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

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Key SHOT messages

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

Abbreviations used in this chapter

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

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

Recommendation

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

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

Introduction

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

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

Transfusion-related serious adverse reactions and events are reported to SHOT and errors continue to account for most of the reports 2908/3499 (83.1%) (Figure 3.1). This figure includes errors with no harm to patients but had the potential to do so such as near misses and right blood right patient errors. The continuing trend of a high percentage of errors may reflect that systemic factors are not properly identified or rectified, leading to short term results rather than sustained improvement.

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

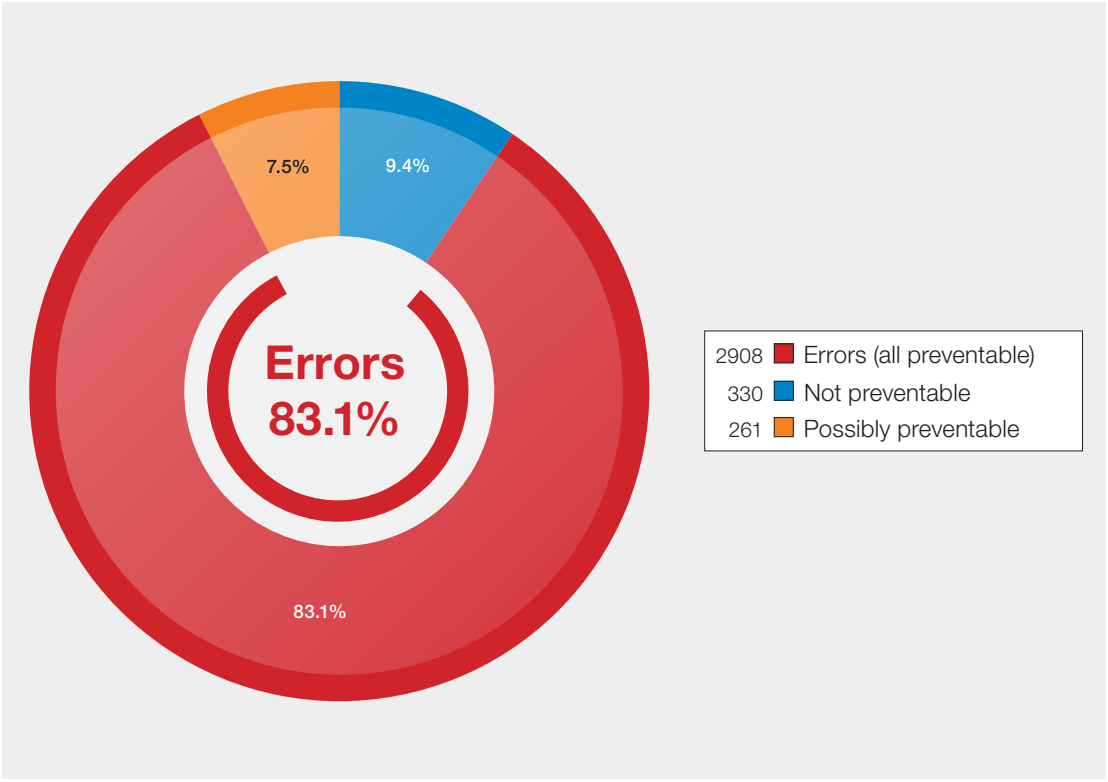


Figure 3.2 shows the trends in transfusion errors reported to SHOT as a percentage of total reports 2014-2022. Errors (including NM and RBRP) continue to account for >80% of reports analysed year on year. Learning from events and improving systems is vital. Analysis of errors is often limited and ineffective.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

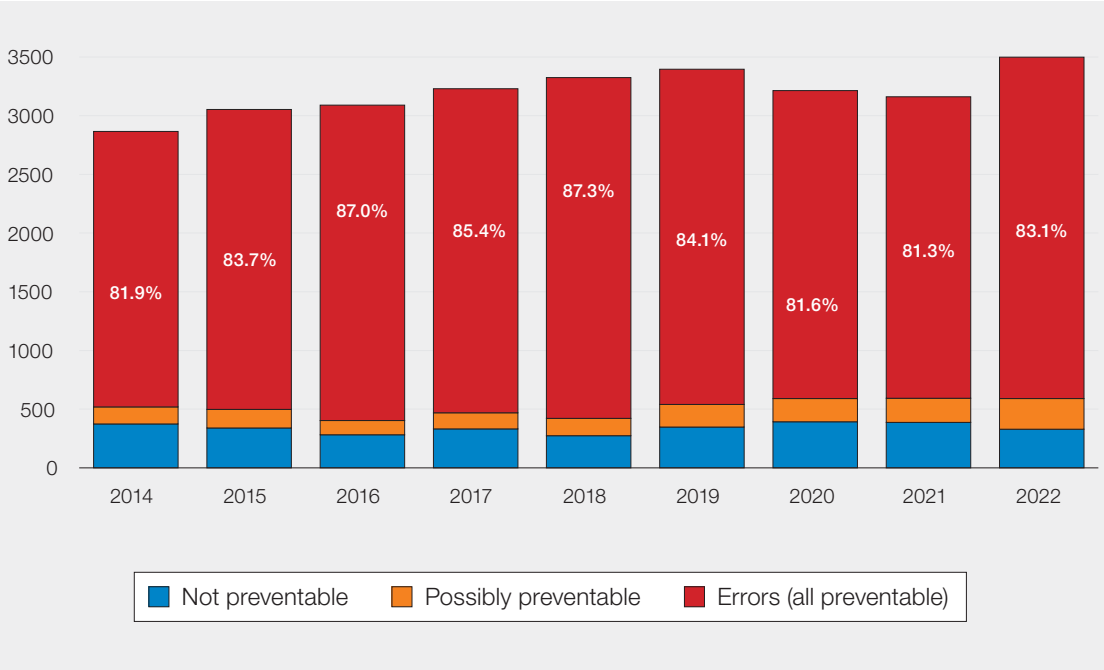


Figure 3.2: Errors as a percentage of total reports 2014-2022

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

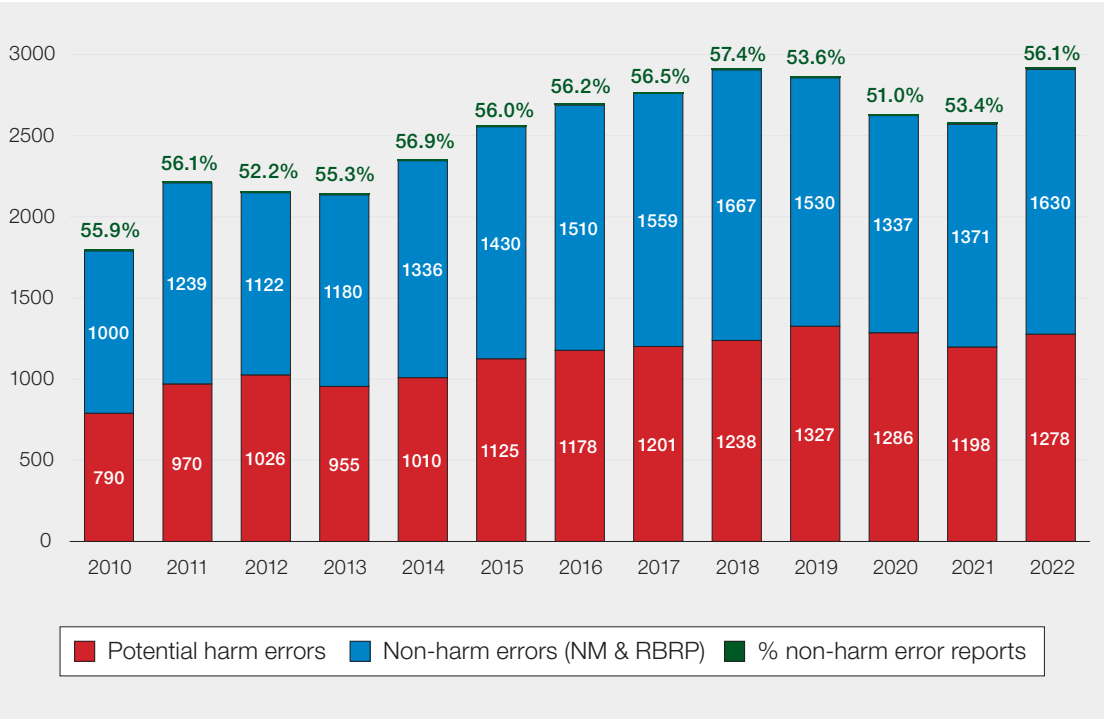


Figure 3.3: No patient-harm and potential patient-harm incidents 2010-2022

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

Deaths related to transfusion n=35

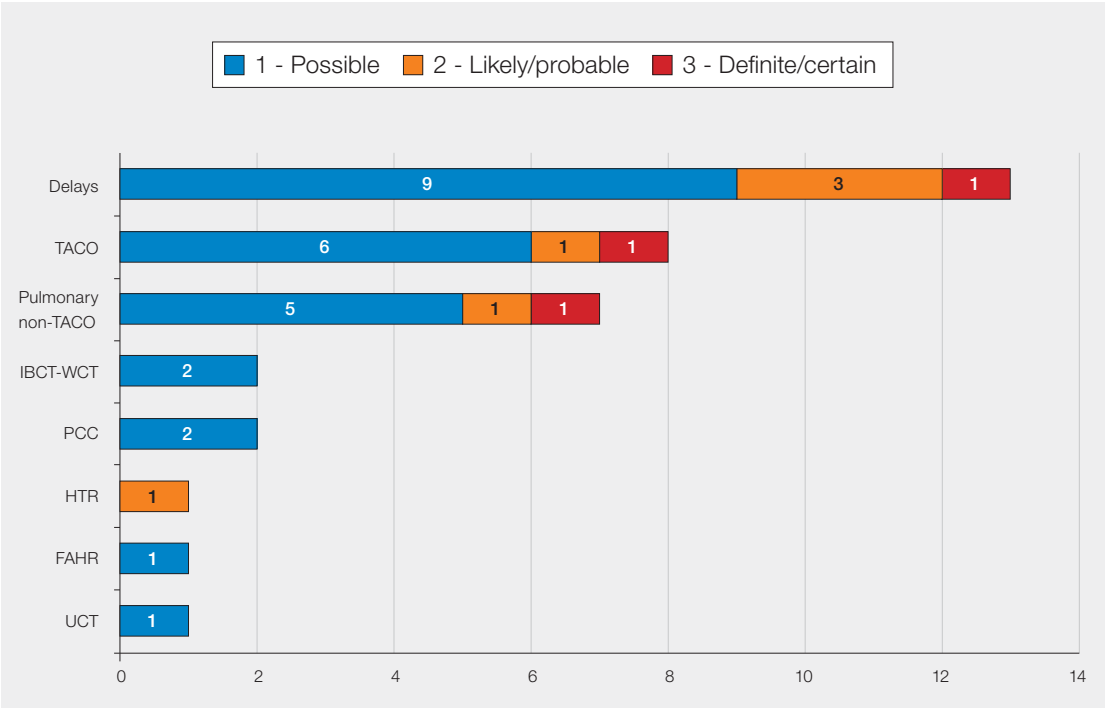
All serious reactions reported to SHOT are assessed for imputability i.e., the relationship of the blood transfusion to the reaction. The imputability criteria are detailed in the table below:

Table 3.1: Definition of imputability levels

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

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

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



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

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

Major morbidity n=144

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

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

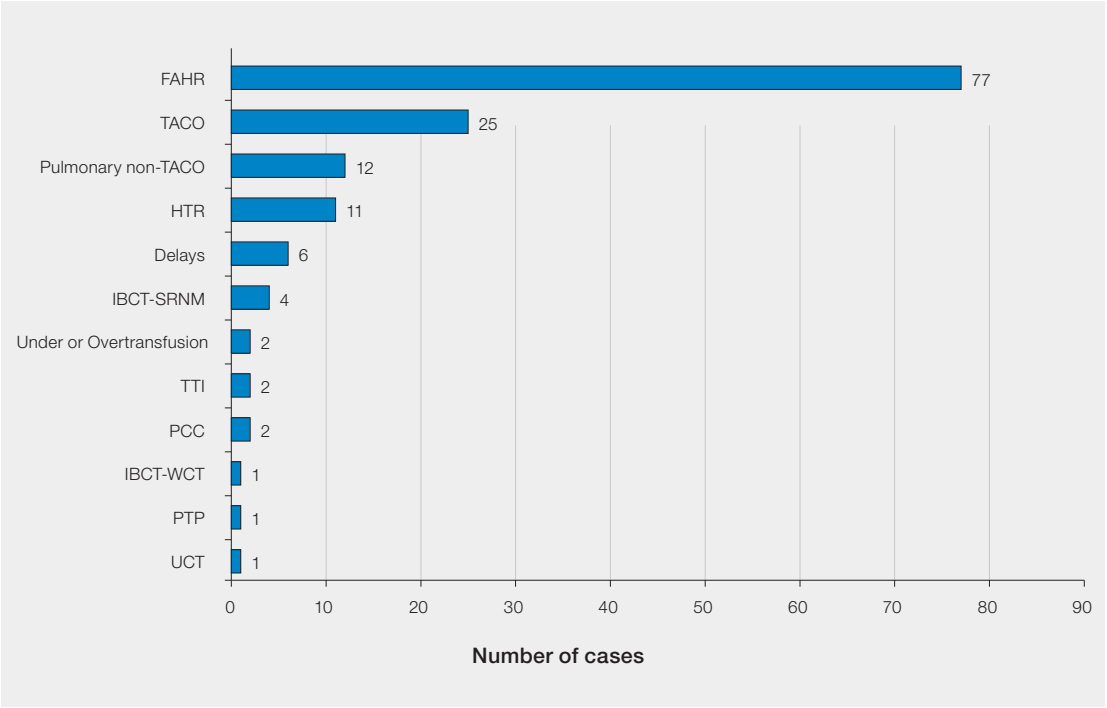


Figure 3.5: Ranking of categories to show number of serious reactions in 2022 (n=144)

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

Summary data and risks associated with transfusion

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

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

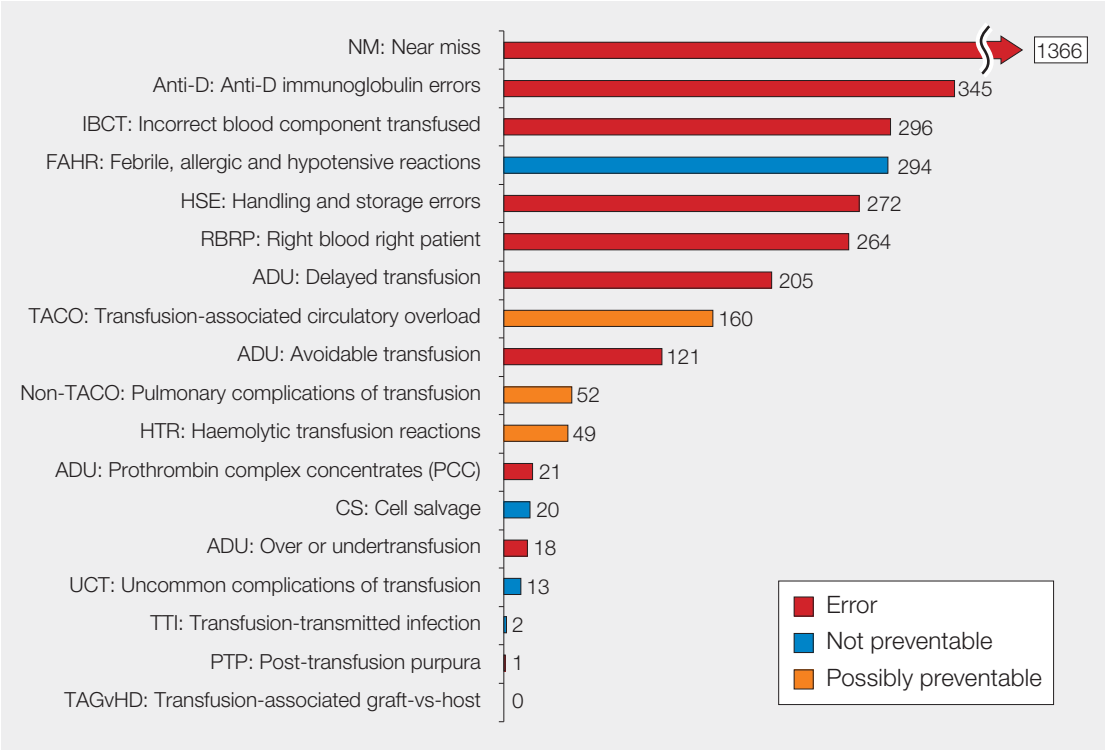
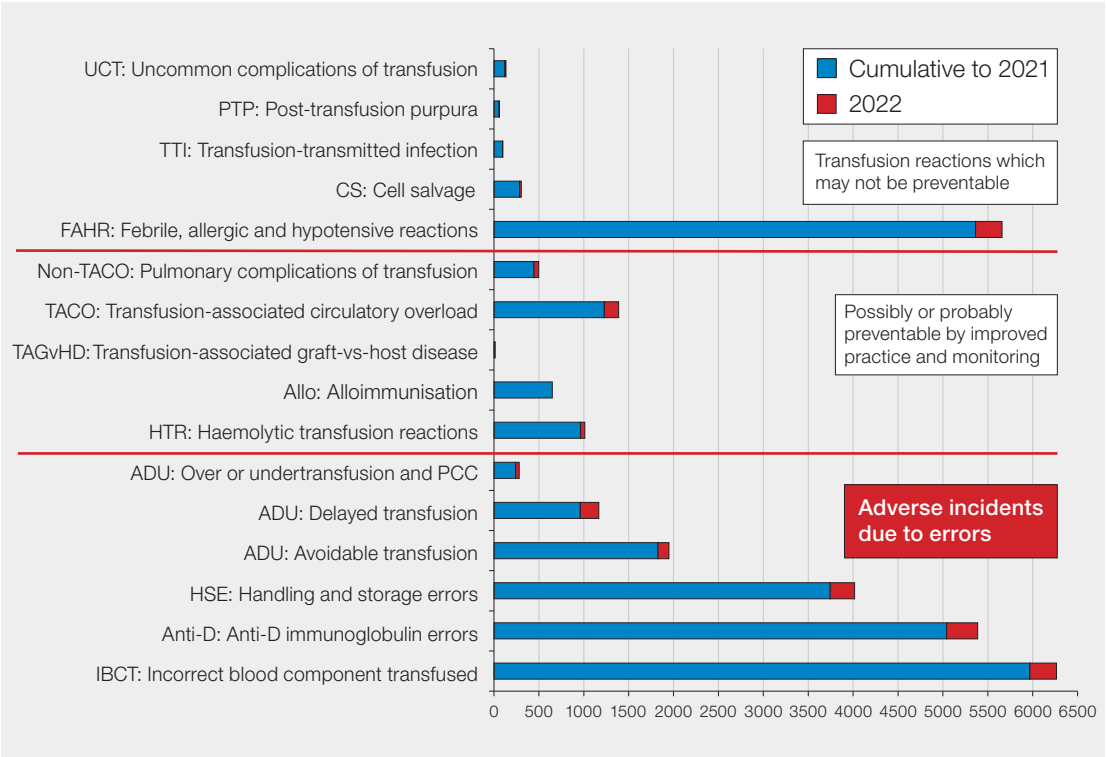


Figure 3.7: Cumulative data for SHOT categories 1996-2022 (n=28877)



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

Cumulative risk data from SHOT

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

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

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

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

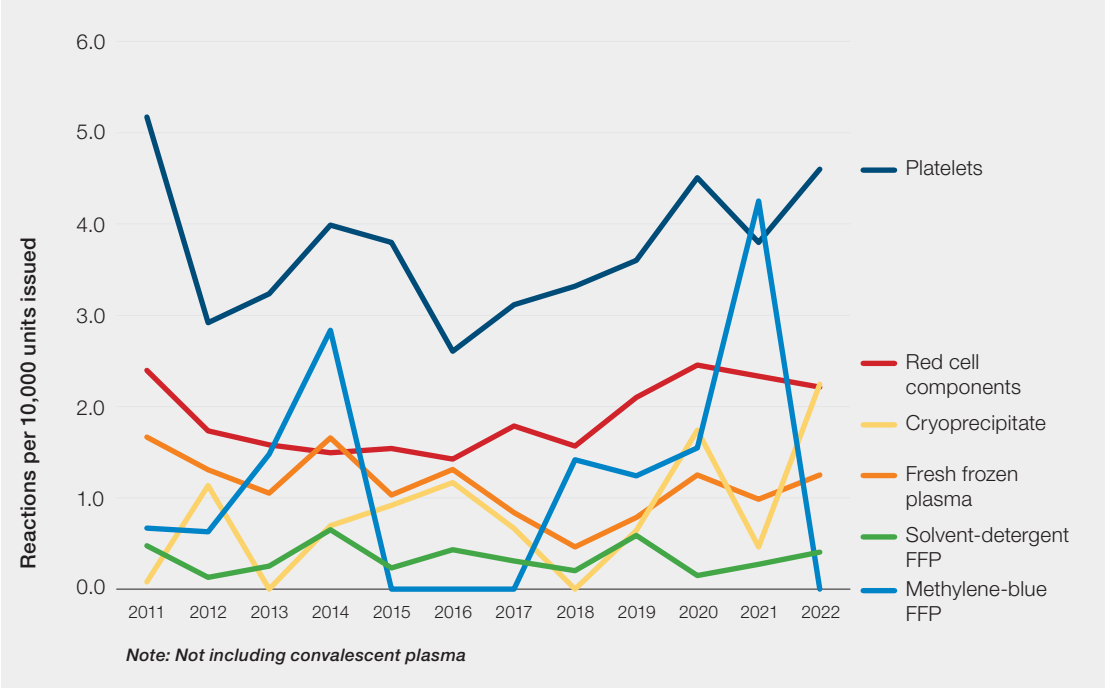


Figure 3.8: Reactions per 10,000 components, by component type 2010-2022

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

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

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

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

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

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

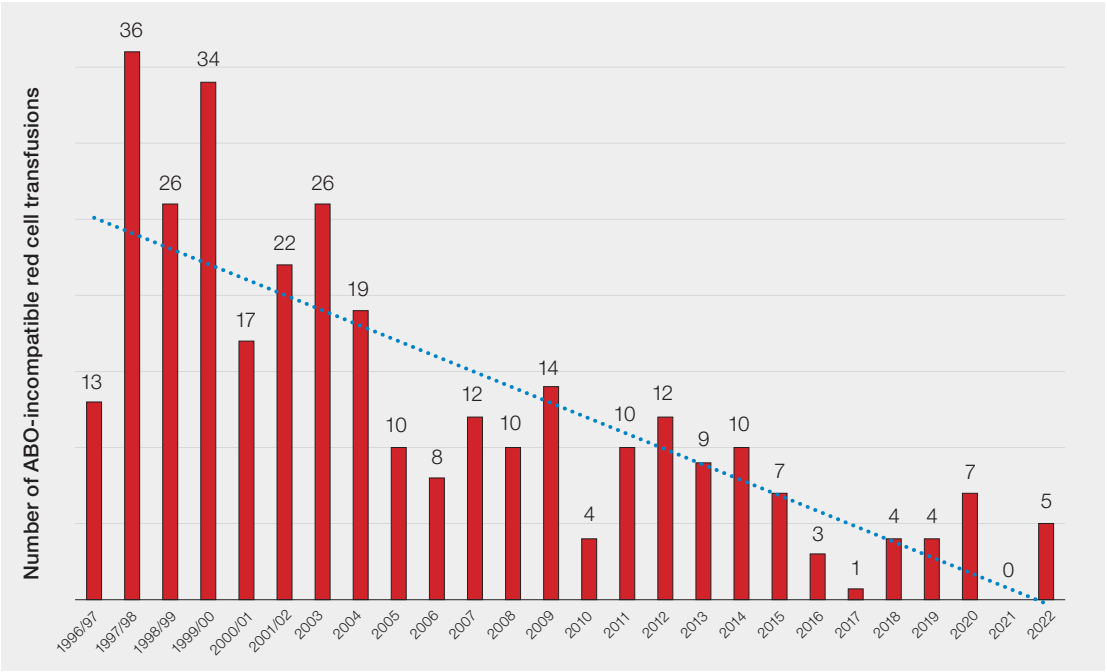
All 5 ABOi red cell cases reported in 2022 were in adult transfusion recipients and following primarily clinical errors. Two were related to blood collection errors, both of which resulted in patient fatalities. Of the remaining 3 ABOi red cell transfusions, 2 were due to primary administration errors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

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

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

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

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



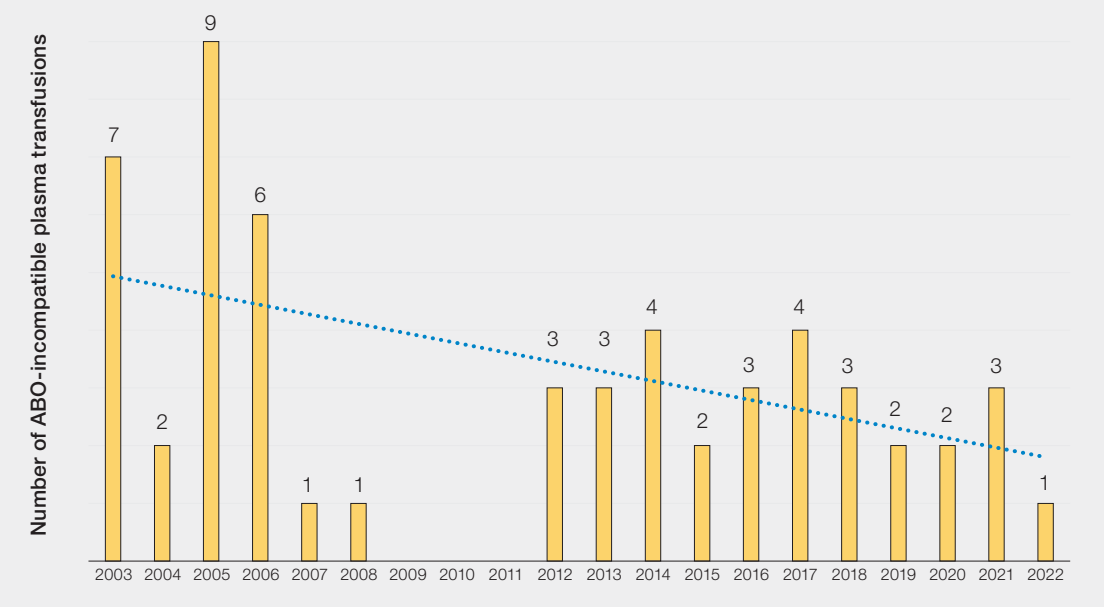


Figure 3.10: Number of ABO-incompatible plasma transfusions 2003-2022

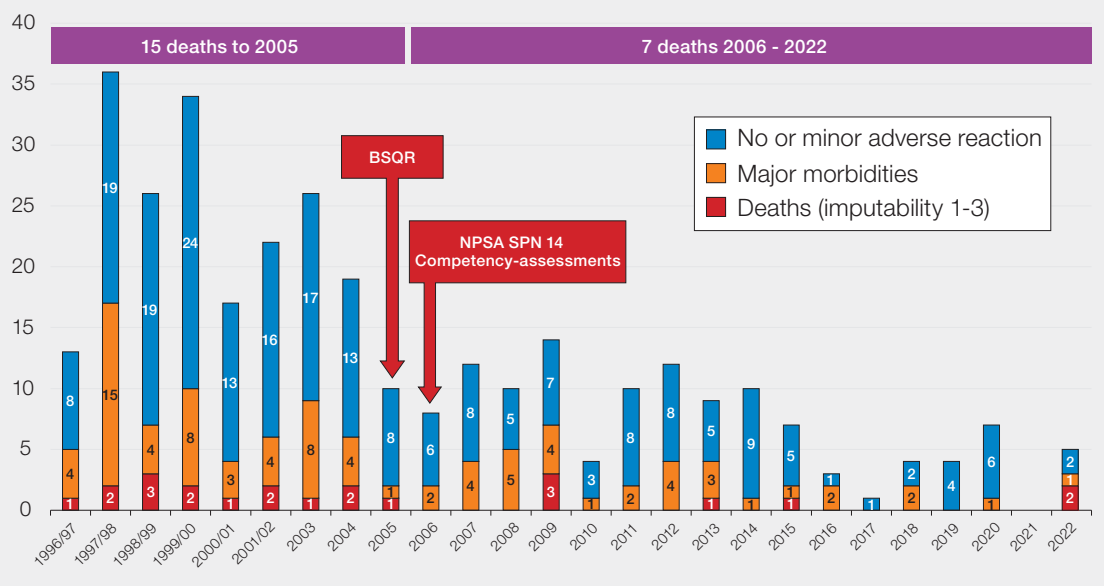


Figure 3.11: Outcome of ABO-incompatible red cell transfusions in 25 years of SHOT reporting

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

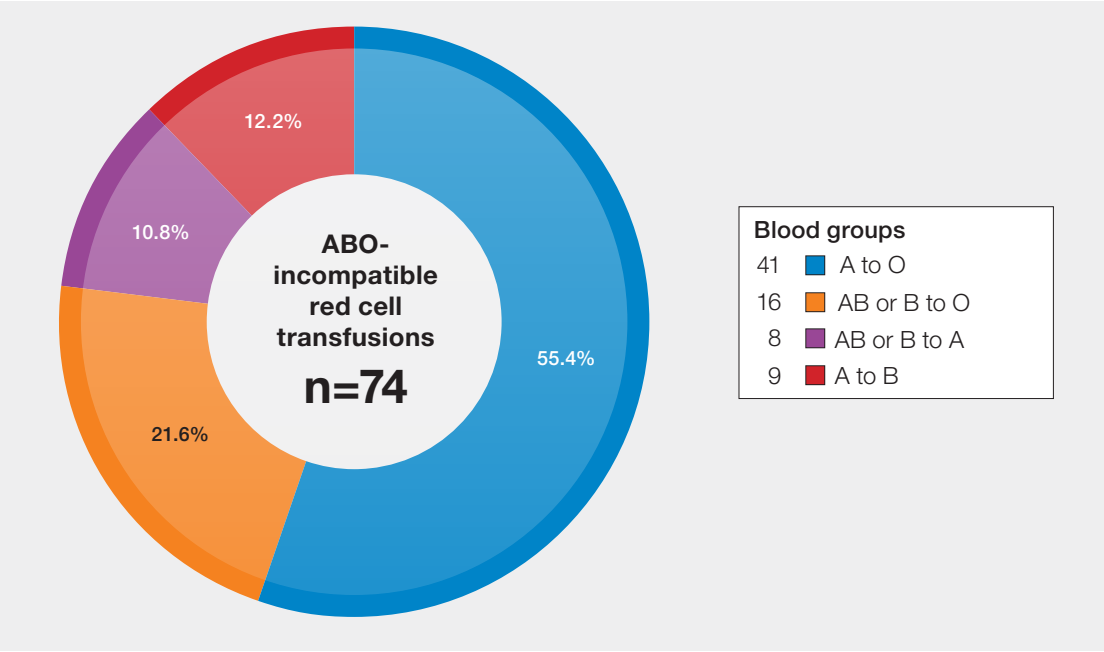
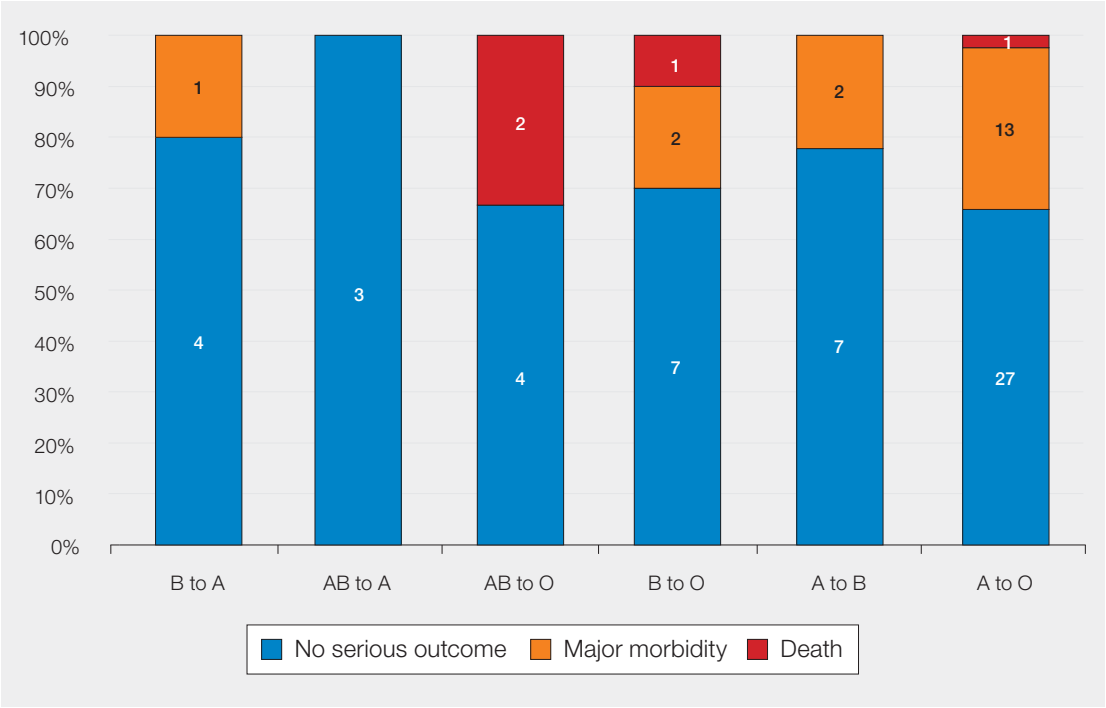


Figure 3.12: Combinations of groups in ABO-incompatible red cell transfusions 2010-2022 (n=74)

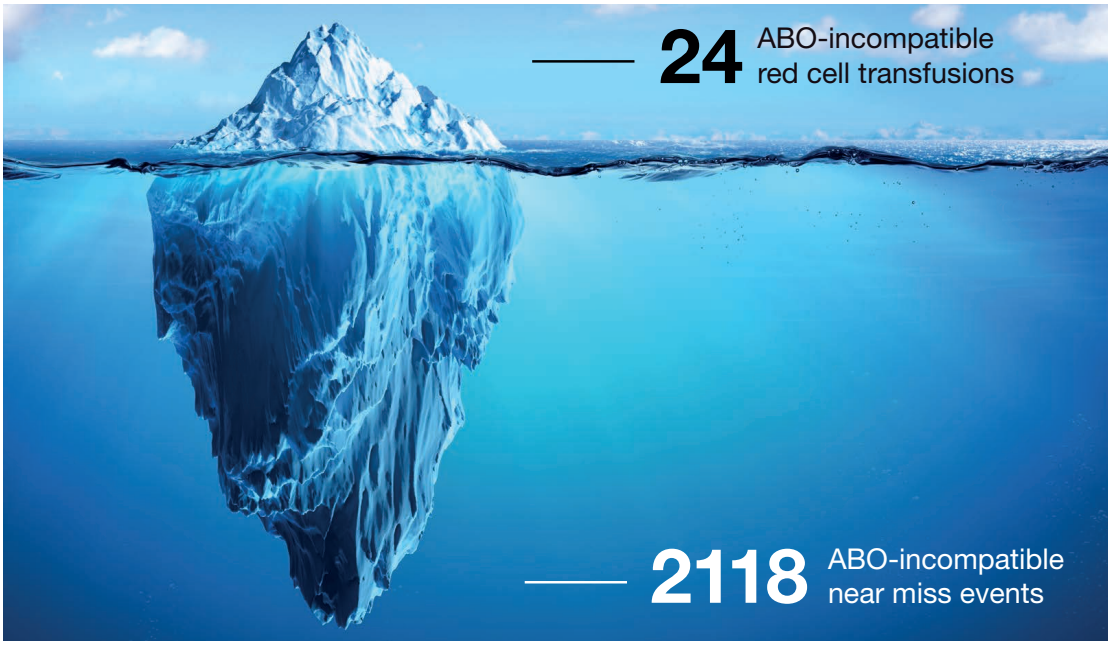
Transfusion of group A red cells to group O patients was associated with the greatest risk of major morbidity, 13/41 (31.7%), but deaths have occurred in group O patients receiving group AB red cells (2 deaths), B red cells (1 death) and A red cells (1 death). These are shown in Figure 3.13 below.

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



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

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

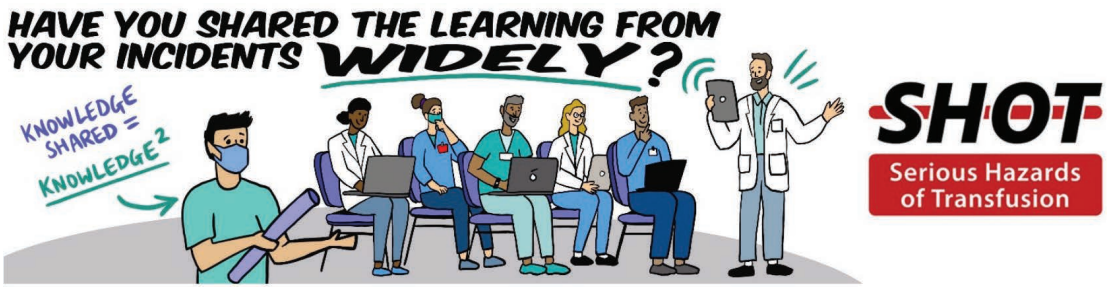


Trending and investigating WBIT, using human factors principles will help identify the causal and contributory factors; and will inform the corrective and preventative actions to improve patient safety and prevent future ABOi transfusions that could result in patient death.

Conclusion

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

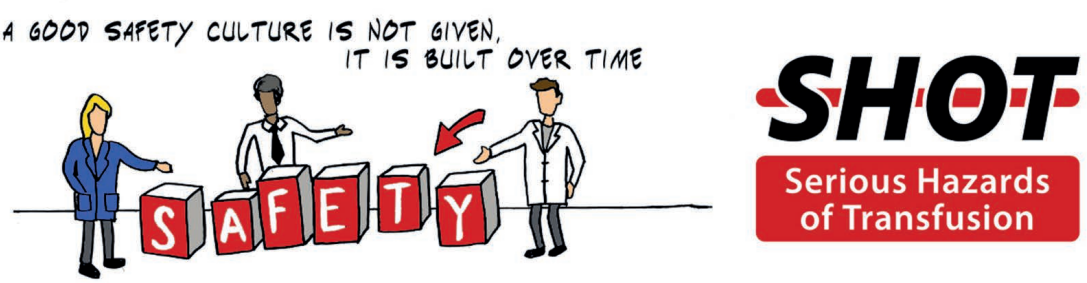
Further information and data can be found in the supplementary information on the SHOT website (https://www.shotuk.org/report-summary-and-supplement-2022/).



Recommended resources

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

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



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