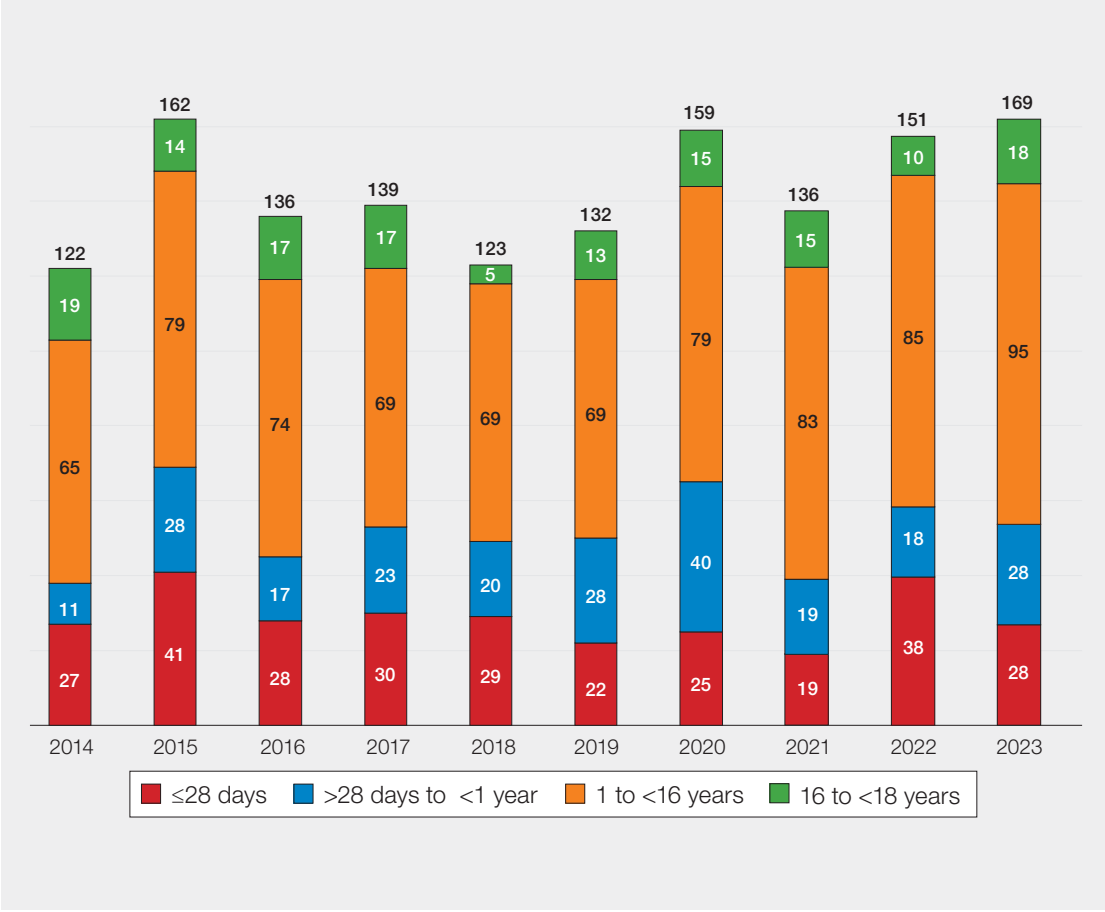
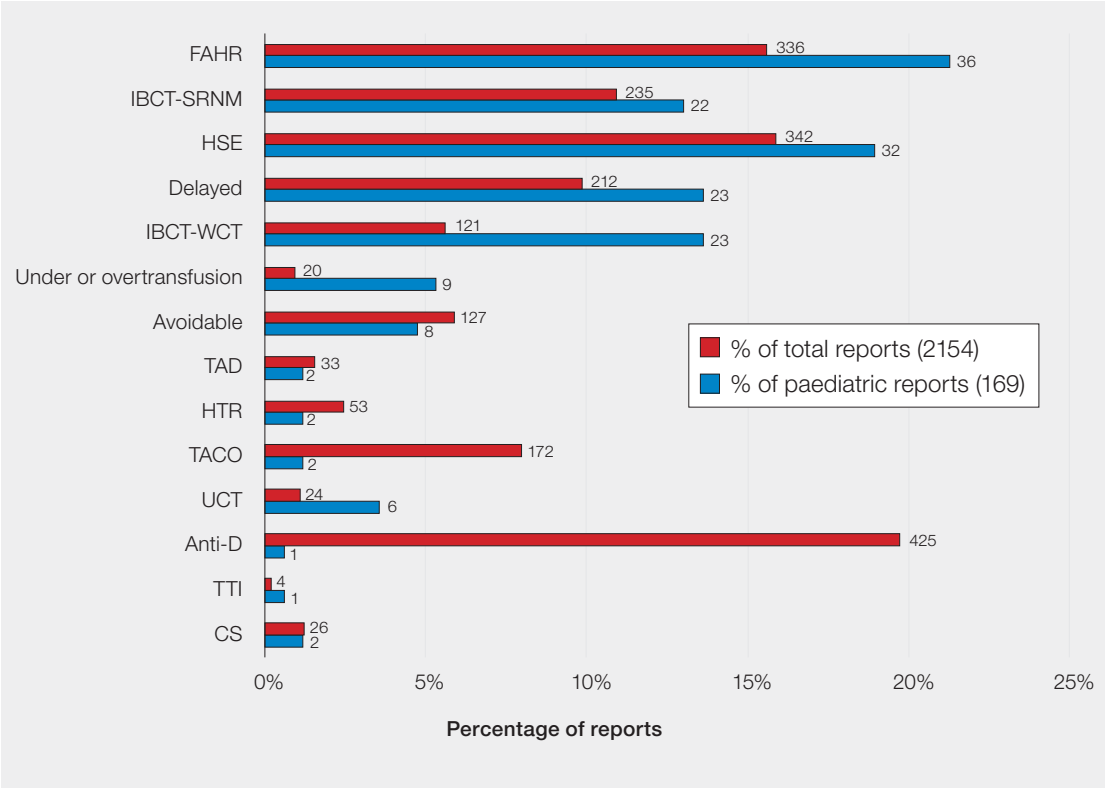


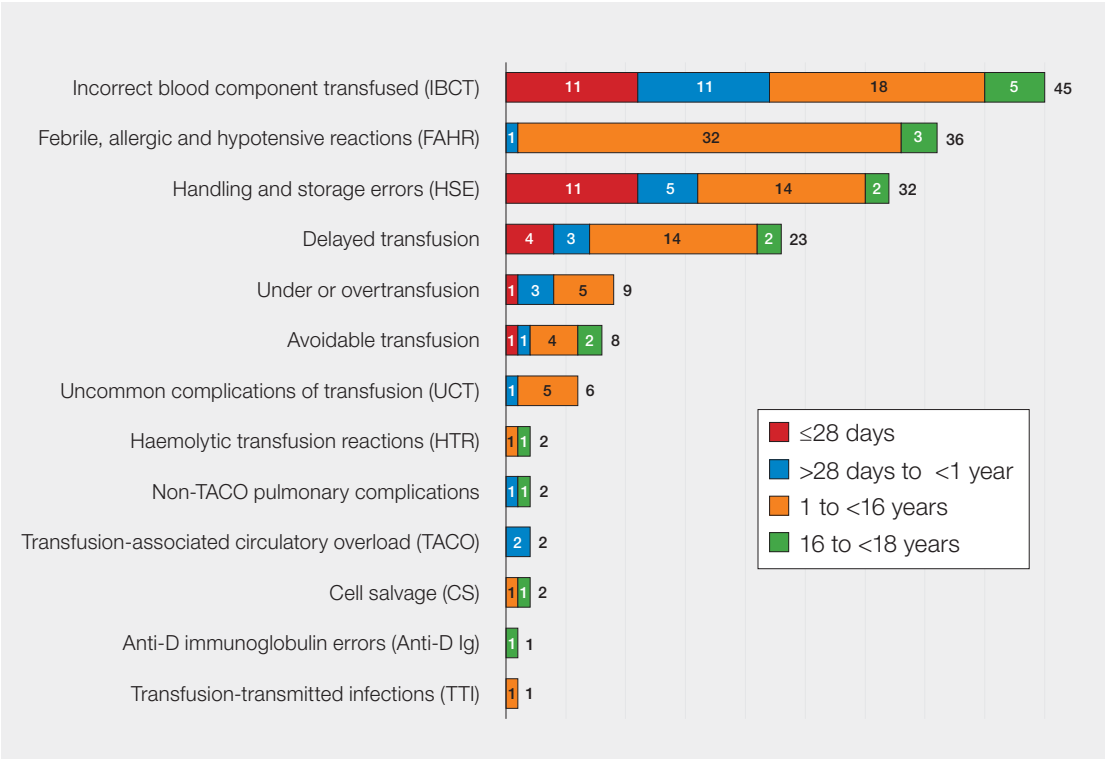
Figure 24.1: Trends in paediatric reports 2014-2023

Figure 24.2: Percentages of paediatric and total reports in each category in 2023 (n=169)



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

Figure 24.3: Summary of paediatric cases by category and age in 2023 (n=169)



Deaths related to transfusion n=1

There was one death possibly related to transfusion (imputability 1) reported in 2023. This was a case of possible TANEC, summarised in Case 24.1 and discussed in Chapter 20, Uncommon Complications of Transfusion (UCT).

Case 24.1: Death due to bowel perforation within 24 hours of red cell transfusion

An extreme preterm neonate (a month old) received a red cell transfusion for anaemia. Eight hours later the neonate developed significant deterioration including a distended abdomen and required reintubation. Abdominal X-ray was suggestive of NEC. The neonate subsequently developed bowel perforation and metabolic acidosis and died.

Major morbidity n=27

There were 27 cases of major morbidity. FAHR remains the largest category with 21/27 cases. The remaining cases were 2 delayed transfusions, 1 overtransfusion, 1 pulmonary non-TACO, 1 TTI and 1 HTR.

Error-related reports n=120

There was a significant increase in paediatric error reports in 2023 (120 versus 101 in 2022, 83 in 2021).

Incorrect blood component transfused (IBCT) n=45

The total number of IBCT reports increased in 2023, particularly for laboratory errors (n=33), in both IBCT subcategories (IBCT-WCT and IBCT-SRNM).

IBCT-wrong component transfused (WCT) n=23

IBCT-WCT clinical errors n=8

Adult specification component to infant or neonate n=3

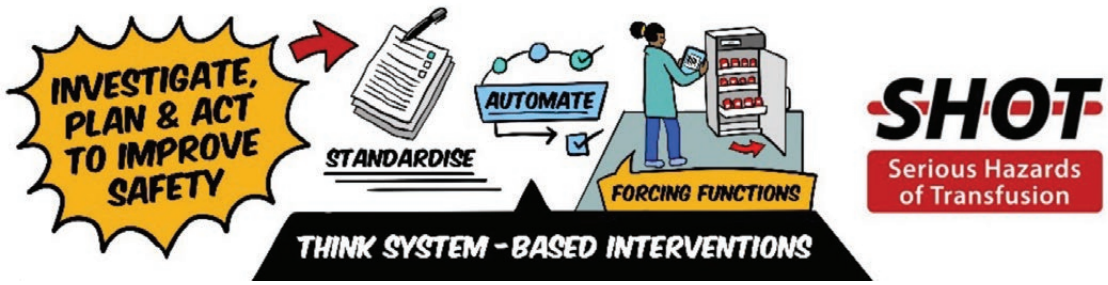
There continue to be reports of neonates receiving adult emergency O D-negative red cells.

Case 24.2: Adult O D-negative red cells given to a neonate in error when neonatal red cells were available

A bleeding neonate required an emergency red cell transfusion. The laboratory instructed the clinical team use the 'emergency paedipack' from the satellite refrigerator. An adult pack was accidentally selected and transfused to the neonate.

Learning point

- SHOT receives recurring reports of incorrect administration of adult specification red cells to neonates in an emergency. Hospitals should ensure that red cells suitable for neonates are clearly distinguished from adult components when stored in the same refrigerator and that clinical staff collecting blood understand the different component types



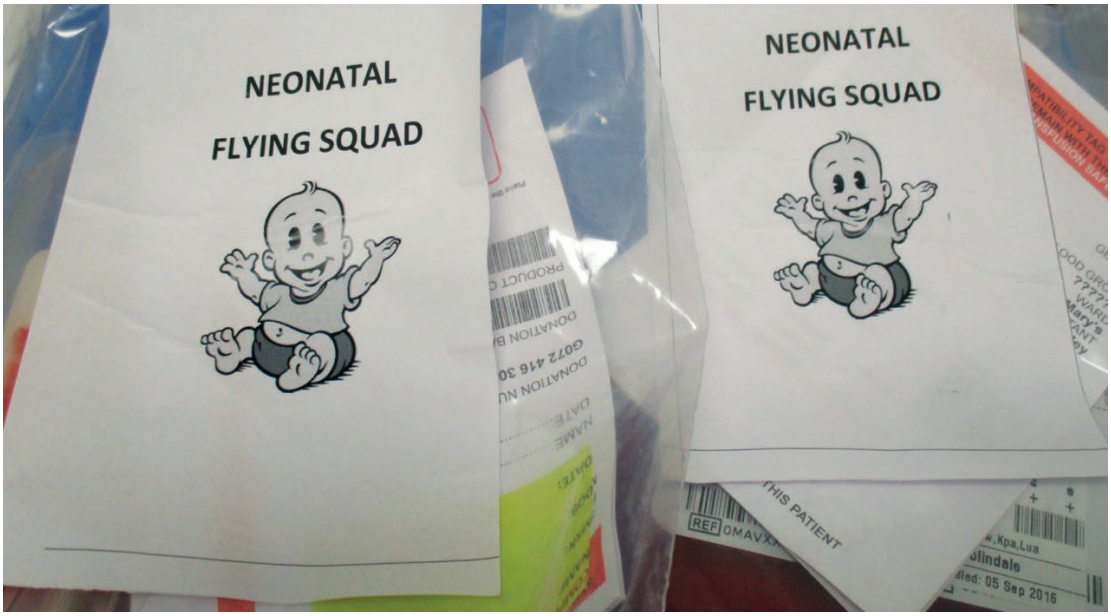


Figure 24.4: Example of how to distinguish neonatal from adult components in a satellite refrigerator

With permission from Rachel Moss, transfusion practitioner at Great Ormond Street Hospital

Incorrect component to HSCT recipient n=4

In 4 cases, a HSCT patient received red cells of the incorrect ABO blood group due to failure of communication between the clinical and laboratory teams or to follow policy.

Other n=1

D-positive red cells were transfused to young female child in trauma/major haemorrhage pre-hospital setting.

IBCT-WCT laboratory errors n=15

Adult specification component to infant or neonate n=4

All 4 were infants who received standard adult red cells rather than neonatal/infant specification large volume red cells. One was transfused during surgery with aliquots from a standard adult unit. The error was discovered postoperatively when the parent found the remains of the unit amongst the child's bag of washing.

Incorrect component to HSCT recipient n=4

The incorrect ABO group component was issued for 4 post-HSCT patients despite clear LIMS instructions.

D-positive red cells to D-negative recipient n=4

A female neonate received a D-positive red cell unit because the theatre refrigerator had been incorrectly stocked with D-positive neonatal emergency blood. Errors in D grouping impacting transfusions occurred in 2 cases.

The final case was a male teenager with major haemorrhage who received eight units of group O D-positive red cells pre-hospital. This was not in line with current BSH guidelines (Milkins, et al., 2013; New, et al., 2016; New, et al., 2020).

Other n=3

Case 24.3: Preterm neonate erroneously assigned as blood group O

The laboratory assigned a preterm neonate as group O and issued group O FFP. It was subsequently determined that the neonate had been grouped as A at birth in a different hospital where they were transfused with emergency blood group O red cells. Of note, the laboratory should have issued group AB FFP as only one group result was on record.

Learning point

- If a neonate is transferred between hospitals, any history of prior transfusion must be communicated to the receiving transfusion laboratory. Caution is required when interpreting neonatal groups, as prior transfusion may result in mixed field or group misinterpretation

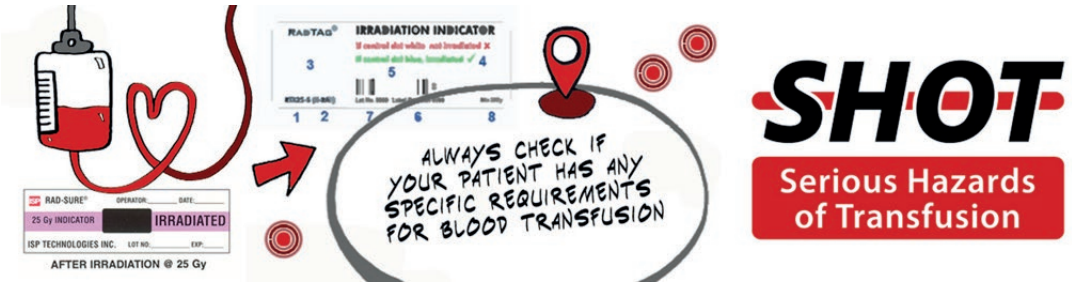
Another neonate received inappropriate transfusion of group O cryoprecipitate with only one grouping sample in the laboratory. The final case was a laboratory mix-up between two packs of apheresis platelets.

IBCT-specific requirements not met (SRNM) n=22

There were 18 laboratory and 4 clinical errors where specific transfusion requirements were not met in paediatric patients. These are detailed in Table 24.1.

Table 24.1: Paediatric SRNM errors in 2023 (n=22)

Type of SRNM error	Number of cases	Detail of errors
Inappropriate electronic issue	6	One teenager with SCD (previous antibodies). Three neonates: 1 with positive antibody screen, 1 without maternal antibody screen results and 1 with a positive DAT. Two children were post HSCT
Failure to request irradiated components	5	4 clinical errors: 1 neonate with prior IUT, 1 young child with DiGeorge syndrome, 1 pre HSCT, 1 had received fludarabine 1 laboratory error due to due to failure to check maternal transfusion history for a neonate with a prior IUT
Incomplete testing	5	Two neonates with incomplete testing where maternal antibody status was unknown; 3 infants over 4 months with no antibody screen performed
Failure to provide phenotyped components	5	One neonate with a maternal antibody and 4 children with SCD
Failure to provide HLA-matched components	1	Routine HLA-matched platelets not provided



Avoidable, delayed, under or overtransfusion n=40

Avoidable transfusions n=8

There were 2 reports of non-bleeding older children with ITP being transfused with platelets.

Case 24.4: Platelet transfusion given to a non-bleeding teenager with acute ITP

A teenager presented with acute ITP. The platelet count was 14x10^9/L, on repeat 10x10^9/L. A platelet transfusion was requested by the ENT team and administered. The patient had no bleeding.

Learning point

- Platelet transfusion in ITP is only indicated for serious bleeding or prior to a procedure when other treatment has failed or if urgent (Estcourt, et al., 2017). The requirement for transfusion should be discussed with a haematologist prior to administering platelets

In 2 cases, unnecessary platelet transfusions were given due to inaccurate results (platelet clumping). One case of failure of communication led to repeat transfusion, 2 were avoidable use of group O

D-negative red cells, and 1 child inappropriately received two units of platelets rather than one prior to central line removal.

Delayed transfusion n=23

Delays in transfusion were again prominent within paediatrics; 15 cases were primarily due to laboratory errors and 8 were clinical.

Laboratory errors n=15

Of the 15 laboratory cases, most appeared unrelated to being paediatric. There were 8 cases which included delays in ordering from/provision by Blood Services; 1 case involved a failure to scan platelets out of an agitator causing confusion and transfusion delay, and 2 cases resulted from grouping issues.

There was failure to communicate the timescale for crossmatch in the presence of red cell alloantibodies in a child with a severe dermatological disorder, resulting in delay due to loss of venous access. In another case, a teenager with leukaemia had a two-unit red cell transfusion requested but only a single unit issued.

Finally, there were delays in decision to issue components under concessionary release in urgent situations for 2 patients, discussed in Cases 24.5 and 24.6.

Case 24.5: Delay in concessionary release of adult specification platelets for a neonate with significant bleeding

Emergency platelet transfusion was requested for a severely thrombocytopenic neonate with liver failure and both rectal and intracranial bleeding. Neonatal/infant specification platelets were not available on site. The clinical team asked for standard adult specification platelets but there was a 2-hour delay in authorising their release due to difficulty in contacting the haematology medical team and the laboratory's inability to authorise emergency release.

Case 24.6: Delay in red cell transfusion for critically unwell teenager with SCD due to failure to issue red cells urgently under concessionary release

A teenager with SCD and multiple red cell antibodies was on the point of cardiac arrest due to rapidly progressive anaemia (from 97g/L to 45g/L), hypoxia, and acidosis. Whilst awaiting frozen thawed red cells, the Blood Service consultant on call advised transfusing ABO, Rh matched, K-negative red cells given the urgency. There was a 3-hour delay in issuing red cells. The pre-transfusion Hb was 26g/L immediately prior to transfusion. The delay contributed to major morbidity in this patient.

Learning points

- For concessionary release of standard adult components to neonates and infants, laboratories are recommended to have pre-agreed hierarchies in place (New, et al., 2016; New, et al., 2020)
- Clear communication between clinicians and laboratory staff is required in urgent situations to ensure timely issue of blood components under concessionary release
- Transfusion laboratories require access to adequate senior support at all times

Clinical errors n=8

In one case, there was a request for a neonate where the maternal antibody was recorded as an anti-'e' but was actually anti-'E'. In another case, an infant received a red cell transfusion with no confirmatory group or consent. Three cases involved failure to order the blood component, to send a group and screen sample pre-surgery, or to communicate with portering staff. Others involved expired staff training, and communication problems in a major haemorrhage.

A teenager with SCD and positive antibody screen had an emergency red cell exchange delayed by 24-hours and is discussed in Case 24.7.

Case 24.7: Delay in provision of appropriate red cells for a teenager with SCD and red cell antibodies

A teenager with sickle chest syndrome required emergency red cell exchange transfusion. There was a 24-hour delay due to poor communication between laboratory and clinical staff regarding degree of urgency, and to failure to send crossmatch samples of sufficient volume to allow required antibody testing. The patient recovered fully with no adverse impact from the delay.

Learning point

- Red cell antibodies can cause delay in obtaining compatible red cell units; additional samples are often required, and good communication is vital to ensure timely provision of blood components

Undertransfusion n=1

A child was issued with a neonatal split red cell pack but required a larger volume.

Overtransfusion n=8

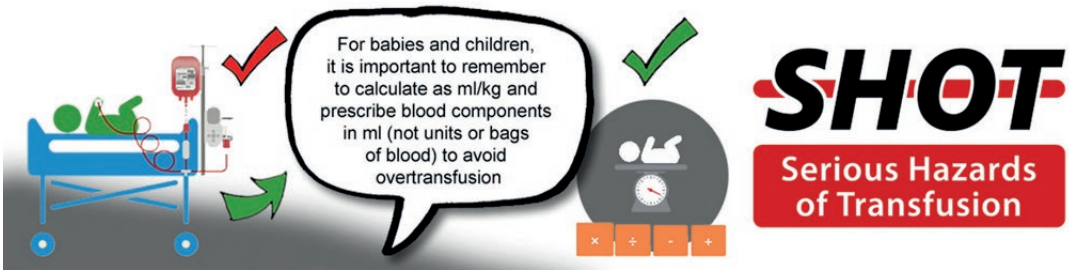
All 8 cases were clinical errors, 6 related to prescribing. In 1, a neonate was prescribed 30mL/kg of red cells in error. Another involved failure to use the prescribing formula. For 1 child with a haematinic deficiency, an inappropriately high Hb target was chosen resulting in a >30mL/kg transfusion (and furosemide requirement). A lower threshold, smaller volume transfusion followed by haematinic replacement would have been appropriate. Two cases involved prescription of a full adult unit to a small recipient, 1 was an adult-sized platelet unit to a 6.5kg infant (40mL/kg) and the other was a full adult red cell unit to a young child.

A significant overtransfusion occurred in a vulnerable preterm neonate described in Case 24.8.

Case 24.8: Overtransfusion in a preterm neonate due to illegible prescription

An extremely pre-term infant (birth weight 0.5kg) with NEC was prescribed platelets. The prescription should have been 7.5mL but was misread as 75mL. The neonate received 43mL (83mL/kg) before this was noticed and subsequently was hypertensive. The reporter commented that electronic prescribing had not been implemented in paediatrics due to complexities.

There were 2 administration errors: a full unit and a part of a second were administered to a child; an infant received excess platelets due to confusion around a pump attached to a three-way tap.



Cell salvage n=2

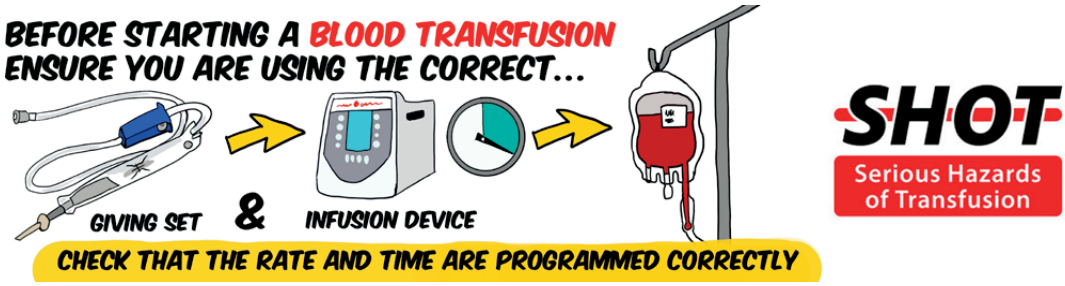
Both cases were in older children (1 a teenager). One was a leak in a cell salvage set, the 2nd was the presence of dark 'spots' in the red cells.

Handling and storage errors (HSE) n=32

There was a striking increase in 2023 (22 in 2022). Again, there were more clinical (26) than laboratory (6) errors.

Table 24.2: Paediatric HSE errors in 2023 (n=32)

Type of HSE error	Number of cases	Detail of errors
Pump-related errors	15	12 pump programming errors 3 were due to a faulty pump
Giving set or infusion errors	5	4 errors involved giving sets 1 involved incompatible fluids
Cold chain errors	4	In 2 cases, neonates were transferred between hospitals with accompanying red cell units. These were transported under suboptimal conditions and without the awareness of transfusion laboratory staff
Inappropriate return to stock/reservation period exceeded	3	
Excessive time to transfuse	2	These transfusions took place over 5 hours and 40-45 minutes (an infant and a teenager)
Other	3	2 unusual cases of contamination of red cells for neonatal/ infant transfusions via needlestick injuries to the nurses drawing up blood from the units using a needle rather than a conventional giving set.



Anti-D immunoglobulin (Ig) n=1

There was an accidental late administration of anti-D Ig for a teenage patient following delivery of a D-positive baby.

Transfusion-related reactions n=49

Febrile, allergic, and hypotensive reactions (FAHR) n=36

The number and proportion of paediatric platelet FAHR were lower this year than in previous years, 19/36 (52.8%). In the preceding 5 years (2018-22) they comprised 66% of paediatric FAHR (Figure 24.5 and 24.6).

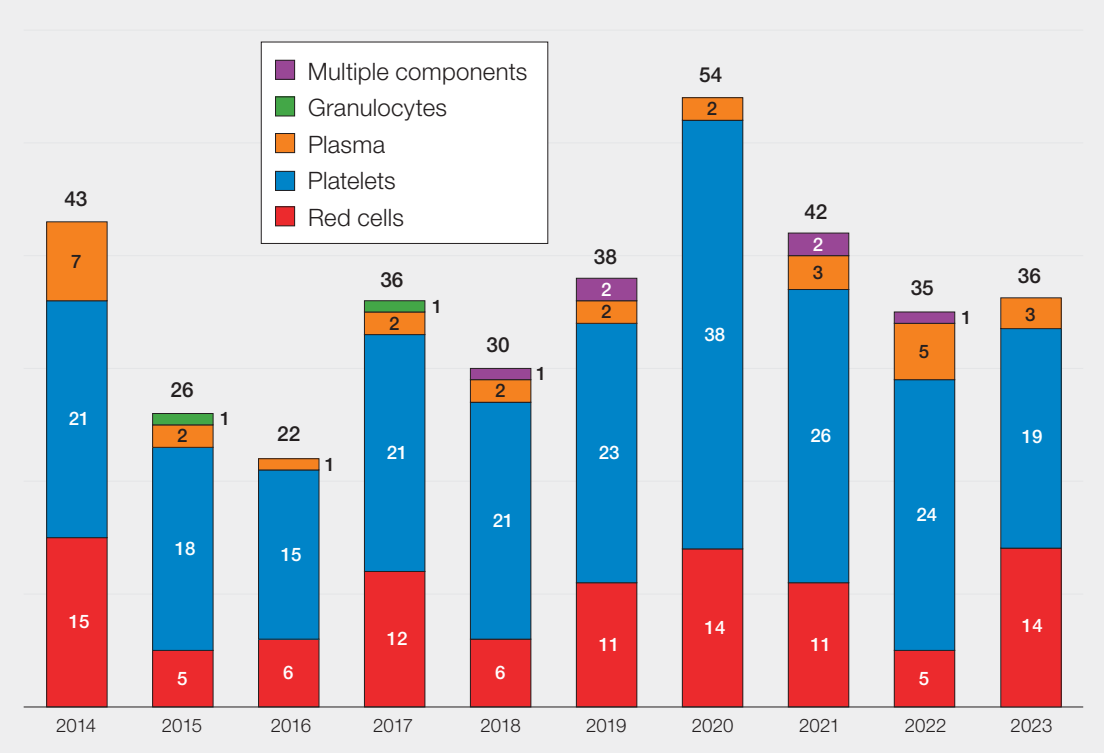


Figure 24.5: Summary of paediatric FAHR reports by component type from 2014-2023

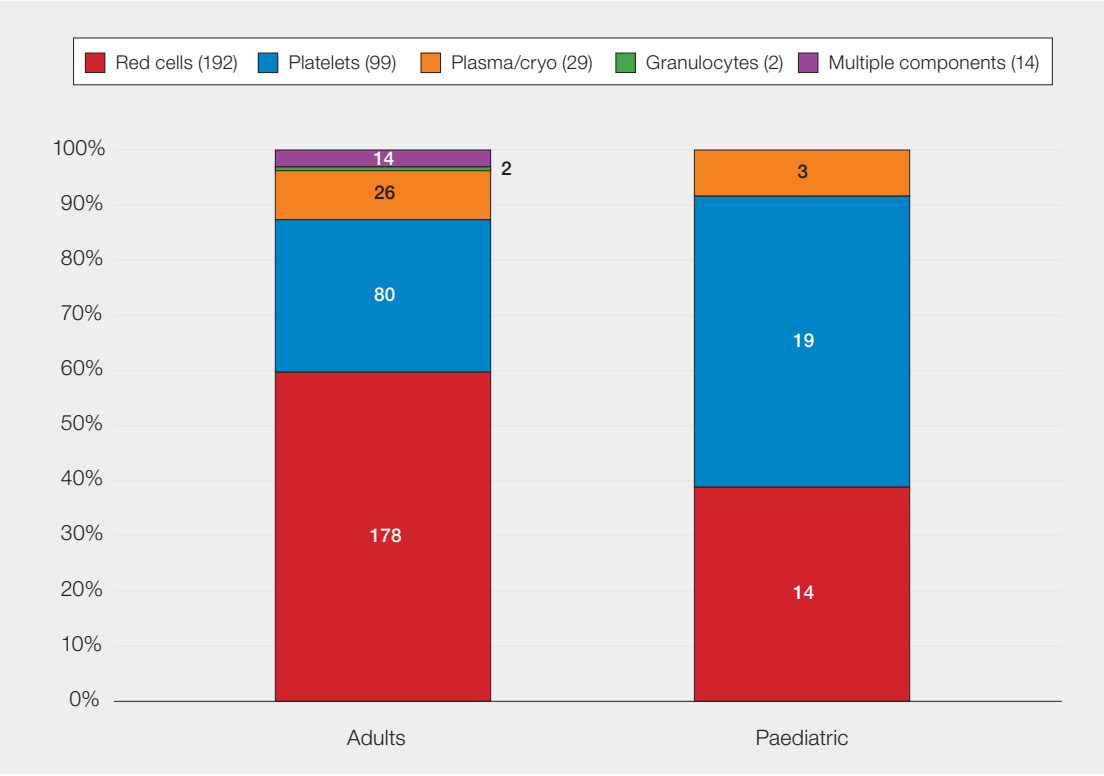


Figure 24.6: Paediatric febrile, allergic, and hypotensive reports (FAHR) in 2023 (n=36)

a: Comparison of proportions of adult and paediatric

Figure 24.6: Paediatric febrile, allergic, and hypotensive reports (FAHR) in 2023 (n=36)

b: Percentages of reaction types by paediatric FAHR related to different component types for paediatric reports

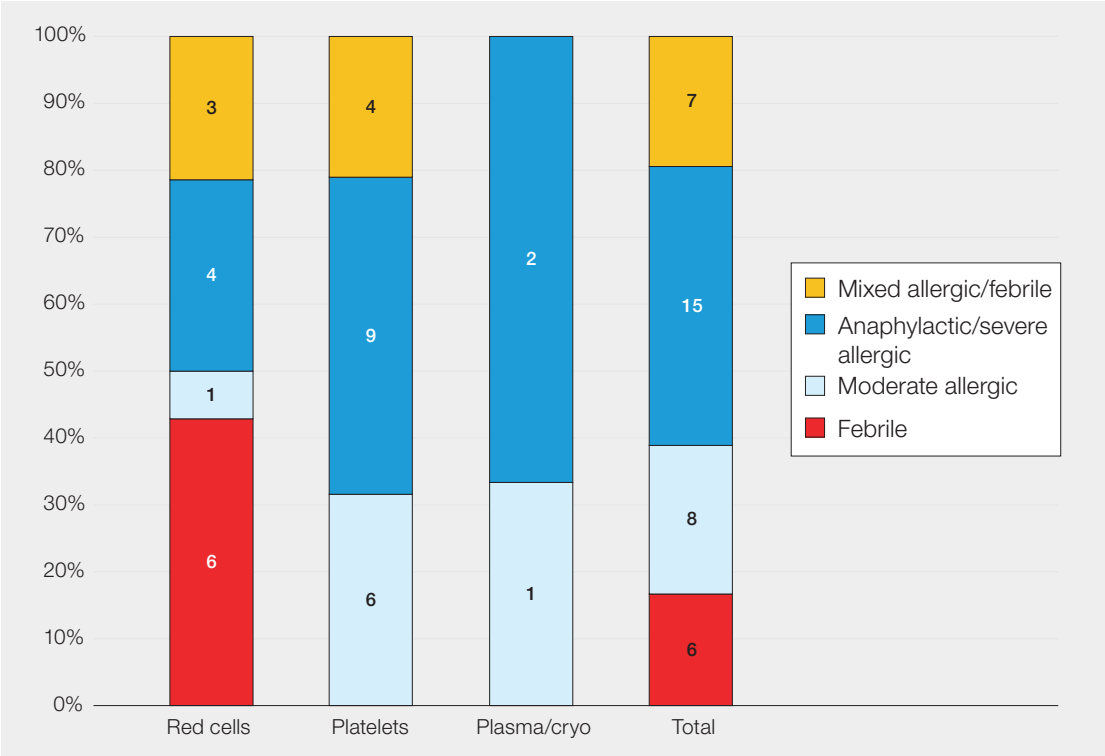


Figure 24.6b shows that 23/36 (63.9%) FAHR were allergic, 6/36 (16.7%) febrile and 7/36 (19.4%) mixed.

Of note, 2 red cell FAHR cases reported in 2023 were part of a cluster of 5 unusual reactions from a single hospital (see example discussed in Case 24.9), the other 3 are discussed in Chapter 20, Uncommon Complications of Transfusion (UCT).

Case 24.9: Allergic reaction to red cell component in multiply transfused patient

A child receiving regular red cell transfusions for a haemoglobinopathy, developed coughing followed by drowsiness after only 4mL of red cells. There was increased work of breathing and prolonged expiratory phase, with a drop in blood pressure. The child received intravenous antihistamine and adrenaline, then further adrenaline with hydrocortisone was administered when the reaction was prolonged. The child recovered and was subsequently given washed red cells.

Learning points

- The management of FAHR is summarised in the BSH guidelines (Soutar, et al., 2023)
- The UK Resuscitation Council guideline 2021, emphasised use of intramuscular adrenaline to treat anaphylaxis, repeated after 5 minutes if required (Working Group of Resuscitation Council UK, 2021)

Haemolytic transfusion reactions (HTR) n=2

One case was a delayed HTR in a teenager transfused for sickle chest crisis, subsequently found to have developed an anti-U.

The second case involved hyperhaemolysis which resulted in PICU admission in a child with SCD. No new alloantibodies were detected.

Pulmonary complications of transfusion in neonates and children n=4

Transfusion-associated circulatory overload (TACO) n=2

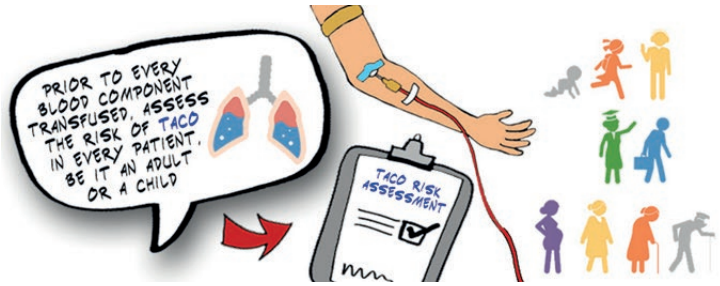
Both cases were in preterm infants less than 4 months old with chronic lung disease. One had low albumin and developed an increased respiratory rate and oxygen requirement 1 hour after the transfusion commenced (received approximately 6mL/kg). They responded to furosemide. The second had a patent ductus arteriosus and developed signs of fluid overload post transfusion (15mL/kg).

A separate TACO risk assessment does not exist for paediatrics, however many of the same risk factors apply. Caution is needed for prescribing transfusions in young children to ensure correct volume is administered. As in these 2 cases, TACO can still occur in at-risk infants when transfused with standard accepted volumes. Commonly used neonatal red cell top-up transfusion volumes (15mL/kg, (New, et al., 2016; New, et al., 2020)) are significantly higher in relation to body weight than the one red cell unit recommended for adults (NICE, 2015).

Non-TACO n=2

Following HSCT transplant, a teenager with SCD developed significant respiratory distress within 2 hours after a platelet transfusion, requiring intensive care admission. Investigations for TRALI were negative.

In the second case an infant with a congenital diaphragmatic hernia and pulmonary hypertension desaturated during a red cell transfusion. The child had been unwell since delivery and had developed sepsis. The infant fully recovered from this event.



SHOT
Serious Hazards of Transfusion

Transfusion-transmitted infections (TTI) n=1

There was 1 confirmed case of transfusion-transmitted malaria in a young child with thalassaemia in 2023. This is described in Chapter 21, Transfusion-Transmitted Infections (TTI), Case 21.5.

Uncommon complications of transfusion (UCT) n=6

There was 1 case of possible TANEC, resulting in the death of the neonate (discussed in Case 24.1 and in Chapter 20, Uncommon Complications of Transfusion (UCT)).

One case involved hypertension following transfusion in a sick young child with acute leukaemia.

In another case there was a report of possible transfusion-associated hyperkalaemia (6.7mmol/L) in a young child (10.4kg) undergoing cardiac surgery on bypass. The red cell unit was 35 days old. There are no recommendations restricting age of red cells for children in this situation other than for large volume infant transfusions. However, it is recommended that potassium concentrations should be checked in the bypass fluid before connecting to the patient (New, et al., 2016; New, et al., 2020).

The other 3 cases were part of an unusual cluster of 5 in multiply transfused patients; 2 met FAHR criteria and are discussed earlier in the chapter, but the other 3 were atypical. The 5 reactions had common features including rapid onset of coughing, chest tightness, drowsiness (4/5) wheeze (2/5) after small red cell volumes were transfused. Four received adrenaline. Despite detailed review and investigation,

no common cause for the reactions were identified. These cases highlight the importance of local review of transfusion reactions: the co-location of cases with similar features would not have been detected by SHOT.

Learning point

- Detection of this cluster of reports highlights the key role of transfusion practitioners and other members of the HTT in reviewing and trending their local transfusion errors and adverse reactions. There is an EU directive stating that data must be routinely analysed 'to identify quality problems that may require corrective action or to identify unfavourable trends that may require preventive action' (European Committee (Partial Agreement) on Blood Transfusion (CD-P-TS), 2023)

Paediatric error reports with no harm n=105

The numbers of cases of no harm/near miss are summarised below. See individual chapters for details.

RBRP n=11

Near miss cases n=27

Near miss-WBIT n=67

Conclusions

Key themes emerging from the paediatric reports submitted to SHOT in recent years, and actions needed to improve transfusion safety are summarised below:

- Paediatric teams should have access to local paediatric transfusion policies which must be aligned with national guidelines
- Induction training of paediatric staff should include specific requirements and weight-based prescribing to prevent errors in calculation of blood transfusion volumes and prescribing specific requirements for transfusion
- Gaps in staff knowledge regarding significance of test results and interpretation should be addressed and staff should be aware when to seek specialist advice
- Effective, timely and clear communication between clinical teams and transfusion laboratories is vital, especially for children undergoing HSCT and patients with haemoglobinopathies as transfusion requirements can be complex
- When transferring patients between hospitals, careful coordination and communication between clinical and laboratory teams is essential to ensure safe transfusions
- Paediatricians and neonatologists should be able to recognise transfusion reactions that can occur in various clinical settings and initiate appropriate management
- Members of the HTT should review and trend their local transfusion errors and adverse reactions in order to promptly detect any clustering of cases and investigate appropriately

Recommended resources

SHOT Bite No 4: Lessons in Paediatrics (including neonates)
SHOT Bite No. 5: FAHR (2021)
https://www.shotuk.org/resources/current-resources/shot-bites/

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

Paediatric SHOT
https://www.shotuk.org/resources/current-resources/videos/

Paediatric Cases Cumulative Data
https://www.shotuk.org/resources/current-resources/data-drawers/paediatric-cases-cumulative-data/

References

Estcourt, L. J. et al., 2017. Guidelines for the use of platelet transfusions. *British Journal of Haematology,* 176(3), pp. 365-394. doi: https://doi.org/10.1111/bjh.14423.

European Committee (Partial Agreement) on Blood Transfusion (CD-P-TS), 21st Edition, 2023. Good Practice Guidelines, paragraph 9.4.2. Directive 2005/62/EC, Annex 9.4.2. In: *Guide to the preparation, use and quality assurance of blood components*. s.l.:European Directorate for the Quality of Medicines and Healthcare (EDQM). Available at: https://freepub.edqm.eu/publications/AUTOPUB_48/detail (Accessed 13 May 2024).

Milkins, C. et al., 2013. Guidelines for pre-transfusion compatibility procedures in blood transfusion laboratories. *Transfusion Medicine,* 23(1), pp. 3-35. doi: https://doi.org/10.1111/j.1365-3148.2012.01199.x.

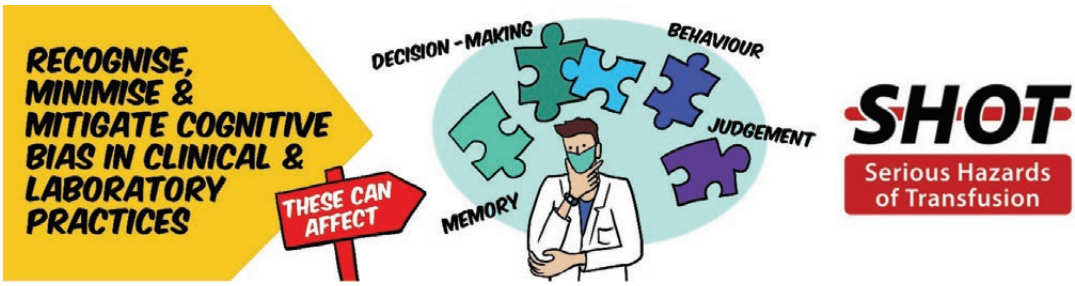
National Institute for Health and Care Excellence (NICE), 2015. *Blood transfusion. NICE guideline [NG24].* [Online] Available at: https://www.nice.org.uk/guidance/ng24 (Accessed 07 March 2024).

New, H. V. et al., 2016. Guidelines on transfusion for fetuses, neonates and older children. *British Journal of Haematology,* 175(5), pp. 784-828. doi: https://doi.org/10.1111/bjh.14233.

New, H. V. et al., 2020. British Society for Haematology Guidelines on transfusion for fetuses, neonates and older children (Br J Haematol. 2016;175:784–828). Addendum August 2020. *British Journal of Haematology,* 191(5), pp. 725-727. doi: https://doi.org/10.1111/bjh.17109.

Soutar, R. et al., 2023. Guideline on the investigation and management of acute transfusion reactions. *British Journal of Haematology,* 201(5), pp. 832-844. doi: https://doi.org/10.1111/bjh.18789.

Working Group of Resuscitation Council UK, 2021. *Emergency treatment of anaphylaxis. Guidelines for healthcare providers,* UK: Resuscitation Council UK. Available at: https://www.resus.org.uk/library/additional-guidance/guidance-anaphylaxis/emergency-treatment (Accessed 10 April 2024).



25 Haemoglobin Disorders n=88

Authors: Asha Aggarwal and Joseph Sharif

Abbreviations used in this chapter

ADU	Avoidable, delayed and under/overtransfusion
APPG	All Party Parliamentary Group
CMV	Cytomegalovirus
DHTR	Delayed haemolytic transfusion reaction
ED	Emergency department
FAHR	Febrile, allergic and hypotensive reaction
G&S	Group and screen
Hb	Haemoglobin
HCP	Healthcare professional
HSCT	Haematopoietic stem cell transplant
HSSIB	Health Services Safety Investigations Body
HSE	Handling and storage error
HTR	Haemolytic transfusion reaction
IBCT	Incorrect blood component transfused
ICU	Intensive care unit
IVIg	Intravenous immunoglobulin
NHR	National Haemoglobinopathy Registry
NHSE	National Health Service England
NHSBT	NHS Blood and Transplant
NTDT	Non-transfusion dependant thalassaemia
RCI	Red Cell Immunohaematology
SaBTO	Advisory Committee on the Safety of Blood, Tissues and Organs
SCD	Sickle cell disease
SCTAPPG	All-Party Parliamentary Group on Sickle Cell and Thalassaemia
Sp-ICE	Specialist Services Integrated Clinical Environment
SRNM	Specific requirements not met
WCT	Wrong component transfused

Key SHOT messages

- 2023 saw the highest number of HTR and hyperhaemolysis in SCD, leading to 2 deaths
- Alloimmunisation and HTR are a significant risk of transfusion in haemoglobinopathy patients and in particular SCD. The importance of weighing up the risks and benefits of transfusion and the need to provide blood components that meet the requirements for these patients may not be appreciated by healthcare professionals without specific expertise

Recommendations

- Haematology teams must be involved in the management of haemoglobinopathy patients presenting to secondary care and be consulted regarding transfusion decisions
- It is important to gain a full transfusion history from the patient and inform the transfusion laboratory when patients present to an unfamiliar hospital. The national database (Sp-ICE or equivalent) should be checked, and the patient's base hospital transfusion laboratory asked for previous transfusion records
- All haemoglobinopathy patients should have a baseline extended red cell phenotype or genotype prior to transfusion (Trompeter, et al., 2020)

Action: Hospital transfusion teams, clinical teams looking after patients with haemoglobin disorders, laboratory management

Introduction

Red cell transfusion is a cornerstone of treatment of SCD and thalassaemia. Transfusions can be given both electively and as an emergency during physiological stress (Davis, et al., 2017).

The number of incidents reported to SHOT in this patient group has been steadily increasing year-on-year. This year has seen the highest number yet, with 88 cases in total. There were 25 cases of major morbidity and 2 transfusion-related deaths reported. Figure 25.1 shows cumulative data for adverse transfusion events in patients with haemoglobin disorders since 2010 when SHOT started collating these reports.

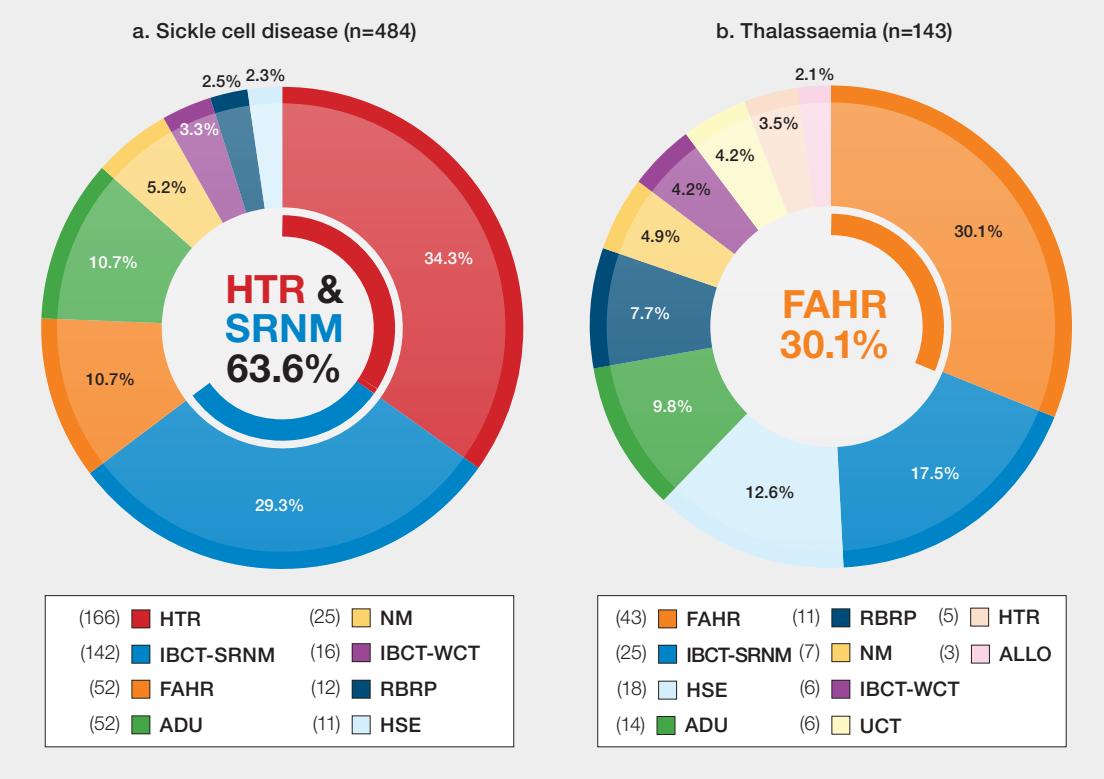


Figure 25.1: Cumulative data for adverse transfusion events in patients with haemoglobin disorders 2010 to 2023
a. Sickle cell disease (n=484)
b. Thalassaemia (n=143)

ADU=avoidable, delayed or under or overtransfusion; ALLO=alloimmunisation; FAHR=febrile, allergic or hypotensive reactions; HTR=haemolytic transfusion reactions; IBCT-SRNM=incorrect blood component transfused-specific requirements not met; IBCT-WCT=IBCT-wrong component transfused; NM=near miss; TACO=transfusion-associated circulatory overload; TAD=transfusion-associated dyspnoea; TTI=transfusion-transmitted infection; UCT=uncommon complications of transfusion

Categories with 2 or fewer reports are not included in the figures

Deaths related to transfusion n=2

There were 2 deaths related to transfusion (imputability 2, probable) reported in 2023 in haemoglobinopathy patients. Both were patients with SCD that died from haemolytic complications following elective transfusions (one had hyperhaemolysis, one had a DHTR). Further details can be found in Chapter 19, Haemolytic Transfusion Reactions (HTR).

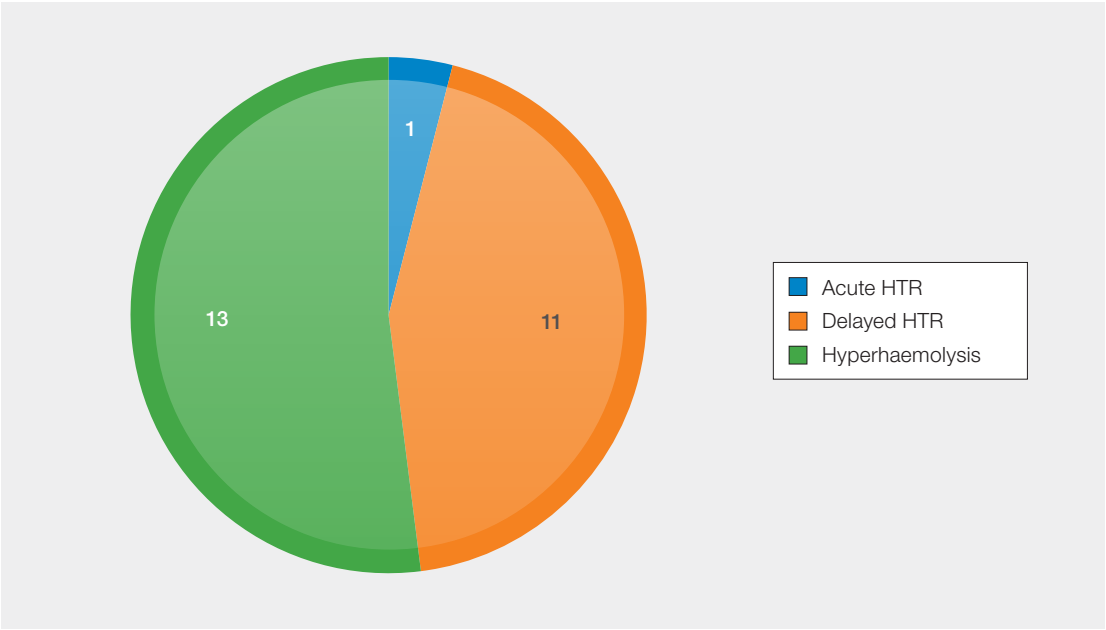
Major morbidity n=25

There were 25 reports associated with major morbidity, including 16 HTR, 6 FAHR, 2 delayed transfusions and 1 TTI.

Haemolytic transfusion reactions n=25

There were 25 reports of HTR in haemoglobinopathy patients, all in the context of SCD. This included 13 reports of hyperhaemolysis.

Figure 25.2: Types of HTR reported in patients with haemoglobin disorders in 2023 (n=25)



HTR=haemolytic transfusion reactions

Case 25.1: DHTR despite best practice

A patient with SCD sustained an ankle fracture and required surgery. They were known to have anti-S and anti-M antibodies. They received two compatible red cell units preoperatively and were discharged with appropriate safety-netting. The patient presented the following week to ED with sickle pain and anaemia. Their blood results showed evidence of significant haemolysis and they were treated with IVIg, steroids, rituximab and eculizumab. The patient received one unit of red cells during this treatment when her Hb dropped to 35g/L and spent 2 days on ICU before making a full recovery.

Case 25.2: Hyperhaemolysis recurrence after miscommunication

A patient with SCD presented to the ED with pain. It was noted that they had a Hb of 49g/L (baseline 50-55g/L). One unit of red cells was transfused overnight, after discussion with the on-call consultant haematologist. The next day, the haematologist noted that the patient had a history of hyperhaemolysis which had not been relayed on the phone overnight. The patient was subsequently started on steroids and was monitored as an inpatient for 2 days. They returned 3 days after discharge with pain and evidence of haemolysis. The patient remained in the hospital for 6 weeks, including 5 days on ICU.

Case 25.3: The importance of informed consent

A patient with SCD was admitted with a painful crisis. Two units of red cells were transfused, despite the Hb being at baseline for this patient. The indication for this transfusion was not clear. Six days later, they had an acute deterioration with hyperhaemolysis. The patient was admitted to ICU for 7 days, treated with IVIg, steroids and tocilizumab and subsequently made a full recovery. On discharge, the patient expressed concern that the rationale for the initial transfusion was not explained to them. There was no documentation of consent for the transfusion.

Another case involving DHTR and death after an exchange transfusion has been described in detail in Chapter 19, Haemolytic Transfusion Reactions (HTR), Case 19.1. It demonstrates the importance of communication and coordination between medical teams in this complex patient group.

Learning points

- Hyperhaemolysis is a serious complication of transfusion in SCD patients and can lead to death and serious morbidity. It can occur despite giving extended phenotype-matched red cells and without laboratory evidence of new alloimmunisation. Alloimmunisation and HTR can have serious implications on future transfusion provision in a cohort who may often need transfusion across their lifespan. Patients should be fully informed about the specific risks of alloimmunisation and HTR during the consent process, and unnecessary transfusions must be avoided
- Timely and effective communication between clinical and laboratory staff, between hospitals and between teams is vital for safe transfusions
- Patient education and understanding of the reasoning behind interventions is fundamental to ensure safety. This may empower them to challenge when things are incorrect. Staff should also question and check whether interventions are required
- A detailed and accurate transfusion history is essential, particularly when patients present to a new hospital

Febrile, allergic and hypotensive reactions n=13

There were 13 reports of FAHR, 7 of which were in patients with SCD, and 6 occurred in patients with thalassaemia. All patients made a full recovery.

IBCT-specific requirements not met n=16

There were 16 cases of SRNM.

Case 25.4: Avoidable alloimmunisation in a patient with thalassaemia

A patient with NTDT required a red cell transfusion during pregnancy. The laboratory was not informed that the patient had thalassaemia on the first 'booking' G&S, so Rh and K typing were not performed. The second G&S sample did include the relevant clinical information, but the required testing was not performed. Three red cell units were issued to the patient without being Rh/K-matched. The patient made an anti-c and anti-E antibody as a result.

Case 25.5: SRNM in SCD

A patient with SCD presented to hospital with a Hb of 49g/L. The LIMS had a flag to say that the patient had SCD, but this was not noted. Rh and K typing were not performed. The patient was O D-positive, but O D-negative red cells were provided for stock management reasons, though the transfusion was not an emergency. No pre-administration checklist was in use in the hospital, so specific requirements were not checked at the bedside. The case was picked up on a subsequent audit of O D-negative red cell use.

Case 25.6: Confusion about red cell matching post HSCT

A patient with SCD required a red cell transfusion after an allograft. Laboratory staff were unclear whether the Rh phenotype would be maintained post transplant, and this was not made clear on the local protocol. This has since been clarified and the post-HSCT protocol updated.

There were 3 reported cases of CMV-unselected red cells being given to pregnant haemoglobinopathy patients on regular transfusion programmes in 2023.

Learning points

- Laboratory staff must be informed when patients have a haemoglobinopathy, particularly when patients are new to a hospital. This will help ensure specific transfusion requirements are met and previous alloimmunisation is not overlooked for this patient cohort
- There may be additional specific transfusion requirements for some patients which must be taken into consideration when issuing blood components, e.g., irradiation post HSCT or CMV-negative components when pregnant (SaBTO, 2012)
- As HSCT for haemoglobinopathy patients becomes more common, protocols for blood provision need to be updated
- A joint statement from NHS Blood and Transplant, National Blood Transfusion Committee, United Kingdom Thalassaemia Society and Sickle Cell Society issued in November 2023 confirms removal of maximum age requirements for red cells transfusion to patients, including those with haemoglobinopathies, and can be accessed at this link: nhsbt-removal-of-maximum-age-requirements-for-red-cells-transfusion-to-patients-including-those-with-haemoglobinopathies.pdf (b-s-h.org.uk). It has been agreed that the BSH guidelines on red cell transfusion in sickle cell disease and on pre-transfusion compatibility procedures in blood transfusion laboratories will be updated in this respect. The SRNM definition and reporting criterial will also be updated in due course to reflect these changes

IBCT-wrong component transfused n=4

There were no reports of ABO-incompatible blood transfusions in patients with haemoglobin disorders in 2023.

Avoidable, delayed or under/overtransfusion n=12

There were 12 cases of avoidable or delayed transfusions, of which 2 led to major morbidity.

Case 25.7: Delayed exchange transfusion

A teenage patient with SCD required an emergency exchange transfusion due to acute chest syndrome. The patient had a new positive antibody screen. The blood had been sent in a paediatric tube, so there was insufficient serum for RCI testing. Two further samples were sent, but one sample tube had expired and the other was both insufficient and incorrectly labelled. Further samples then had to be collected. In the end, provision of appropriate red cell units took 22 hours.

Learning points

- Acute chest syndrome can result in rapid deterioration and respiratory failure. Multiple guidelines and consensus statements support the use of early transfusion in this condition (Howard, et al., 2015)
- Effective inventory management should be in place to avoid using expired sample tubes. Reminders for upcoming expiry dates, clear labelling and minimising overstocking can mitigate the risk of using expired items

Handling and storage errors n=8

There were 8 cases of handling and storage errors when transfusing patients with haemoglobinopathies in 2023. Most of these involved issues with infusion pump settings including staff being unfamiliar with equipment. None of these incidents led to major morbidity.

Transfusion-transmitted infections n=1

There was 1 confirmed case of transfusion-transmitted malaria in a young child with thalassaemia in 2023. This is described in Chapter 21, Transfusion-Transmitted Infections (TTI), Case 21.5.

NHR-NHSBT data linkage

The National Haemoglobinopathy Registry (NHR) is a register of people in the UK with all types of inherited red cell disorders. The register is held by NHSE and is intended to support direct clinical care, and for commissioning services within England. The NHR-NHSBT data linkage went live on Tuesday 12th March 2024. NHSBT red cell antibody data held on NHSBT systems is now available in the NHR on the transfusion tab and will be clearly marked as NHSBT red cell antibody records. This is a significant improvement in transfusion safety for patients who may need blood transfusion either as part of routine care or as an emergency. The data transfer will happen routinely every night to ensure new results move into the NHR, so the data is as up to date as possible.

This is a key milestone for NHSBT and NHSE in ensuring that critical results important for safe transfusion practice are available to clinical teams who need the information. All hospitals will continue to communicate with the patient's normal haemoglobinopathy centre transfusion laboratory to ensure that any results that may not be part of the NHSBT antibody record are also included in any decision-making regarding transfusion.

Conclusion

This year saw the highest number of SHOT reports in patients with haemoglobinopathies. Most major morbidity came from HTR, particularly hyperhaemolysis. Patients must be adequately informed and consented for these risks when a transfusion decision is being considered. This should be clearly documented in the patient's notes in line with SaBTO guidance. Consent should be reviewed frequently for those on regular transfusion treatment (SaBTO, 2020).

To reduce the risk of HTR and alloimmunisation, all haemoglobinopathy patients are eligible for full red cell genotyping as part of the 'Haem Match' project, which should help to more accurately match appropriate donors to patients (Gleadall, et al., 2020).

A common theme in the case studies above is the lack of adequate communication. Effective communication between hospitals, within hospital teams and between clinicians and the laboratory is vital to ensure that transfusion errors do not occur. In addition, good communication with patients to explain interventions and to take a thorough transfusion history is also crucial, particularly when patients present to unfamiliar hospitals. The antibody history for haemoglobinopathy patients is available to laboratory staff on Sp-ICE or other similar national databases. This has recently been added to the NHR.

The lack of experience in managing SCD patients in areas outside of haematology was highlighted in the APPG 'No One's Listening' report (SCTAPPG, 2021). The HSSIB recommended that NHS England review whether there should be a minimum training requirement for all HCP about SCD after an investigation in 2023 (HSSIB, 2023). The case studies above demonstrate that this is an ongoing problem. The message that haemoglobinopathy patients outside of haematology wards should have haematologists closely involved in their care and their transfusion decisions needs emphasising further.

A recent Lancet article summarised strategies to improve outcomes for SCD patients worldwide (Piel, et al., 2023). Transfusion availability and safety were key aspects of this. While the UK has a relatively robust and safe blood supply, as demonstrated above, improvements must be made to enhance transfusion safety for this patient group.

Recommended resources

SHOT Bite No. 14: Transfusion errors and reactions in patients with 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/

SHOT Safety Notice 02: SRNM 2022
https://www.shotuk.org/resources/current-resources/safety-notices/

References

All-Party Parliamentary Group on Sickle Cell and Thalassaemia (SCTAPPG), 2021. *No One's Listening – A Report* [Online] Available at: https://www.sicklecellsociety.org/no-ones-listening/ (Accessed 10 April 2024).

Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO), 2012. *SaBTO report of the Cytomegalovirus Steering Group.* [Online] Available at: https://www.gov.uk/government/publications/sabto-report-of-the-cytomegalovirus-steering-group (Accessed 10 April 2024).

Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO), 2020. *Guidelines from the expert advisory committee on the Safety of Blood, Tissues and Organs (SaBTO) on patient consent for blood transfusion.* [Online] Available at: https://www.gov.uk/government/publications/blood-transfusion-patient-consent/guidelines-from-the-expert-advisory-committee-on-the-safety-of-blood-tissues-and-organs-sabto-on-patient-consent-for-blood-transfusion (Accessed 10 April 2024).

Davis, B. A. et al., 2017. Guidelines on red cell transfusion in sickle cell disease Part II: indications for transfusion. *British Journal of Haematology,* 176(2), pp. 192-209. doi: https://doi.org/10.1111/bjh.14383.

Gleadall, N. S. et al., 2020. Development and validation of a universal blood donor genotyping platform: a multinational prospective study. *Blood Advances,* 4(15), pp. 3495-3506. doi: https://doi.org/10.1182/bloodadvances.2020001894.

Health Services Safety Investigations Body (HSSIB), 2023. *Management of sickle cell crisis.* [Online] Available at: https://www.hssib.org.uk/patient-safety-investigations/management-of-sickle-cell-crisis/ (Accessed 29 April 2024).

Howard, J. et al., 2015. Guideline on the management of acute chest syndrome in sickle cell disease. *British Journal of Haematology,* 169(4), pp. 492-505. doi: https://doi.org/10.1111/bjh.13348.

Piel, F. B. et al., 2023. Defining global strategies to improve outcomes in sickle cell disease: a Lancet Haematology Commission. *The Lancet,* 10(8), pp. E633-E686. doi: https://doi.org/10.1016/S2352-3026(23)00096-0.

Trompeter, S., Massey, E. & Robinson, S., 2020. Position paper on International Collaboration for Transfusion Medicine (ICTM) Guideline 'Red blood cell specifications for patients with hemoglobinopathies: a systematic review and guideline'. *British Journal of Haematology,* 189(3), pp. 424-427. doi: https://doi.org/10.1111/bjh.16405.

26 Transfusion Errors in Transplant Cases n=97

Authors: Jennifer Davies, Vera Rosa and Shruthi Narayan

Abbreviations used in this chapter

ABOi	ABO-incompatible
BMS	Biomedical scientist
BSBMTCT	British Society of Blood and Marrow Transplantation and Cellular Therapy
EBMT	European Group for Blood and Marrow Transplantation
EI	Electronic issue
HSCT	Haematopoietic stem cell transplant
IBCT	Incorrect blood component transfused
ID	Identification
IT	Information technology
LIMS	Laboratory information management system
NBTC	National Blood Transfusion Committee
NM	Near miss
PLS	Passenger lymphocyte syndrome
RCPath	The Royal College of Pathologists
SCRIPT	The SHOT United Kingdom Collaborative Reviewing and reforming IT Processes in Transfusion
SOT	Solid organ transplant
SRNM	Specific requirements not met
TA-GvHD	Transfusion-associated graft-versus-host disease
WBIT	Wrong blood in tube
WCT	Wrong component transfused

Key SHOT messages

- Flags and notes in the LIMS are not effective in preventing selection and release of ABOi components if staff do not pick these up and follow up with appropriate actions
- Communication is critical for the management of transfusion in transplant patients, particularly where there is shared care across multiple organisations
- Recommendations from the 2022 Annual SHOT Report continue to be relevant this year

Recommendations

- Processes should be in place to ensure effective communication of transplant timetables to all clinical and laboratory teams involved in patient care
- Laboratories should have a process that ensures information relating to appropriate component selection is recorded or updated in the LIMS in a timely manner, and not depend on one individual
- Laboratories should review the functionality of the LIMS with the supplier to ensure all currently available functionality is optimised for safe component selection. Where deficiencies are noted a roadmap for further development should be agreed, with timeframes, to include algorithms that support safe selection and are not dependent on flags and notes
- Where LIMS are dependent on alerts or notes for safe selection of blood components, these must be clear, unambiguous, not easily overridden and account for all component types. It should be recognised that these may not prevent ABOi events and so risk assessments must address the current situation and future plans for improvement

- Pre-transfusion checklists for transplant patients should include confirmation that components received have the correct specific requirements and ABO/D type in accordance with the transplant protocol

Action: Laboratory management, IT departments, clinical teams with responsibility for transplant patients

Introduction

For transplant recipients, decisions on which ABO/D group of components for transfusion must take account of the ABO and D types of both the recipient and the donor. Approximately 40-50% of HSCT are ABOi, this incompatibility may be major or minor. Major and minor incompatibility each occur in approximately 20-25% of transplants, and bidirectional incompatibility in 5% (Worel & Kalhs, 2008). The ABO and D group transfusion requirements of these patients change over time during the clinical course of the transplant. Bidirectional incompatibility includes both major and minor mismatch, with the presence of antibodies in both the recipient and donor plasma which can react with donor and recipient red cells respectively.

Guidance is available on the irradiation requirements for cellular component transfusion in patients at risk of developing TA-GvHD (Foukaneli, et al., 2020). The EBMT Handbook provides information on transfusion support for HSCT patients (Schrezenmeier, 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 and can be incorporated into local procedures and policies.

A national guidance document for transfusions in SOT recipients is being developed by British Society for Haematology. PLS is a complication of both solid-organ and stem cell transplant, caused by donor B lymphocytes producing antibodies that can result in destruction of recipient red cells (Moosavi, et al., 2020; Yazer & Triulzi, 2007).

Summary of cases from 2023

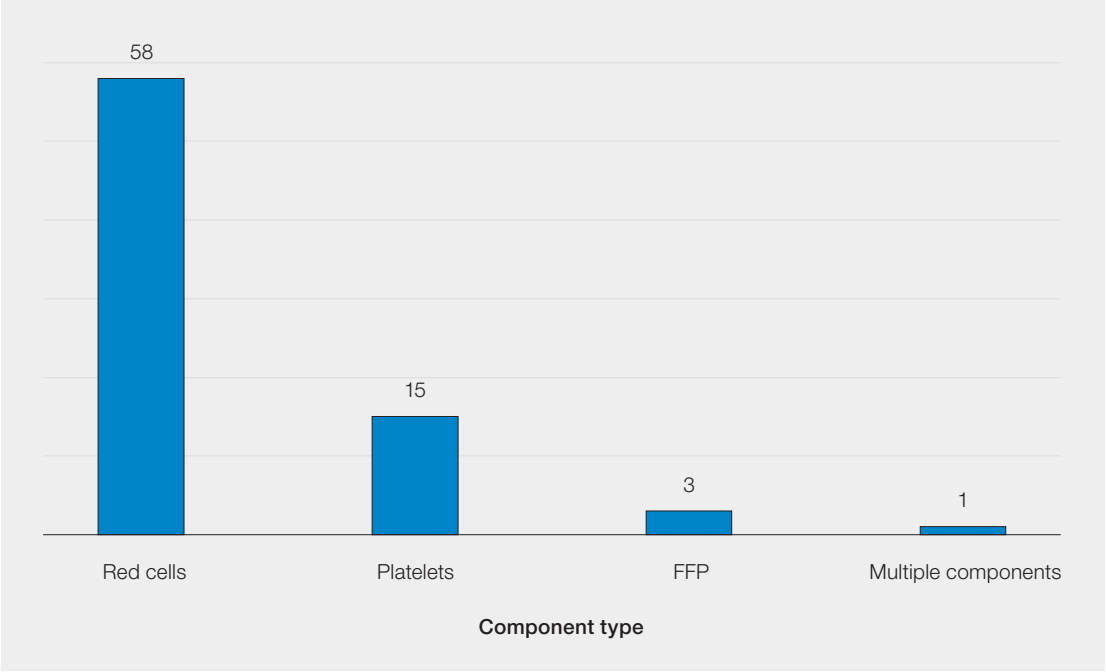
A total of 97 cases were reported to SHOT in 2023, an increase from 58 in 2022. Cases included SOT (n=19) and HSCT (n=78) recipients. Table 26.1 shows the distribution of all the cases reported. There were no deaths reported that were directly attributed to the transfusion error. Many cases, 37/97 (38.1%) were instances where the specific requirements for transfusion were not met. The majority of these (21/37) were failure to provide irradiated components, inappropriate use of electronic issue accounted for 6/37 cases. Of the 40 cases of IBCT-WCT, 37 cases involved transfusion of the wrong ABO/D group to the recipient. One case of suspected PLS was reported in a group O patient post transplant with a group A liver. In addition to the 77 transfused errors, there were 20 near miss reports.

Table 26.1: Total cases of IBCT-WCT, IBCT-SRNM and NM transfusion errors in SOT and HSCT recipients reported to SHOT in 2023 (n=97)

Type of error	IBCT-WCT and IBCT-SRNM cases	NM cases	Total cases
Wrong ABO and/or D group	37	2	**39**
Not irradiated	21	6	**27**
Wrong blood in tube	-	9	**9**
Inappropriate electronic issue	6	-	**6**
Incomplete testing	5	-	**5**
Not antigen-negative	3	-	**3**
Wrong patient	1	2	**3**
Wrong component type	2	-	**2**
Not HLA-matched	2	-	**2**
Not high-titre negative	-	1	**1**
Total	**77**	**20**	**97**

The most commonly implicated blood component in the WCT and SRNM errors reported were red cells. Figure 26.1 shows the distribution of blood components involved in these cases. In 1 case, multiple blood components were implicated.

Figure 26.1: Blood component implicated in the IBCT-WCT and IBCT-SRNM errors reported in 2023 (n=77)



FFP=fresh frozen plasma

As shown in Figure 26.2, the number of IBCT-WCT and IBCT-SRNM cases have been increasing with the highest number of incidents for both categories reported in 2023.

SHOT
Serious Hazards of Transfusion

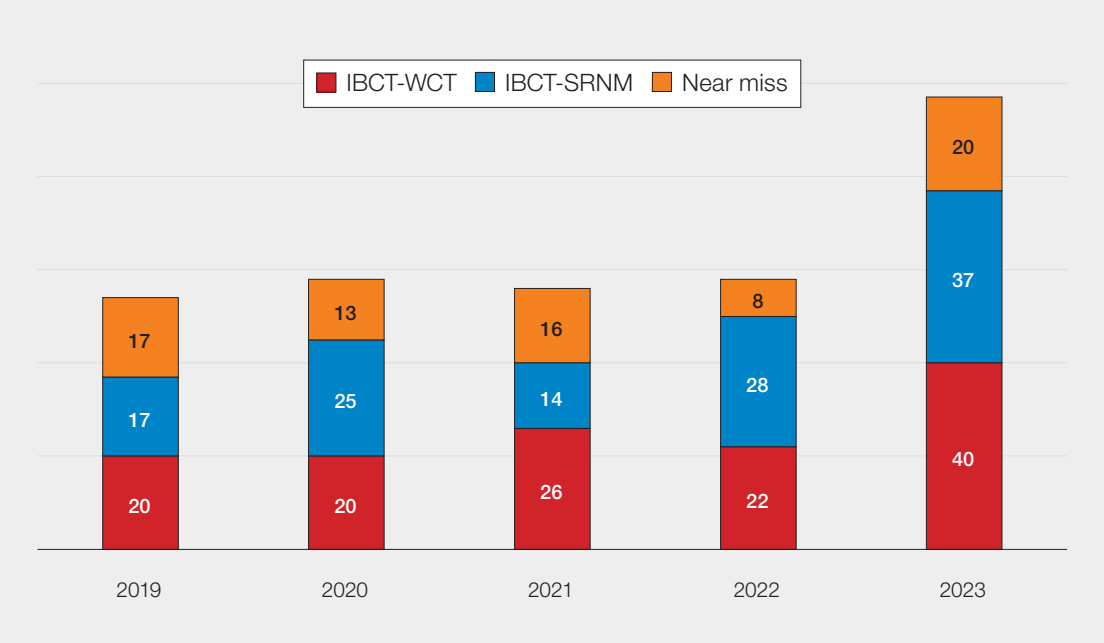


Figure 26.2: Number of transplant-related reports (HSCT and SOT) from 2019 to 2023

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

IT-related transplant cases n=72

There were 72/97 (74.2%) cases that had an IT element involved in the error. These themes are demonstrated in Figure 26.3.

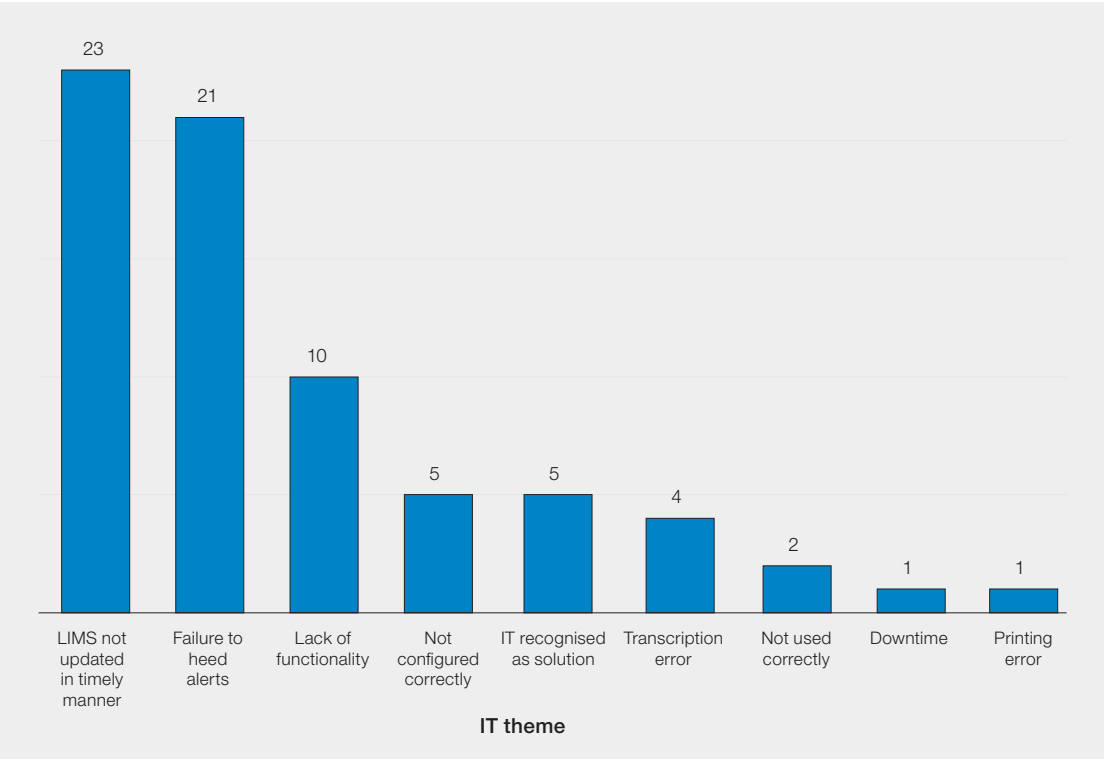


Figure 26.3: Themes related to IT in transplant error cases reported in 2023 (n=72)

IT=information technology; LIMS=laboratory information management system

Case 26.1: ABO-incompatible red cell transfusion

A HSCT patient (patient group A and donor group O) was transfused group A red cells. The information related to appropriate selection of ABO group for blood components was available in the notes in the LIMS but was not read by the BMS.

Reliance on notes and alerts in the LIMS that can be missed or easily overridden do not provide effective IT barriers to preventing error.

Case 26.2: Specific transfusion requirements not met: information not added to LIMS in timely manner

A notification of irradiated blood components requirement for a patient pre HSCT was sent to the laboratory manager by email. The patient was admitted to the ward and required a transfusion before the laboratory manager had acknowledged the email and updated the LIMS. The patient was transfused with red cells that were not irradiated.

Processes for notification of transplant information relating to appropriate selection of blood components should not be reliant on a single point of failure. In this case, notifications were sent to an individual rather than a team email, hence dependent on a single individual being able to act in a timely manner.

Case 26.3: Incorrect red cells selected for patient with suspected passenger lymphocyte syndrome

A group A patient received a liver transplant from a group O donor. Post transplant, the patient was noted to have a positive direct antiglobulin test, and group A red cells were noted to be incompatible in serological crossmatch. A sample was referred for further testing and anti-A1 eluted from the patient red cells. A requirement for group O red cells was added to the LIMS for future transfusion. However, two units of group A red cells were transfused to the patient at a later date. The units were serologically crossmatch-compatible and there was no evidence of haemolysis in the patient.

PLS is an uncommon condition. This case illustrates the importance of effective flags and algorithms in the LIMS to support safe selection of appropriate red cells. In this case, a serological crossmatch was performed, however, SHOT data continue to demonstrate that inappropriate EI occurs with this patient cohort.

Near miss errors n=20

In 2023, 11 near miss cases related to IBCT-SRNM (7/11) and IBCT-WCT (4/11) were reported, and 9 cases related to NM-WBIT. In all but 1 of the IBCT-WCT and IBCT-SRNM cases the error was detected at the pre-administration check. A formal pre-transfusion checklist was used in only 5/11 cases. In a single case, the laboratory team became aware of the transplant only when the clinical team called to discuss specific transfusion requirements.

Of the NM-WBIT cases, 6/9 were due to failure to identify the patient correctly at the time of phlebotomy, 2 due to failures to label the sample at the patient side and 1 sample was not labelled by the person taking the sample. Samples were handwritten in 8/9 cases. In 1 case the sample was labelled using an electronic system, investigation showed that the wrong ID band had been printed for the patient and positive patient identification was not performed at the time of phlebotomy.

In 2 NM-WBIT cases the reporting organisation stated that the laboratory did not employ the confirmatory sample policy (Milkins, et al., 2013). In the remaining cases 5/7 stated that the error was detected as a result of the confirmatory sample policy.

Commentary

Most transfusion-related errors in HSCT and SOT patients are either transfusion of ABO/D-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 patient care (clinical and laboratory) resulting in failure to update the LIMS and failure to heed alerts in IT systems continue to be the most common errors noted. 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. A SHOT SCRIPT LIMS user survey in 2019 noted deficiencies in compatibility algorithms for post-transplant patients. This was explored in a LIMS supplier survey in 2020 (see 'Recommended resources' section) where these were noted as improvements in future releases by some suppliers. Where LIMS are dependent on alerts or notes for guidance on safe selection, these must be clear, unambiguous and take into account appropriate selection for red cells, plasma and platelet components. Alerts should prompt appropriate actions and not be easily overridden by the user. LIMS functionality in terms of assigning blood groups to patients where testing results are indeterminate has also been implicated in flawed decision-making.

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 multiple centres and laboratories. Where notifications are made by email, laboratories should ensure that these are accessed regularly, accessible to a team, not an individual and are not a single point of failure. Notification processes should include fail-safes, including laboratory feedback to the clinical team that the information has been added to the LIMS, incorporation of specific requirements (irradiated) into component orders and inclusion of expected component ABO types and specific requirements in pre-administration checklists.

SHOT data show that transfusion of the wrong ABO or D group in ABO- or D-mismatched transplants, and failure to provide irradiated components continues to be a problem. Although improved functionality in LIMS could reduce 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' below) should be easily accessible and incorporated into local procedures and guidance. The impact of human factors and ergonomics on provision of safe transfusions must not be underestimated. The key to eradicating transfusion errors and advancing patient safety is to create systems for reliable healthcare delivery and systems should be designed with human factors and ergonomics at the forefront (Narayan, et al., 2023).

Recommended resources

Safe transfusions in haemopoietic stem cell transplant recipients - 2021
https://www.shotuk.org/resources/current-resources/

SHOT Bite No. 18: Transplant Patients (2021)
SHOT Bite No. 20: IBCT-SRNM (2022)
SHOT Bite No. 27: Solid Organ Transplant (SOT) 2023
https://www.shotuk.org/resources/current-resources/shot-bites/

SCRIPT survey reports
https://www.shotuk.org/resources/current-resources/script/

References

Foukaneli, T. et al., 2020. Guidelines on the use of irradiated blood components. *British Journal of Haematology,* 191(5), pp. 704-724. doi: https://doi.org/10.1111/bjh.17015.

Milkins, C. et al., 2013. Guidelines for pre-transfusion compatibility procedures in blood transfusion laboratories. *Transfusion Medicine,* 23(1), pp. 3-35. doi: https://doi.org/10.1111/j.1365-3148.2012.01199.x.

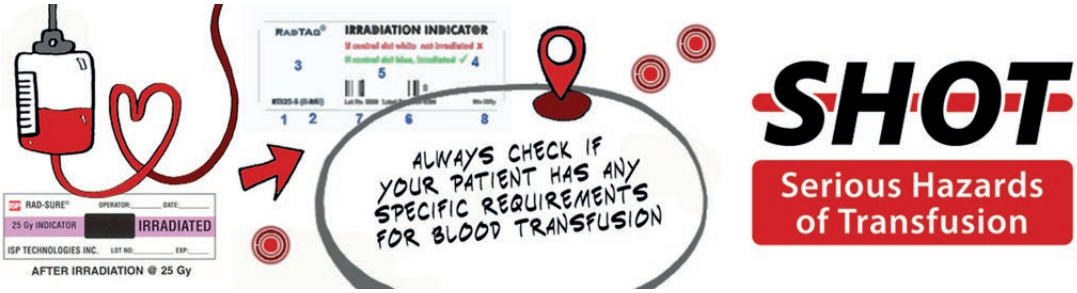
Moosavi, M. M. et al., 2020. Passenger Lymphocyte Syndrome; a Review of the Diagnosis, Treatment, and Proposed Detection Protocol. *Transfusion Medicine Reviews,* 34(3), pp. 178-187. doi: https://doi.org/10.1016/j.tmrv.2020.06.004.

Narayan, S. et al., 2023. *The 2022 Annual SHOT Report,* Manchester: Serious Hazards of Transfusion (SHOT) Steering Group. doi: https://doi.org/10.57911/WZ85-3885.

Schrezenmeier, H., Körper, S., Höchsmann, B. & Weinstock, C., 2019. Chapter 23 Transfusion Support [Online]. In: *The EBMT Handbook: Hematopoietic Stem Cell Transplantation and Cellular Therapies 7th ed.* s.l.:Springer, pp. 163-170. doi: https://doi.org/10.1007/978-3-030-02278-5.

Worel, N. & Kalhs, P., 2008. AB0-incompatible allogeneic hematopoietic stem cell transplantation. *Haematologica,* 93(11), pp. 1605-1607. doi: https://doi.org/10.3324/haematol.2008.001057.

Yazer, M. H. & Triulzi, D. J., 2007. Immune hemolysis following ABO-mismatched stem cell or solid organ transplantation. *Current Opinion in Hematology,* 14(6), pp. 664-670. doi: https://doi.org/10.1097/moh.0b013e3282e9a576.



Immune Anti-D in Pregnancy n=42 27

Authors: Vera Rosa and 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

APH	Antepartum haemorrhage	**IUD**	Intrauterine death
BMI	Body mass index	**IV**	Intravenous
BSH	British Society for Haematology	**NICE**	National Institute for Health and Care Excellence
cffDNA	Cell-free fetal deoxyribonucleic acid	**NPP**	No previous pregnancies
FMH	Fetomaternal haemorrhage	**PP**	Previous pregnancies
HDFN	Haemolytic disease of the fetus and newborn	**PSE**	Potentially sensitising event
IAT	Indirect antiglobulin test	**PVB**	Per vaginal bleeding
Ig	Immunoglobulin	**RAADP**	Routine antenatal anti-D Ig prophylaxis

Key SHOT messages

- There are ongoing missed opportunities where pregnancy management is not ideal
- Obesity, delivery beyond 40 weeks and high FMH are potential risk factors for D sensitisation
- Cases of D sensitisation are still occurring even when best practice is followed
- Lack of long-term follow-up of patients following significant FMH impacts management of future pregnancies as immune anti-D may not be detected promptly
- In cases where immune anti-D resulted from an error related to anti-D Ig administration, SHOT reports should be submitted for both categories

Recommendations

- Healthcare organisations must ensure that local policies reflect national guidance to allow best practice
- Healthcare organisations must embed a reviewing process of local policies against current versions of national guidance

Action: Healthcare organisations, transfusion service managers, maternity teams

- Hospital transfusion teams should perform a comprehensive investigation with a system-focused approach when pregnancy management is not ideal

Action: Healthcare organisations, hospital transfusion teams, maternity teams

- Training, education resources and competency-assessments relating to anti-D Ig administration and management of D-negative pregnancies must be extended to non-maternity services e.g., non-gynaecology wards and emergency departments

Action: Training leads

- Cases of immune anti-D found for the first time in pregnancy should be reported to SHOT, aiming to provide a complete data set after delivery

Action: Transfusion teams

Introduction

To improve understanding of the causes of continuing anti-D immunisations, SHOT has been reviewing cases where immune anti-D has been detected for the first time in the current (index) pregnancy since 2012. The reporters are requested to provide data on booking weight and BMI, 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). In cases where patients had been previously pregnant, details of delivery including anti-D Ig administration should be reported.

Results

In 2023 a total of 42 cases were reported, 7 cases occurred in women with NPP, and 35 in women with PP. Reporting is fairly consistent, however, the available data would suggest that D sensitisation 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 139 women with NPP and 388 women with PP.

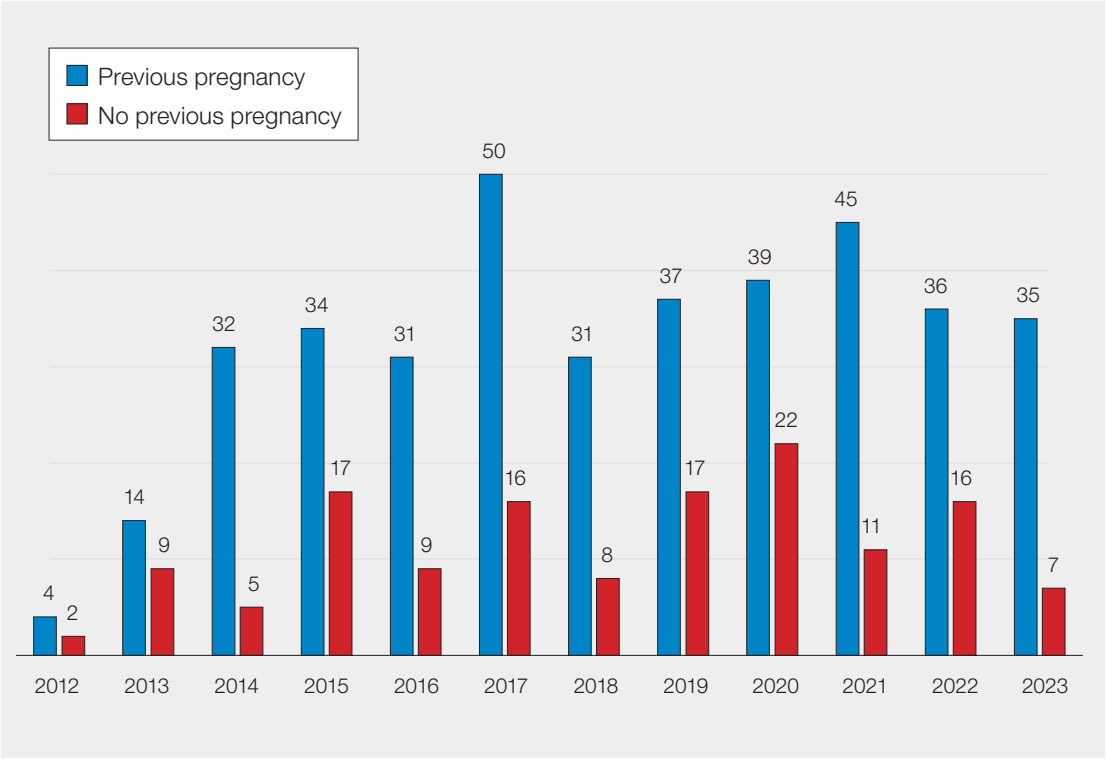


Figure 27.1: Number of reports of anti-D immunisation in pregnancy by year, 2012-2023

No previous pregnancy (NPP) n=7

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/shot-reports/report-summary-and-supplement-2023/).

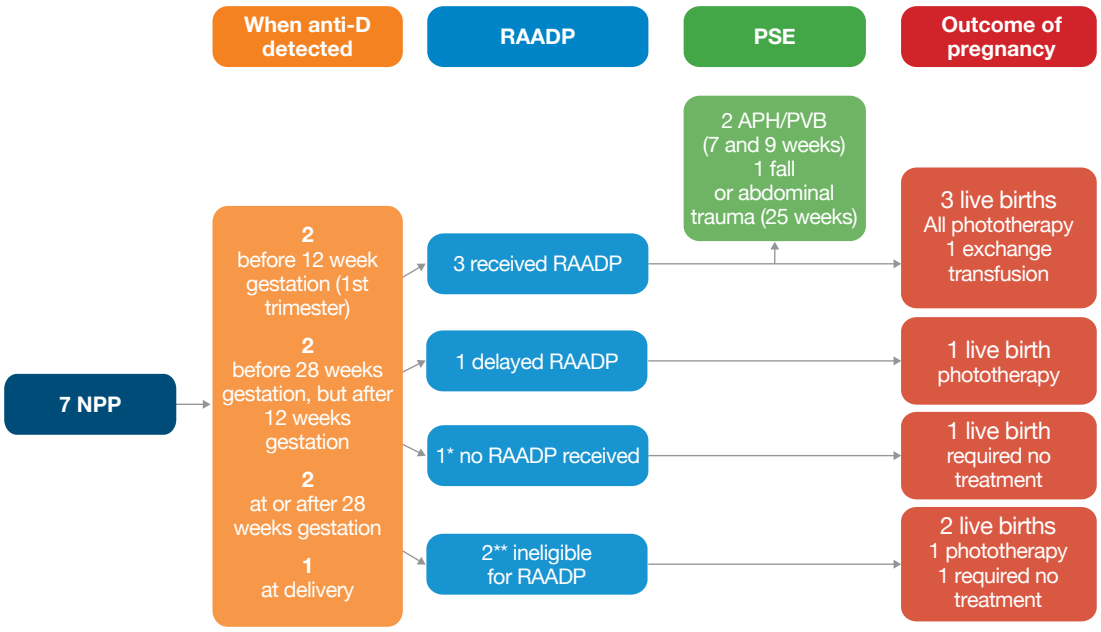


Figure 27.2: Summary of the 2023 NPP data (n=7)

APH=antepartum haemorrhage; NPP=no previous pregnancy; PSE=potentially sensitising event; PVB=per vaginal bleeding; RAADP=routine antenatal anti-D Ig prophylaxis

**RAADP appointment was not arranged. Anti-D detected at 38 weeks gestation*

***Immune anti-D detected before 28 weeks gestation (at 11 weeks and 9 weeks gestation)*

Illustrative cases

Case 27.1: Incorrect management of pregnancy results in development of clinically significant antibodies

A woman delivered at 38^{+6} weeks gestation and suffered post-partum major haemorrhage. Anti-D and anti-C were detected in this sample for the first time. This could have led to a delay in issuing crossmatched units while further testing was performed, but fortunately there was no delay in providing appropriate blood. During pregnancy, the woman had not received RAADP and was not offered cffDNA testing to enable correct management of pregnancy and prevent development of clinically significant antibodies.

The initial anti-D Ig error in this case has been described in Chapter 9, Adverse Events Related to Anti-D Immunoglobulin (Ig) in the major morbidity section.

The presence of maternal alloantibodies not only affects blood supply at delivery but also future transfusions and subsequent pregnancies. The requirement for antigen-negative red cells and IAT crossmatch can cause delays with potential adverse consequences for the patient including unavailability of suitable red cells. In emergency situations, the benefit versus risk of haemolytic transfusion reaction needs to be assessed by the clinical team on a case-by-case basis. In Case 27.1, emergency O D-negative red cells should be suitable for transfusion as the phenotype selected for these units are C- and E- (rr). It is important to note that emergency group O red cells may not always be suitable for patients with alloimmunisation to other antigens from different blood group systems.

Case 27.2: High anti-D level contributed to premature induction of labour

A woman attended the early pregnancy assessment unit with pain and bleeding at 9^{+5} weeks gestation. Pregnancy booking had been completed and the blood group was available. Anti-D Ig was not administered as per organisational guidelines. Immune anti-D was detected at 28 weeks. At 34^{+5} weeks the anti-D quantification was 170.6IU/mL. Labour was induced at 34^{+5} weeks. After delivery the baby required double volume exchange transfusion and phototherapy due to HDFN and recovered.

In this pregnancy, the management following PSE was not ideal and was likely the cause of the D sensitisation. According to the current BSH guideline, PSE in pregnancies occurring at <12 weeks gestation where uterine bleeding is associated with abdominal pain require administration of a minimum 250IU anti-D Ig (Qureshi, et al., 2014). Healthcare organisations must ensure that local policies reflect national guidance for best practice. In this case the presence of immune anti-D resulted in premature induction of labour, and consequently the baby required phototherapy as well as double volume exchange transfusion as part of the treatment for HDFN.

Learning points

- The presence of alloantibodies has an impact in blood provision for mother and baby with potential to cause delays due to blood unavailability and serological crossmatch requirement
- Local policies must reflect national guidelines for best practice to avoid maternal alloimmunisation

Previous pregnancies (PP) n=35

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/shot-reports/report-summary-and-supplement-2023/).

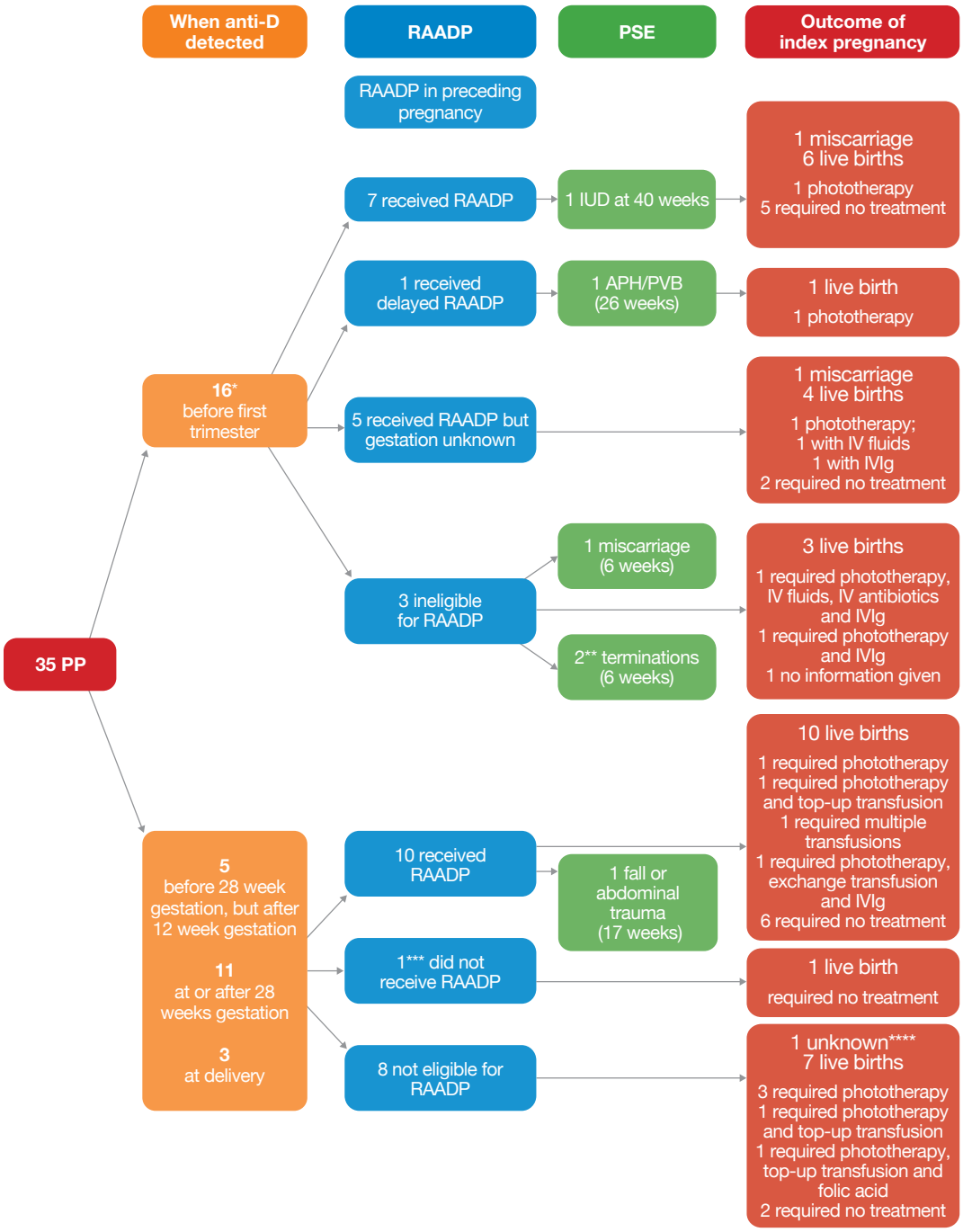


Figure 27.3: Summary of the 2023 PP data (n=35)

APH=antepartum haemorrhage; IUD=intrauterine death; IV=intravenous; IVIg=intravenous immunoglobulin; PP=previous pregnancy; PSE=potentially sensitising event; PVB=per vaginal bleeding; RAADP=routine antenatal anti-D Ig prophylaxis

**In 1 case, the anti-D was detected at delivery in previous pregnancy but regarded as prophylactic. Detected at booking in the index pregnancy*

***No information provided of the gestation when pregnancy was terminated*

****D-variant, patient regarded as D-positive throughout pregnancy*

*****Patient moved to India*

Illustrative cases

Case 27.3: Two-dose RAADP regime and no group and screen sample at delivery

Immune anti-D was detected for the first time at booking (11^{+2} weeks) during the 4^{th} pregnancy. No red cell antibodies were detected in the previous pregnancy up to 1 month prior to delivery (no group and screen sample taken at delivery). The Kleihauer test performed after delivery at 36 weeks

gestation estimated <2mL fetal bleed and 500IU anti-D Ig was given within 72 hours. The RAADP regime followed in the preceding pregnancy was two 500IU doses.

In this case, D sensitisation was not confirmed as to have occurred prior to or after delivery as a group and screen sample was not taken post delivery. From the information provided, the postnatal management appeared to be correct considering the estimated FMH, dose of anti-D Ig administered and the time frame of administration (within 72 hours). In 2023, cases of D sensitisation continue to be reported to SHOT where the management of pregnancy was deemed to be appropriate.

Current guidelines recommend either a two-dose regime (2x500IU) or one-dose regime (1x1500IU) (NICE, 2008). The one-dose regime has been associated with higher compliance as the patient only needs to attend one appointment (MacKenzie, et al., 2011). However, the two-dose regime can provide a higher protection to D sensitisation. A study conducted in Australia showed that a higher proportion of women who had received a two-dose RAADP regime had detectable anti-D Ig levels at delivery compared to those who had received a one-dose regime (White, et al., 2019).

Case 27.4: Immune anti-D detected for the first time in a patient with multiple risk factors for D sensitisation and previous IUD

Immune anti-D was detected for the first time in the index pregnancy at 12^{+1} weeks gestation. The patient had a high BMI >30 in both the previous and index pregnancies. This was the fifth pregnancy, with two previous live births, one miscarriage and one IUD.

The preceding pregnancy resulted in an IUD at 40^{+4} weeks gestation. The FMH volume was 56mL and 5600IU anti-D Ig was administered IV. In the follow-up sample, taken 48 hours after anti-D Ig administration and after delivery of the stillbirth at 40^{+5} weeks, a repeat FMH sample detected a fetal bleed volume of 4mL and further 500IU of anti-D Ig was administered. No follow-up sample was taken after the repeat 500IU dose. It is unclear if the decision to not take further follow-up samples for FMH testing was discussed with the haematology consultant.

In this case, there were multiple risk factors for D sensitisation; delivery beyond 40 weeks gestation, high BMI, and previous high volume FMH. In cases where multiple risk factors are present, it may be beneficial to consider a follow-up after 6 months for assessment of D sensitisation. Current BSH guidelines for FMH considers long term follow-up following significant FMH (Austin, et al., 2009) but it might be of benefit to extend this consideration to other risk factors. In addition, it is recommended that follow-up samples should be taken every 72 hours post anti-D Ig administration until fetal cells are no longer identified in the FMH test (Austin, et al., 2009).

Good practice was noted in this case as the treating team administered anti-D Ig IV appropriately in view of the high volume of fetal bleed and a follow-up sample was taken within the correct time frame considering the route of administration (48 hours when anti-D Ig administered IV).

Learning points

- When fetal cells are detected on follow-up samples, repeat FMH testing should be continued until clearance of fetal cells is confirmed
- The benefit of a long-term D sensitisation follow-up should be considered on a case-by-case basis

Conclusion

The 2023 data demonstrate that issues continue to occur in the management of D-negative pregnant patients. This is not only reflected in this chapter but also in Chapter 9, Adverse Events Related to Anti-D Immunoglobulin (Ig). The cases reported in both categories highlight missed opportunities for correct management relating to anti-D Ig administration following PSE and RAADP.

In 2 cases, the immune anti-D was assumed to be prophylactic where there were no records of anti-D Ig administration in the index pregnancy. In 1 case, the patient did not receive anti-D Ig following a PSE (>20 weeks gestation) nor as part of RAADP.

When considering risk factors for immune anti-D, it is important to evaluate not only the physical factors such as high BMI, large FMH and delivery beyond 40 weeks gestation, but also social and mental health factors that may impact patient's access to receive optimal treatment. These are contributory factors for non-compliance or non-reporting PSE during pregnancy and can result in incomplete, insufficient or absence of management throughout pregnancy.

When reporting these cases to SHOT, it is important to provide the BMI as well as the weight at booking because the BMI can provide a more accurate estimation of the risk obesity poses to D sensitisation.

SHOT appreciate that the information relating to previous pregnancies is not always easily accessible. However, to identify and understand the possible causes for D sensitisation, especially in those cases where the anti-D is detected at booking in the index pregnancy, the report should be completed as fully as possible.

Recommended resource

SHOT Bite No.29: Differences of reporting errors related to anti-D Ig and immune anti-D
https://www.shotuk.org/resources/current-resources/shot-bites/

References

Austin, E. et al., 2009. Guidelines for the Estimation of Fetomaternal Haemorrhage. *British Committee for Standards in Haematology (BCSH),* pp. 1-23. Available at: https://b-s-h.org.uk/guidelines/guidelines/the-estimation-of-fetomaternal-haemorrhage (Accessed 20 February 2024).

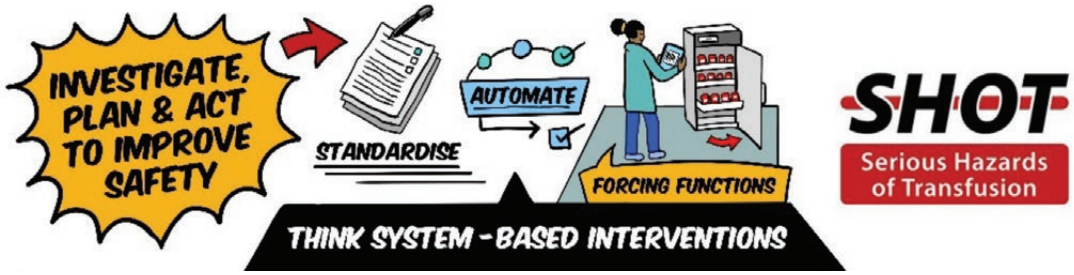
MacKenzie, I. Z., Dutton, S. & Roseman, F., 2011. Evidence to support the single-dose over the two-dose protocol for routine antenatal anti-D Rhesus prophylaxis: a prospective observational study. *European Journal of Obstetrics and Gynecology and Reproductive Biology,* 158(1), pp. 42-46. doi: https://doi.org/10.1016/j.ejogrb.2011.04.033.

Narayan, S. et al., 2019. *The 2018 Annual SHOT Report,* Manchester: Serious Hazards of Transfusion (SHOT) Steering Group. doi: https://doi.org/10.57911/4ENZ-ET89.

National Institute for Health and Care Excellence (NICE), 2008. *Routine antenatal anti-D prophylaxis for women who are rhesus D negative TA156.* [Online] Available at: https://www.nice.org.uk/guidance/ta156
(Accessed 12 February 2024).

Qureshi, H. et al., 2014. BCSH guideline for the use of anti-D immunoglobulin for the prevention of haemolytic disease of the fetus and newborn. *Transfusion Medicine,* 24(1), pp. 1-66. doi: https://doi.org/10.1111/tme.12091.

White, S. W. et al., 2019. Single dose v two-dose antenatal anti-D prophylaxis: a randomised controlled trial. *The Medical Journal of Australia,* 211(6), pp. 261-265. doi: https://doi.org/10.5694/mja2.50266.



Acknowledgements

The Steering Group take this opportunity to thank the following individuals and organisations for their contributions without which the publication of this 27th 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
  - Mrs Emma Haworth, Marketing Manager, 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
- Raquel Lopez, SHOT Office Administrator
- 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.

Medicines and Healthcare products Regulatory Agency (MHRA) Report 28

Authors: Chris Robbie, Mike Dawe, Shirley Stagg

Abbreviations used in this chapter

BCR	Blood compliance report
BE	Blood Establishment
BMS	Biomedical Scientist
BSQR	Blood Safety and Quality Regulations 2005 (as amended)
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
EDQM	European Directorate for the Quality of Medicines & Healthcare
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 continues to work 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
- Staffing and workload issues remain a factor in the errors reported. It is the third most common ‘system error’ after inadequate processes and ineffective training
- Hospital transfusion teams should implement an effective tracking and trending system of root cause to identify emerging trends so effective CAPA can be implemented
- Attention should be made to the SAE and root causes highlighted in this chapter to ensure these are being reported consistently and that QMS are reviewed for robustness and effectiveness

Summary

There has been an increase in the total number of reports received during 2023. The increase is seen to be as a result of more SAE reports being received. While the increase in the number of reports looks sharp compared to last year, it must be remembered that the reports for the previous few years have been influenced by the effects of COVID-19. When viewed in the context of the last 10 years the increase in numbers of reports demonstrates a steadier increase. While this might demonstrate an increase in

potential risk of harm to patients, it could also be a natural increase in reporting due to greater awareness of the types of SAE reportable under the BSQR.

The proportion of SAE reported to be due to process and system deficiencies has risen to 70% and the proportion due to human error dropped to 30%. These figures should be seen as encouraging rather than discouraging as it represents a greater proportion of reporters are identifying one or more system improvements rather than holding individual staff members responsible for 'human errors'.

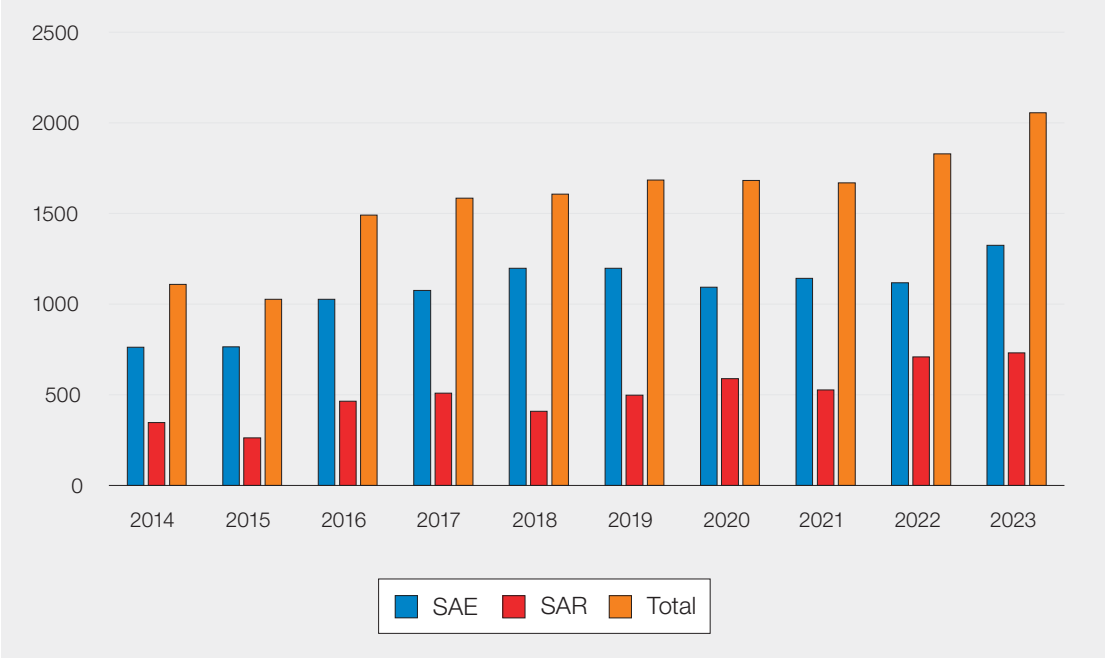
SABRE report data

Table 28.1 and Figure 28.1 show the total numbers of reports and the numbers of reports submitted as SAE and SAR for the previous 10 years. There has been a 19% increase in the total number of reports submitted in 2023. Most of these are in the SAE categories. Overall, the number of reports received show an upward trend over ten years.

Table 28.1: Submitted confirmation reports 2014–2023

	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023
SAE	762	764	1027	1076	1198	1197	1093	1143	1118	1325
SAR	346	262	464	508	408	497	590	526	710	731
Total	1108	1026	1491	1584	1606	1694	1683	1669	1828	2056

Figure 28.1: Submitted confirmation reports 2014-2023



Serious adverse events n=1325 (+207)

Definition: (Department of Health, 2005) Any untoward occurrence associated with the collection, testing, processing, storage and distribution, of blood or blood components that might lead to death or life-threatening, disabling or incapacitating conditions for patients or which results in, or prolongs, hospitalisation or morbidity

Event category	Number of reports
Materials	0
Apheresis collection	2
Whole blood collection	6
Testing of donations	8
Processing	10
Distribution	16
Donor selection	83
Storage	326
Other	874
Grand total	**1325**

Table 28.2: Total number of SAE reports by event category

Table 28.2 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 15% increase in 'other' SAE and a 33% increase in the number of storage SAE following a reduction last year.

Storage data n=326 (+81)

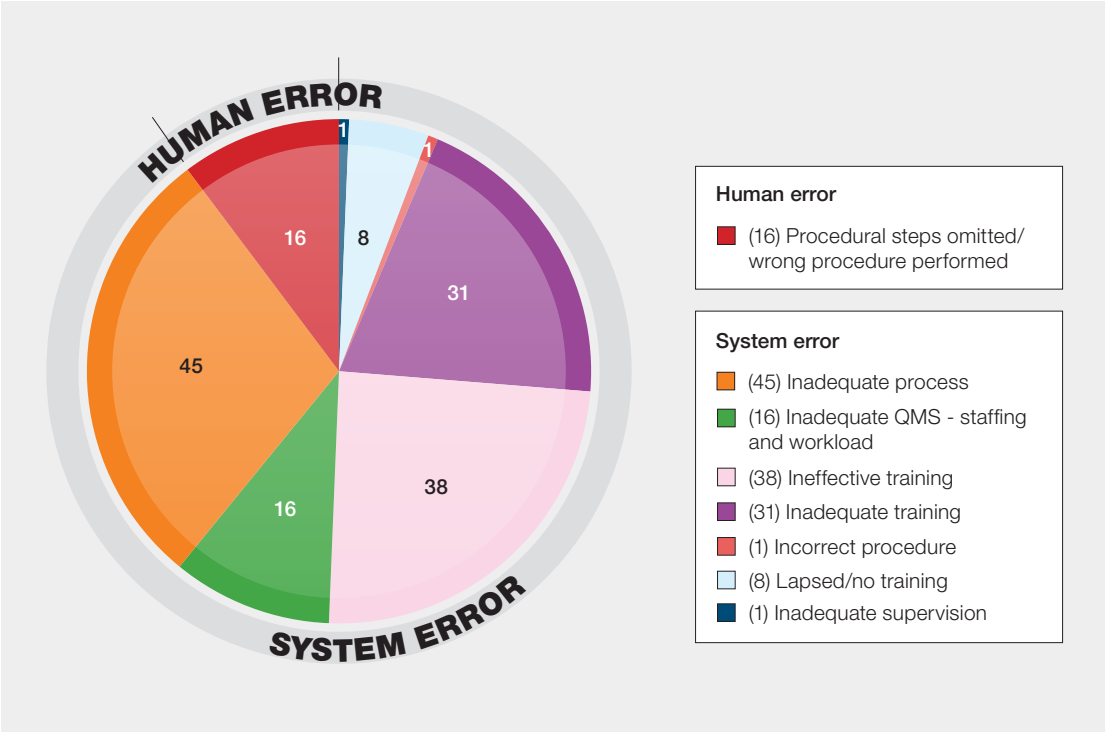
Storage remains the second largest individual error category (after 'other') and comprises of all BSQR reportable storage SAE in both the laboratory and clinical areas. The MHRA Haemovigilance Team lead has broken this category down further to try and identify specific storage error sub-types, Table 28.3. For a description of the sub-categories used, see Appendix 1.

Storage sub-classification	2023 (+/- 2022)	2022 position
Incorrect storage of component	156 (+38)	1
Component expiry	58 (+20)	2
Return to stock error	37 (+15)	4
Sample expiry	36 (+7)	3
Security	13 (-1)	5
Storage temperature deviation	9 (+2)	7=
Failure to action alarm	9 (+1)	6
Miscellaneous	7 (NC)	7
30- or 60-minute rule	1 (-1)	9
Total	**326 (+81)**	**X**

Table 28.3: SAE storage error sub-classifications

Following a decrease in the number of storage errors last year, there has been a 33% increase in total in 2023. The top 4 storage sub-categories have all shown an increase with the largest increase in incorrect storage of component.

Figure 28.2
Root causes of incorrect storage of components sub-category (n=156)



QMS=quality management system

As the single largest sub-category of storage, Figure 28.2, shows the breakdown of incorrect storage of component by root cause.

90% of all Incorrect storage of component errors are related to one or more deficiencies in the quality system. Only 10% were related to human error where staff have knowingly followed the wrong procedure or skipped steps in a process.

29% demonstrate either inadequate design of processes designed to maintain the quality and safety of blood and blood components or involved multiple errors within the system in use.

49% are in some way related to training;

- 24% show the training to be ineffective
- 20% show the training to be inadequate
- 5% show staff have either not received training or their previous training has lapsed

Common themes from the narratives of incorrect storage of component reports shows;

- Processes and procedures are not clear on how blood should be stored safely and correctly
- Errors are made when staff do not handle blood regularly and have forgotten their training
- Training of staff in blood and blood component storage is not given a high enough priority during staff induction training and continuous training thereafter
- Training material does not always cover all aspects of storage e.g., how to distinguish between components and their different storage requirements
- Errors often occur because shifts are not staffed with adequate numbers of trained staff
- Agency/bank staff training is inadequate
- Agency/bank staff are expected to handle components without having been trained in the local procedures

All storage errors are covered by the requirements of the BSQR. Most of these storage errors occur in clinical areas. It is still a widely held belief that storage errors in clinical areas are clinical errors and that investigation and reporting of these errors is not covered by the BSQR. This is incorrect. All storage

errors that affect the quality and safety of blood and blood components must be fully investigated as per the requirements of the BSQR and GPG.

Recommendation

- Hospital Trusts/Health Boards must improve all areas relating to the quality and safety of blood and blood component storage and the investigation of such storage errors

Action: Hospital transfusion teams

Other n=874 (+118)

Table 28.4: 'Other'

Other sub-category	2023 (+/- 2022)	2022 position
Incorrect blood component issued (IBCI)	194 (+58)	2
Pre-transfusion testing error (PTTE)	148 (+24)	4
Sample processing error (SPE)	146 (-1)	1
Component collection error (CCE)	127 (-9)	3
Component labelling error (CLE)	115 (NC)	5
Data entry error (DEE)	89 (+27)	6
Failed recall (FR)	24 (+9)	7
Component available for transfusion past de-reservation (CATPD)	10 (+6)	9=
Incorrect blood component ordered (IBCO)	7 (-2)	8
Expired component available for transfusion (ECAT)	6 (+3)	11
Incorrect blood component accepted (IBCA)	4 (+3)	12=
Handling damage (HD)	3 (+3)	14
Unspecified (UNSPEC)	1 (-3)	9=
Total	**874 (+118)**	**X**

Table 28.4 shows the number of reports in the 'other' category of SAE. There has been a 15% increase in events that fall into this category. The majority of the increases have been in the sub-categories;

- Incorrect blood component issued
- Data entry error
- Pre-transfusion testing error

Please see Appendix 2 for a description of the sub-categories.

Human and system error categories and human factors

The BSQR requires that 'preventable causes' of SAE are investigated and reported (Department of Health, 2005). The GPG also states 'Where human error is suspected or identified as the cause of the deviation, this should be formally justified and care should be exercised so as to ensure that process, procedural or system-based errors or problems are not overlooked, if present.' (EDQM, 2023).

What this means is that for all SAE reported on SABRE, the root cause investigation must first identify any system-based causes, or 'human factors'. 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.

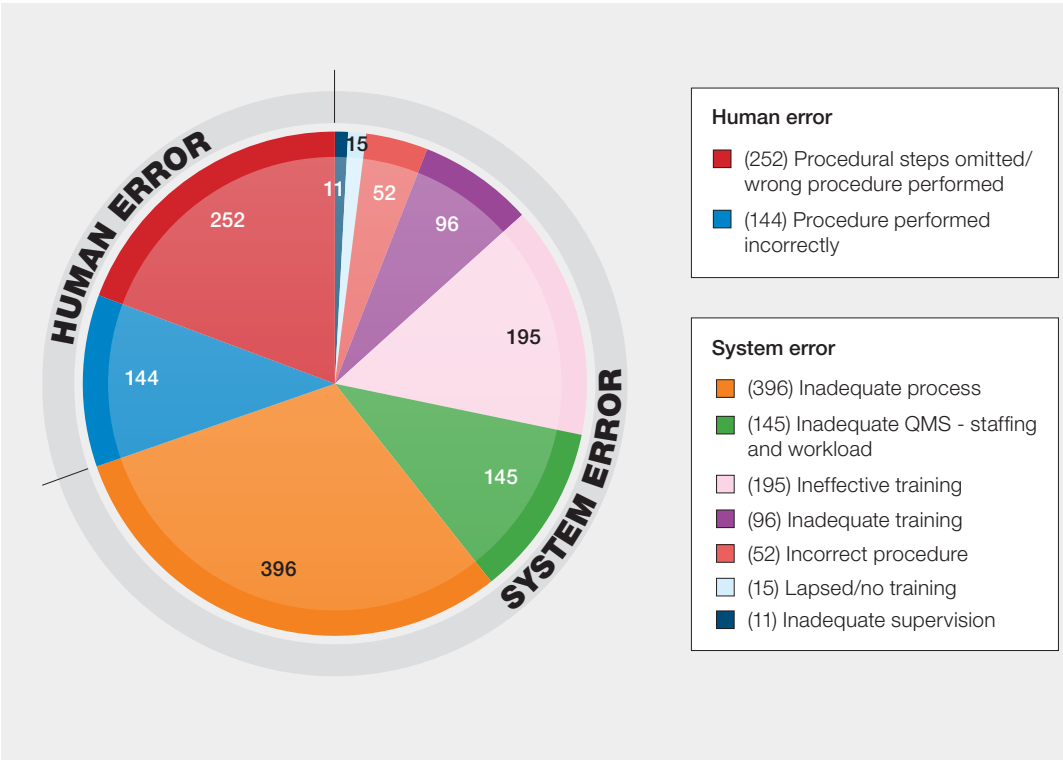
MHRA assign a category on review of an SAE report to reflect the most prominent causative factor. Assessment of these reports can distinguish between events caused by system errors and human errors (slips/ lapses/ omissions). For a description of the categories used, see Appendix 3.

Table 28.5 shows the breakdown of reports in the human/system error sub-categories.

Table 28.5: Human/ system error sub-categories, 2023

Human error sub-category	Total 2023 (+/- 2022)	2022 position
System error/ Inadequate process	396 (+121)	1
Human error/ Procedure performed incorrectly	252 (+25)	2
Human error/ Procedural steps omitted/wrong procedure performed	195 (+70)	5
System error/ Inadequate QMS – staffing and workload	145 (+5)	4
System error/ Ineffective training	144 (-32)	3
System error/ Inadequate training	96 (+16)	6
System error/ Incorrect procedure	52 (+9)	7
System error/ Lapsed/no training	15 (-7)	8
System error/ Inadequate supervision	11 (+1)	9
Total	**1306 (+208)**	**X**

Figure 28.3: Human/system error sub-categories (n=1306)



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 continues to work with reporters to improve the quality of SAE investigations. 14 training sessions were undertaken either with individual hospital trusts or regional

groups. These training sessions in investigation of events, RC and CAPA are available free of charge on request. The team continues to be strict 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 28.5 shows a 19% increase in the number of reports due to human factors. However, 70% of these reports have identified one or more system improvements as a result of their investigations. This demonstrates a continued improvement in the quality and depth of investigations, either initially or after a request for more detail by the MHRA haemovigilance team. The remaining 30% are either genuine slips or lapses by individuals, or examples of reports that may have benefitted from a more in-depth investigation.

Common themes from the narrative of these investigation reports show;

- 30% of these reports either demonstrate a weak process or system design or involve multiple system deficiencies
- Inadequate process errors may involve the poor identification and mitigation of distractions
- 11% of these reports are directly related to staffing, workload, or skill-mix issues and is the third largest 'system error' sub-category. However, it must be noted that some of the 30% Inadequate process reports, may also include some aspects of staffing and workload issues, since this category may reflect multiple system or process deficiencies
- Many reports note errors are made when staff are 'busy'. It may not always be possible to directly link these to staffing and workload since improved prioritisation of workloads may have prevented the error from occurring
- Many reports do not reflect the seriousness of the event as they only reflect actual harm and not potential harm
- Many confirmation reports initially assign a RC as Human error without fully identifying process or system deficiencies
- Many CAPA are initially proposed to be reminding staff to 'be more vigilant' and to 'follow procedures'. This is not an appropriate CAPA as it demonstrates a failure to identify genuine causes and the implementation of effective CAPA
- RC are often identified as a failure to perform an adequate second check. Failure to perform second checks are not RC as the error has already occurred by the time the second check was performed
- Many reports continue not to be reported 'as soon as known'
- Many confirmation reports are delayed due lack of engagement from clinical areas or by reviews of investigation reports

Recommendations

- All reporters must continue to thoroughly investigate all SAE, even those with no actual harm to patients. It is through thorough investigations that improvements can be identified to reduce risks to the quality and safety of blood and blood components and reduce the risk of harm to patients
- When investigating an incident, reporters must have taken care to ensure that process, procedural or system-based errors or problems have not been overlooked. For example, if distractions have been identified then these distractions must be addressed in the CAPA to avoid reoccurrence
- CAPA must correct the error made and not just rely of making error checking more robust

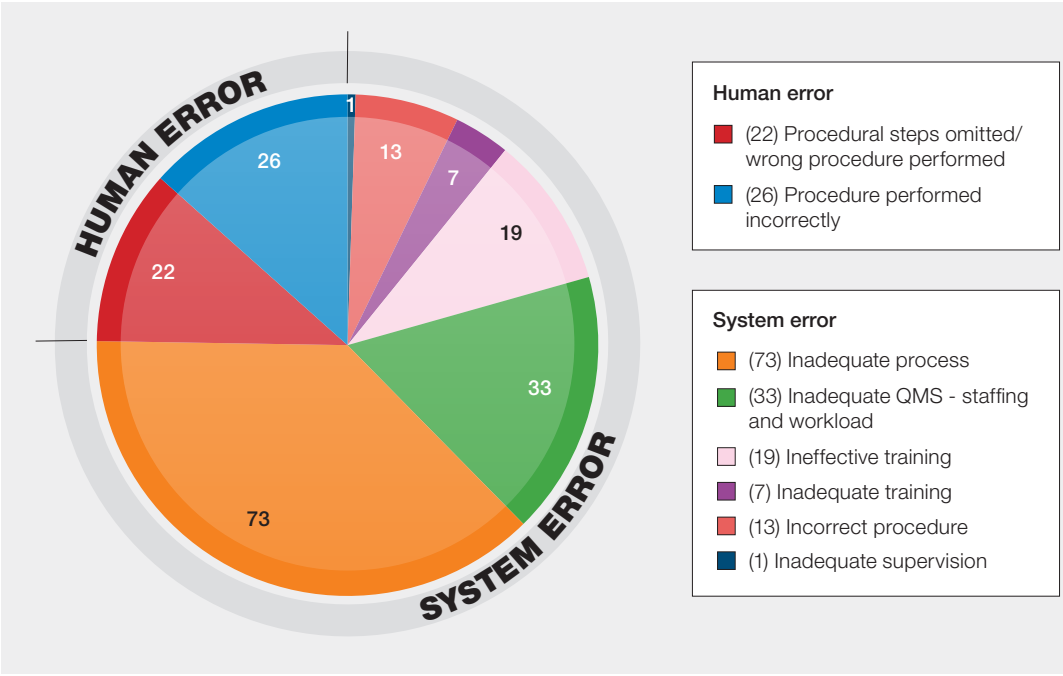
- Engagement from staff in clinical areas must be improved. It is the responsibility of the Trust or Health Board to ensure all SAE are investigated and reported in a timely manner as per the requirements of the BSQR
- Reporters are reminded to report 'as soon as known'. You are required only to submit a Confirmation report with RC and 'Proposed' CAPA. Changes to CAPA following review can be added to SABRE reports as Footnotes

Action: Hospital transfusion teams

Top 5 SAE

Presented below are the top 5 SAE that originate from the 'other' category. These have been broken down into their specification or 'human factors' sub-categories.

Figure 28.4: Incorrect blood component issued - IBCI (n=194)



QMS=quality management system

Nearly three quarters of Incorrect blood components issued (76%) are related to system errors and the rest (24%) are due to slips lapses and omissions. The largest proportion are due to inadequately designed processes or a combination of system errors. 17% are a direct result of staffing and workload issues which affect the selection of the correct requirements for patients.

As the single most common SAE sub-category and following a 43% increase in the number of IBCI reports it is imperative that reporters thoroughly investigate and address the RC and identify effective CAPA. Reporters are reminded that CAPA must ensure that the correct component is selected in the first place and not rely on ensuring that checks later in the process identify errors already made.

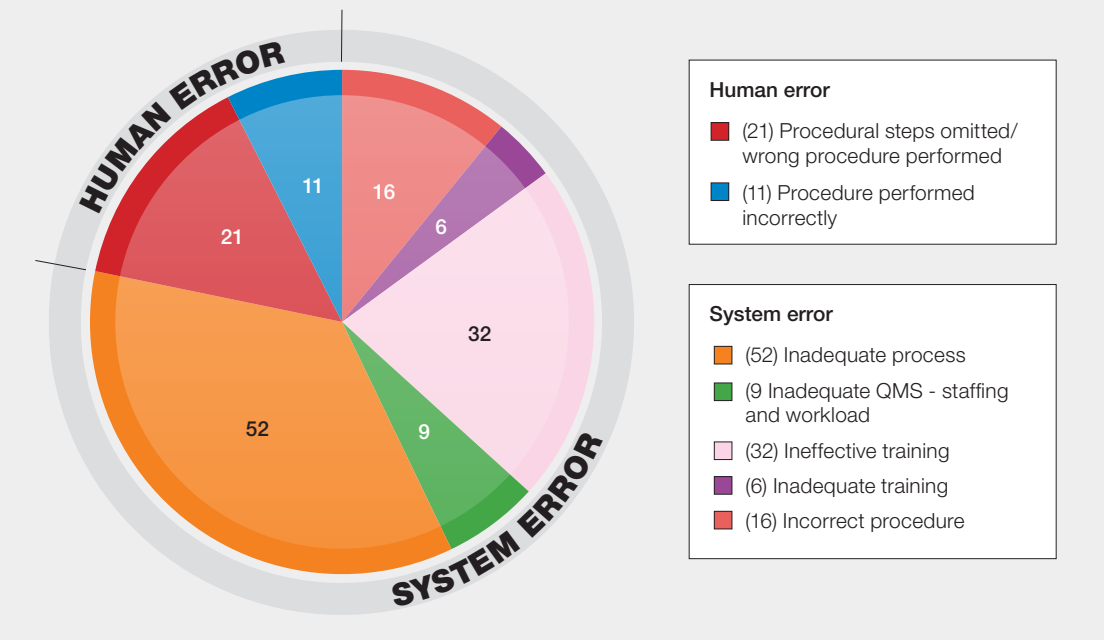


Figure 28.5: Pre-transfusion testing error (PTTE) (n=148)

QMS=quality management system
1 equipment failure is not included in the figure

78% of PTTE are due to 1 or more weaknesses in the quality system. 21% appear to be due to slips and lapses in concentration. The most commonly reported cause of PTTE 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 (11%) and training issues (26%). 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.

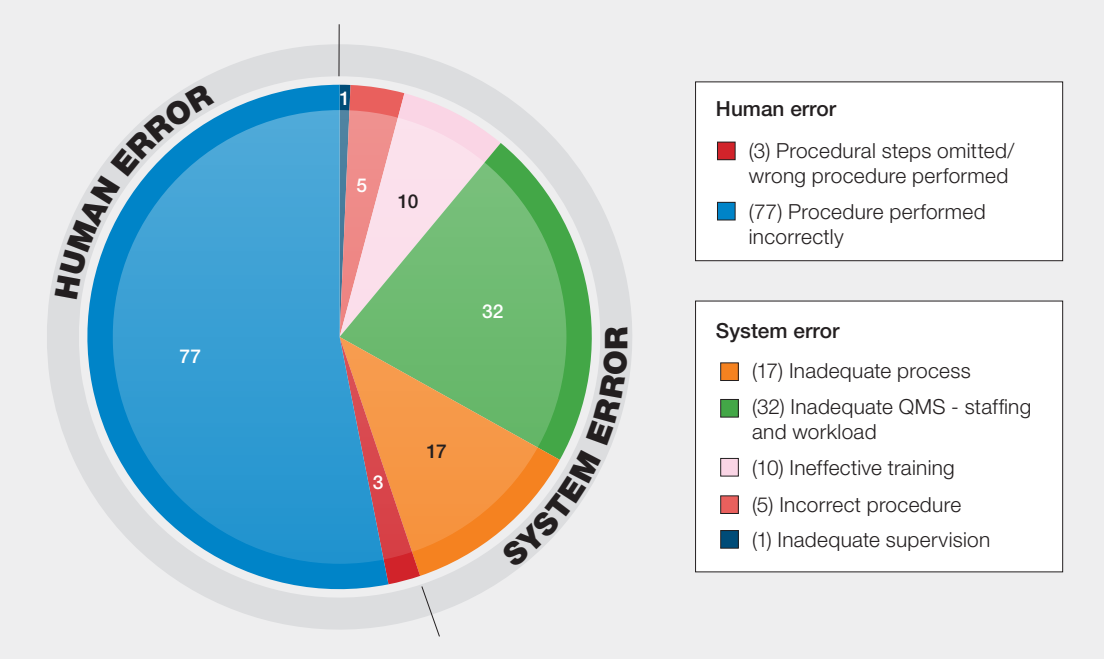
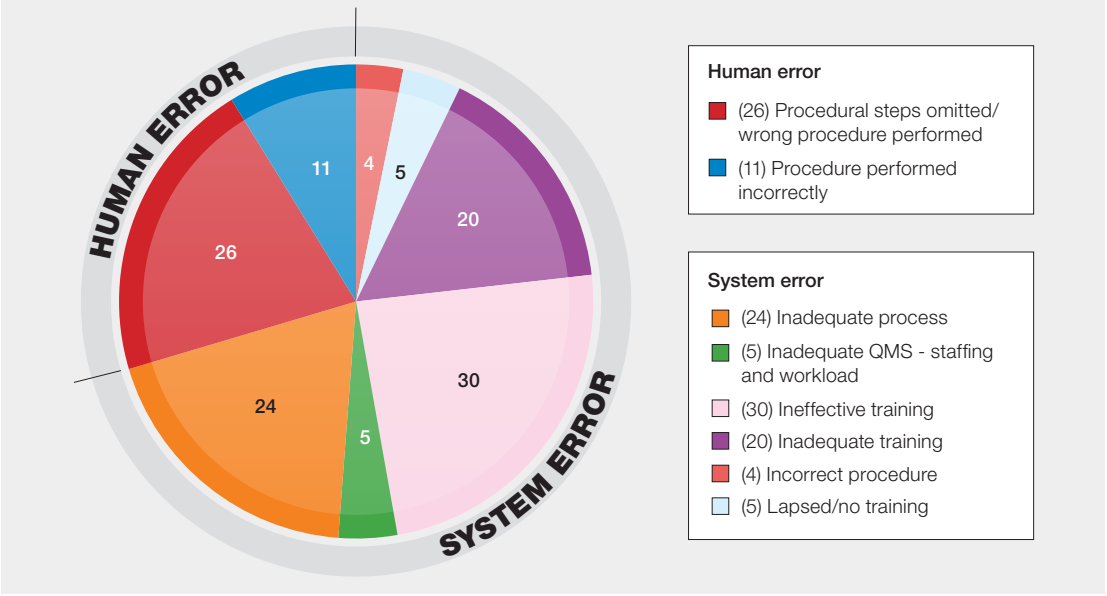


Figure 28.6: Sample processing error (SPE) (n=146)

QMS=quality management system
1 equipment failure is not included in the figure

SPE fall into similar human factor sub-categories as last year. The sample acceptance 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, 22% 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 and increase in available capacity to assist staff conducting these tasks.

Figure 28.7: Component collection error (CCE) (n=127)

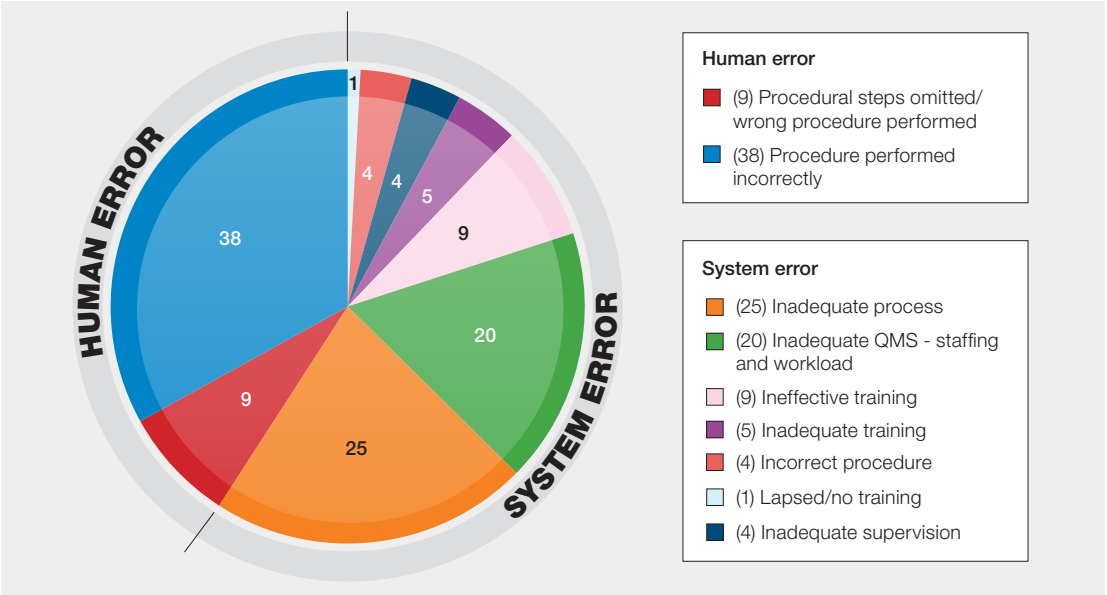


QMS=quality management system
2 equipment failures is not included in the figure

As a largely manual process that relies on visual checks around 29% of CCE are reported to be a result of human errors. However, where investigations have been conducted to an acceptable level of depth 71% of reports have been concluded to be a result of some form of system error. Training issues account for 44% whether that is because people haven't been trained at all or because training has been poorly delivered or not clearly understood.

CCE must always be thoroughly investigated and RC and CAPA identified due to the possible knock-on effects. Many undetected collection errors end up being detected at the bedside. Unfortunately, not all do, and there are a small number of cases where blood has been transfused to the wrong patient as a direct result of an initial CCE.

Figure 28.8: Component labelling error (CLE) (n=115)



QMS=quality management system

53% of CLE in the previous year's report were determined to be due to slips and lapses. However, last year this percentage dropped to 41% indicating improvements to investigations which identified process and system deficiencies.

39% of reports were due to staffing and workload or weak processes identifying one or more system or process deficiencies. It is important to fully define the process for labelling components that map out all the required steps and checks and that that process is described in a comprehensive SOP. This will ensure standardisation of practice and guard against individuals improvising and following non-standard practices increasing the risk of error.

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
- Where staffing and workload is determined to be a factor, these factors must be addressed with a plan to increase staffing or to re-prioritise workloads, or both, to support safety for patients and staff
- Distractions must be designed out of processes and where they cannot be, mitigations must be put in place to minimise their effect

Action: Hospital transfusion teams

Blood establishment reporting n=145 (+33)

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 28.10 displays the reported BE SAE in 2023.

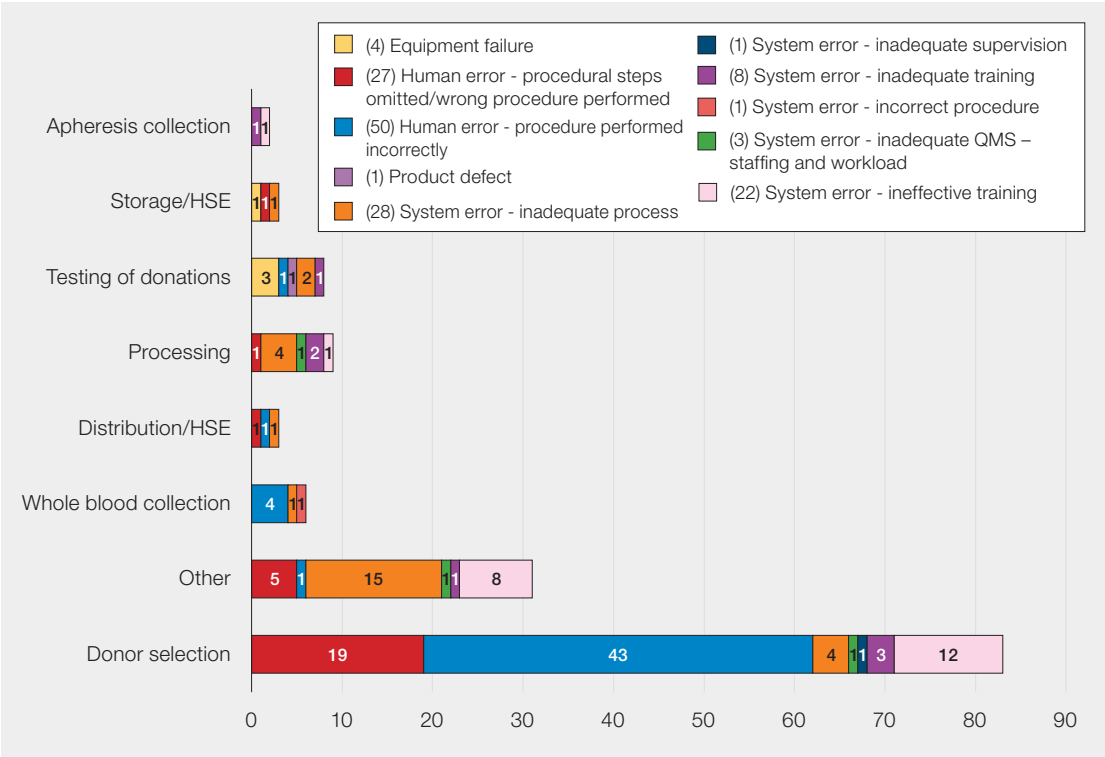


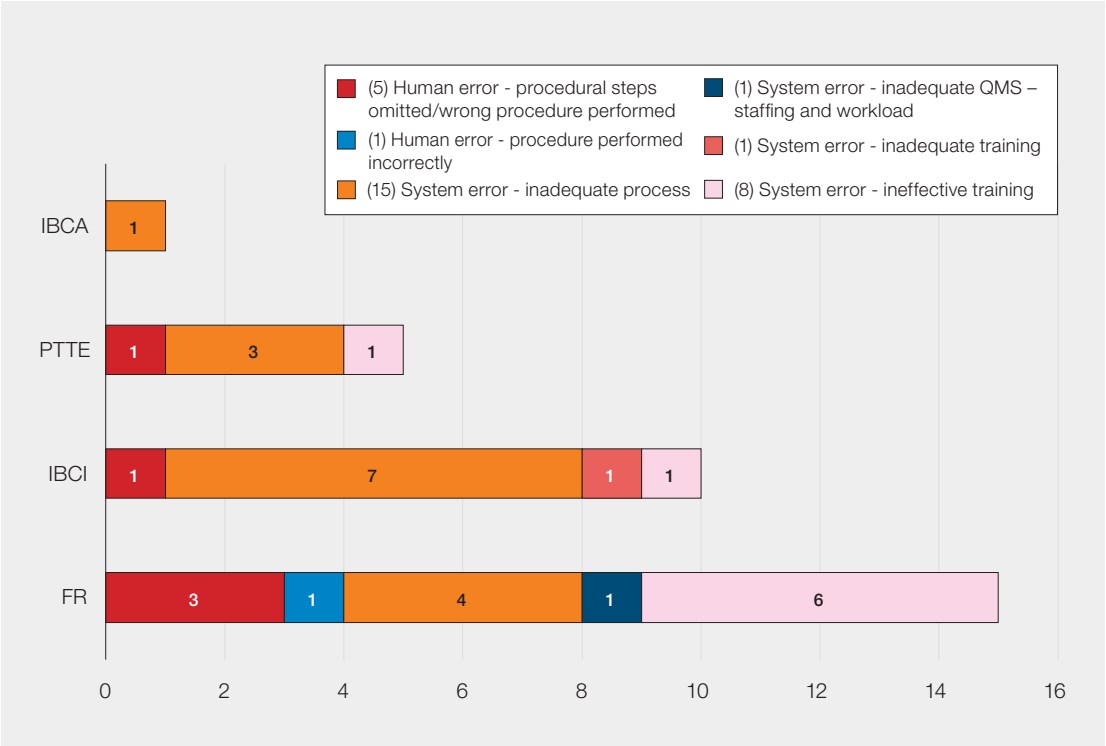
Figure 28.9: Blood establishment SAE event category by specification (n=145)

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 28.11 shows a breakdown of the 31 reports which fall into the 'other' category.

Figure 28.10: BE reports in 'other' category (n=31)



See Appendix 2 for key to category abbreviations
QMS=quality management system

Serious adverse reactions (SAR)

Definition: (Department of Health, 2005) an unintended response in a donor or in a patient that is associated with the collection, or transfusion of blood or blood components that is fatal, life-threatening, disabling or incapacitating, or which results in or prolongs hospitalisation or morbidity… blood establishments and the person responsible for the management of a hospital blood bank shall notify the Secretary of State (Competent Authority) of any serious adverse reactions observed during or after transfusion which may be attributable to the quality or safety of blood or blood components:

(i) Collected, tested, processed, stored or distributed by the blood establishment, or

(ii) Issued for transfusion by the hospital blood bank

Blood products

Adverse reactions involving blood products (i.e. licensed medicines such as anti-D Ig, Octaplas® (Solvent-Detergent 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 28.12.

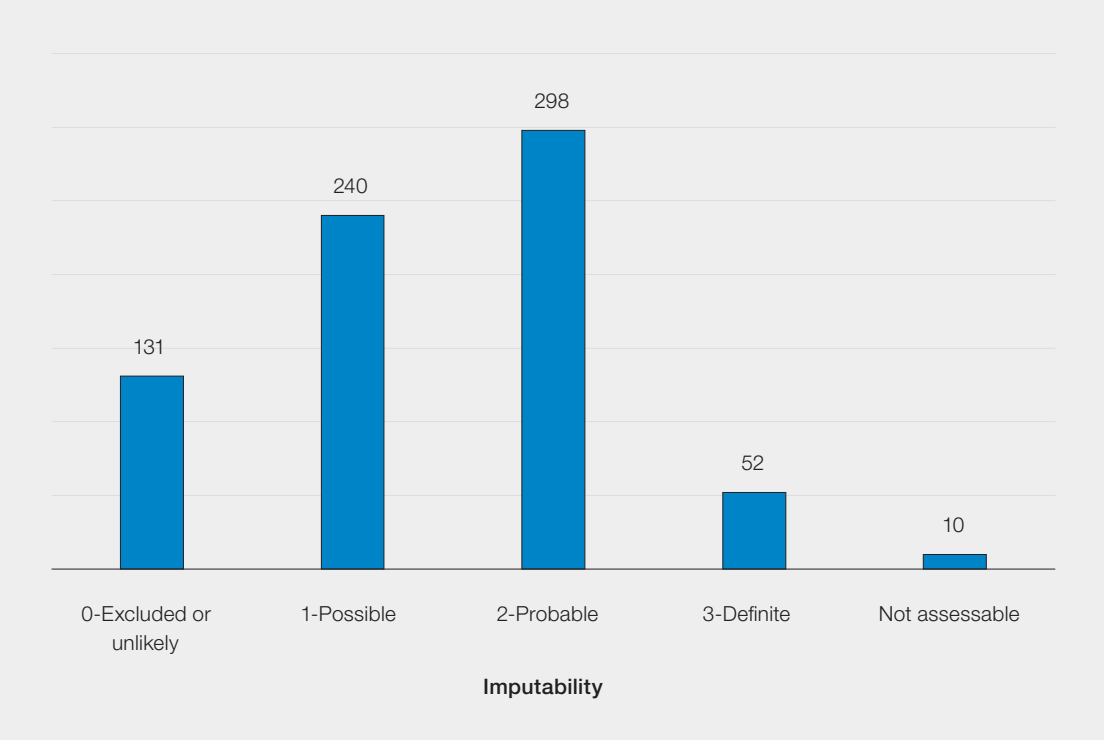


Figure 28.11: SAR reports, by imputability, reported to SABRE in 2023

Inspection report

The MHRA inspectorate have continued to verify blood compliance reports and have conducted 25 inspections since April 2023. A total of 289 BCR were submitted for review for the reporting period 01 April 2022 to 31 March 2023.

The BCR were scored and discussed at a meeting of the BCR Assessment Team (BAT) in August 2023. The BAT meeting discusses the risk scores from the BCR submitted. In addition, risks raised due to haemovigilance data from the SABRE reports received, major changes to blood banks and previous inspection history are discussed.

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
- The lack of a validation master plan (VMP) to guide management through the validation and qualification of the change.
- 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:

- Inadequate investigation for an appropriate root cause therefore the inadequate implementation of an effective CAPA to avoid reoccurrence
- Failure to consider the potential for harm as well as actual harm especially Trusts using the Datix system
- The lack of an adequate justification for human error being identified as a root cause
- The lack of justification for the late closure of deviations and performing impact risk assessments
- Tracking and trending systems employed not identifying recurring problems due to an emphasis on consequence rather than root cause
- Inspections are also identifying a worrying trend that Trusts are not reporting incidents to the competent authority as soon as known

The availability of trained and competent staff

Issues with adequate capacity within the laboratory is an ongoing problem and is often raised as highlighted by:

- The absence of an effective capacity management plan or similar document to ensure adequate management of blood transfusion operations and the quality management system
- The inadequate management of risk register entries such as reducing the risk score without an appropriate justification
- Staff working significantly above their contracted hours to ensure staff rotas are adequately staffed
- Trusts failing to meet several quality metric targets

Blood collection and training

Blood collection and training was not being adequately managed in that:

- Blood collection training and competency audits showing that Trusts were not meeting their KPI for staff blood collection training
- Inadequate systems in place to control infrequent users of the system and blocking staff who had left the Trust

Recall

Although there were 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: https://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

Comment from Julie Staves, NBTC, Transfusion Laboratory Managers, Chair

This year's MHRA report on the BSQR is somewhat concerning to me and I feel it reflects the issues are being experienced across hospital transfusion laboratories.

The increase in the number of reports being made, remains a positive, it shows there is a continued commitment to reporting and the increase in the acknowledgement that errors are frequently due to process, or system deficiencies is pleasing.

70% of SAE are assigned to system errors as the causative factors which does mean that we should be able to address them. More thorough investigation of the 30% of SAE related to human errors may mean even more errors can be addressed with system improvements. This increase in errors such as incorrect blood component issues, pre-transfusion testing errors and data entry errors is something we should try and address in our own laboratories. The MHRA commentary flags the issues we are all facing daily that of maintaining adequate staffing levels who are suitably trained, and competency assessed.

The 15% increase in the storage errors being report is of concern after a reduction in these in 2022, the fact that many of these errors are related to one or more deficiencies in the quality system means that it is imperative that all Trusts/Hospitals take the time to look at their own systems and consider what changes we should be considering to prevent similar issues within our own departments, including clinical areas.

I would like to flag the recommendations with this report, they are something we should all review carefully and ensure that if we find our systems are not compliant, then we act accordingly to address the issues.

MHRA haemovigilance team update 2023

The haemovigilance team continues to provide an education service. During 2023 there have been 14 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 haemovigilance 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

Department of Health, 2005. *The Blood Safety and Quality Regulations 2005.* [Online] Available at: https://www.legislation.gov.uk/uksi/2005/50/introduction/made (Accessed 11 April 2024).

European Directorate for the Quality of Medicines & Healthcare (EDQM), 2023. *Guide to the preparation, use and quality assurance of blood components.* [Online] Available at: https://www.edqm.eu/en/blood-guide (Accessed 29 April 2024).

Appendices

Appendix 1: Storage subcategories

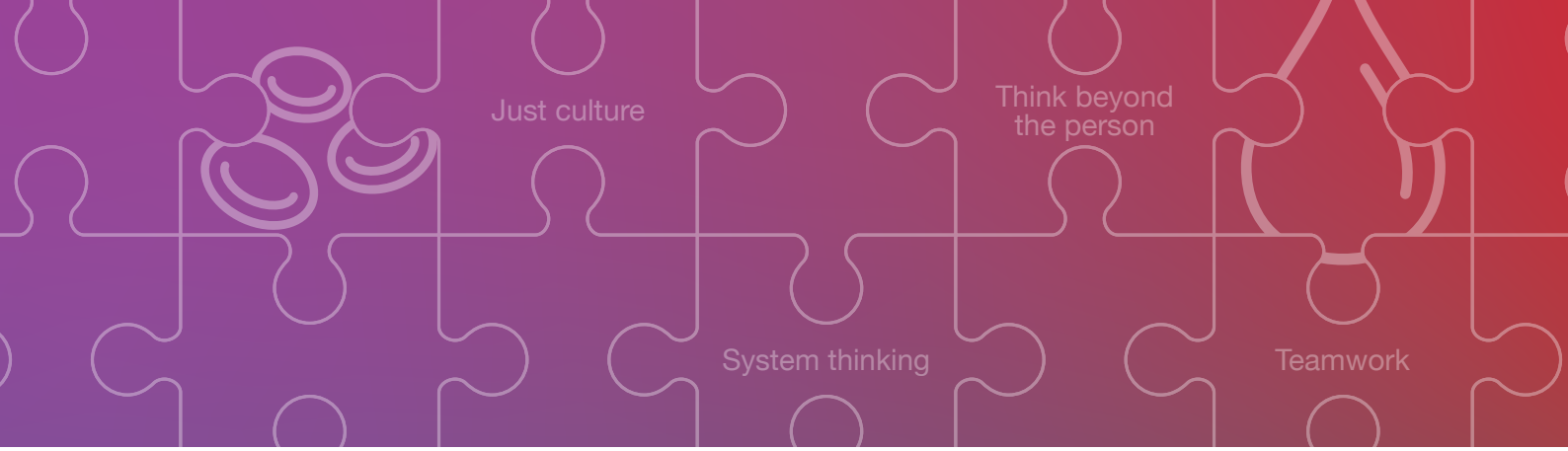
Component expiry	A component has time expired and not been removed from the storage location according to laboratory procedures
Incorrect storage of component	A component has not been stored in the correct location
Sample expiry	A sample has expired and the component has not been removed from the supply 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

Printed on paper from responsible sources.

print & plant

A collaborative initiative to restore forests around the globe.
For more information please visit: www.e-arc.co.uk/environment

Certified CARBON QUOTA CARBON MEASURED OPERATION

This report was printed by ARC UK,
a certified Carbon Measured Operation.