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

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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)

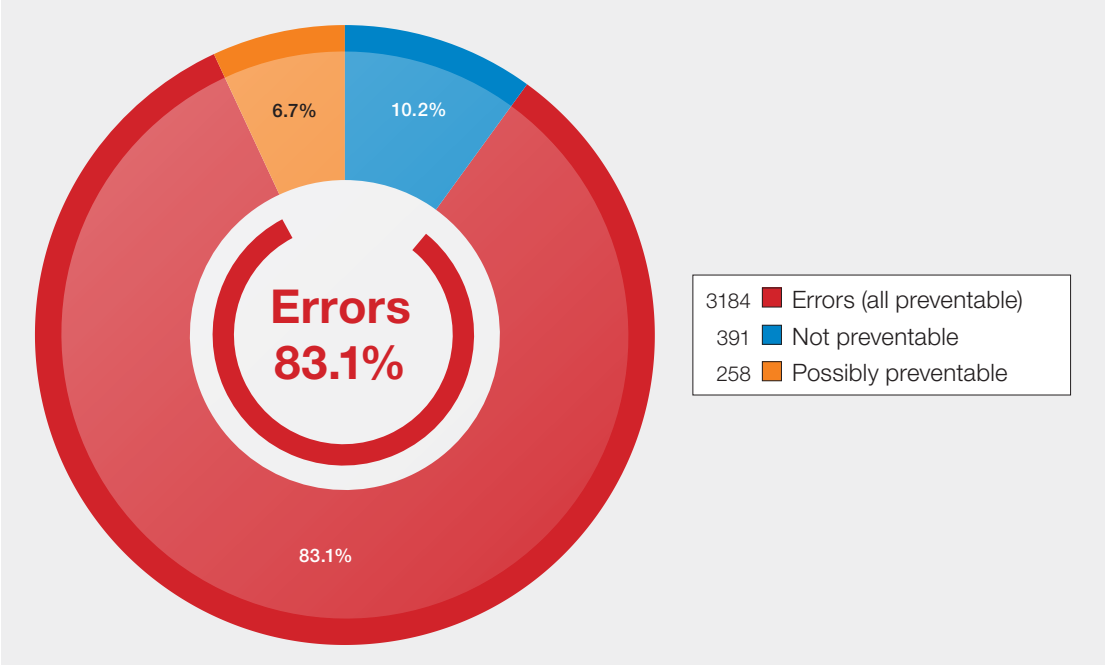


Figure 3.2 shows the percentage of no harm incidents in the errors reported to SHOT in recent years. It is concerning to note a dip in the percentage of no-harm incidents in 2023 which conversely means an increase in potential patient-harm incidents reported. This highlights the urgent need for actions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

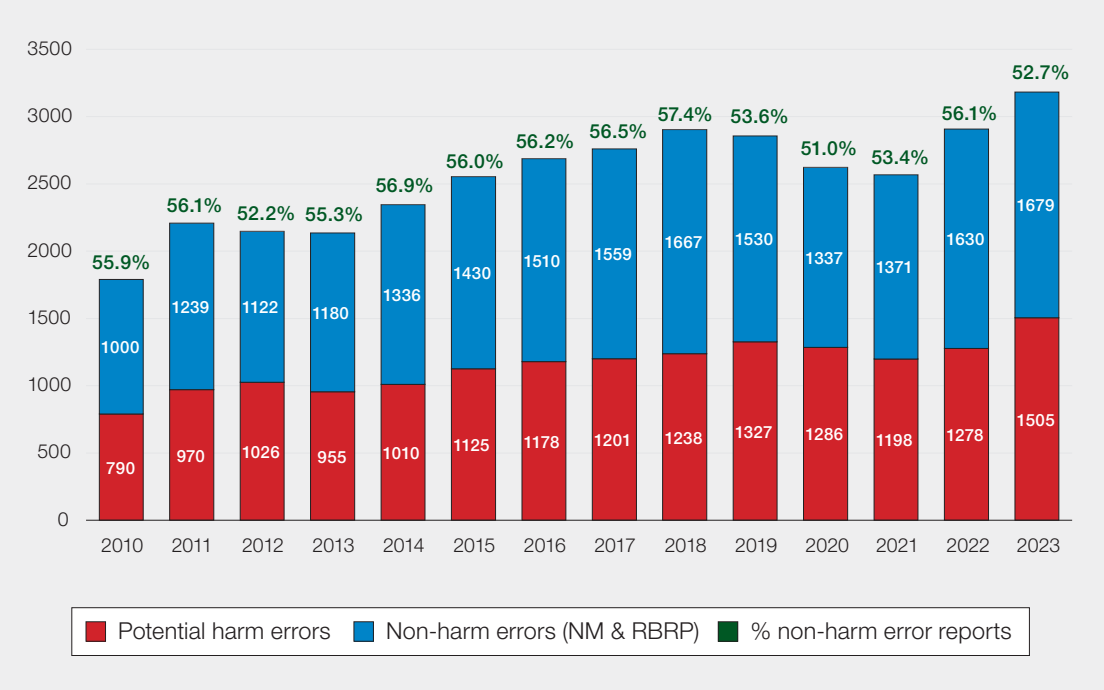


Figure 3.2: No patient-harm and potential patient-harm incidents 2010-2023

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

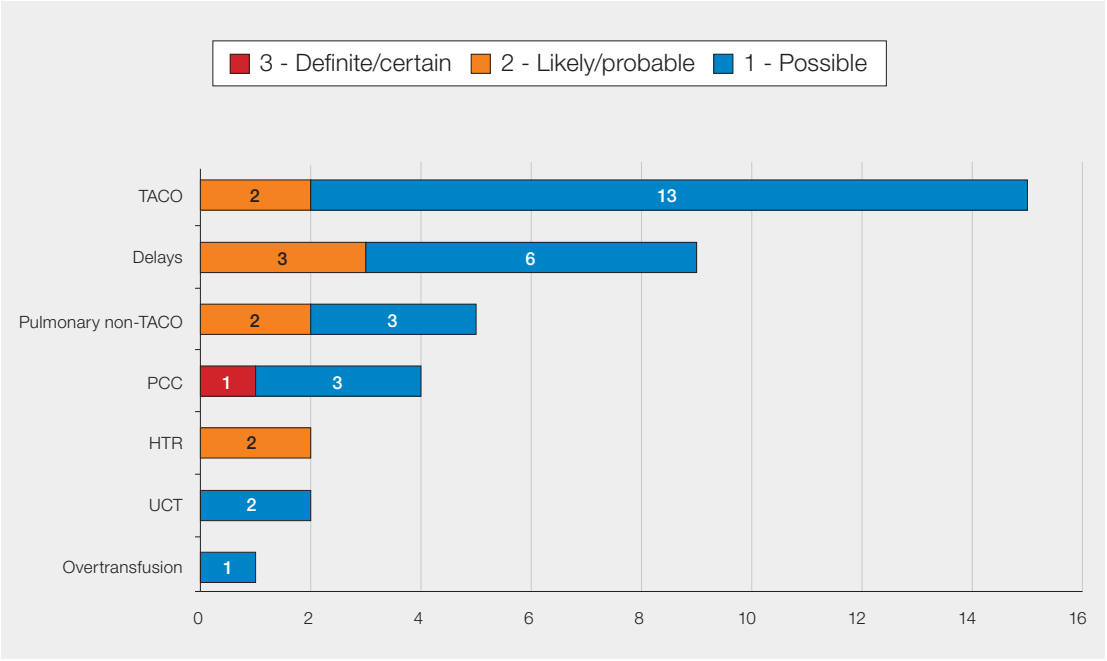
Non-harm incidents include near miss (NM) and right blood right patient (RBRP) errors

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.

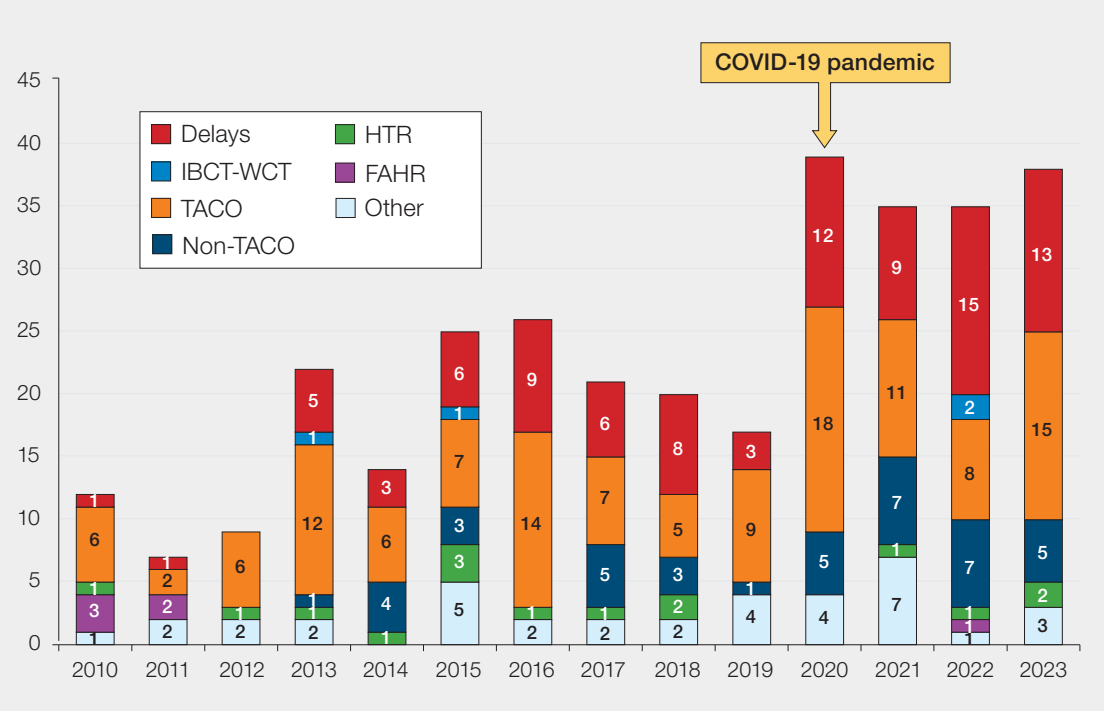


Figure 3.4: Transfusion-related deaths 2010 to 2023 (n=320)

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').

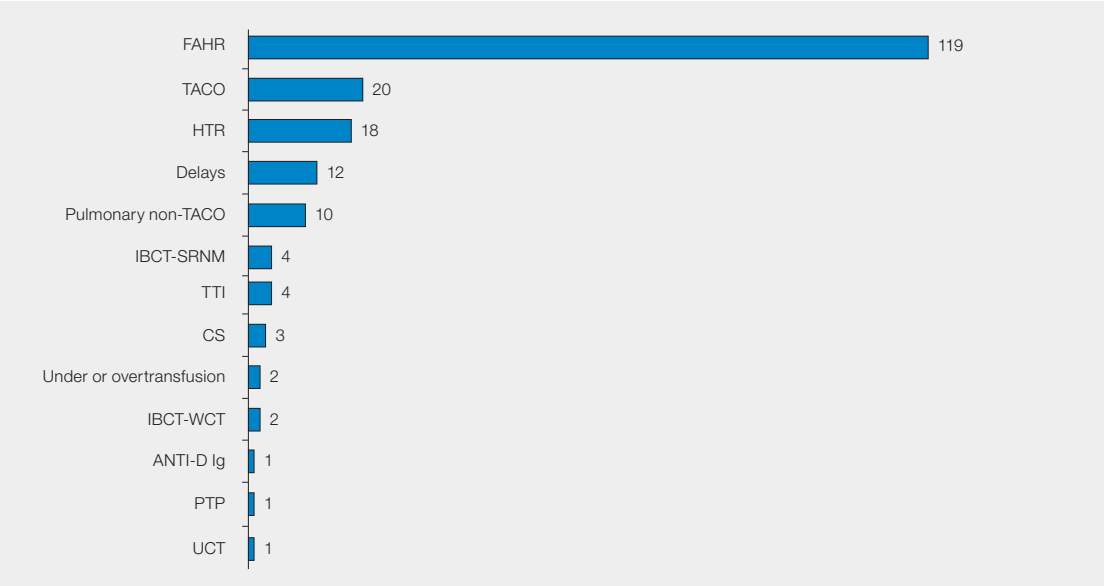


Figure 3.5: Ranking of categories to show number of serious reactions in 2023 (n=197)

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

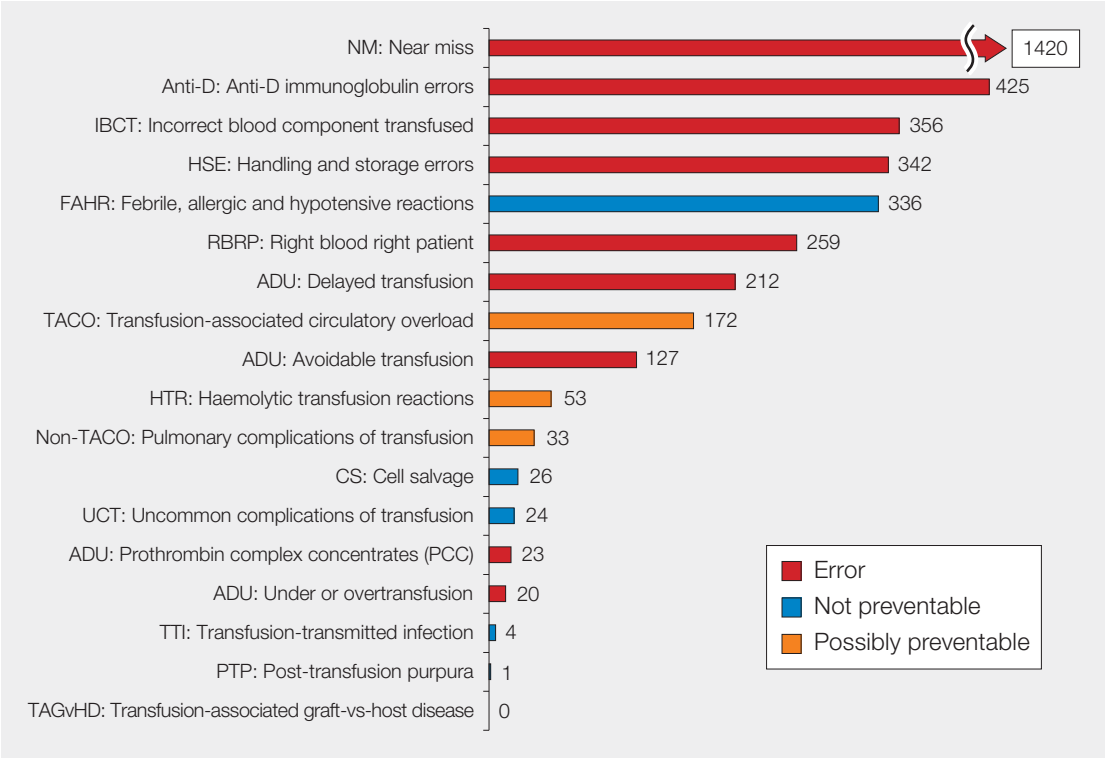
This study's aim is to estimate the costs of acute management of SHOT-reported events resulting in major morbidity or death from the hospital perspective. All transfusion-related deaths reported to SHOT in 2018-2022 where it was likely or definite that the reaction was caused by the blood (imputability 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)



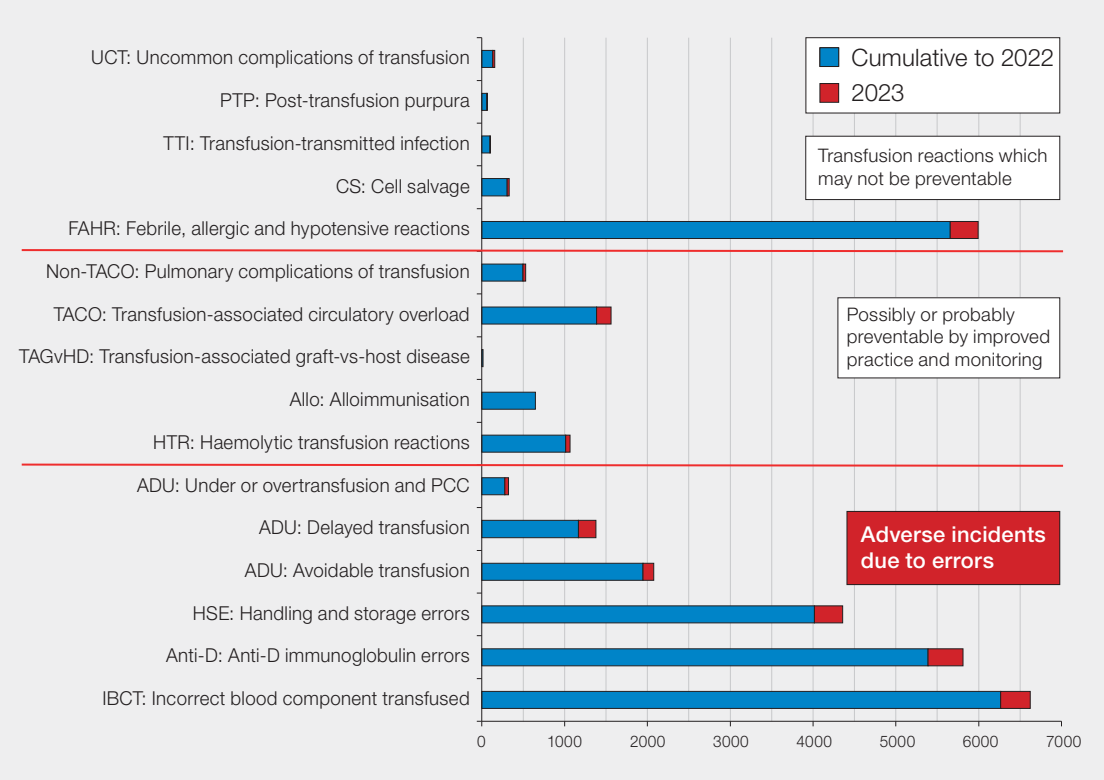


Figure 3.7: Cumulative data for SHOT categories 1996-2023 (n=31025)

**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

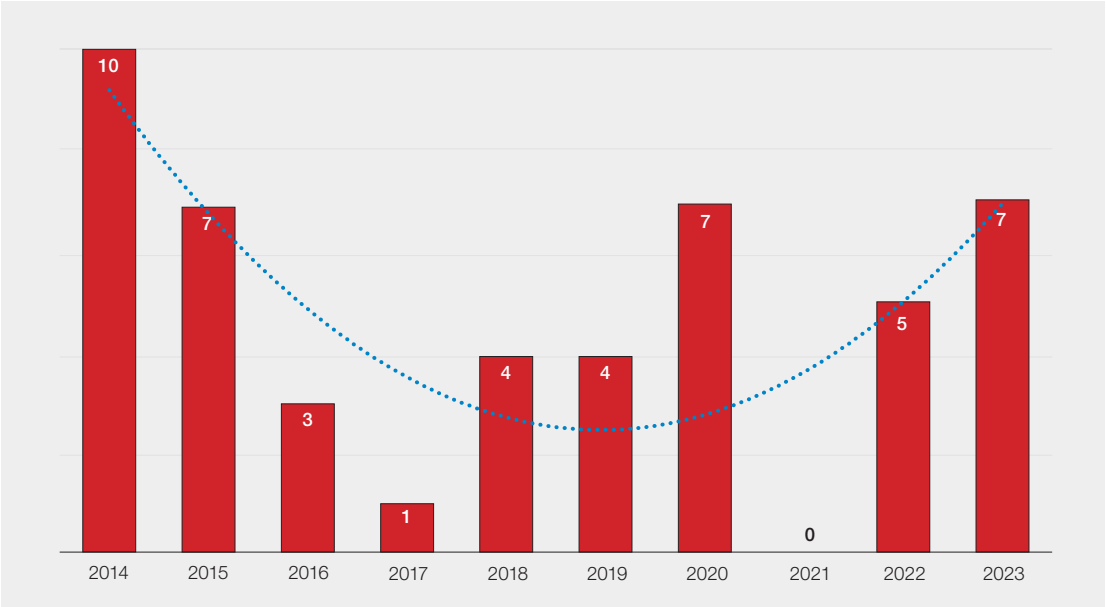


Figure 3.9: Number of ABO-incompatible plasma transfusions 2014-2023

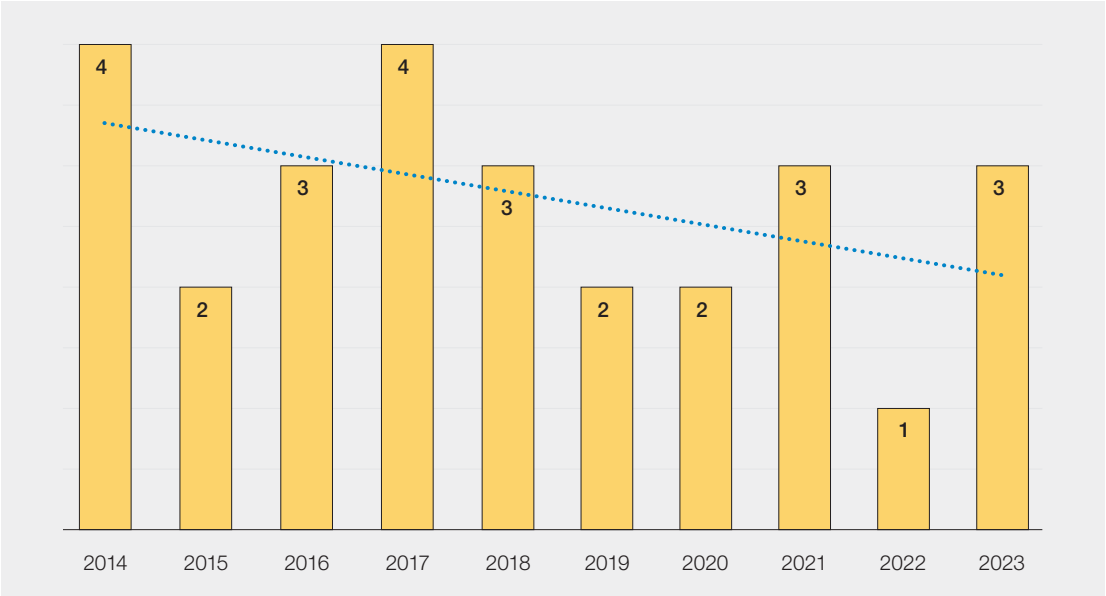
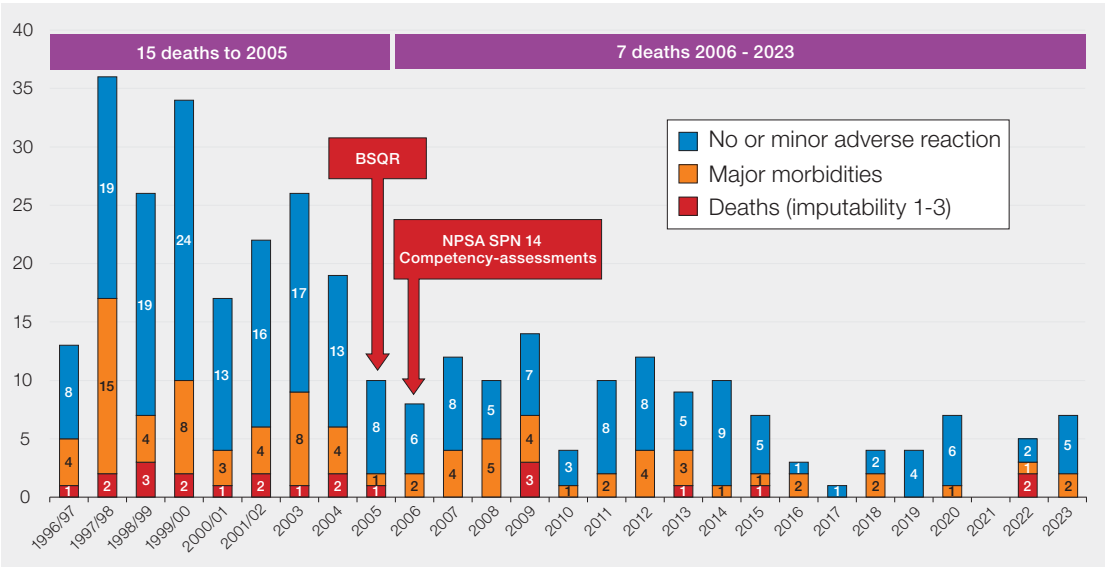


Figure 3.10: Outcome of ABO-incompatible red cell transfusions in 26 years of SHOT reporting



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.

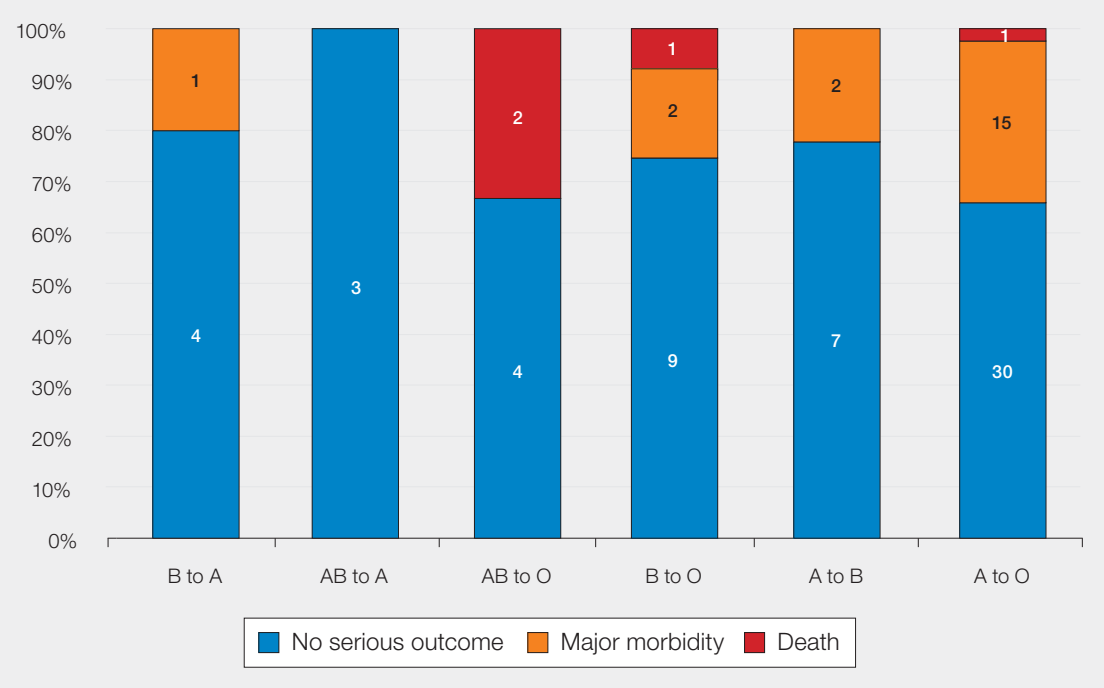


Figure 3.11: ABO-incompatible transfusions and outcome by groups 2010-2023 (n=81)

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.

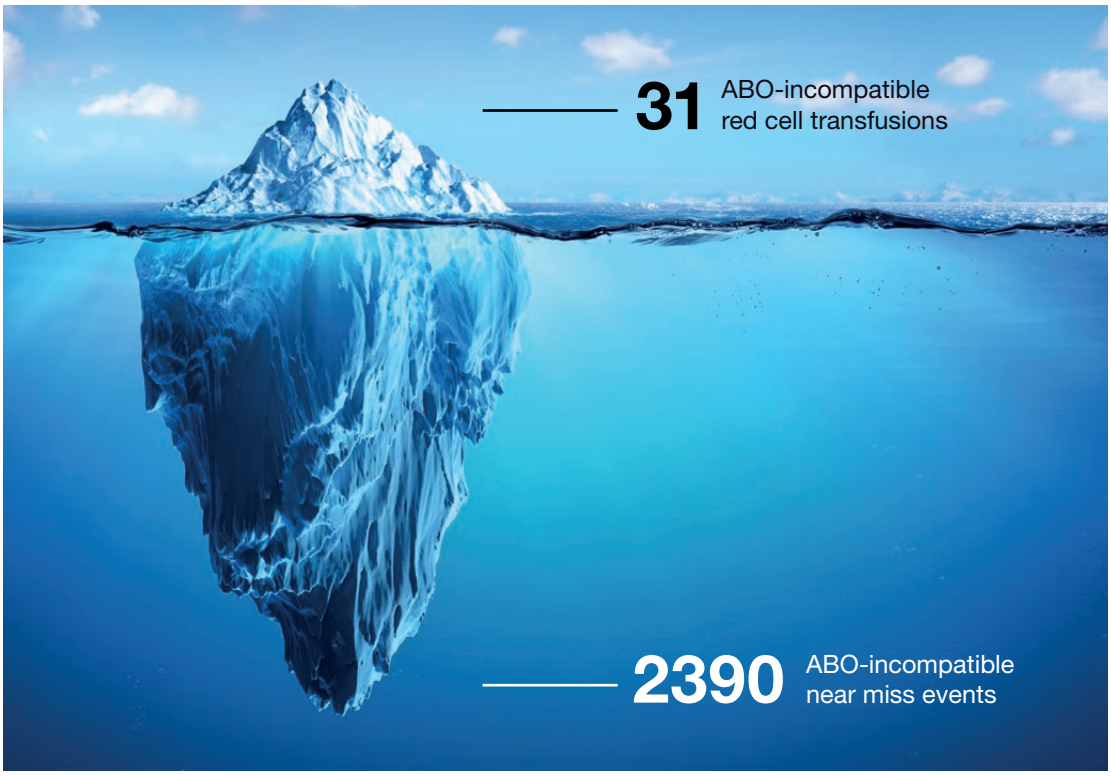


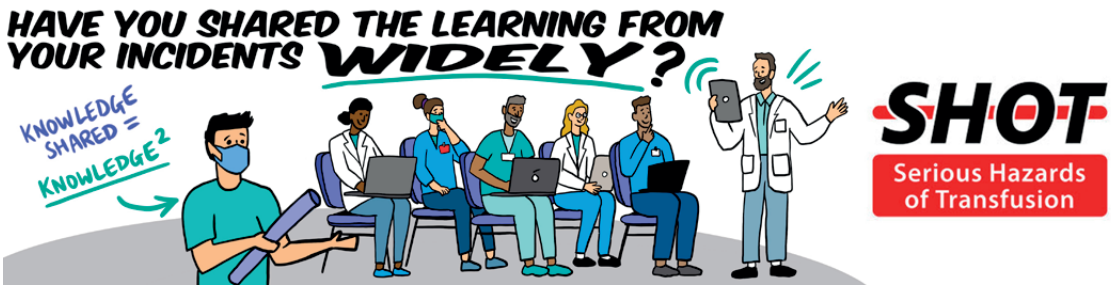
Figure 3.12: ABO-incompatible red cell transfusions 2016-2023: few events (n=31) but many near misses (n=2390)

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

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