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

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Key SHOT messages

- Errors account for 87.3% (2905/3326) of all reports (including near miss (NM) and right blood right patient (RBRP); Figure 3.1), and 74.7% of incidents excluding NM and RBRP
- Near miss events continue to account for a large proportion (1451/3326, 43.6%) of the incidents reported to SHOT and have increased again this year, n=1451 in 2018, compared to n=1359 in 2017
- Staff involved in transfusion need to be vigilant at each step in the transfusion process - they should verify each step, particularly where patient identification is involved, and should never make the assumption that errors could not have been made in the preceding steps in the process or anytime in the past. Staff should aim to get it right the first time and every time. Clinicians need to be aware of the risks of transfusion-associated complications in patients with severe anaemia and should be extra cautious when the patients have additional risk factors
- Staffing challenges are noted as contributory to many events reported to SHOT. Staffing levels must be appropriate in all areas involved in transfusion. Inadequate staffing, lack of training and poor supervision is associated with an increased risk of errors putting patient safety at risk
- Emergency transfusion saves lives. Do not delay. Do not let the patient bleed to death or die from anaemia
- A just and learning culture is vital to promote safety in organisations. Incident investigations should be thorough and identify attributable system-related and human factors so that appropriate actions can be instituted

Deaths where transfusion was implicated n=20

This number includes deaths definitely, probably and possibly related to the transfusion. Delays in transfusion and pulmonary complications were the main causes of reported transfusion-related deaths in 2018. Transfusions with pulmonary complications contributed most to both deaths and major morbidity.

Major morbidity n=109

Most major morbidity was 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

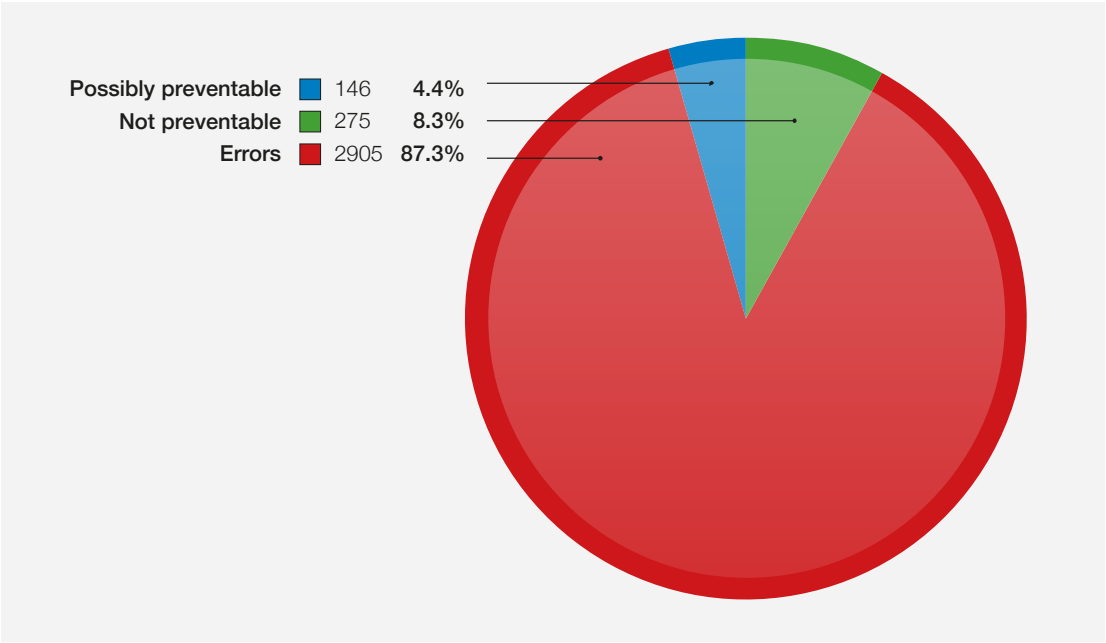
Potential for major morbidity: potential risk of D or K sensitisation in a woman of childbearing potential

Table 3.1: Mortality and major morbidity data by reporting category in 2018

	Death definitely related	Death probably related	Death possibly related	Major morbidity
Delayed transfusion		2	6	
Overtransfusion			1	
FAHR				60
HTR		2		4
IBCT-WCT (clinical)				1
IBCT-WCT (laboratory)				2
IBCT-SRNM (laboratory)				1
UCT				3
TACO		2	3	36
TAD			2	1
TRALI		1		
TTI		1		1
Total	**0**	**8**	**12**	**109**

FAHR=febrile, allergic and hypotensive reactions; HTR=haemolytic transfusion reaction; IBCT-WCT=incorrect blood component transfused; IBCT-SRNM=IBCT-specific requirements not met; UCT=unclassifiable complications of transfusion; TACO=transfusion-associated circulatory overload; TAD=transfusion-associated dyspnoea; TRALI=transfusion-related acute lung injury; TTI=transfusion-transmitted infection

Figure 3.1: Errors account for the majority of reports: 2905/3326 (87.3%)



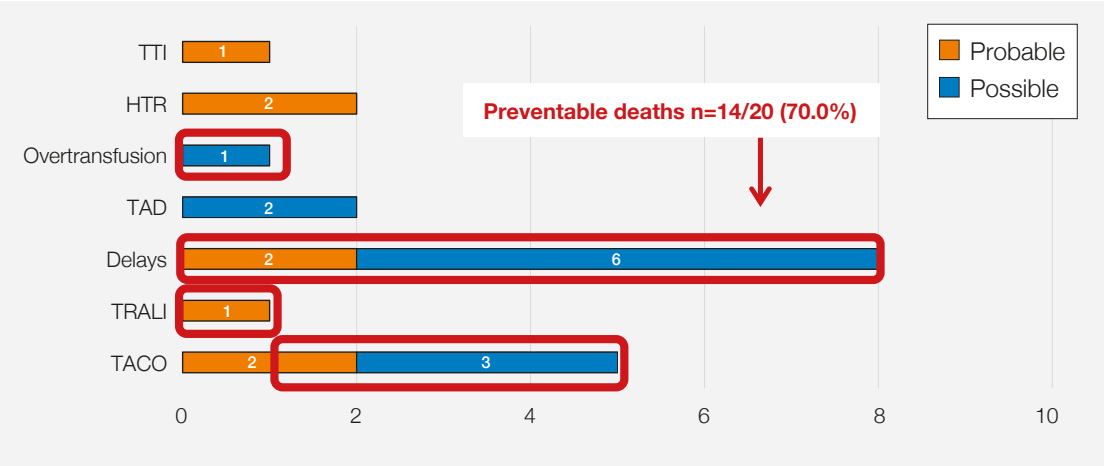


Figure 3.2: Deaths related to transfusion (with imputability) reported in 2018 n=20

HTR=haemolytic transfusion reaction; TAD=transfusion-associated dyspnoea; TRALI=transfusion-related acute lung injury; TACO=transfusion-associated circulatory overload; TTI=transfusion-transmitted infection

Most of the deaths attributable to transfusion are associated with delays and TACO. Review of cumulative data shows that pulmonary complications are the leading cause of transfusion-related death, and nearly a quarter were related to delays. In this period (2010-2018) there were 2 deaths from ABO-incompatible transfusion.

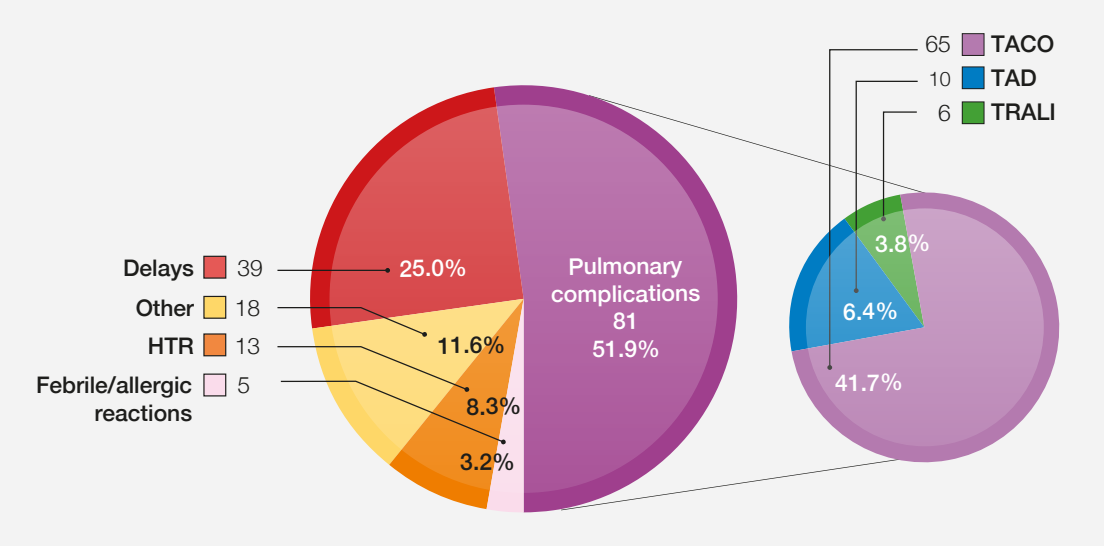


Figure 3.3: Transfusion-related deaths 2010 to 2018 n=156

HTR=haemolytic transfusion reaction; TRALI=transfusion-related acute lung injury; TACO=transfusion-associated circulatory overload; TAD=transfusion-associated dyspnoea

'Other' includes 1 each for post-transfusion purpura (PTP), transfusion-associated graft-versus-host disease (TAGvHD) and anti-D immunoglobulin related; there were 6 in the avoidable, over or undertransfusion (ADU) category, 2 transfusion-transmitted infections (TTI), and 7 deaths related to other unclassified reactions

Errors without harm to patients n=1667 (near miss and right blood right patient reports).

Other errors with actual or potential harm n=1238 (handling and storage errors, avoidable and delayed transfusions, anti-D Ig errors and incorrect blood component transfused); see Figure 2.5 in Chapter 2, Participation in UK Haemovigilance Reporting.

Summary data and risks associated with transfusion

Data collected in 2018 are shown in Figure 3.4. Near miss reporting continues to teach valuable lessons and contributed to 1451 (43.6%) of the total 3326 reports.

Cumulative data for 22 years are shown in Figure 3.5.

Figure 3.4: Summary data for 2018 all categories n=3326 (ranked by number)

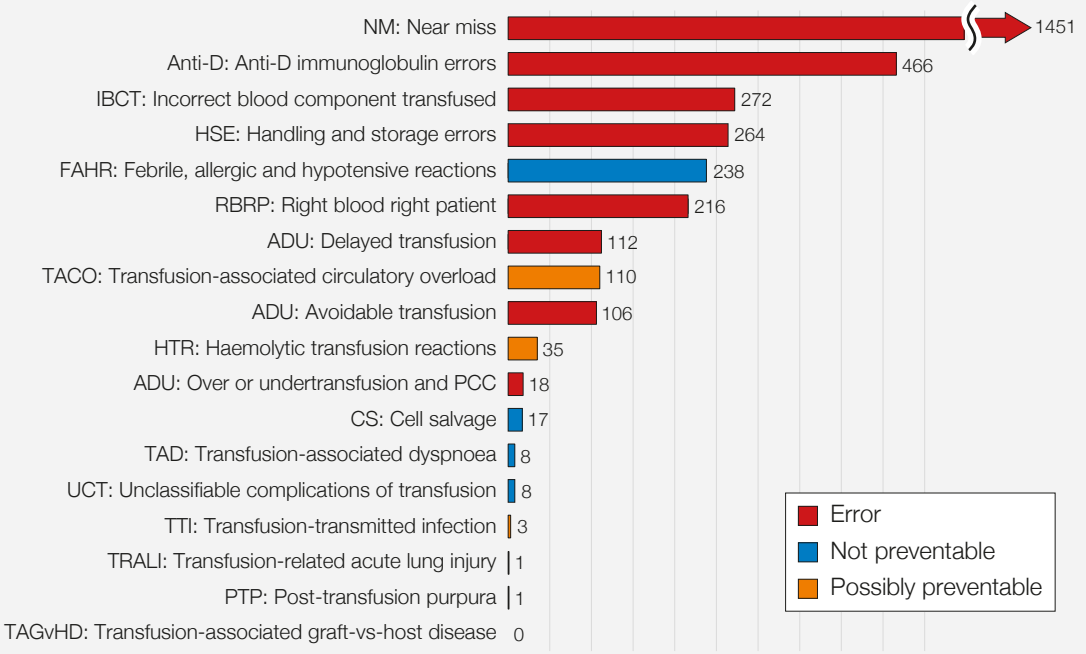
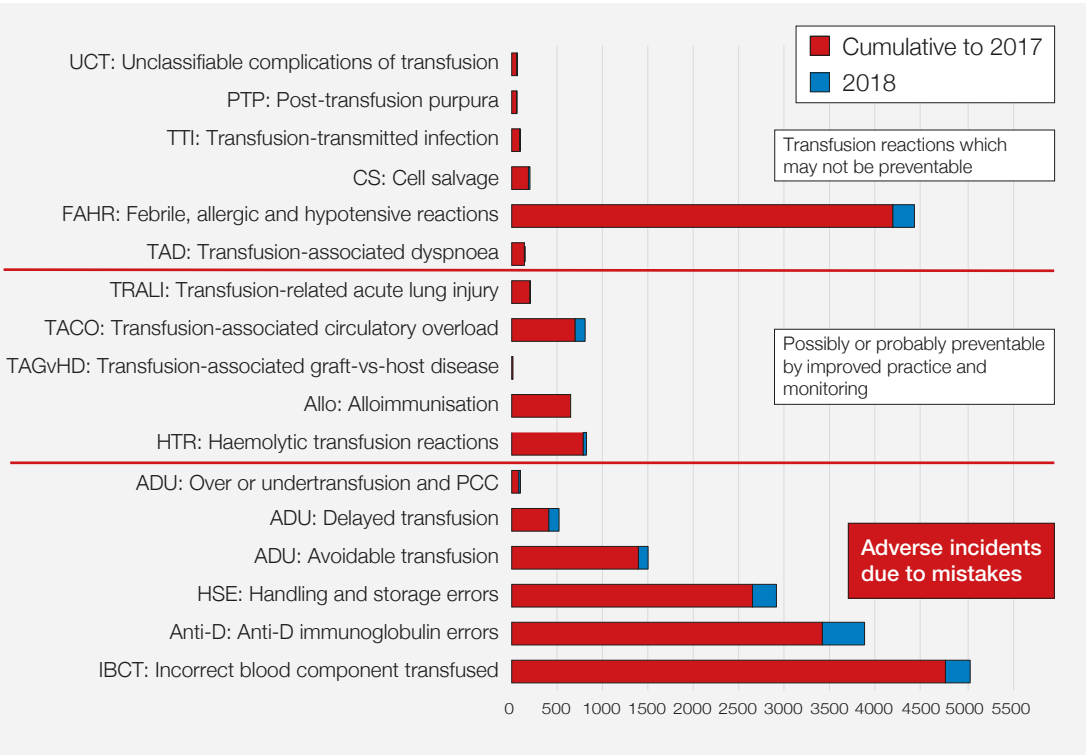


Figure 3.5: Cumulative data for SHOT categories 1996 to 2018 n=21474



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

Risks for transfusion are calculated per 10,000 components issued. This translates into a risk of death close to 1 in 117,000 and of serious harm close to 1 in 21,000 components issued in the UK. The risks of transfusion-transmitted infection are much lower than all other transfusion-related complications.

Total morbidity	0.467 per 10,000 components issued	1 in 21,418
Total mortality	0.086 per 10,000 components issued	1 in 116,726

Table 3.2: Risks of death or major morbidity from transfusion in 2018

The following figure 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.

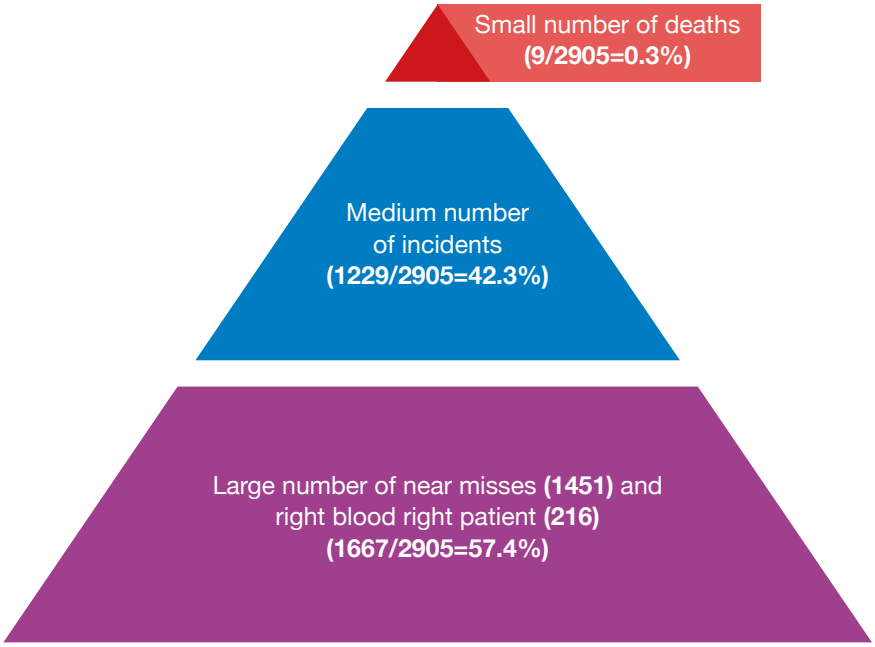
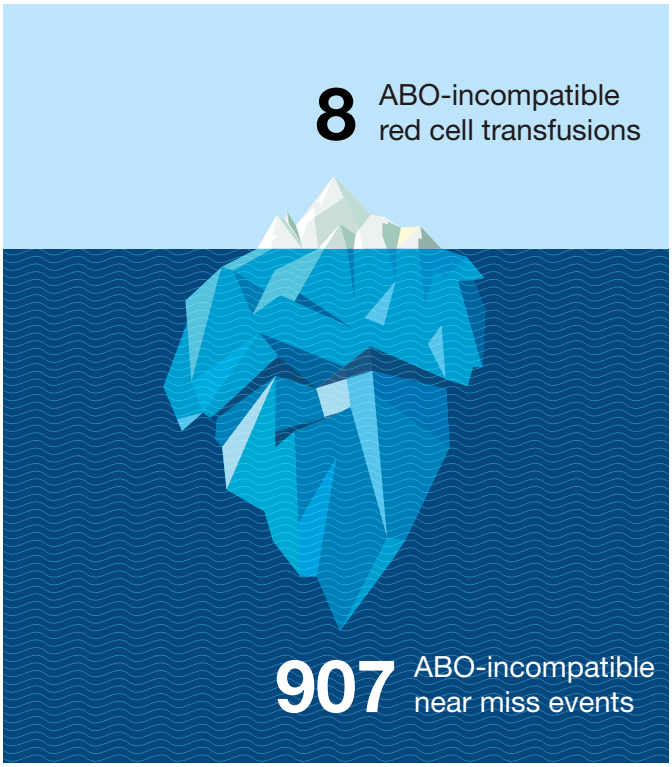


Figure 3.6: Reported errors triangle

ABO-incompatible red cell transfusions n=4

There were 4 ABO-incompatible red cell transfusions reported in 2018, of which 3 were errors that could have been identified at administration. No patient deaths were reported, however this resulted in major morbidity in 2 patients. These are further described in Chapter 8, Incorrect Blood Component Transfused (IBCT) (Cases 8.1 and 8.2). Review of near miss data shows that these are the tip of a much larger iceberg. Data from 2016-2018 shows that although there were 8 ABO-incompatible red cell transfusions there were 907 near misses where an ABO-incompatible transfusion would have resulted. In 2018, 290/792 (36.6%) of wrong blood in tube (WBIT) errors could have resulted in an ABO-incompatible transfusion (Chapter 12a, Near Miss – Wrong Blood in Tube (WBIT)). These will not be detected unless there is a previous 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 correct patient identification at the time of sampling, and the correct full completion of the final bedside check (a rule not a guideline).

Figure 3.7: ABO-incompatible red cell transfusions 2016 to 2018



In addition, there were 3 inadvertent transfusions of ABO-incompatible blood components, 2 of fresh frozen plasma and 1 of cryoprecipitate; no harm resulted. As before, such incidents demonstrate that either local protocols were not in place or not being followed appropriately. All clinical staff involved in transfusion must check compatibility properly at the time of transfusion and is one of the essential steps in the bedside check (BSH Robinson et al. 2018, DH 2017).

Erroneous transfusion of ABO-incompatible blood components almost always reflects a preventable breakdown in transfusion protocols and standard operating procedures and can have disastrous consequences, with significant morbidity and mortality. These incidents need to be investigated in a systematic manner to identify system vulnerabilities to mitigate risks and improve patient safety. Investigations should not focus only on staff failings as in doing so will miss identifying system-wide changes that need to be incorporated to address prevalent issues.

A recent review of NHS England Never Events, 'Opening the door to change' (CQC 2018) revealed 'the failure to reduce the toll of never events tells us there is something fundamental about the safety culture of our health care' and the majority of investigations into never events require human factors-based solutions.

Caution when transfusing patients with very low haemoglobin

It has been well known that both chronic and acute anaemia is associated with compensatory circulatory and cardiac changes irrespective of the aetiology of anaemia (Hegde 2006; Metvier 2000; NATA online and Song 2018). This can be further compounded by the underlying cause for the anaemia for example haematinic deficiency that can independently affect myocardial function. The hyperdynamic circulation related to anaemia increases the load on the heart, causing myocardial ischaemia and hypoxia and if the anaemia is not corrected, eventually leads to heart failure. Clinicians need to be aware of the risks and be vigilant when transfusing patients with severe anaemia with or without other additional risk factors. Details of a couple of such cases can be found in Chapter 17b, Transfusion-Associated Circulatory Overload (TACO).

Delays in transfusion

Delays in transfusion contribute to death and morbidity and are often caused by poor communication between the clinical and laboratory staff. The total number of reports of delayed transfusion has increased with time: 101, 95, 112 reports in the last 3 years. Problems with the management of major haemorrhage were reported in 34 cases in 2018, 19 being delays in transfusion. In 1 case the patient's death was possibly related to the delay. The most important factor in major haemorrhage cases was poor communication, often at several points. In major haemorrhage every minute counts and delays threaten patient safety. All staff working in areas where major haemorrhage may occur must be trained with drills to understand procedures and how to rapidly access appropriate blood components. Teams must ensure debriefs after every incident. Attention needs to be paid to interprofessional team learning to help prevent delays. Every hospital should audit major haemorrhage protocol activations to ensure appropriateness and to learn from each episode. For further details, see Chapter 10a, Delayed Transfusions.

Missed irradiation of cellular components where indicated

Irradiation of cellular components was missed in 81 patients in 2018. In 64/81 (79.0%) cases the error was made in clinical areas and 17 in the laboratory. The cumulative number of reports of patients known to have missed irradiation is now 1478 since 1999. Patients were exposed to one or more components. There have been no cases of TAGvHD reported since 2001 in patients who received leucodepleted red cells. Irradiation of cellular components for susceptible patients was introduced several decades ago and guidelines were published in 1996, and revised in 2010 (BSH Treleaven et al. 2010). The case reported in 2012 was caused by an intrauterine transfusion (IUT) with maternal blood (not leucodepleted, not irradiated and human leucocyte antigen (HLA)-related). None of the 13 cases reported up to 2001 occurred in patients with conditions where irradiation was recommended in the guidelines: 6 occurred in patients with B-cell diseases; 3 after cardiac surgery; 2 had no recognised risk factors. Two others were subsequently found to have immune deficiency. At least 4/13 (30.8%) were documented to have shared HLA haplotypes with their red cell donors and 2 received red cells less than 7 days old.

There is insufficient evidence to recommend any change in practice, but it is important to continue reporting to SHOT so that the evidence can inform change in practice in the future.

Investigating incidents

Incident investigations continue to be an area of concern and are often identified to lack depth, detail and scope. Actions generally identified target individuals and are therefore less impactful. Opportunities to address systemic/organisational factors are regularly missed with suboptimal attempts to identify trends and corrective and preventative actions.

Investigations must be systematic, comprehensive, and efficient with appropriate allocation of resources. An effective investigation requires a methodical, structured approach to information gathering, collation and analysis. In general, incidents should be investigated and analysed as soon as possible and identify the right causes through application of the right model. This should identify and implement the right solutions and monitor the impact of the solutions. It is equally important to share lessons learnt with other healthcare professionals. It is vital that investigations avoid routine assignment of blame. Analyses of incidents is a powerful method of learning about healthcare organisations and lead directly to strategies for enhancing patient safety.

Root cause analyses (RCA), a structured facilitated team process to identify root causes of an event that resulted in an undesired outcome is routinely used when investigating adverse incidents. This helps identify breakdowns in processes and systems that contributed to the event and helps develop effective, credible and tangible corrective and preventative actions. Effective RCA should therefore reduce the risk of future harmful events by minimising or eliminating the root causes. Further details can be found in Chapter 25, Medicines and Healthcare products Regulatory Agency (MHRA) Report.

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