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

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Key SHOT messages

- Transfusion in the United Kingdom (UK) is generally safe and SHOT data for the last five years show the risk of death from transfusion as 0.87 per 100,000 components issued
- Non-infectious complications, especially operational procedural errors and those related to transfusion decisions continue to be the most common causes of transfusion-related deaths in the UK. Delays in transfusion and pulmonary complications (mainly transfusion-associated circulatory overload (TACO)) were the main causes of reported transfusion-related deaths in 2019
- Errors continue to account for majority of the reports. In 2019, 84.1% (2857/3397) of all reports (including near miss (NM) and right blood right patient (RBRP)), and 74.7% of incidents excluding NM and RBRP were due to errors
- Near miss events continue to account for a large proportion (1314/3397, 38.7%) of the incidents reported to SHOT
- Inadequate staffing, lack of adequate training, poor supervision and poor safety culture have been identified as contributory to numerous incidents reported to SHOT. These need to be addressed urgently to reduce the risk to patient safety
- Trends in pathological transfusion reactions, like the 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

Abbreviations used in this chapter

ABOi	ABO-incompatible	**TAD**	Transfusion-associated dyspnoea
HTR	Haemolytic transfusion reaction	**TACO**	Transfusion-associated circulatory overload
MHRA	Medicines and Healthcare products Regulatory Agency	**TRALI**	Transfusion-related acute lung injury
NHS	National Health Service	**TTI**	Transfusion-transmitted infections
NM	Near miss	**UCT**	Uncommon complications of transfusion
RBRP	Right blood right patient	**UK**	United Kingdom

Recommendation

- 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

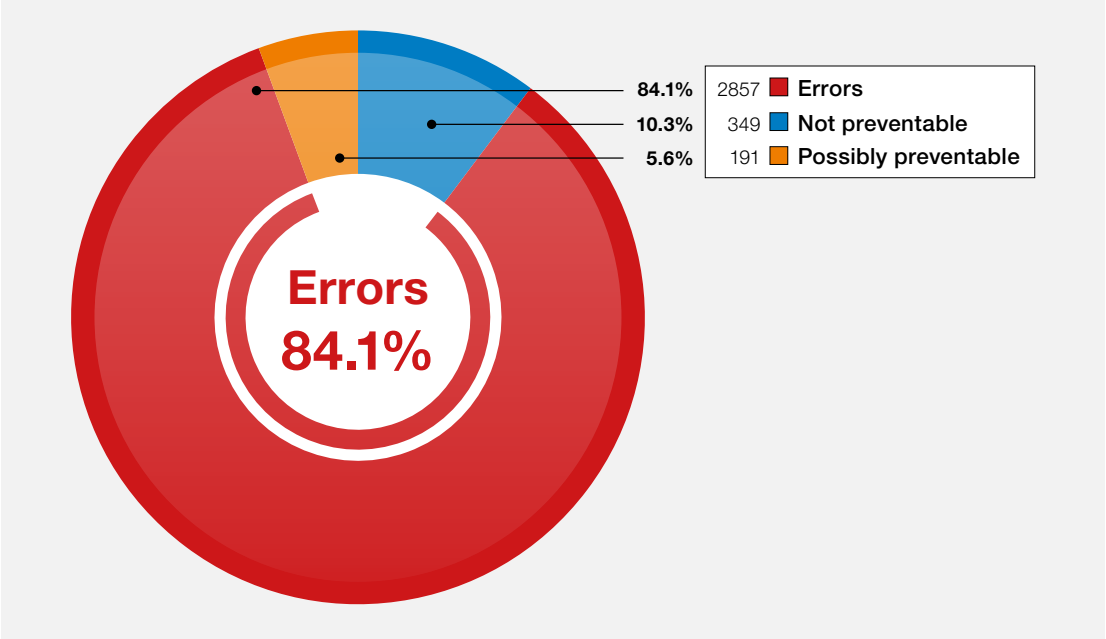
Action: Hospital chief executives and medical directors, National Blood Transfusion Committee (or the equivalent for the devolved countries), hospital transfusion teams

Introduction

Reporting transfusion adverse events and reactions to SHOT and the Medicines and Healthcare products Regulatory Agency (MHRA) supports the National Health Service (NHS) to learn from mistakes and to take action to improve transfusion safety. A reporting culture is a key aspect of patient safety and this is reflected in the continuing high number of reports received by SHOT, and a good level of participation and engagement with the haemovigilance scheme (see Chapter 2, Participation in United Kingdom (UK) Haemovigilance). Evaluation of submitted reports continues to provide assurance that transfusions in the UK are generally safe with around 18 reports submitted to SHOT per 10,000 components.

Errors continue to account for most reports and may reflect that systemic factors are not properly identified or rectified, leading to short term results rather than sustained improvement.

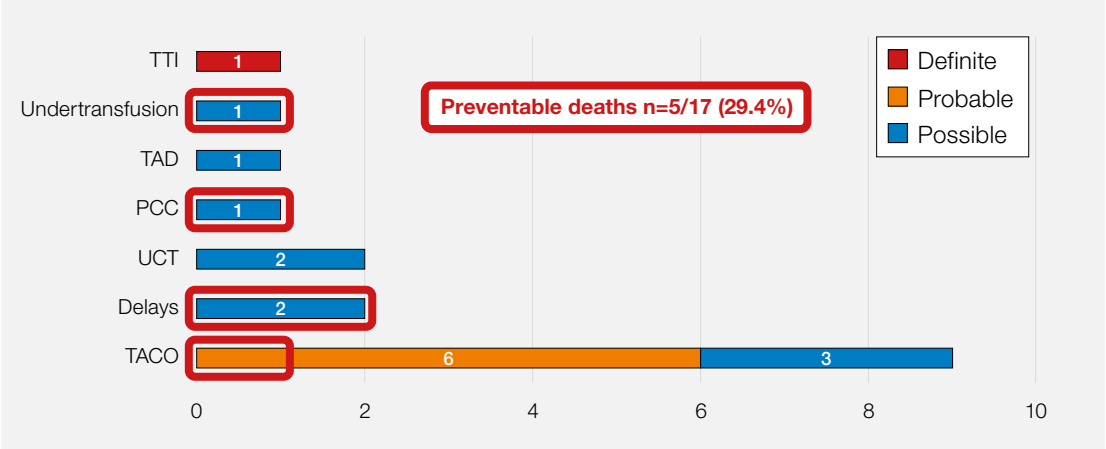
Figure 3.1: Errors account for most reports: 2857/3397



Deaths n=17

There were 17 deaths in total and this number includes deaths definitely, probably and possibly (imputability 3, 2, and 1 respectively) related to the transfusion. Delays in transfusion and pulmonary complications (mainly TACO) were the main causes of reported transfusion-related deaths in 2019. Transfusions with pulmonary complications contributed most to both deaths and major morbidity.

Figure 3.2: Deaths related to transfusion (with imputability) reported in 2019 n=17



TTI=transfusion-transmitted infections; TAD=transfusion-associated dyspnoea; PCC=prothrombin complex concentrate; UCT=uncommon complications of transfusion; TACO=transfusion-associated circulatory overload

Non-infectious complications, especially TACO and delays in transfusion, continue to be the most common causes of transfusion-related deaths in the UK. Figure 3.3 shows the distribution of causes of transfusion-related deaths reported from 2010-2019.

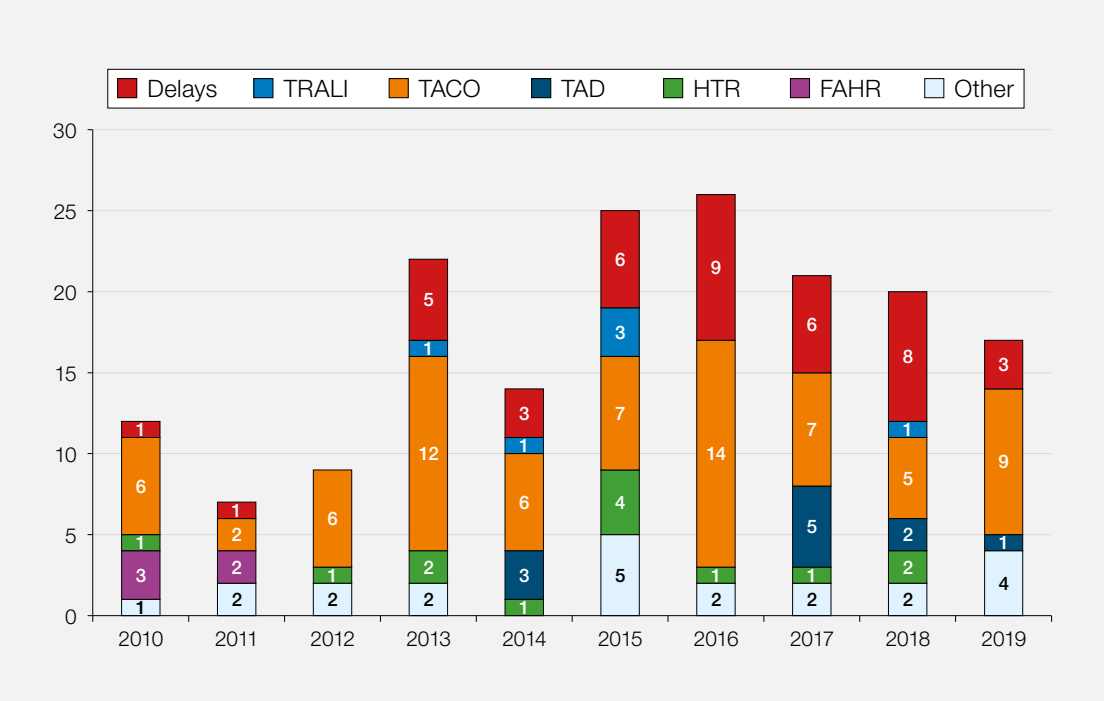


Figure 3.3: Transfusion-related deaths 2010 to 2019 n=173

TRALI=transfusion-related acute lung injury; TACO=transfusion-associated circulatory overload; TAD=transfusion-associated dyspnoea; HTR=haemolytic transfusion reaction; FAHR=febrile, allergic and hypotensive reaction

Delays include 1 delay due to PCC in 2019; HTR includes 2 deaths due to ABO-incompatibility; 'Other' includes 1 each for post-transfusion purpura, transfusion-associated graft-versus-host disease (2012) and anti-D related; there were 7 in the avoidable, over or undertransfusion category, 3 transfusion-transmitted infections, and 9 deaths related to other unclassified reactions

Improved decision making, patient monitoring and education, addressing factors contributing to errors, building safer systems and continued vigilance are vital in improving transfusion safety.

Major morbidity n=129

Most cases of major morbidity were caused by febrile, allergic or hypotensive transfusion reactions and pulmonary complications. These are further detailed in the respective subject chapters in this report.

Major morbidity is defined as:

- Intensive care or high dependency admission and/or ventilation, renal dialysis and/or renal impairment
- Major haemorrhage from transfusion-induced coagulopathy
- Evidence of acute intravascular haemolysis e.g. haemoglobinaemia or severe 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 to cause risk to life unless there is immediate medical intervention

Potential for major morbidity is defined as:

- Potential risk of D or K sensitisation in a woman of childbearing potential

Summary data and risks associated with transfusion

Data collected in 2019 are shown in Figure 3.4. Near miss reporting continues to provide valuable learning opportunities and contributed to 1314 (38.7%) of the total 3397 reports. Cumulative data for 23 years are shown in Figure 3.5.

Figure 3.4: Summary data for 2019, all categories (includes RBRP and NM) n=3397

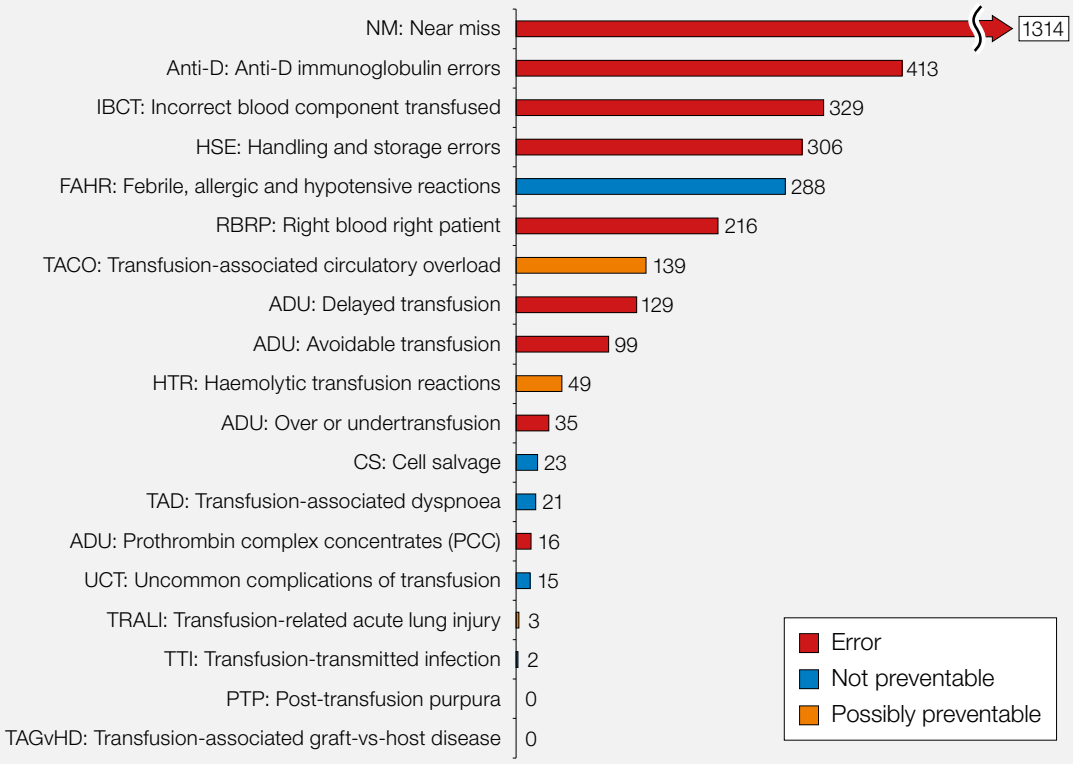
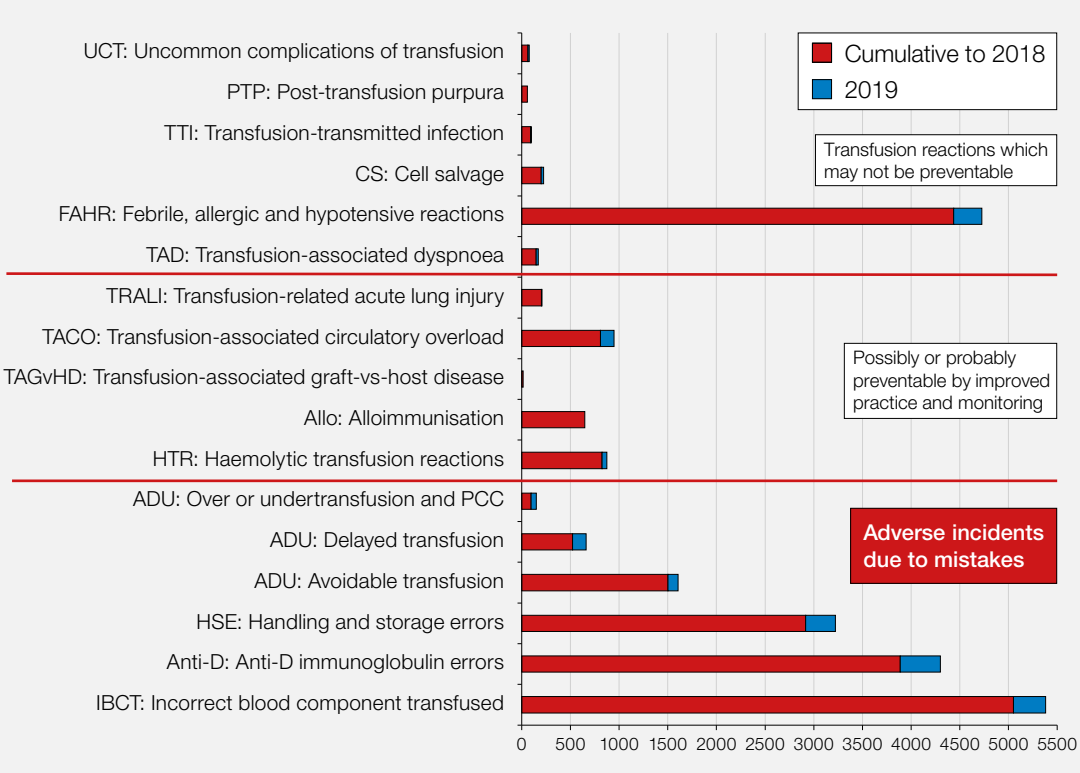


Figure 3.5: Cumulative data for SHOT categories 1996-2019 n=23341



**Data on alloimmunisation has not been collected since 2015*

Transfusion risks are calculated per 10,000 components issued. This translates into a risk of death close to 1 in 135,705 components and of serious harm close to 1 in 17,884 components issued in the UK. The risks of transfusion-transmitted infection are much lower than all other transfusion-related complications (see Chapter 20, Transfusion-Transmitted Infections (TTI)).

The following Figure 3.6 provides a useful reminder of why it is important to report and investigate near misses. Though recording and investigating incidents presents a more detailed picture, this is still a lagging indicator - measuring 'after' the event. Recording and investigating near misses, on the other hand, not only helps us to assess the strength of safety management systems but also provides an opportunity to fix problems before the occurrence of any adverse impact on patients, donors or staff i.e. a 'proactive approach' to safety. Building a strong safety culture is seeing risk where none was seen before, and actively mitigating risks before they become fatal.

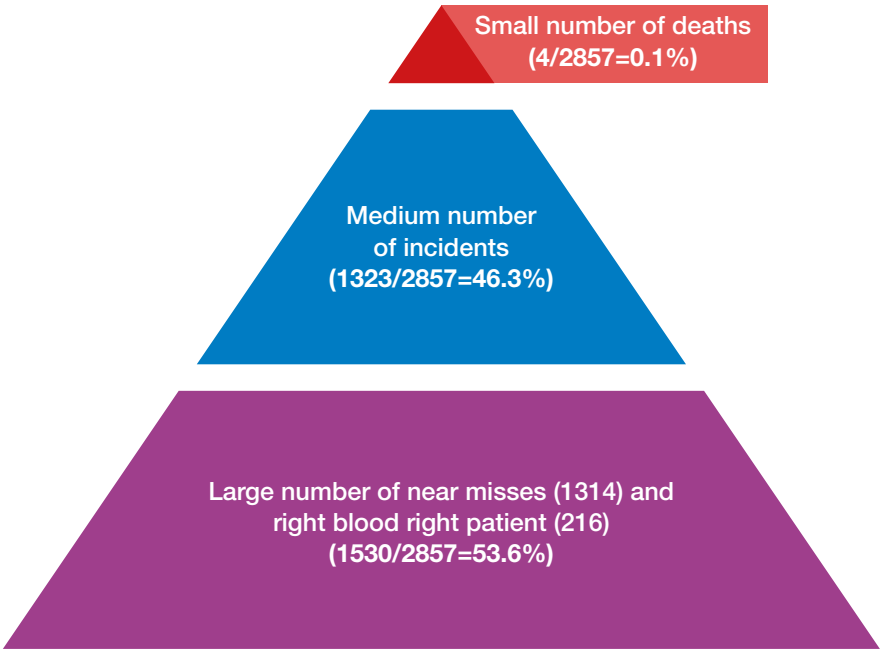
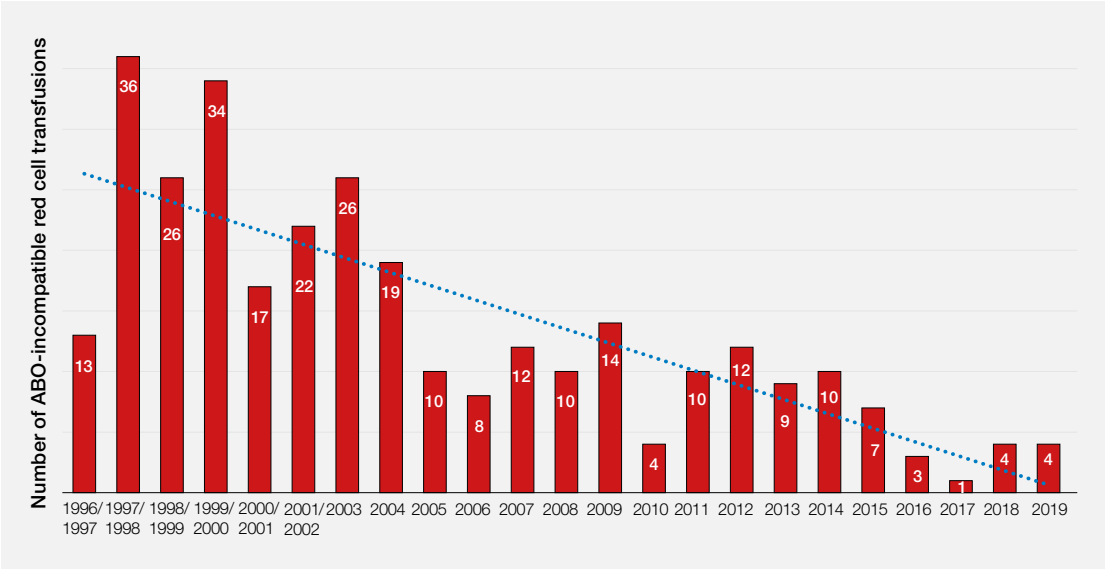


Figure 3.6: Reported errors triangle

ABO-incompatible (ABOi) transfusions n=6

In total, there were 4 ABO-incompatible red cell transfusions and 2 ABOi FFP transfusions reported in 2019. Of these, 3 were related to errors at component selection, 2 were primarily collection errors and 1 was related to an error at administration of the blood component. No patient deaths or major morbidity were reported in any of these cases. One of these was a paediatric case while the other 5 were in adult patients. These are further described in Chapter 9, Incorrect Blood Component Transfused (IBCT). Of note, in 4/6 (66.7%) cases, transfusions occurred between 20:00-08:00, reflecting the need to avoid unnecessary elective transfusions out-of-hours when staffing levels are low but also the importance of due diligence and vigilant monitoring of patients having transfusions at any time. It is also disturbing to note that despite previous SHOT recommendations and a recommendation from the Chief Medical Officer (Department of Health 2017), a bedside checklist is not universally applied, and this safety check could potentially have picked up these ABOi transfusions. Mistakes have also occurred as staff have not been adequately trained or their competencies assessed. Sources of cognitive bias and inattention blindness have been identified as contributory factors such as unfamiliarity with process, interruptions, assumptions, fatigue, etc.

Figure 3.7: Number of ABO-incompatible red cell transfusions 1996-2019



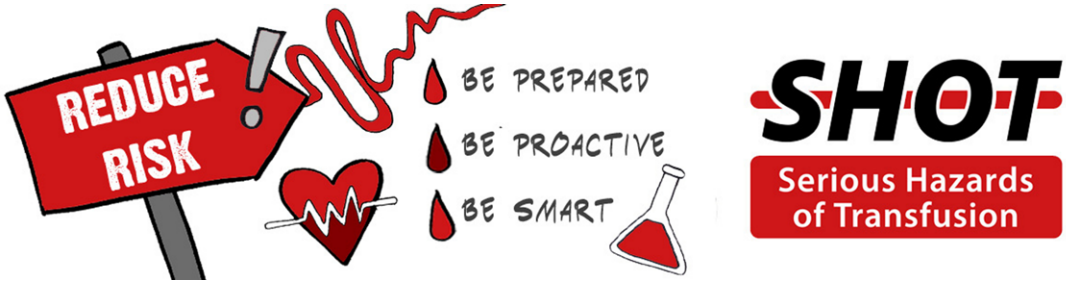
The trend over time towards reduced numbers of potentially fatal ABO-incompatible red cell transfusions is encouraging (Figure 3.7). However, review of near miss data shows that these are the tip of a much larger iceberg. Data from 2016-2019 show that although there were 12 ABO-incompatible red cell transfusions there were 1236 near misses where an ABOi transfusion would have resulted. Most of these in 2019, 308/329, resulted from wrong blood in tube (WBIT) errors. These will not be detected unless there is a historical record in the transfusion laboratory and demonstrate the importance of the group-check policy (BSH Milkins et al. 2013). In reports of WBIT samples, most reports (625/728, 85.9%) had this policy in place and 308/625 (49.3%) instances of WBIT were detected as a result of this. These errors, which could have lethal outcomes, demonstrate the importance of correct patient identification at the time of sampling, and the correct accurate completion of the final bedside check (BSH Robinson et al. 2018).

Figure 3.8: ABO-incompatible transfusions 2016-2019: few events (n=12) but many near misses (n=1236)

Healthcare organisations should consider strategies to increase the awareness of cognitive biases and promote work conditions that can detect, protect against, and recover from cognitive biases and associated risks. Cognitive biases, also known as 'heuristics', are cognitive short cuts used to aid our decision-making (O'Sullivan 2018). Errors persist although they should be reduced by good clinical and laboratory practices, automation, warning flags, education, and competency-assessment. Cognitive bias and inattention blindness are known to contribute to errors in healthcare, with lapses increasing during excessive workload and distraction (e.g. answering telephone queries and multitasking). These factors are often identified during incident investigation but are not always given weight when formulating a root cause, therefore are not addressed in corrective action (Grissinger 2012). Laboratory errors may be reduced if procedures and quality management systems are examined, then redesigned to complement the environment. For example; allocating a further member of staff to deal with queries will reduce distractions, variation in simple tasks will reduce 'autopilot', and removing ineffective computer flags will draw attention to the key safety checks. For additional discussion of cognitive bias, please see Chapter 7, Human Factors.

Conclusion

It is imperative that lessons learnt from incidents reported to SHOT are used to improve and adapt healthcare systems, transfusion policies and practices including training/education and investigation of incidents. These measures will help improve transfusion safety and can be evidenced by a reducing trend of such reports to SHOT in the future. Near misses also present valuable learning opportunities and should be investigated thoroughly. System level changes are needed to ensure that healthcare is a robust, safe and effective learning system with feedback loops.



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O'Sullivan ED and Schofield SJ. (2018) Cognitive bias in clinical medicine. *J R Coll Physicians Edinb* 2018;**48**: 225–232. doi:10.4997/JRCPE.2018.306.