ANNUAL SHOT REPORT 2021

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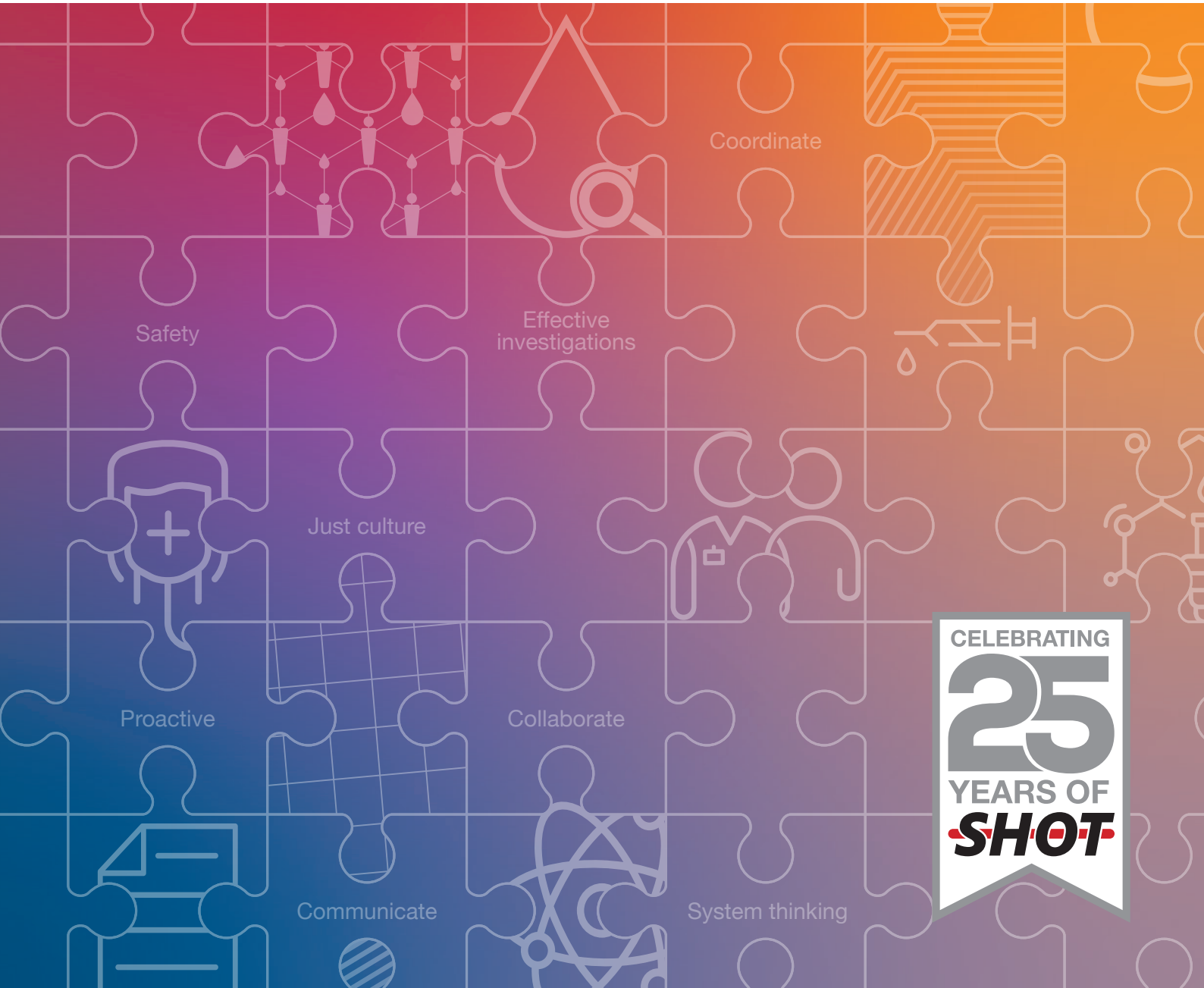
MHRA

SHOT
Serious Hazards of Transfusion



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

Foreword

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This year is a year of jubilees. It is the Queen's platinum jubilee, and, here at SHOT, our silver jubilee. While Her Majesty's platinum jubilee represents a seeming eternity of service, it is also true that a silver jubilee is a significant milestone. Twenty-five years is a long time, particularly in the world of transfusion safety. SHOT is the world's pre-eminent haemovigilance scheme, and, although there are other models and systems for haemovigilance, the lessons SHOT has learned have in most cases either been mirrored or directly adopted in other countries.

The very early years of SHOT, and the first Annual SHOT Report, addressed a very high rate of transfusion error. Much of this error related to ABO-incompatibility. Both the number of incidents, and severity of outcomes, was high. Introduction of a reporting scheme, with systems for learning from incidents and disseminating this information, led to a rapid and substantial reduction in the number and severity of incidents, with a shift towards near misses and unmasking of more complex problems. However, for many years, there has been a low but persistent, fluctuating level of both errors and near misses, which has steadfastly refused to go away. So, where do we go from here?

We often draw parallels with the aviation industry and aviation safety. The first aviation fatality occurred only 4 years after the beginning of flight. On the 17th of September 1908, Orville Wright was demonstrating an aircraft to the American army. The aircraft was piloted by Wright, and his passenger was one Thomas Selfridge. In the ensuing crash, Orville Wright was seriously injured, and Thomas Selfridge killed, becoming aviation's first fatality. As more aircraft were built, and more pilots tried to push the boundaries, the number of aviation accidents increased rapidly. This led to the creation of the Bureau of Air Commerce in 1926, in the United States of America, and the first formal accident inquiry in 1931, following the fatal crash of a TWA flight. This enquiry was a landmark which introduced the concept that the causes of accidents should not be a secret. It also marked the starting point for the use of engineering principles, in aircraft design and construction, as a key to reducing the risk of accidents.

A major collision over the Grand Canyon in 1956 led to a further shakeup, with most aviation regulation in the United States falling under the umbrella of the Federal Aviation Administration (FAA), in a joined-up and systematic way. Importantly, however, investigation of accidents remained independent: there are parallels with SHOT today.

Most of the structures were now in place to investigate and manage aviation safety incidents. The next major change came in 1967, with the introduction of the cockpit voice recorder. For the first time, the emphasis in accident investigation shifted from describing what had happened, to describing how and why it happened. It was very soon evident that in a number of accidents, there were common factors, and that all resources available were not utilised to prevent these. This led to the rapid development of 'crew resource management' (CRM), which looked in detail at human factors, interactions, and the best way of utilising all available resources. Within a very short period, the number of aviation accidents reduced dramatically. The greatest number of aviation fatalities was in 1972, just short of 3500. Since then, the number of passenger miles has increased dramatically, but the number of fatalities have fallen. For every trillion passenger kilometres, in 1970, there were just over 3000 fatalities. This has reduced exponentially, falling below 500 in 1999, and is now consistently well under 100.

This begs the question, how has this been achieved in aviation, and how has that industry managed to sustain its improvements, on a logarithmic scale? How can we learn from that approach?

In recent SHOT symposia, there have been several presentations on human factors, and on safety management systems. However, throughout the NHS, the most commonly used tool for investigating

accidents remains 'root cause analysis'. Unfortunately, the final output of many such investigations is around improved staff training, or retraining, and in some cases around disciplinary action or replacing staff. This has not been an approach adopted by SHOT, but one which poses a cultural barrier to progress.

Many of us are familiar with the work of the Danish safety guru, Professor Erik Hollnagel, who has for many years promoted the concept of 'Safety-II', which focuses on systems resilience. Nancy Leveson is professor of aeronautical and aerospace safety at the Massachusetts Institute of Technology. She and her group have, for many years, researched and applied a 'Safety–III' approach across a wide range of safety critical industries. Safety-III is based on the assumption that losses result from inadequate control of hazards.

Her recent article on Safety-III is not only a critical dissection of Hollnagel's ideas, which makes interesting reading, but lays out how implementation of safety systems at every level (Safety-III, or systems safety) is the most effective and consistent way forward (Leveson 2020).

As an example of this, I would like to quote from aviation safety expert, Professor David Newman. Professor Newman is medically qualified and served as an officer in the Royal Australian Air Force for many years. An expert in human factors, he has taken part in many air accident enquiries. The important question he poses is this: could the same accident have happened, at another place, or at another time, with a different crew, or if the crew had been replaced or undergone remedial training? Often, the answer is yes. He discusses the truths and misconceptions around human error, but emphasises that ultimately, human error cannot be eliminated. Rather, it can be understood, minimised, and controlled, so as to mitigate its consequences. He goes on to talk about two categories of error:

(1) Active errors, often committed by frontline operators, such as pilots, doctors, air traffic controllers (and by extrapolation in our world, laboratory staff and clinical bedside staff). These errors are very common, and may or may not lead to accidents or incidents; and

(2) Latent conditions or failures (errors), including poor systems design, poor procedure design, poor decision-making by managers/supervisors etc. These may lay dormant in a system for a long time and can potentially cause accidents without an active error.

So, where does this leave us? Through SHOT, we have learned a huge amount about transfusion incidents, both accidents and near misses. We have developed great experience in collecting and collating data, analysing patterns of error, and investigating the ways in which systems and systems design contribute to these. In other words, in Professor Newman's terms, we have progressed to a recognition of both active and latent errors. In aviation, through integrated agencies such as the FAA, this understanding has been implemented in a mandatory, industrywide way. In healthcare, and particularly in the NHS, we still face a disjointed approach and significant cultural barriers to implementing what we have learned. And this is likely to be the greatest challenge SHOT faces in the coming years. But in this year, SHOT congratulates Her Majesty on her platinum jubilee.

References

Leveson N. Safety III: A Systems Approach to Safety and Resilience (2020). http://sunnyday.mit.edu/safety-3.pdf [accessed 26 April 2022].

Participation in United Kingdom (UK) Haemovigilance

2

Authors: Debbi Poles and Chris Robbie

Abbreviations used in this chapter

ADU	Avoidable, delayed and under/overtransfusion
CCP	COVID-19 convalescent plasma
CHM	Commission on Human Medicines
ED	Emergency department
FFP	Fresh frozen plasma
HBB	Hospital blood bank
MB	Methylene-blue treated
MHRA	Medicines and Healthcare products Regulatory Agency
NHS	National Health Service
NHSBT	NHS Blood and Transplant
NHSEI	NHS England and Improvement
SABRE	Serious adverse blood reactions and events
SaBTO	The Advisory Committee on the Safety of Blood, Tissues and Organs
SD	Solvent detergent-treated
UK	United Kingdom
vCJD	Variant Creutzfeldt Jakob Disease

Key SHOT messages

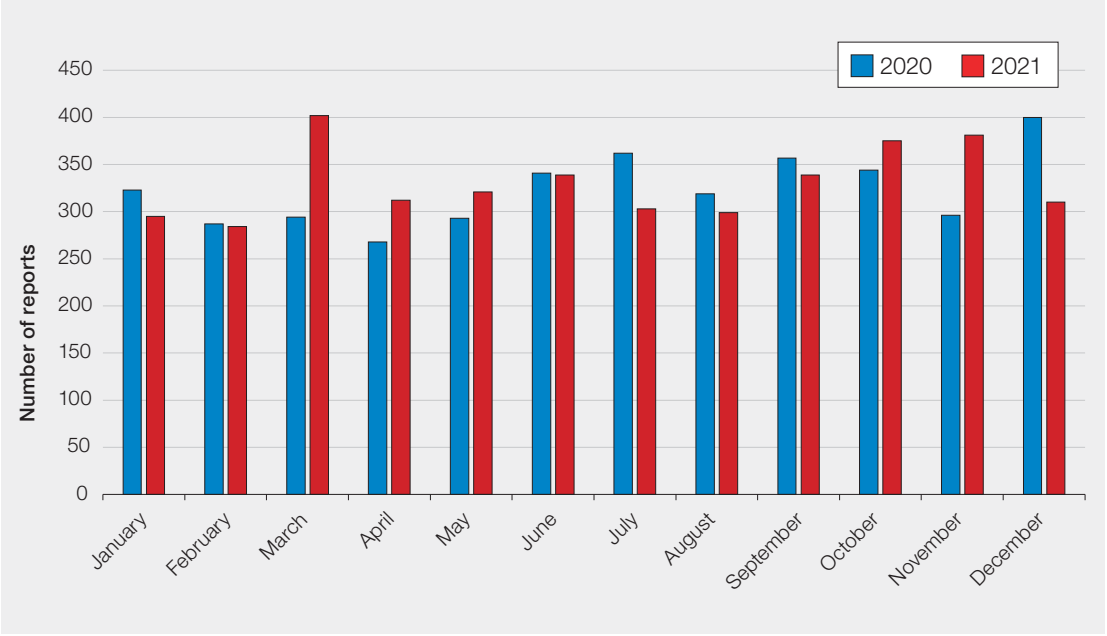
- 2021 was the first year that at least 1 report was submitted by every NHS Trust/Health Board in the UK
- High levels of reporting indicate a good reporting culture with an openness to share the learning when incidents occur. Timely submission and completion of reports enables identification of trends in errors, facilitating early shared learning
- Reporters are encouraged to review their participation benchmarking data on an annual basis, to ensure all appropriate reporting is captured

Introduction

In the first year of SHOT reporting in 1996, 169 initial reports were submitted from 94 different hospitals. Now, 25 years later, in the calendar year 2021, a total of 4088 reports were received from all NHS Trusts/Health Boards in the UK and some non-NHS organisations. In 1996 reporting was voluntary but is now professionally mandated. Increased participation is thought to be due to the confidential anonymised data, and acknowledgement that reporting to haemovigilance schemes helps to support improvements in patient safety.

Reporting levels are similar to the previous year, with only 25 more reports received compared to 2020 (n=4063). Reporting has again fluctuated by month during 2021, with a large spike submitted in March 2021, which could be due to reporters catching up after the winter pressures. However fewer reports were submitted during December 2021, which was the month that most reports were submitted during 2020.

Figure 2.1: SHOT reporting by month during 2020 and 2021



The 4088 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. There are differences in reporting criteria for both organisations.

Figure 2.2 details how the 4088 reports were included by each organisation. Only 1045/4088 (25.6%) of reports were accepted for inclusion in the 2021 analysis by both SHOT and the MHRA, and this demonstrates the differences in reporting criteria between the two organisations. The main differences in reporting criteria are that the MHRA does not accept reports related to clinical errors, which account for a large proportion of SHOT-reportable incidents. SHOT only accept reports that involve a named patient for whom a blood product or component has been prescribed and collected. The MHRA accepts reports from UK Blood Services, and laboratory errors which don't involve a named patient.

These differences account for the large numbers of reports that were withdrawn or excluded by each organisation. There were only 294/4088 (7.2%) reports that were withdrawn by both SHOT and the MHRA as not fulfilling either organisation's reporting criteria. Of these 294 reports, 49 were mild reactions, which are not reportable to either SHOT or the MHRA, and 23 were duplicate reports submitted in error.

There were 465 reports to SHOT that were submitted during 2021, but still incomplete at the end of December 2021. Whilst there will always be incomplete cases, especially for those reports that were not submitted until towards the end of the calendar year, this is a 17.7% increase from 2020, where there were 395 incomplete reports. This could be due to worsening workload and staffing pressure on haemovigilance reporters impacting their ability to gather all the necessary information in a timely manner. In 2021 there were less reports submitted during December than in 2020.

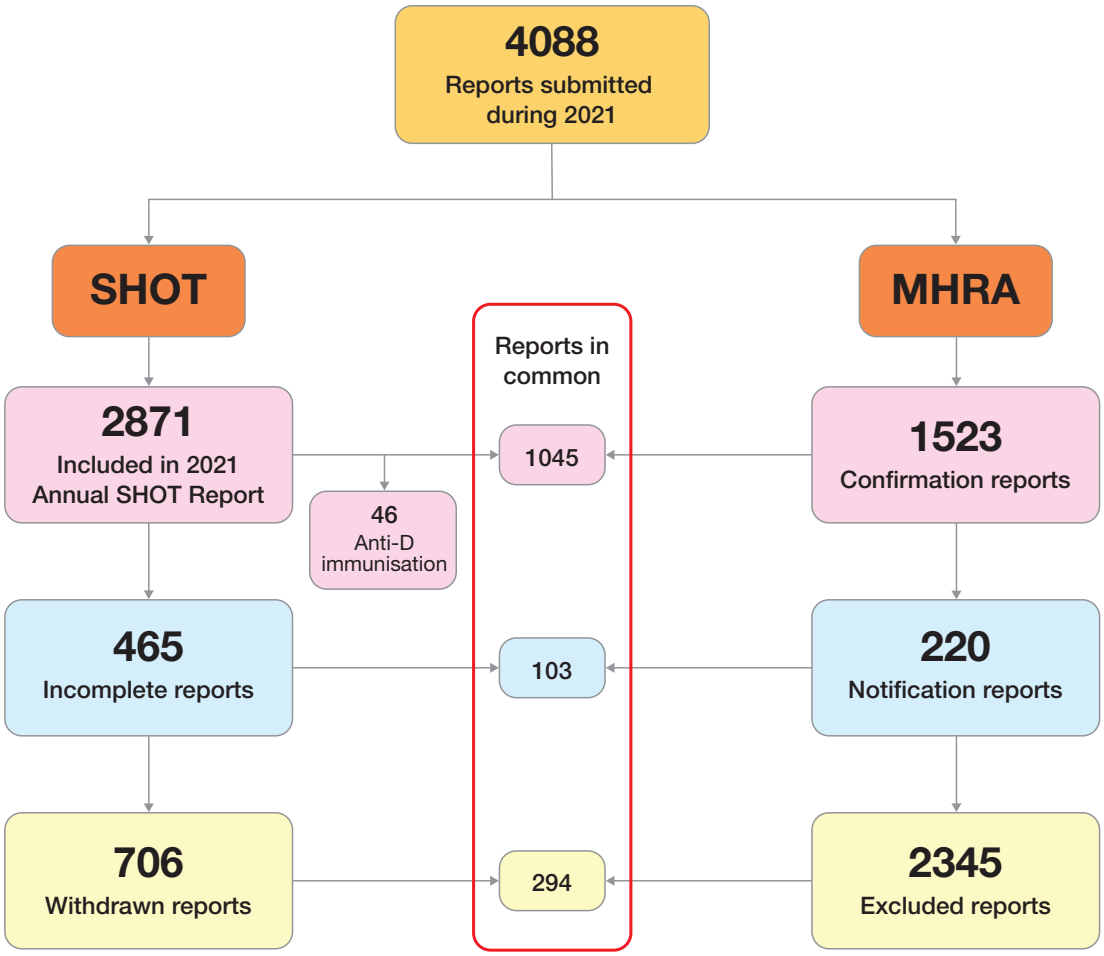


Figure 2.2: Reports submitted to SHOT and the MHRA in the calendar year 2021 (n=4088)

Reporting organisations in 2021

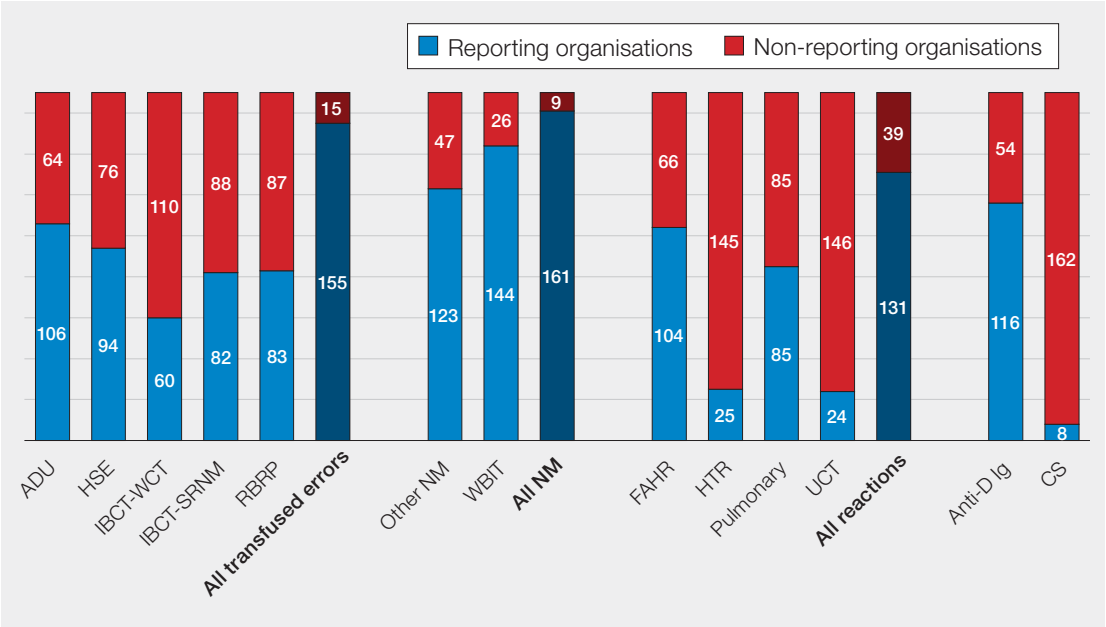
During 2021, 100% of UK NHS Trusts/Health Boards involved in transfusions submitted reports. This is the first year that there have been reports received from all registered Trusts/Health Boards since participation was first analysed in the Annual SHOT Report. This is commendable in what has been another difficult year for NHS staff. Whilst there may have been individual hospitals that did not submit reports, for participation purposes, SHOT consolidates reporting accounts into their respective Trust/Health Board as a whole.

There were 19 non-NHS organisations that submitted 49 reports in 2021.

Although the fact that all NHS organisations submitted reports is extremely positive, it is important to ensure that reporting covers a wide range of categories to minimise under-reporting. Analysis has been carried out on the reports included in this year's Annual SHOT Report to determine how many NHS Trusts/Health Boards contributed to each reporting category, and overall type of report (Figure 2.3).

The error category with the largest amount of reporting organisations was ADU with 106/170 (62.4%) of organisations making reports. The overall number of organisations that submitted error reports where a component was transfused was 155/170 (91.2%). Of the 15 organisations that did not submit error reports, 1 was a high user of blood, and 3 were medium users (according to the blood usage levels used for the 2020 participation benchmarking data https://www.shotuk.org/reporting/shot-participation-benchmarking/). Out of the 9 reporting organisations that did not submit any type of near miss report, 1 was a very high blood user, and 1 was a high user. There were a higher number of organisations that did not report any reaction reports, and 19/39 (48.7%) of these were medium, high or very high usage organisations.

Figure 2.3: Number of NHS Trusts/Health Boards submitting reports by reporting category included in the 2021 Annual SHOT Report

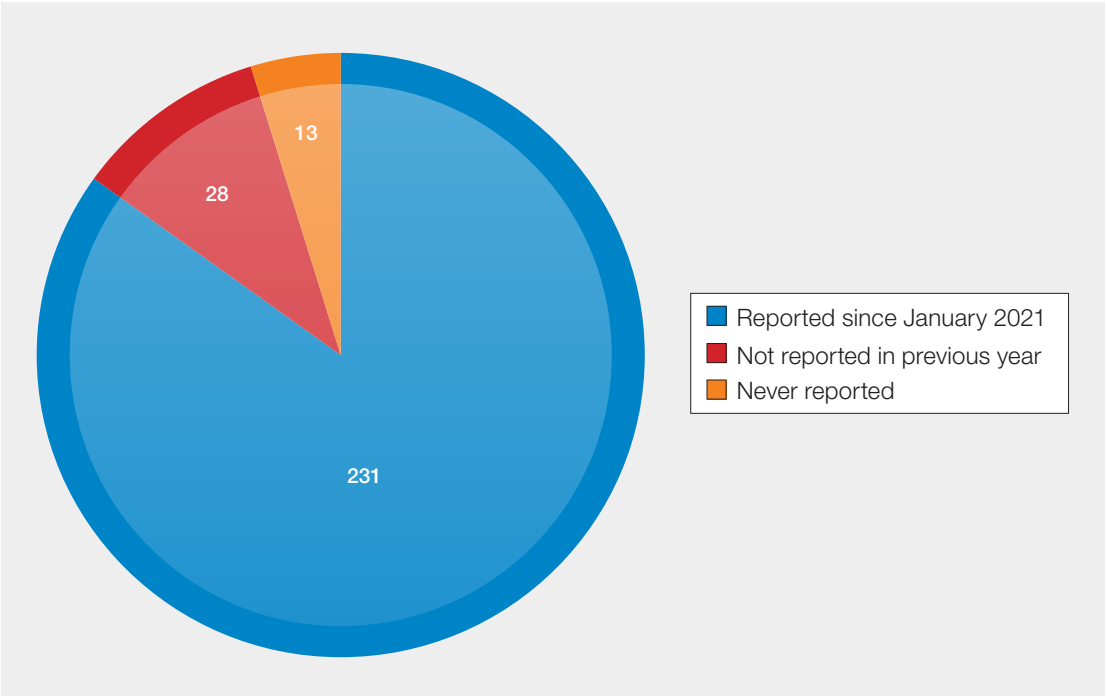


ADU=avoidable, delayed and under/overtransfusion; HSE=handling and storage errors; IBCT-WCT=incorrect blood component transfused-wrong component transfused; IBCT-SRNM=IBCT-specific requirements not met; RBRP=right blood right patient; NM=near miss; WBIT=wrong blood in tube; FAHR=febrile, allergic and hypotensive reactions; HTR=haemolytic transfusion reactions; UCT=uncommon complications of transfusion; Ig=immunoglobulin; CS=cell salvage

Analysis from SABRE

Figure 2.4 demonstrates excellent involvement in the SHOT and MHRA haemovigilance systems, with most organisations reporting at least once in the previous few months. There are a small number of reporters who report less frequently. Most of those who have not reported at least once in the past 12 months are hospitals without HBB or small NHS organisations or a private HBB.

Figure 2.4: Participation in haemovigilance reporting from active SABRE accounts



MHRA participation data reflects SABRE reporting accounts rather than NHS Trusts/Health Boards whilst for SHOT, the individual accounts are amalgamated into the appropriate NHS Trusts/Health Boards, as reporting arrangements can differ widely between different organisations.

Blood component issue data 2021

Table 2.1 lists the total number of blood components issued from the UK Blood Services in 2021 and excludes CCP.

	Red cells	Platelets	FFP	SD-FFP	MB-FFP	Cryo	Totals
NHS Blood and Transplant	1,356,335	245,221	157,831	66,400	1,874	39,111	**1,866,772**
Northern Ireland Blood Transfusion Service	39,886	8,163	4,047	3,120	84	796	**56,096**
Scottish National Blood Transfusion Service	135,054	23,171	14,164	2,450	394	3,028	**178,261**
Welsh Blood Service	75,899	10,502	6,540	1,865	-	410	**95,216**
Totals	**1,607,174**	**287,057**	**182,582**	**73,835**	**2,352**	**43,345**	**2,196,345**

FFP=fresh frozen plasma; SD=solvent detergent-sterilised; MB=methylene blue-treated; Cryo=cryoprecipitate

SD-FFP data supplied by Octapharma

Paediatric/neonatal MB-FFP are expressed as single units; cryoprecipitate numbers are expressed as pools and single donations as issued; all other components are adult equivalent doses

Table 2.1: Total issues of blood components from the Blood Services of the UK in the calendar year 2021

Although blood component issues increased in 2021 compared to 2020, the larger reduction in 2020 was likely due to the pandemic, and Figure 2.5 demonstrates that the overall downward trend in blood component issue data is continuing. It is important to note that in 2021, NHSBT started collecting plasma for medicines from blood donors mainly through apheresis but also recovered plasma from whole blood donations. In February 2021, the UK Government lifted a decades old ban on using plasma from UK blood donors for medicinal products such as immunoglobulins. SaBTO evaluated the risk of transmission of vCJD and recommended that the current risk-reduction measures be withdrawn (Thomas et al. 2021). In 2020, the MHRA undertook a comprehensive review of the safety of using UK plasma to make immunoglobulins. The CHM considered the evidence and recommended that UK-sourced plasma can be used for the manufacture of immunoglobulins subject to several risk-mitigation measures. The UK has had to rely on importation of these medicines which are in scarce supply worldwide due to disproportionate demand. The Secretary of State for Health and Social Care directed NHSEI, NHSBT and MHRA to begin preparations to appoint a fractionator(s) through a competitive process with an aim to secure a domestic supply of immunoglobulins. The Welsh and Scottish Governments and the Northern Ireland Executive have also directed their respective Blood Services to take forward work on this (Department of Health and Social Care 2021).

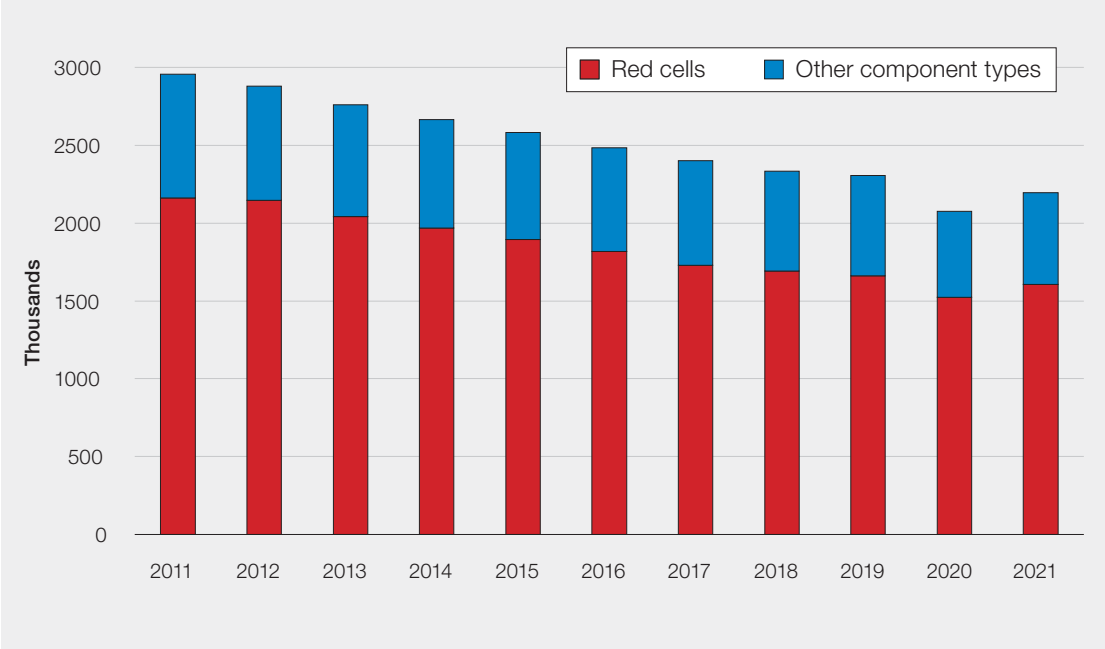
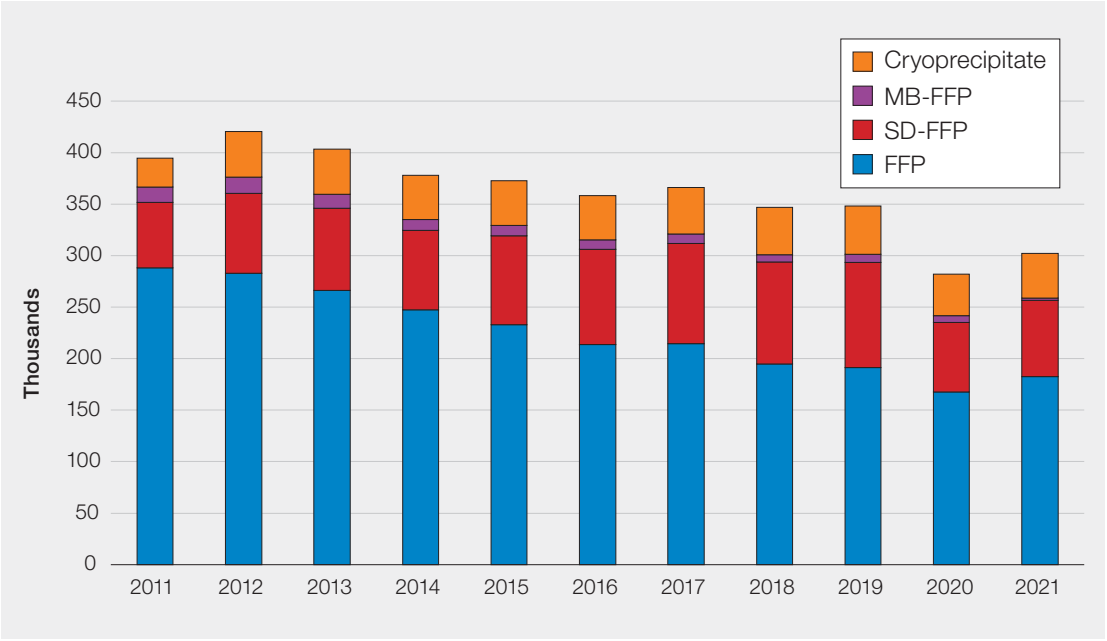


Figure 2.5a: Blood component issue data in the UK 2011-2021

Figure 2.5b: Non-cellular component issue data in the UK 2011-2021



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

SHOT reporting by UK country

Full tables containing the breakdown of data from 2021 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-2021/).

Cases included in the 2021 Annual SHOT Report n=3161

The total number of reports analysed and included in the 2021 Annual SHOT Report is 3161. This is a decrease of 53 from the 3214 reports analysed in the 2020 Annual SHOT Report (Narayan et al. 2021).

In addition to these 3161 reports, there were 56 reports of immunisation against the D-antigen. These are counted separately as part of a stand-alone study.

The total number of 3161 is made up of the 2871 completed reports submitted in 2021 (Figure 2.2) plus 290 reports that were submitted in earlier years, but not finalised until 2021.

The number of reports with potential for patient harm (excluding 'near miss' and 'right blood right patient') is 1790, a small decrease from 2020 (n=1877).

Analysis of errors by location

The number of incidents reported from the emergency department has increased substantially from 2020, and is still on an upward trend. The large rise could be due to multiple factors including pandemic pressures, increasing workload, worsening staffing pressures and longer patient stays in the ED due to poor patient flow within organisations. The numbers of reports from theatres remain consistent with previous years. Reports from general wards and adult critical care continue a downwards trend since this data has been analysed from 2010. Although the number of reports from adult critical care increased slightly in 2021, the percentage of total reports is still lower than 2010.

Unfortunately, there are no denominator data available with regard to the number of transfusions undertaken in each of these areas, so it is difficult to draw any meaningful conclusions.

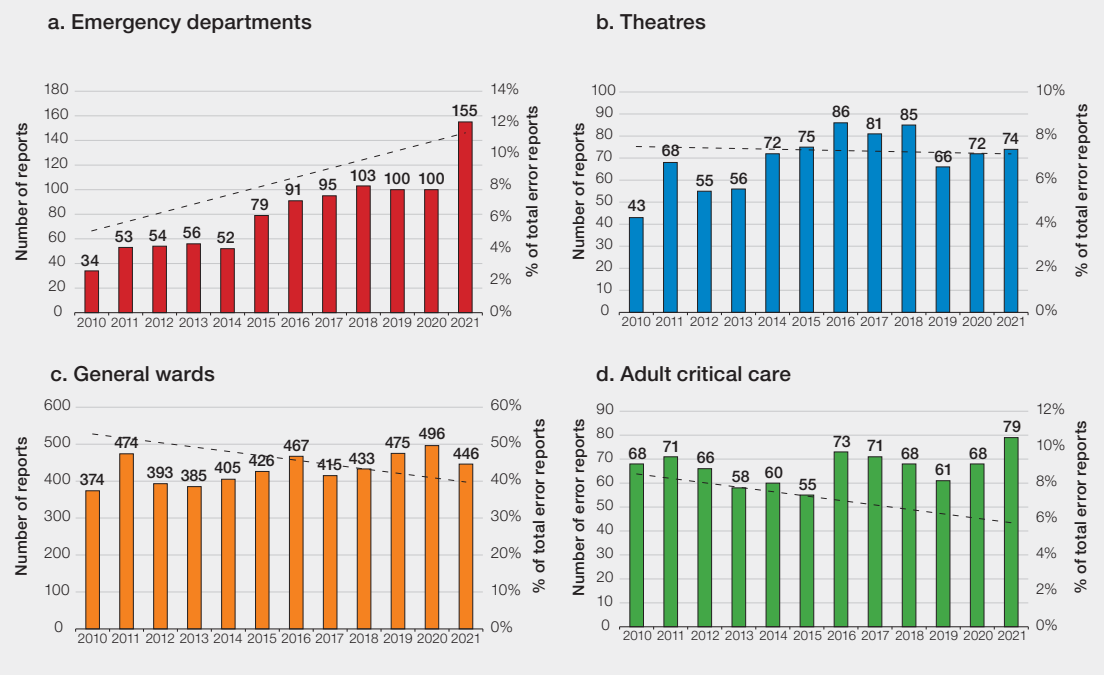


Figure 2.6: Trend of error reports from different departments

SHOT participation benchmarking data

SHOT participation data provides a useful benchmarking tool which is an integral part of continuous improvement in healthcare. Measuring, comparing to similar users, and identifying opportunities for tangible improvements will help improve patient safety. This supports local governance processes as well. Figure 2.7 illustrates how the SHOT participation data can be used to benchmark and drive local improvements in practices.

Data are collated and published annually in the autumn, and the 2021 participation data will be available on the SHOT website during October 2022.

SHOT also provides participation data on a monthly basis, which includes the number of reports submitted, and the number of reports completed in each category. However, these numbers are subject to change until they have been reviewed by the SHOT working expert group.

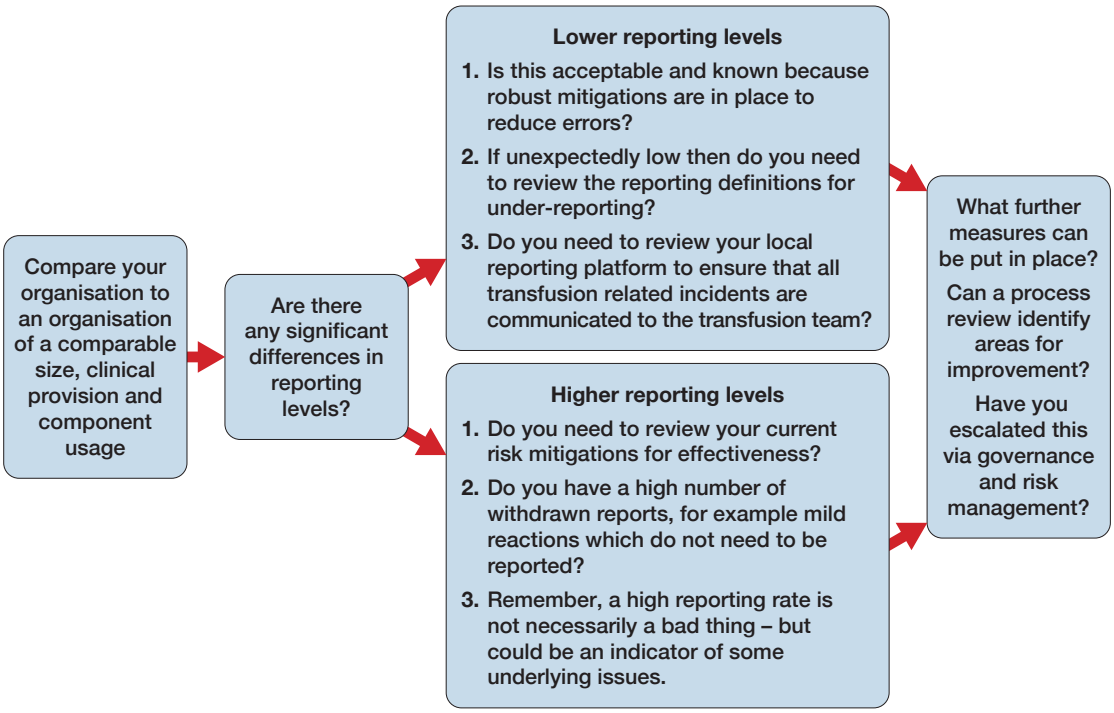


Figure 2.7: Using SHOT participation benchmarking data to drive improvements

All reporters and local governance teams should access and use this participation data to inform local improvements. These discussions should be included in local and regional transfusion meetings.

Conclusion

A continuing high level of participation in haemovigilance reporting is a sign of good reporting culture and reflects that an open and fair culture largely exists in the NHS where staff learn from things that go wrong. Organisations with a culture of high reporting are more likely to have developed proactive reporting and learning to ensure the services they provide are safe. Participation has continued despite the pandemic-related challenges and benchmarking of this data helps identify areas for improvement. Analysis of submitted data allows identification of risks so that appropriate measures can be initiated to mitigate these risks and improve transfusion safety.

Recommended resources

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

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

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

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

Authors: Shruthi Narayan and Debbi Poles

Key SHOT messages

- Transfusion in the UK continues to be safe and SHOT data for the last 10 years show the risk of death from transfusion as 0.92 per 100,000 components issued. This includes all deaths reported with imputabilities ranging from possible, probable, or confirmed
- Non-infectious complications, especially procedural errors and errors 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 TACO) were the main causes of reported transfusion-related deaths in 2021 contributing to 77.1% (27/35 deaths reported to SHOT in 2021)
- Errors (including near miss) continue to account for majority of the reports. In 2021, 2569/3161 (81.3%) of all reports were due to errors
- Near miss events continue to account for a large proportion, 1155/3161 (36.5%) 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. Ensuring process-based safety for transfusions through a multipronged approach, adequate training, appropriate resources, having user-centred design and learning from experiences are essential
- Overriding alerts and flags on LIMS continue to contribute to errors reported. Incorporating human factors principles into designing alerts and avoiding unnecessary alerts will help improve usability and reduce errors
- 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

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.

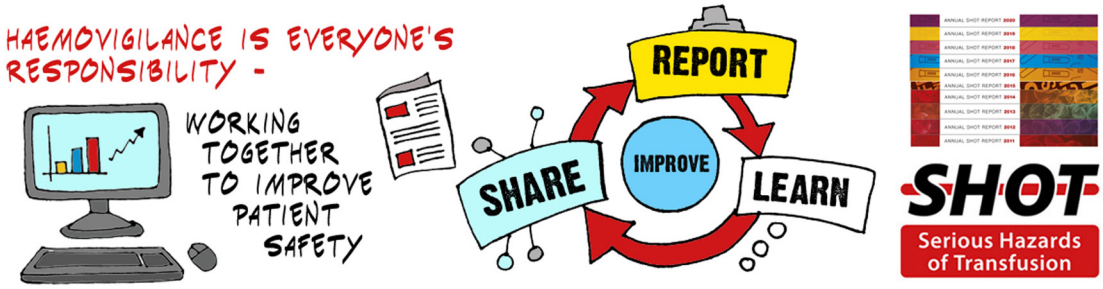
Recommendation

- 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

Abbreviations used in this chapter

ABOi	ABO-incompatible
BSH	British Society for Haematology
CCP	COVID-19 convalescent plasma
CMV	Cytomegalovirus
FAHR	Febrile, allergic and hypotensive reactions
FFP	Fresh frozen plasma
IBCT	Incorrect blood component transfused
ISTARE	International Surveillance of Transfusion-Associated Reactions and Events
LIMS	Laboratory information management system
MB	Methylene blue
NHS	National Health Service
NM	Near miss
PAS	Platelet additive solution
RBRP	Right blood right patient
SaBTO	The Advisory Committee on the Safety of Blood, Tissues and Organs
SCRIPT	SHOT Collaborative Reviewing and reforming IT Processes in Transfusion
SMART	Specific, measurable, achievable, realistic, and timely
SRNM	Specific requirements not met
TACO	Transfusion-associated circulatory overload
UCT	Uncommon complications of transfusion
UK	United Kingdom
vCJD	Variant Creutzfeldt Jakob Disease
WBIT	Wrong blood in tube



Introduction

Haemovigilance is instrumental in improving transfusion safety, both for donors and patients. Without it, there would be no way to assess the safety of blood components. Haemovigilance is designed to protect patients and blood donors and enables the dissemination of knowledge amongst professionals to minimise the risk of adverse events. Haemovigilance is not a recordkeeping function but focuses on proactively identifying safety issues ('signals') and taking actions to minimise or mitigate risk to patients and donors. SHOT reporting is mainly a passive process while being professionally mandated, analysis of these data is limited by the report being submitted and the details included in the submitted report by reporters. This highlights the importance of a good reporting culture with reporters providing as much detail as possible. Analysis of the submitted reports from both a qualitative and quantitative standpoint forms the basis of signal detection, identification of key learning points and recommendations. Haemovigilance data from 2021 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, and 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 62,753 components issued and the risk of serious harm is 1 in 17,431 components issued.

Serious adverse reactions and events related to transfusion are reported to SHOT and errors continue to account for most of the reports 2569/3161 (81.3%) (Figure 3.1).

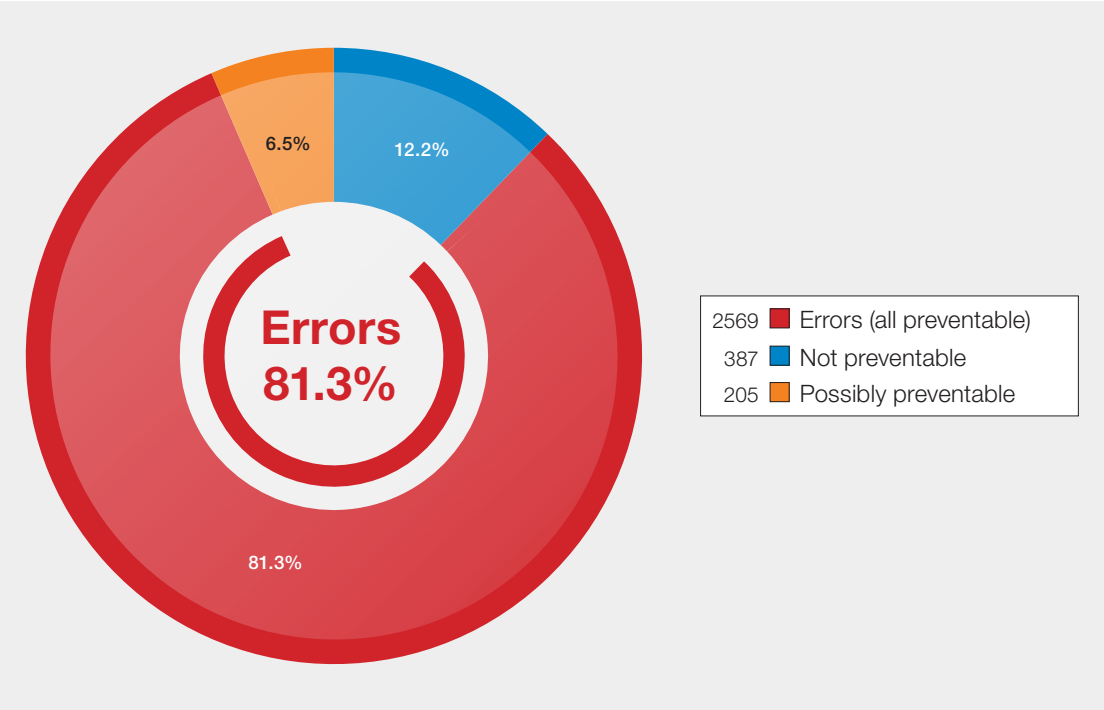


Figure 3.1: Errors account for most reports: 2569/3161

Figure 3.2 shows the trends in transfusion errors reported to SHOT as a percentage of total reports 2014-2021. There is a slight downward trend, but errors continue to contribute to more than 80% of submitted reports and with similar errors reported year on year, it is clear that learning from these incidents is not optimal and incident investigations may not be effective. All systemic causal and contributory factors must be addressed to ensure better transfusion safety.

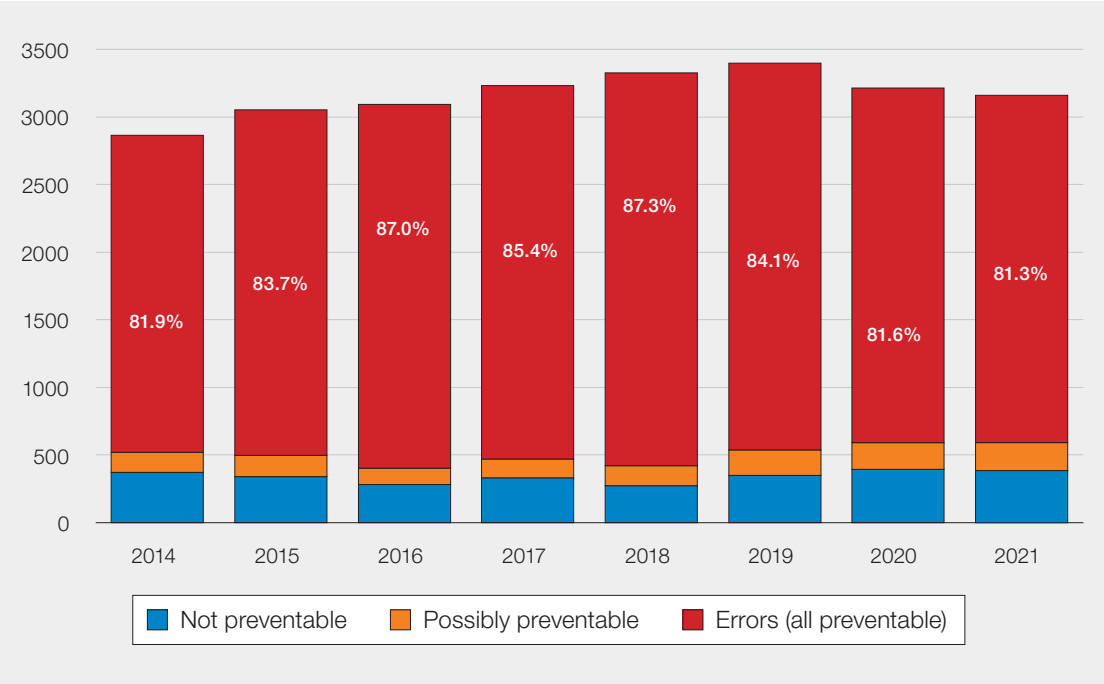


Figure 3.2: Errors as a percentage of total reports 2014-2021

Deaths related to transfusion n=35

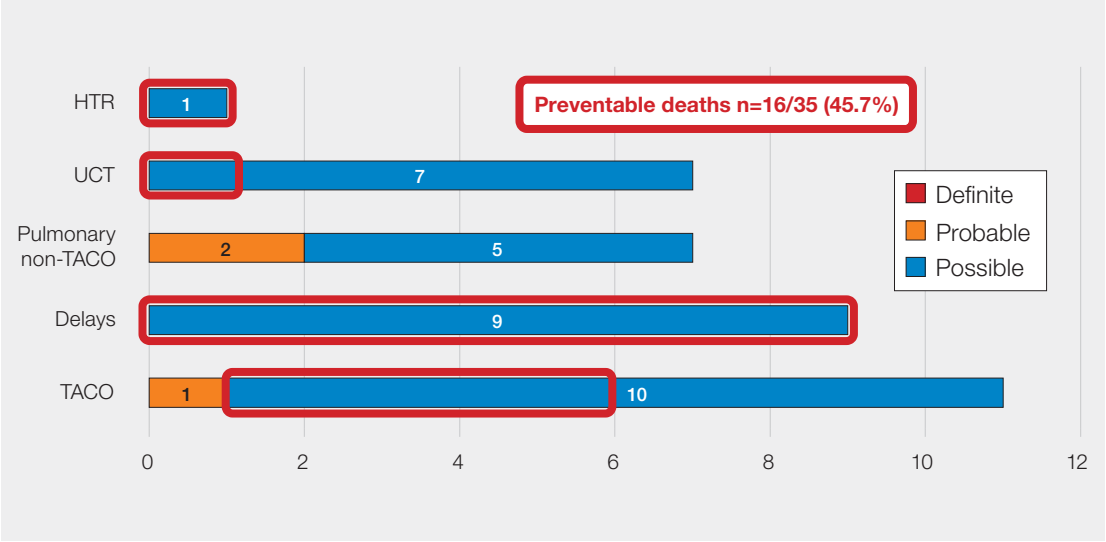
All deaths reported to SHOT are assessed for imputability i.e., the relationship of the blood transfusion to the reaction. The imputability criteria are detailed in the table below

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	Certain	When there is conclusive evidence beyond reasonable doubt

Deaths reported in 2021 were noted mostly relating to TACO (n=11), pulmonary non-TACO (n=7) and delays (n=9). The 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 2021.

Figure 3.3: Deaths related to transfusion (with imputability) reported in 2021 n=35



HTR=haemolytic transfusion reactions; UCT=uncommon complications of transfusion; TACO=transfusion-associated circulatory overload

TACO and delays continue to be the leading causes of transfusion-related deaths in the UK, accounting for 20/35 deaths reported (57.1%). A TACO checklist was not completed prior to transfusion in 5/11 cases potentially representing missed opportunities to identify and mitigate risks in vulnerable patients. Incident investigation was carried out in 10 of the TACO deaths reported. Transfusion delays continue to contribute significantly to patient deaths and communication issues were identified in 3/9 cases as one of the most important contributory factors. A higher number of deaths were reported due to non-TACO pulmonary causes and in the UCT category. All are described in detail in the respective chapters with COVID-19 infection and sequelae also noted to be contributing to the patient decline in several cases.

Haemolytic transfusion reaction was responsible for 1 of the deaths reported in 2021, this was a thalassaemia intermedia patient in her 70s with a history of previous transfusion reactions who inadvertently received antigen-positive blood. Acute haemolytic transfusion reaction was listed on the death certificate as a significant condition contributing to death. This case is a reminder that haemolytic transfusion reactions can be lethal and highlights the importance of obtaining previous transfusion history and antibody status. Avoiding alloimmunisation is key especially in multi-transfused patients.

Where deaths are potentially avoidable, it is vital that thorough incident investigations using human factors principles are performed and are generally of good quality with SMART (specific, measurable, achievable, realistic, and timely) improvement actions. The COVID-19 pandemic has been cited as a contributory factor in several of these cases relating to staff pressures and high levels of patient admissions.

Major morbidity n=126

Febrile, allergic or hypotensive transfusion reactions and pulmonary complications 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 is defined in the SHOT definitions document as:

- Intensive care or high dependency admission and/or ventilation, renal dialysis and/or renal impairment
- 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 an individual of childbearing potential
- Reaction resulting in a low or high 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 an individual of childbearing potential

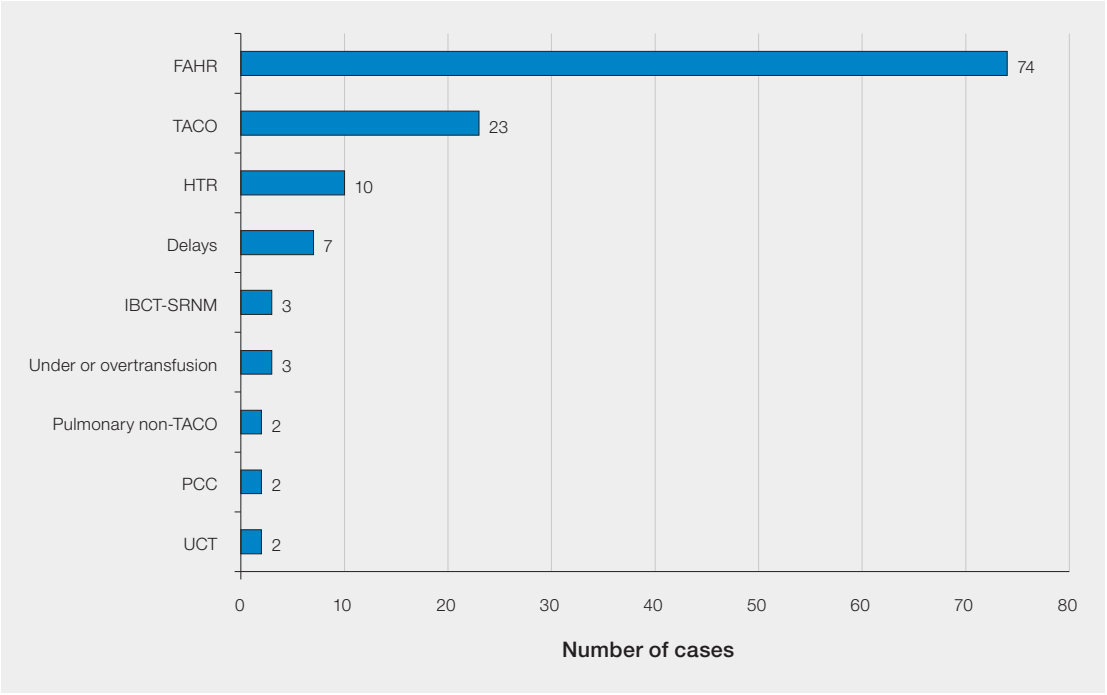


Figure 3.4: Ranking of categories to show number of serious reactions in 2021 n=126

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; PCC=prothrombin complex concentrate; UCT=uncommon complications of transfusion

Most cases that resulted in major morbidity were related to FAHR (74/126, 58.7%) with 14 cases reported in paediatric patients of which 10 were related to platelet transfusions. All were allergic reactions except for 1 which was a hypotensive reaction. Minor sequelae were noted in 1 patient, but all others made a complete recovery. In the FAHR cases reported in adults that resulted in major morbidity, 24 were reactions to platelets, 15 of these noted as apheresis platelets. Fourteen patients suffered a reaction following transfusion of multiple components and 20 following a red cell transfusion. Four patients were noted to have had a transfusion that was not clinically indicated according to BSH guidelines. In 57 cases, the patients made a complete recovery, 1 minor sequalae and 2 where outcome was not known. The adult FAHR cases with major morbidity included 37 allergic reactions, 16 febrile, 1 hypotensive and 6 mixed.

In 12/23 cases of TACO that resulted in major morbidity, reporters stated the case had been reviewed but only 3 noted a change in transfusion management for the patient. No incident investigation was carried out in 12/23 cases.

Delays accounted for 7 of the cases with major morbidity and in only 3 cases, reporters stated that an incident investigation had been completed.

Summary data and risks associated with transfusion

Data collected in 2021 are shown in Figure 3.5. Near miss reports are again the largest reporting category, 1155/3161 (36.5%). Reporting and investigating near misses helps identify and control risks before actual harm results, providing valuable opportunities to improve transfusion safety.

Cumulative data for 25 years are shown in Figure 3.6.

Cumulative risk data from SHOT

Figure 3.7 shows the number of reactions reported per 10,000 components issued in the UK between 2010-2021. Although red cells are the most common blood component transfused, platelets overall 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 taken into account 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).

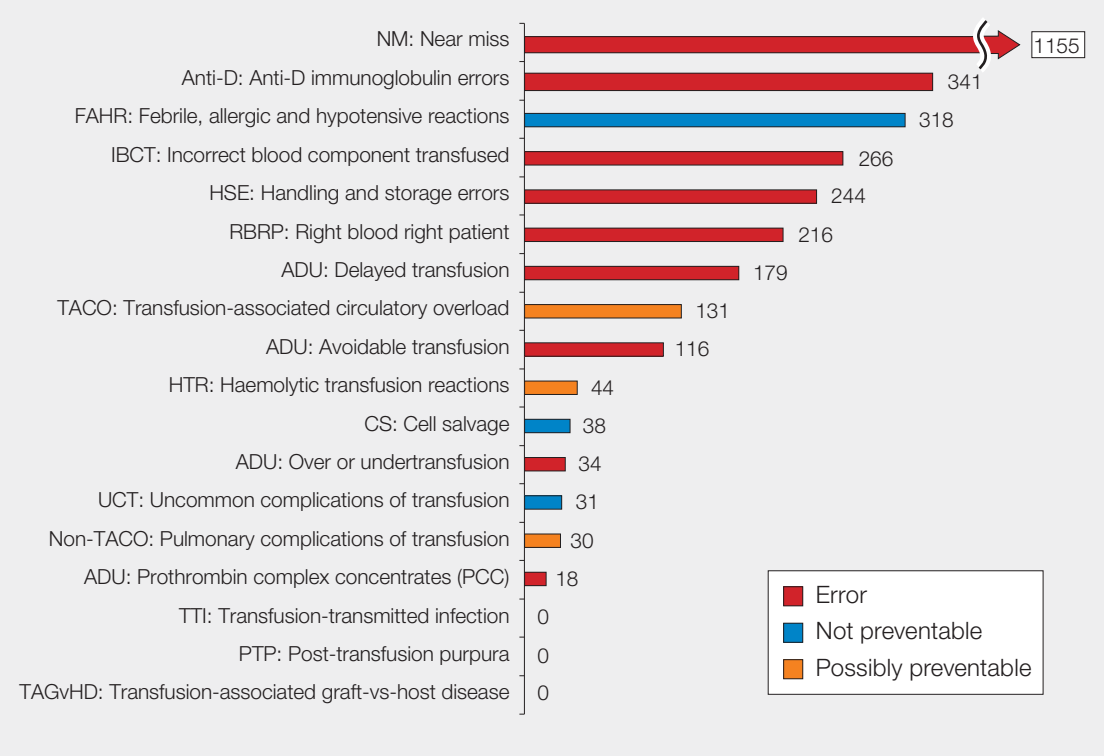


Figure 3.5: Summary data for 2021, all categories (includes RBRP and NM) n=3161

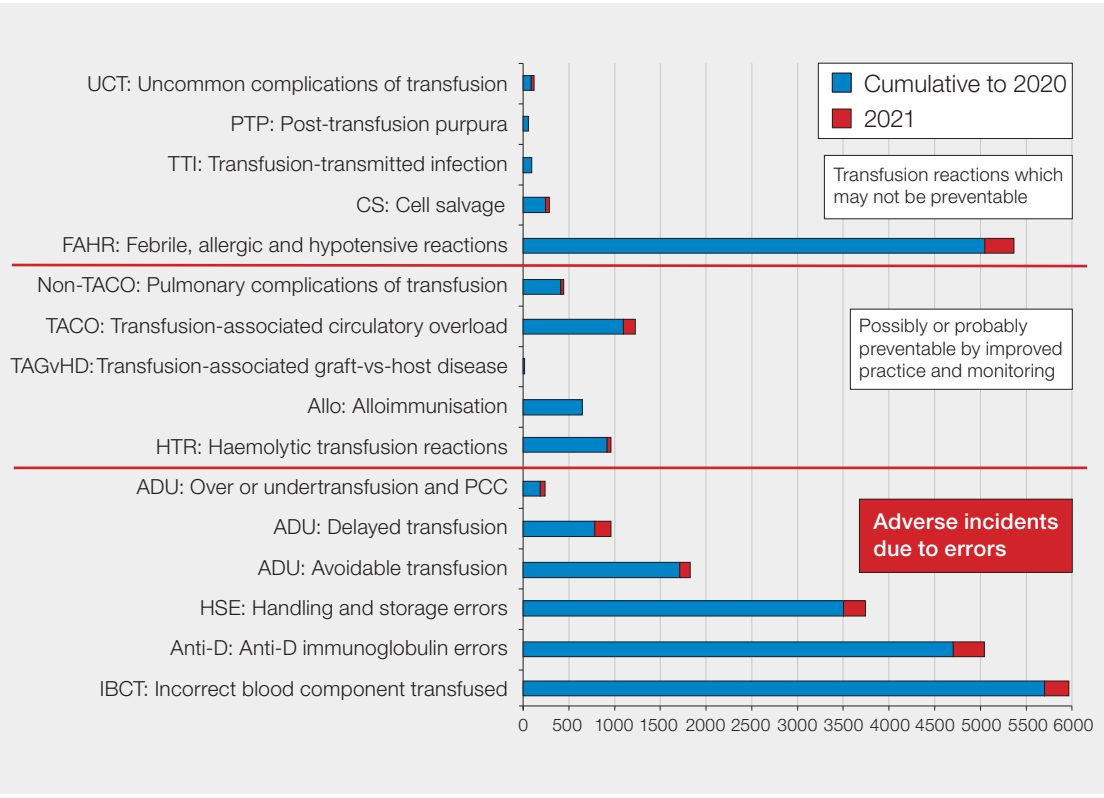
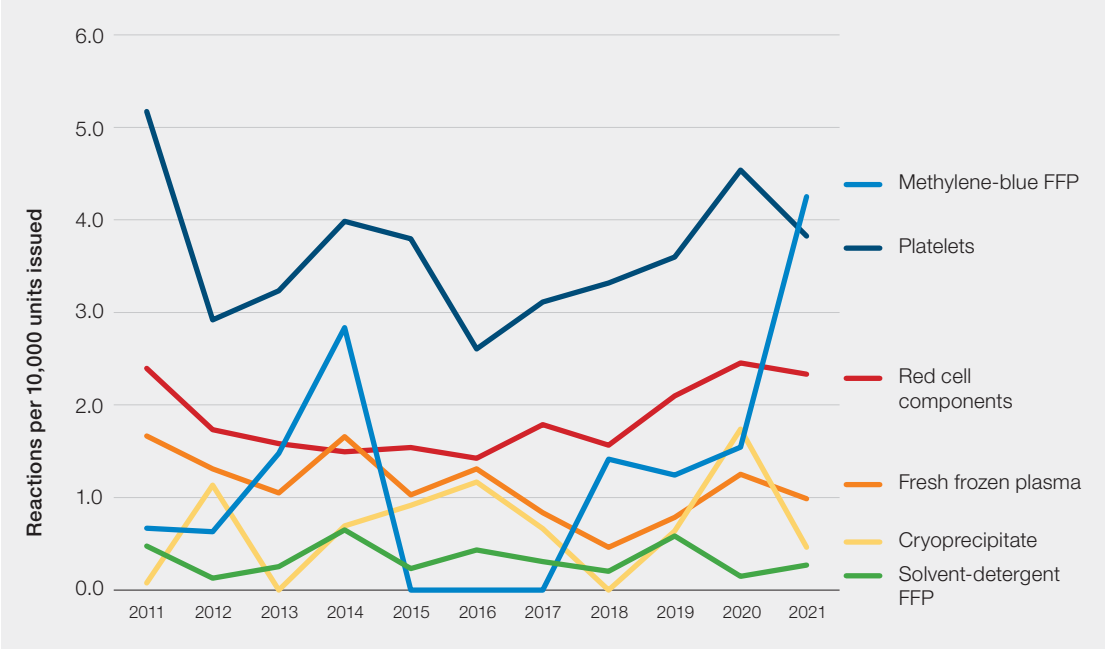


Figure 3.6: Cumulative data for SHOT categories 1996-2021 n=27008

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

Figure 3.7: Reactions per 10,000 components, by component type 2011-2021



**Not including COVID-19 convalescent plasma*

The following table shows the risk of transfusion reactions based on SHOT data 2012-2021. It should be noted that these are based on the number of blood components issued as accurate data regarding actual number of transfusions is lacking. 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 2012-2021

Transfusion reaction	Risk of transfusion reaction based on SHOT data 2012-2021
Febrile, allergic or hypotensive reactions	1 in 8,138
Transfusion-associated circulatory overload	1 in 23,175
Haemolytic transfusion reactions	1 in 55,216
Pulmonary non-TACO	1 in 117,530
Post-transfusion purpura	1 in 3,085,171
Transfusion-associated graft vs host disease	1 in 24,681,368

ABO-incompatible (ABOi) transfusions n=3

Transfusion safety involves a series of complex events from appropriate specimen collection, compatibility testing, and component issue from the blood bank to administration of the blood component at the patient's bedside. Transfusion of blood to the wrong patient is one of the most serious hazards of transfusion which can potentially result in patient death. The chain of events may be initiated by a WBIT leading to transfusion of a wrong component and are the result of procedural errors that are generally preventable with missed opportunities to pick up these errors. Inadvertent ABOi transfusions represent failure of the hospital transfusion process, which needs to be identified and subsequently corrected to prevent similar events happening in the future. Effective investigation of these process failures will help identify measures that need to be taken to improve safety.

In 2021, there were no ABOi red cell transfusions reported and all the 3 ABOi reports were in adult patients involving plasma components; 1 each involving CCP, FFP and cryoprecipitate. Figure 3.8 shows the number of ABOi red cell transfusions reported to SHOT between 1996 and 2021 and Figure 3.9 shows the number of ABOi plasma transfusions reported from 2003 onwards. Figure 3.10 shows the outcome of ABOi red cell transfusions in the 25 years of SHOT reporting. ABOi red cell transfusions can be fatal. Compatibility issues and potential impact on patients in case of plasma components is different. Plasma components such as FFP, cryoprecipitate and CCP should be compatible with the ABO group

of the recipient to avoid potential haemolysis caused by donor anti-A or anti-B. ABO group identical FFP should be given whenever possible; if not possible, FFP of a different ABO group may be acceptable as per BSH guidelines (BSH Green et al. 2018). Haemolysis after the transfusion of ABOi plasma is rare but is of particular risk to infants (Handbook of Transfusion Medicine, 2013).

All 3 cases reported in 2021 were due to a component selection error in the transfusion laboratory with group O plasma component being transfused to non-group O recipient. These occurred despite alerts and/or manual notes on LIMS with staff overriding the alerts. While there was no clinical reaction in 2 cases, 1 patient had complained of loin pain approximately 20 minutes into the transfusion when the error was detected, and the transfusion was stopped. The patient recovered uneventfully. Two of these transfusions occurred during core working hours while 1 was out-of-hours. Pre-administration safety checks were said to have been carried out in all 3 cases. Contributory factors identified in these incidents included staffing issues, high workload, knowledge gaps, suboptimal and unclear handovers, decision fatigue and assumption bias. These are explored in more detail in Chapter 9, Incorrect Blood Component Transfused (IBCT) and Chapter 14, Laboratory Errors in this Annual SHOT Report.

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 FFP to any patients other than group O; but as was evident in the cases reported in 2021, staff were overriding these alerts and not heeding the safety messages. Unjustified overriding of these safety alerts threaten patient safety. A safe alerting system has high specificity and sensitivity, presents clear information, does not unnecessarily disrupt workflow, and facilitates safe and efficient handling. It is recommended that LIMS block release of group O plasma components to non-group O patients. Reducing the number of inappropriate alerts would help in addressing alert fatigue.

In the SCRIPT UK LIMS suppliers survey conducted, all 10 LIMS providers state that ABO/D incompatibilities are controlled for issue of red cells and plasma, with 50% stating override is configurable, and 50% stating ABOi is a ‘hard stop’. ABO/D compatibility rules for haemopoietic stem cell transplant 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.

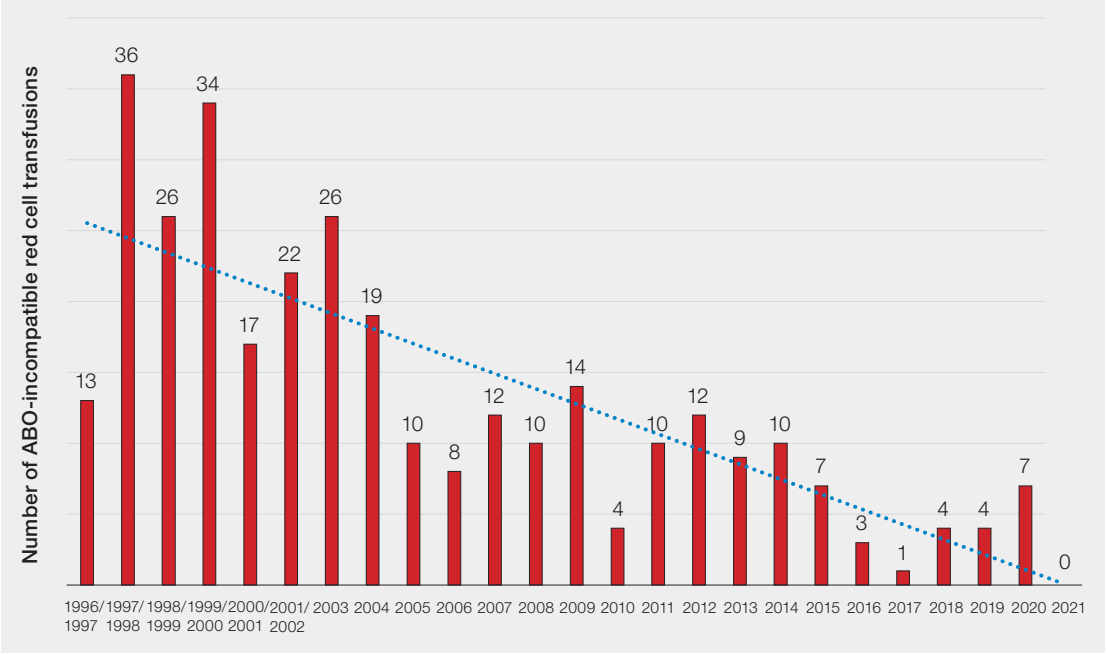
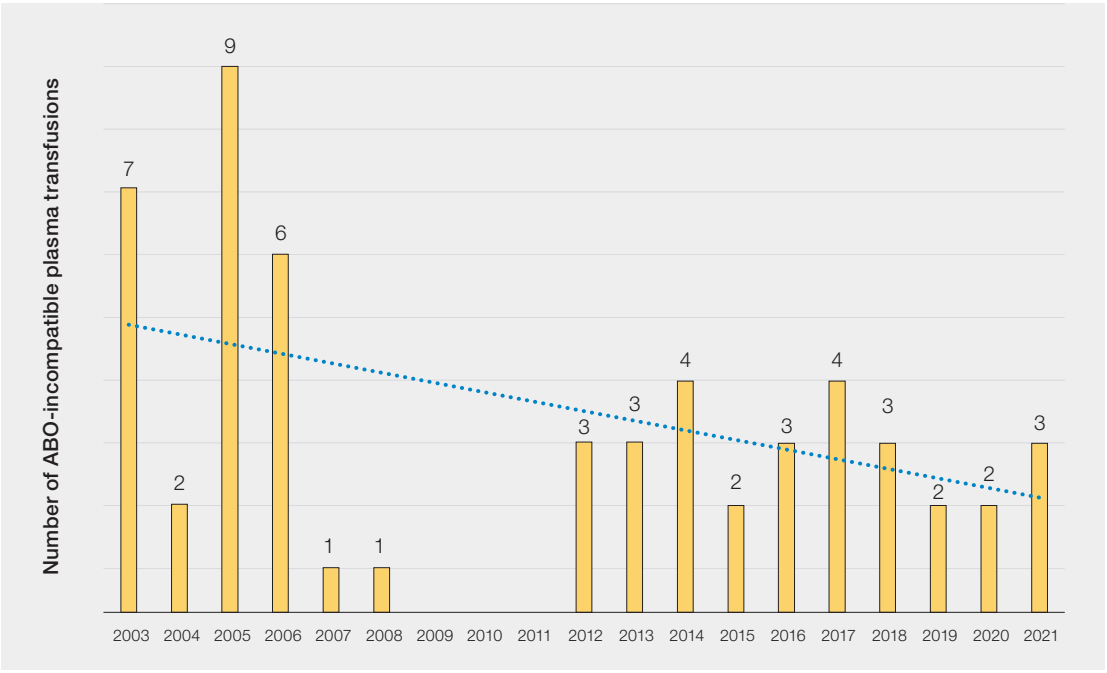


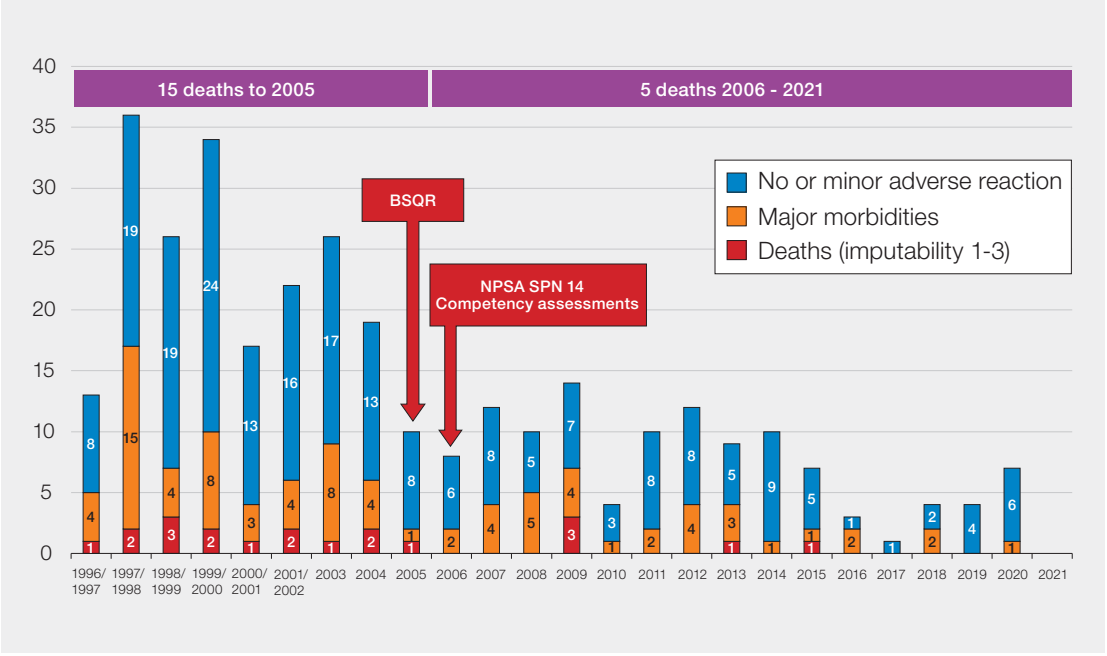
Figure 3.8: Number of ABO-incompatible red cell transfusions 1996-2021

Figure 3.9: Number of ABO-incompatible plasma transfusions 2003-2021



Cryoprecipitate ABOi reports in 2018 and 2021 (n=1); COVID-19 convalescent plasma ABOi in 2020 and 2021 (n=1)

Figure 3.10: 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

Laboratory transfusion staff can get overwhelmed by multiple alerts resulting in 'alert fatigue' i.e., tendency to ignore notifications when they become too frequent and hence potential for errors and impact on transfusion safety. Staff can overcome alert fatigue, identify, and respond to critical issues in real time, and reduce risk continuously over time if these alerts can be transformed into relevant and actionable intelligence.

A structured, proactive approach is suggested to address this by using the following practices:

1. Regularly review and reduce redundant alerts
2. Make all alerts contextual and actionable
3. Ensure appropriate escalation of alerts

4. Apply human factors principles when designing alerts (e.g., format, content, legibility, and colour of alerts). Consider having tiered alerts according to severity, consistently throughout laboratories, so that attention is drawn to those more clinically consequential thus allowing staff to maintain situational awareness and responsiveness

5. Improve the culture of safety in transfusion by creating a shared sense of responsibility between users and suppliers, paying careful attention to safe IT implementation, and engaging leadership in IT planning, implementation, and evaluation.

Data from 2016-2021 show that although there were 19 ABOi red cell transfusions, there were 1778 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 2021, 734/1155 (63.5%) 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 below (Figure 3.11), 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.

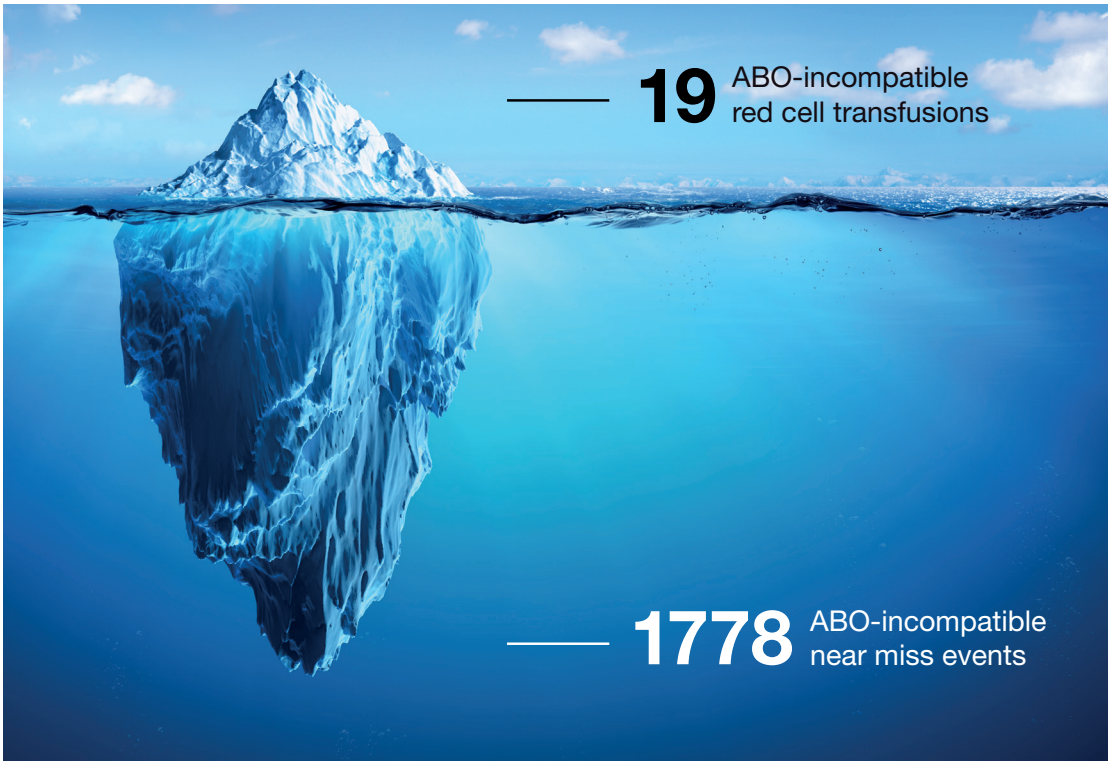


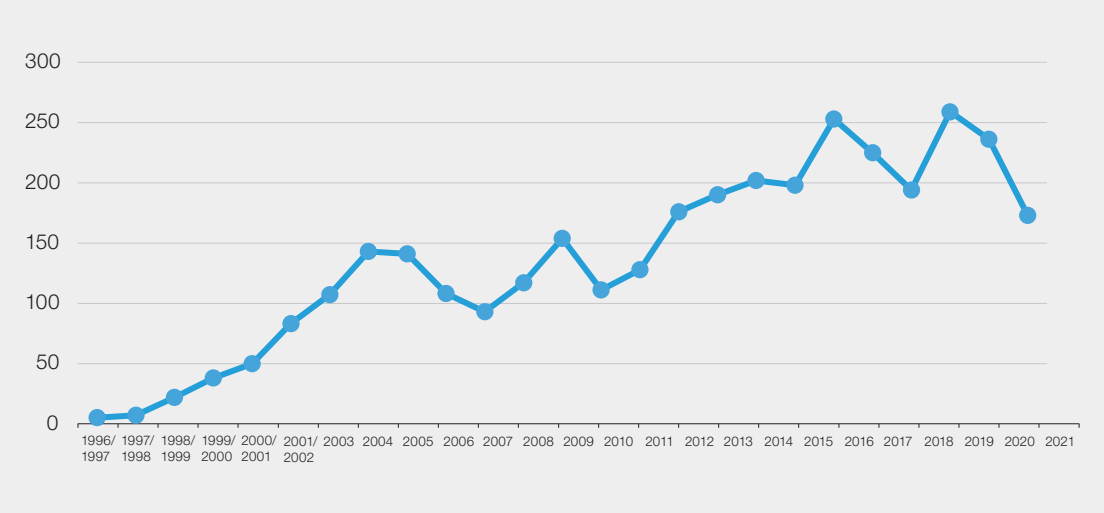
Figure 3.11: ABO-incompatible transfusions 2016-2021: few events (n=19) but many near misses (n=1778)

Investigating these incidents, including 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.

Transfusion errors where specific transfusion requirements were not met

Reports related to IBCT-SRNM have been increasing since SHOT reporting began in 1996 (Figure 3.12).

Figure 3.12: IBCT-SRNM errors by year of Annual SHOT Report 1996-2021



Between 2016-2021, IBCT-SRNM errors accounted for 1340/16402 (8.2%) of errors analysed and included in the Annual SHOT Reports. Of these, 135/1340 (10.1%) cases involved paediatric patients. No deaths occurred due to IBCT-SRNM during this period, but 15 cases of major morbidity resulted due to these errors. Errors have been reported from both clinical and transfusion laboratory settings. Most clinical errors are failure to request irradiated or CMV-screened components, and most laboratory errors are failure to complete testing prior to issue, inappropriate use of electronic issue or providing the incorrect phenotype. These are detailed further in Chapter 9, Incorrect Blood Components Transfused (IBCT).

Staff involved in blood transfusions must have basic knowledge of blood components, indications for use, rationale for specific transfusion requirements and an understanding of the availability of alternative options. Staff authorising, prescribing, and ordering blood should be aware of the risks and benefits of transfusions including risks of not meeting specific transfusion requirements for patients and must be able to identify and manage and possible reactions and their management.

Conclusion

Transfusion remains very safe with few serious incidents or deaths related to pathological events. However, patients continue to be at risk from potentially preventable causes, particularly TACO and avoidable transfusion delays. Error-related transfusion incidents continue to be the largest group reported to SHOT, and it is essential that the learning from incidents reported to SHOT inform healthcare improvements. Errors made at any point in the transfusion pathway can have a serious patient impact and interventions introduced to address/prevent these must be system oriented and sustainable.

Near misses present valuable learning opportunities and should be investigated thoroughly. As emphasised in recent Annual SHOT Reports, system level changes are needed for safer transfusions. With the transfusion process being multidisciplinary, staff training should ensure that each participant is aware how important their individual role is as part of the whole process to ensure patient safety. Ensuring transfusion process safety is as important as blood component safety and quality. Potential for error exists at each step in the process of transfusion and learning from incidents should drive improvements in healthcare.

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/

Safe transfusions in transplants document
https://www.shotuk.org/resources/current-resources/

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SaBTO (2019) Importation of plasma and use of apheresis platelets as risk reduction measures for variant CreutzfeldtJakob Disease. https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/829906/SaBTO_PC_report.pdf [accessed 03 May 2022].

4 Key Messages and Recommendations

Authors: Shruthi Narayan, Jennifer Davies and Mark Bellamy

Abbreviations used in this chapter

ABOi	ABO-incompatible
BMS	Biomedical scientist
BSH	British Society for Haematology
BSQR	Blood Safety and Quality Regulations
CAS	Central alerting system
GP	General practitioner
IHI	Institute for Healthcare Improvement
IT	Information technology
LIMS	Laboratory information management system
NHS	National Health Service
SOP	Standard operating procedure
TACO	Transfusion-associated circulatory overload
UK	United Kingdom
UKTLC	UK Transfusion Laboratory Collaborative
WHO	World Health Organisation

Key SHOT messages

- **Addressing transfusion errors:** Errors continue to be the source of most SHOT reports (81.3%). While transfusions are largely safe, errors can result in patient harm. Many of these are caused by poor communication and distraction. These must be investigated using human factors principles-based incident investigations and appropriate mitigating measures implemented
- **Learning from near misses:** Reporting and investigating near misses helps identify and control risks before actual harm occurs, 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) investigate near miss, (3) develop and implement a corrective and preventative action plan and (4) monitor effectiveness of interventions
- **Safe staffing is paramount:** Staffing challenges in both clinical and laboratory areas threaten transfusion safety. 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
- **Risk assessment before transfusion:** TACO continues to be the most common cause of death and of major morbidity and may be potentially preventable. Vulnerable patients should be assessed prior to transfusion and appropriate measures instituted to reduce risk
- **Addressing transfusion delays:** Avoidable transfusion delays continue to contribute to patient deaths and measures recommended in the SHOT CAS Alert (SHOT 2022) must be implemented to address these

Blood components continue to be very safe. Morbidity and mortality associated with transfusions are often due to suboptimal practices and ill-judged transfusion decisions that need to be improved. The risk of death from transfusion in the UK is very low despite the steady increase in the number of reports submitted to SHOT year on year (see Chapter 3, Headline Data: Deaths, Major Morbidity and ABO-Incompatible Transfusions).

All staff involved in blood transfusions need to have basic knowledge of the blood components, indications for use, alternate options available, risks and benefits and possible reactions and their management.

One of the main SHOT recommendations in the 2018 Annual SHOT Report was to ensure all transfusion decisions are 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 (Narayan et al. 2019).

Use of checklists, embedding the use of electronic identification systems, incorporation of human factors and ergonomics principles in transfusion practices will help in improving decision making in transfusion. The key messages and recommendations from the previous Annual SHOT Reports remain relevant and all healthcare organisations involved in transfusion are encouraged to continue implementing these and ensuring measures have been effective.

The Safe Transfusion Checklist that is available to download from the SHOT website covers all the key aspects of the transfusion process at the bedside. The ABCDE approach to transfusions helps in the transfusion decision-making process (see 'Recommended resources').

Transfusion safety, more than just blood safety: six simple rules for safe transfusions

Transfusion is a complex multistep process involving members of several different professional groups i.e., nurses, doctors, laboratory scientists as well as the donors and recipients. Transfusion safety depends upon the coordinated linkage of all processes from collection of the blood component from blood donors to transfusion in the recipient. There are various steps in the transfusion pathway from making the decision to transfuse to administration of blood components and monitoring/management of complications (See 'Recommended resources'). This highlights the importance of safe and effective communication, timely coordination and collaboration between all teams involved in patient care both clinical and laboratory to ensure transfusion safety.

Blood transfusion has never been safer than it is today, but it is still not completely free of adverse events. Transfusions have become a lot safer over the last few decades with the advances in component preparation practices. Improvements in donor selection and screening, and advances in microbiological testing have reduced the transmission of infectious agents; however, non-infectious complications continue to be a serious risk. Non-infectious transfusion-related adverse events could happen due to a wide variety of reasons specific to a blood component, amount of transfusion, and transfusion errors. With more than 80% of submitted reports to SHOT being related to transfusion errors, it is vital to understand the systemic gaps that lead to these errors and help initiate modifications to clinical and laboratory practices to mitigate the incidence and impact of these adverse events. Figure 4.1 highlights the importance of ensuring both safety of blood components and safety in the transfusion processes for the overall transfusion safety.

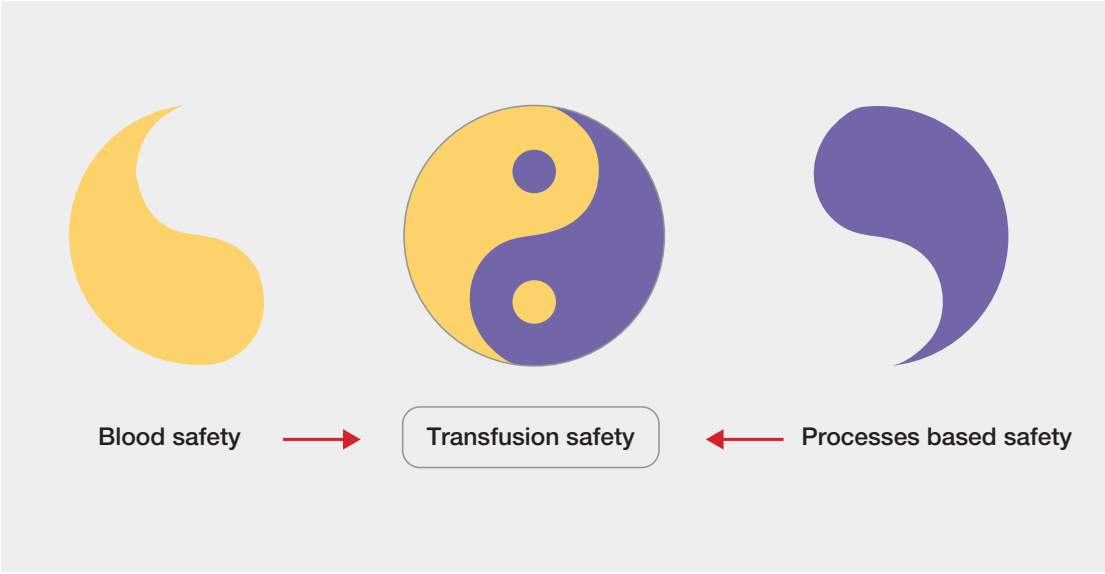


Figure 4.1: Transfusion safety

It is critical that individualised transfusion decisions are made taking into consideration available guidelines, clinical assessment, and blood results. Unnecessary transfusions should be avoided. Clear, timely and accurate communication and co-ordination between clinical and laboratory teams both at the hospital and at the Blood Service is essential to ensure safe transfusions. All team members involved in the transfusion chain play an integral role in preventing errors or early identification of transfusion complications. Therefore, proper training and regular education of interdisciplinary teams consisting of laboratory staff, physicians, nurses, and phlebotomists involved in the transfusion process is paramount to achieve safe transfusion.

The key messages and recommendations from the previous Annual SHOT Reports remain relevant and all healthcare organisations involved in transfusion are encouraged to continue implementing these and ensuring measures have been effective. Here are 'six simple rules' for safe transfusions based on the collective learning from haemovigilance reports and previous key SHOT recommendations. These are the themes emerging from submitted reports year on year reinforcing the urgent need to address gaps in these areas and improve safety.

1. **S**afety culture: A good patient safety culture that is open and just which promotes learning from all events not just when things go wrong but also from near misses and from excellence. An organisational safety culture should be one that ensures psychological safety for staff and promotes civility at work
2. **A**ppropriate transfusion decisions: Appropriate and safe transfusion decisions taken after considering benefits, risks and transfusion alternatives with clinical and laboratory staff at hospitals and Blood Services working together collaboratively and co-ordinating efforts to always ensure timely provision of blood components
3. **F**ocus on people: People-centred healthcare systems are critical for safety-partnering with patients and blood donors, co-creating systems for optimal care and having an engaged workforce committed to patient safety
4. **E**ffective communications and documentation: Effective, clear and timely communications supported by accurate documentation and safe handovers in both clinical and laboratory areas support safe transfusions
5. **T**raining that is holistic and competency-assessment of staff involved in transfusions: All staff involved in transfusions must receive both technical and non-technical skills training to ensure safe transfusions. Non-technical skills should include awareness of human factors principles and principles for effective incident investigations. A team-based approach to learning with multi-professional learning strategy is essential to promote safe and effective delivery of patient care. A thorough competency-assessment for technical skills as mandated by the BSQR 2005 must be carried out
6. **Y**es, to safe, adequately resourced systems: Adequate staffing, equipment, use of safety measures such as risk assessments and checklists and effective use of transfusion IT vein to vein is critical to support safe transfusions. All these factors are interdependent and safety measures can only be effective if these building blocks for safe systems are all in place.

These themes are captured in the figure below:

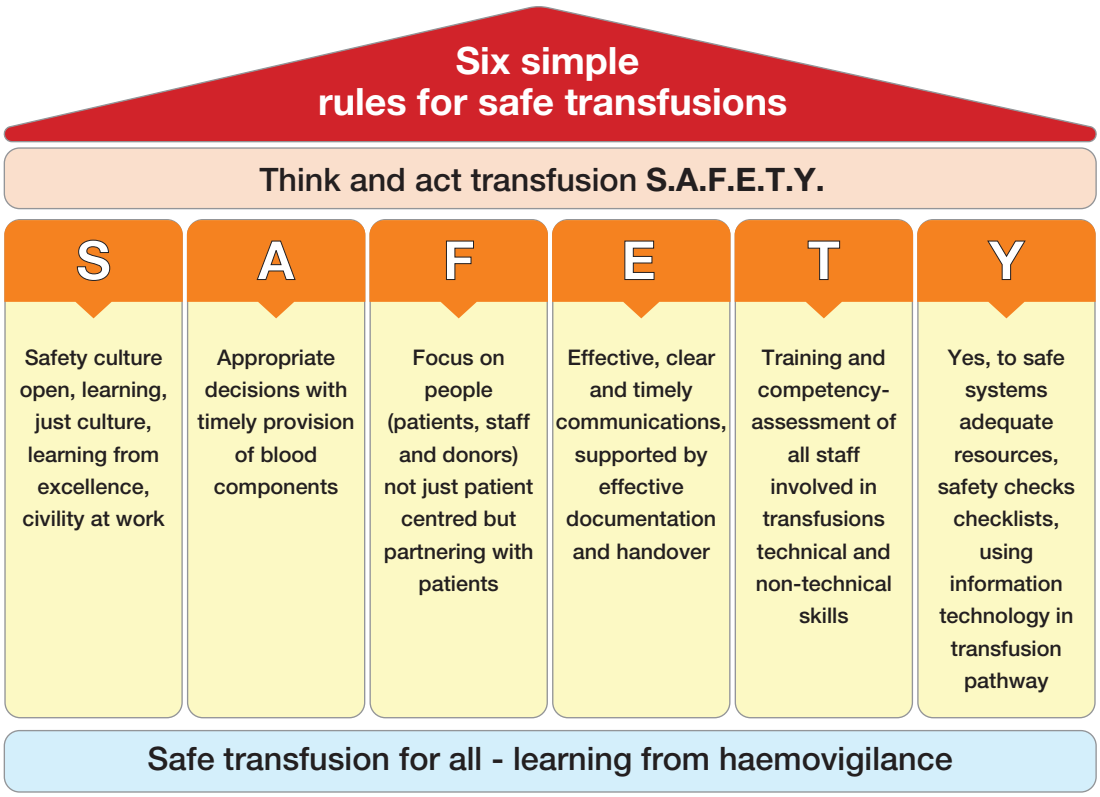


Figure 4.2:
Six simple rules for safe transfusions

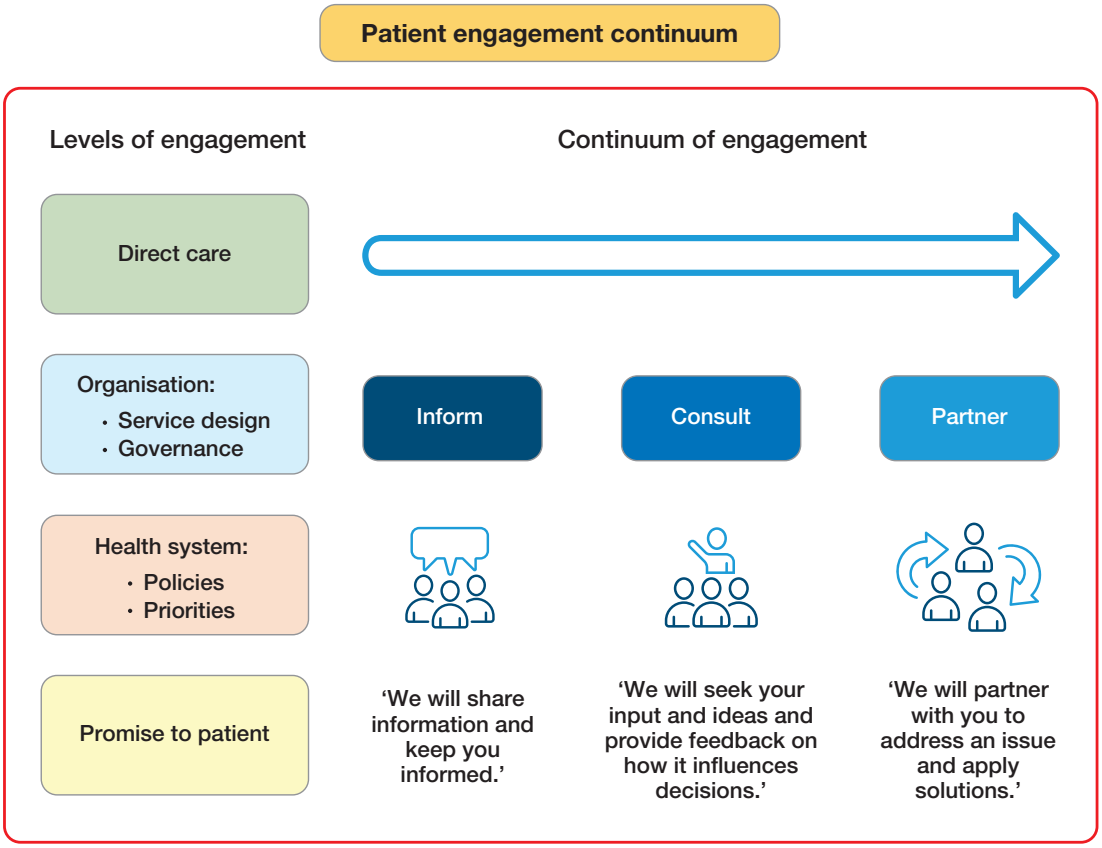
Key SHOT recommendations for 2021

The following main recommendations have been drafted to address the common themes identified as causal or contributory to adverse events that impact transfusion safety. Several reviews and patient safety incident investigations at a national level in the recent past have identified similar themes such as an urgent need to address staffing levels and poor resources, staff training, poor safety culture and the need to partner with patients for safer healthcare (Ockenden 2022, Cumberlege 2020, Paterson 2020).

Partnering with patients to improve transfusion safety

There is ample evidence that demonstrates when healthcare providers work closely with patients and their families, the healthcare system is safer, and patients have better experiences and health outcomes (Bombard et al. 2018). Partnering with patients and families shows respect, values their insights and experience, and empowers them to take an active role in their care. Engagement from patients can be both with their own safety and organisational safety measures. The engagement continuum ranges from low-level, where information is shared by providers with patients, to high level partnership, collaboration, and shared decision-making. All engagement levels are appropriate, and patients, families, and carers should be determining together with care providers and leaders what the most appropriate level of engagement is for each situation (Patient Engagement Action Team 2019).

Figure 4.3: Patient engagement continuum



Taken from: Engaging Patients in Patient Safety – a Canadian Guide (Patient Engagement Action Team 2017)

The NHS Patient Safety Strategy released in July 2019 recognises the importance of involving patients, their families and carers and other lay people in improving the safety of NHS care, as well as the role that patients and carers can have as partners in their own safety. As part of this strategy, a framework has been released that sets out how NHS organisations should involve patients in patient safety. This is relevant to all NHS Trusts and commissioners, and should also be useful to other NHS settings, including primary care and community services. It has been recommended that integrated care systems should consider how they can involve patients as part of their safety governance processes as they develop and mature (NHS England 2019).

Healthcare Improvement Scotland has a key role in supporting healthcare providers to make sure that their services are safe, effective, and 'person-centred' so that people are informed and involved in their care and treatment and are treated with dignity and respect. The 'engaging people strategy' outlines the strategy with the Scottish Health Council Committee having delegated responsibility for monitoring the implementation of the strategy – reporting to the Board on progress against key priorities, and the delivery of operational plans (Healthcare Improvement Scotland 2014).

A Healthier Wales is a policy developed by the Welsh Government in June 2018 and makes recommendations on how health and care services might be realigned to manage current and future demands. This makes a commitment on public engagement and a subsequent report sets how this might be translated into an evidence-informed programme of activity (Worthington et al. 2020).

Similar policies and frameworks with supporting useful resources for personal and public involvement are available for Northern Ireland where there is a statutory duty to involve and consult with service users and carers (directly or indirectly through their representatives) and the Patient Client Council in the planning, development of the provision of care and efficacy of that care. In 2018 the Health and Social Care services in Northern Ireland was further directed to move towards a co-productive approach (where appropriate) (HSC Public Health Agency 2022).

There are several opportunities along the transfusion pathway to involve patients as shown in the table below. The degree to which patients might be actively engaged in the transfusion process depends on several factors including the patient's awareness about how to be involved, their ability to participate which largely depends on their physical and cognitive capacity and their willingness to participate and take on an active role (Davis et al. 2011).

Table 4.1: Opportunities for patient involvement in the transfusion pathway

Step in the transfusion pathway	Opportunities for patient involvement
1. Decision to transfuse and consent	Questioning the rationale and appropriateness for transfusion, risks, benefits, alternatives, number of units and type of components, and providing consent Provide information about any past transfusion history, complications/ reactions, and any known antibodies
2. Sample taking	Checking the wristband or other means of identification with correct details; blood samples have been labelled correctly, positive patient identification asking for name and date of birth and address
3. Administration and monitoring	Checking the wristband or other means of identification with correct details; positive patient identification asking for name, date of birth and details checked against the unit of blood Patients asking questions about what they can and cannot do while receiving a transfusion Asking how they should feel during the transfusion and what to expect e.g., how often their temperature, observations should be checked/taken Making sure their observations are taken Monitoring how they feel Reporting to staff if they do not feel well or if they think there is a treatment complication, both during and after transfusion
4. Communications	Discharge summary, post-transfusion information, GP
5. In case of any incidents	Participate in incident investigations, provide information

An aide memoire has been developed to help improve patients' awareness about how to be involved and collaborate with healthcare professionals in ensuring transfusion safety. See 'Recommended resources'.

As is evident from several incidents reported to SHOT and included in this Annual SHOT Report, while patients have raised concerns and queries regarding the transfusion support they were receiving (either when they felt the component being transfused was not right or whether that was needed at all), they are not being listened to effectively resulting in missed opportunities to ensure and enhance safety. Education of clinical staff, in addition to clinical knowledge, skills and technical expertise, must include effective skills to communicate with and listen to patients.

Communication skills form the foundation for a more positive patient-provider relationship, leading to greater patient satisfaction and better patient compliance. Communication skills are not just restricted to talking, but also to listening and nonverbal communication. In the patient's eyes, the ability to communicate well forms a major component of the clinical competence of the staff involved. The ability to communicate effectively with patients can contribute significantly to improved patient outcomes. These skills can be taught and learned. There is a new call to extend the checklist concept to develop safety checklists that can be used by patients to help empower their involvement in safety practices. Only a handful of studies around patient-completed checklists exist, but those that do indicate a positive impact on patient empowerment and involvement in safety-related behaviours (Harris et al. 2021).

Main recommendation 1: Patients as safety partners

Staff must ensure that they involve, engage and listen to patients as 'partners' in their own care, including transfusion support. Engaging patients, their families, and carers as 'safety partners' helps co-create safer systems, identify, and rectify preventable adverse events. The responsibility of delivering safe care remains in the hands of the healthcare professionals and patients should not feel that if they do not wish or are unable to contribute to their own safety they will, as a result, receive substandard care. Involvement should be encouraged, but patients should not feel pressured into being partners in their own safety if they are not comfortable or able to do so. It is important to note that patients taking ownership of their own care does not and should not diminish the responsibility of health professionals.

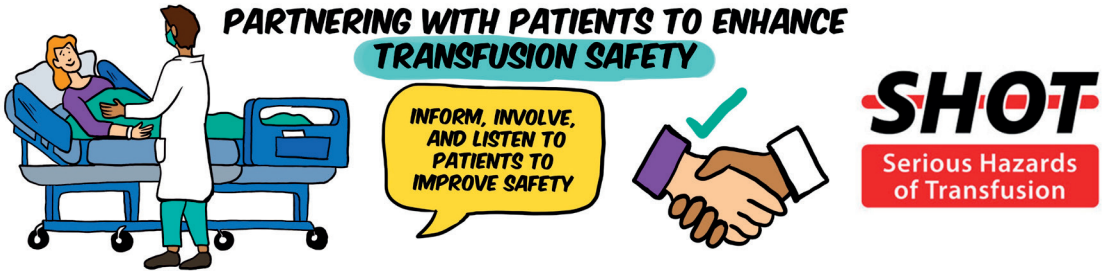
Actions required:

Hospital senior management should:

- Ensure that organisational systems and processes are designed to be patient-centred
- Develop/implement policies and procedures for engaging patients, families and carers in their own care as well as in quality improvement patient safety initiatives and healthcare design

Clinical transfusion staff should:

- Be trained to listen to patients, communicate effectively using structured communication tools and involve patients in decision making where possible
- Encourage patients to ask questions and provide leaflets, signpost videos and apps as relevant relating to transfusion support as applicable to the patient
- Ensure that patients receive copies of all clinical letters including discharge summaries, outlining their condition and treatment, in simple language, as well as copying these letters to the patient's GP
- Proactively involve patients in their care (monitoring, follow up, making choices regarding treatment) with shared decision making
- Encourage patients to raise concerns, participate in incident investigations as appropriate and provide feedback on actions taken
- Recognise when patients may not want to take any responsibility for safety issues and instead trust that they are being provided with competent care



Investing in safety - ensuring adequate staffing and a well-resourced system to ensure transfusion safety

Having the right infrastructure is vital in promoting improved standards of care and wellbeing 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 thus means addressing key constraints in each of these areas. Transfusion errors reported to SHOT are commonly errors caused by faulty systems, processes, and conditions that lead people to make mistakes. The key to eradicating transfusion errors and advancing patient safety is to create systems for reliable healthcare delivery. A major new comparison of global health systems places the UK second to bottom across a series of major healthcare outcomes, including life expectancy and survival rates from cancer, strokes,

and heart attacks (Knox 2022). Improvements in safety do not occur unless there is commitment and support from senior executive managers.

The NHS workforce is in crisis and urgent action is required to tackle a vicious cycle of shortages and increased pressures on staff, which has been exacerbated by the COVID-19 pandemic (The King's Fund 2022). Sufficient staffing levels and effective training and education of staff underpins safe practice. Such staffing challenges prevail within transfusion teams both clinical and laboratory and is evident from previous UKTLC surveys, BSH and Royal College of Pathologists workforce surveys. Workforce shortages increase the pressure on staff, leading to high levels of stress and absenteeism, and high staff turnover. This has a direct impact on the quality of people's care and is evident from several reports submitted to SHOT. Staffing issues need to be addressed urgently to improve safety.

Improvement in patient safety is a continuous cycle, including learning from Safety-I and Safety-II principles and adapting to change. Incident, and near miss, investigation should include review of human factors that may have contributed to the event. It should look at every aspect of the system, including training and competency-assessment, documentation, procedures, environment, equipment, staffing levels, workload, and leadership. The actions identified for improvement should be systems based, not focused on the individual(s) involved in the event. Improvements require investment, this may be purchase of equipment or information technology solutions, it may be staff training and education and it may be re-design of systems. Investments in reducing patient harm can lead to significant financial savings, and more importantly better patient outcomes (WHO 2019). Healthcare organisations should utilise processes for identification of risk, incorporate basic principles and innovations for safe design and use this knowledge in understanding the reasons for hazardous conditions and the ways to reduce vulnerabilities (Institute of Medicine 2000).

The COVID-19 pandemic has provided opportunities for new platforms for staff training including virtual and e-learning, that have now been embedded into routine practice. Staff should be provided with protected time for training, they should have the opportunity to attend external educational activities and they should have regular update training. Competency-assessment provides assurance that staff have the knowledge and skills to perform their role. But safe practice should not be reliant on good memory or vigilance, the system that the staff work within should be designed such that it supports good practice and incorporates alerts or fail safes to reduce errors. Process mapping helps understand the actions required to complete tasks, to release results or components for transfusion. It is an important aspect of understanding practice and identification of potential risk and should be incorporated into incident investigation.

Following an error, it is tempting to add additional actions to an existing process, a new checklist, a second checking process, but simplification of the process is often a more effective method for reducing risk of error. Where inclusion of a checklist is deemed appropriate it should be effective, supporting good practice without being overly long and prescriptive. Policies and SOP provide reference documents for safe practice, they should be clear and concise whilst including all relevant information. Although policies and SOP are a vital aspect of staff training it is accepted that it may not be possible or appropriate for staff to read these documents before performing activities and so they are often supported by shorter protocols, flow charts or scripts. Wherever possible systems should incorporate barriers to unsafe practice, these are often IT-related including LIMS, electronic blood management systems and electronic blood ordering systems. The IT system may block certain activities, such as the LIMS preventing release of ABOi red cells, or they may alert the user to a potential mismatch but allow continuation with appropriate override, such as release of non-irradiated red cells in an emergency. Where alerts are used, they must be clear, relevant, and not easily overridden to reduce risk of inappropriate override. It is important to recognise that rules and algorithms in IT systems are not there to replace the knowledge and skills of the BMS staff. Effective education and regular competency-assessment for lab staff are key to ensuring safe transfusion practice, supported by robust rules and algorithms in LIMS.

User-centred design is a framework where systems/processes are designed with the focus on the users and their needs in each phase of the design process. Users are involved throughout the design process to create highly usable and accessible products/services for them. The key principles for user-centred design were originally highlighted by Donald Norman (Norman 1988) and continue to be relevant. These should be applied to designing systems in healthcare including transfusion to enhance safety. Systems-based strategies with a collaborative effort by everyone from executive board to ward in healthcare are

needed urgently to reduce, if not eliminate, transfusion errors and bring about sustainable and tangible improvements in patient safety

Main recommendation 2: Workforce planning, safe staffing, and a well-resourced healthcare system

Healthcare leaders must ensure that systems are designed to support safe transfusion practice and allocate adequate resources in clinical and laboratory areas to support the following:

- Safe staffing levels
- Staff training in technical and non-technical skills
- Appropriate equipment, including IT systems

Actions required:

Hospital chief executives, senior leaders, medical directors, nursing directors, pathology service managers should ensure:

- Safe staffing levels in both clinical areas and transfusion laboratories. Minimum staffing levels should ideally be based on the overall workload, the acuity and complexity of work involved, considering the 3 previous years' data, for all absences including sickness, mandatory training, annual leave, and maternity leave. Senior leaders should ensure adequate staffing levels so that requisite time needed for staff training and competency-assessments is provided
- There is a clear escalation and mitigation policy where staffing levels fall below the minimum staffing levels for all health professionals. Staff must be able to escalate concerns if necessary
- A proportion of the budget is ring-fenced for training staff involved in transfusion. Staff must receive training in technical and non-technical skills including the NHS National Patient Safety Syllabus and those involved in incident investigation must receive appropriate training in relevant skills
- Adequate resources are available for staff to carry out transfusions safely. This includes implementation of effective and reliable transfusion IT systems to reduce the risk of errors at all steps in the transfusion pathway, provided they are configured and used correctly
- Policies, procedures, and resources including IT are set up based on user-centred design principles and are simple, easy to follow

SHOT
Serious Hazards of Transfusion

Organisational safety culture and leadership

Fostering a strong and effective safety culture is vital to reducing transfusion incidents and errors, thereby directly improving patient safety. The safety culture of an organisation is a combination of individual and group values, attitudes, perceptions, competencies, and patterns of behaviours that determine the commitment to, and the style and proficiency of, an organisation's health and safety management. Strong, collective, empathetic, and authentic leadership is critical in safety culture. Organisations with a positive safety culture are characterised by communications founded on mutual trust, shared perceptions of importance of safety and by confidence of the efficacy of preventative measures (Stavrianopoulos 2012).

Safety culture demonstrates the ownership of safety throughout the organisation and at all levels. It is about the mindset of the organisation and its people, looking at how their values and beliefs influence the way health and safety procedures are implemented and used on a day-to-day basis, and allows people at all levels to take ownership of their own, and others safety. Safety culture isn't just about simple compliance to health and safety policy but also about staff's approach to said policy.

Five critical elements have been identified for an engaged organisation with a good safety culture (Haddon-Cave 2009):

- **Reporting culture**: an organisational climate where people readily report problems, errors and near misses
- **Just culture**: an atmosphere of trust where people are encouraged and even rewarded for providing safety-related information; and it is clear to everyone what is acceptable and unacceptable behaviour
- **Flexible culture**: a culture that can adapt to changing circumstances and demands while maintaining its focus on safety
- **Learning culture**: the willingness and competence to draw the right conclusions from its safety information and the will to implement major safety reforms
- **Questioning culture**: It is vital to ask, 'What if?' and 'Why?' questions. Questions are the antidote to assumptions, which so often incubate mistakes

Figure 4.4: Critical elements of a safety culture

A just culture ensures balanced accountability for both individuals and the organisation responsible for designing and improving systems in the workplace. NHS Improvement's 'A just culture guide' provides a powerful tool to help promote cultural change in organisations or teams where a blame culture is still prevalent (NHSI 2021). Such a culture helps empower employees to proactively monitor practices in the workplace and ensure safety. Risk reduction will be achieved by focusing on human behaviours and redesigning systems. One of the 2018 key SHOT recommendations was that all NHS organisations must move away from a blame culture and towards a just and learning culture (Narayan et al. 2019). While there are still instances of punitive blame culture, there is increasing awareness and adoption of just culture in healthcare organisations in the UK.

Leadership is the critical element to ensure safe care in all healthcare organisations. Only senior leaders can influence and foster the culture and commitment required to address the underlying systems causes of errors in healthcare and harm to patients. Senior leaders include chief executive officers and the executives who report to them, senior clinical leaders, and board members. The unique role of leadership is to establish the value system in the organisation; set strategic goals for activities to be undertaken; align efforts within the organisation to achieve those goals; provide resources for the creation, spread, and sustainability of effective systems; remove obstacles to improvements for clinicians and staff; and require adherence to known practices that will promote patient safety. When leaders begin to change their responses to mistakes and failure, asking what happened and why; instead of who made the error, the culture within their healthcare institutions will begin to change.

IHI provided the following key steps to achieving patient safety and high reliability in healthcare organisations (Botwinick et al. 2006):

Step One: Address strategic priorities, culture, and infrastructure
Step Two: Engage key stakeholders
Step Three: Communicate and build awareness
Step Four: Establish, oversee, and communicate system-level aims
Step Five: Track/measure performance over time, strengthen analysis
Step Six: Support staff and patients/families impacted by medical errors
Step Seven: Align system-wide activities and incentives
Step Eight: Redesign systems and improve reliability

In October 2021, the government launched a review of leadership in health and social care. This landmark review has been led by General Sir Gordon Messenger and Dame Linda Pollard. The recommendations from the report, which was released in June 2022, are aimed at ensuring the right leadership is in place at all levels and that services can deliver the best possible care, tackle the COVID-19 backlog and address the disparities the pandemic has exposed across the country (Messenger and Pollard 2022). This report helps support a consistent approach to developing leaders. Collective, inclusive, and compassionate leadership is now increasingly recognised as essential for delivering high-quality care and cultural change throughout the NHS (Jones et al. 2022).

Main recommendation 3: A just, learning safety culture in all organisations

All healthcare leaders must promote a just, learning safety culture with a collective, inclusive, and compassionate leadership. Effective leaders must ensure staff access to adequate training, mentorship, and support. All staff in clinical and laboratory areas have a responsibility to speak up in case of any concerns and help embed the safety culture in teams.

Actions required:

Hospital senior management should:

- Ensure staff feel able to talk about their concerns and report when things go wrong
- Ensure policies state what staff should do following an incident, how it should be investigated, and what support should be given to patients, families, and staff. They should promote a just and learning culture dealing with people in a just, compassionate way with an inclusive approach, acknowledging through learning to support the changes required when people make errors
- Ensure all staff have access to complete the NHS Patient Safety Syllabus training programme
- Ensure that staff involved in incident investigations receive adequate training in using human factors principles-based investigation frameworks and identifying effective corrective and preventative actions
- Ensure that staff have access to a good mentorship programme
- Regularly assess their organisation's safety culture using a safety assessment survey and take appropriate actions to address any concerns identified

Clinical and transfusion laboratory staff should:

- Ensure they complete the NHS Patient Safety Syllabus training programme and are compliant with the relevant current national legislation, guidelines, and recommendations
- Be familiar with human factors principles and application and be able to identify system focused sustainable solutions if involved in incident investigations
- Demonstrate to their team the measures the organisation takes to ensure reports are dealt with fairly and that the appropriate learning and action takes place

SHOT
Serious Hazards of Transfusion

Recommended resources

Aide memoire for patients - tips to help improve transfusion safety
Safe Transfusion Checklist
The A-E decision tree to facilitate decision making in transfusion
The ten steps in transfusion
https://www.shotuk.org/resources/current-resources/

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Acknowledging Continuing Excellence in Transfusion (ACE)

5

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Definition:

Exceptional transfusion practice by a team or department, that was above and beyond routine practice and effective interventions that have widespread learning opportunities.

Abbreviations used in this chapter

ACE	Acknowledging continuing excellence in transfusion
AI	Appreciative inquiry
BMS	Biomedical scientist
FBC	Full blood count
GMP	Good manufacturing practices
NHS	National Health Service
SABRE	Serious adverse blood reactions and events
SOP	Standard operating procedure
TALK	Target, analysis, learning points, key actions
UK	United Kingdom
WBIT	Wrong blood in tube

Introduction

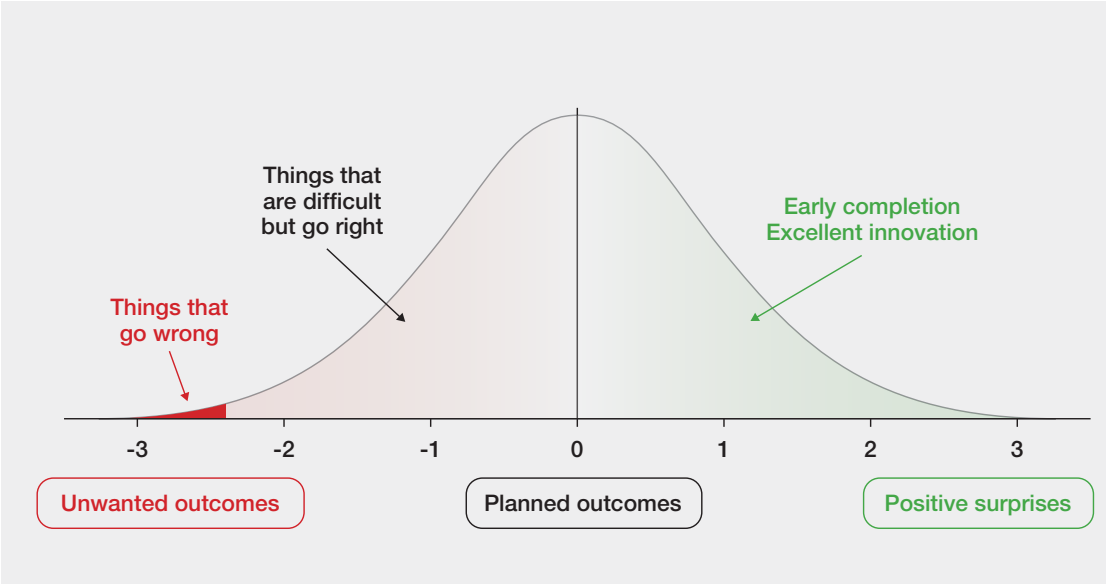
Recognising that studying excellence in healthcare can create new opportunities for learning, help improve resilience and staff morale, SHOT has recently introduced Acknowledging Continuing Excellence in Transfusion (ACE). ACE reports recognise the excellence and outstanding practices of teams or departments and effective interventions that have promoted transfusion safety and are submitted to SHOT, via SABRE, through a questionnaire on the SHOT database (Dendrite). ACE provides a platform to share learning opportunities from these examples of excellence. High quality care becomes the norm by embedding the learning from good practice into the system (Hollnagel et al. 2015). A reporting guide is available on the SHOT website (see 'Recommended resources' at the end of this chapter) to help staff submit reports in this category. This hopefully will encourage transfusion teams to identify excellent practice locally and report it to SHOT so that learning from excellence is embedded widely across the NHS.

Recognising errors and identifying improvement actions to prevent recurrence is the primary focus when incidents are investigated, which is typical of a Safety-I approach. While incident investigation templates may include recognition of notable practice, investigating a good practice event to see if there is any learning is often lacking. The linear approach of Safety-I, which involves tracing causes of events and mapping out steps in procedures, does not truly reflect the complexity and adaptability of healthcare which is constantly changing.

The Safety-II approach seeks to understand the ability of healthcare staff to adapt to problems and pressures and considers how resilient an organisation is. It has a focus on productivity and ensuring the best possible outcomes. Safety-II is a proactive approach that seeks to strengthen the ability of staff to prevent problems before they occur and ensure high quality care even when there are pressures and competing demands. Learning from how things go right, rather than wrong, is an important element of

Safety-II and is especially powerful since things go right much more often than they go wrong. Learning how staff provide good care under difficult circumstances helps ensure it happens more often. A Safety-II approach facilitates learning from excellence and provides a positive learning model which can be utilised alongside a Safety-I approach (Figure 5.1).

Figure 5.1: Event probability and safety focus (Hollnagel et al. 2015)



ACE – a form of learning from excellence

The prevailing approach to patient safety mainly considers safety from a deficit-based perspective. Efforts to reduce errors in healthcare may result in the creation of more complex systems. Reframing allows safety to be considered from a strengths-based perspective and allows alternative methods and tools to be used to improve safety. Strengths-based approaches, such as learning from excellence can be used to unmask the positive characteristics of safety, many of which are behavioural, cultural, and relational. Learning from excellence is being increasingly introduced across teams within healthcare, but still needs to be embedded fully into practice. Often staff are unaware of the various reporting systems and don't capture the excellent information (Preckel et al. 2020).

Learning from excellence has been promoted by SHOT to support the development of a just, learning and questioning culture within the transfusion community. Studying excellence creates opportunities for shared learning experiences and improves staff resilience and staff morale (Magwenzi 2021).

Opportunities to discuss examples of good practice and excellence can also be captured in event debriefs, including major haemorrhage activations. Debriefing is a prime opportunity to reflect on events, thank staff and acknowledge success. Debriefings should be learning orientated, a sharing of experiences in a supportive environment which will in turn lead to the improvements in patient care. A debriefing tool such as TALK (target, analysis, learning points, key actions) can assist teams to develop a shared learning culture and improve patient safety. The TALK tool supports the Safety-II principles, promoting reflectivity in the team, looking at what went well and endorsing collaborative change (Kolbe et al. 2021). Making changes that are effective and sustainable and can be built into the system to enable consistent good practice is vital to improve patient safety. While often things went well because of good communications and good teamwork, the challenge is ensuring this happens every time regardless of the individuals involved. Tangible actions are needed from these excellence reports that do not just include reminders, staff training and shared learning. System changes that support good practice every time are essential.

ACE reports

In January 2021 SHOT introduced a new category for reporting exceptional transfusion practice for teams or departments that go above and beyond the routine practices and effective interventions that have widespread learning opportunities. This process was created with the Safety-II approach in mind,

encouraging the reporting of excellence and using these reports to optimise learning. It also provides a platform to share the learning from these events. The SHOT ACE working group aims to promote reporting in this category but also pick out instances of good practice in error reports and highlight such examples.

An example of such a report being submitted related to a WBIT incident where the patient was transfused platelets based on incorrect FBC results. This incident has been described in detail in the supplementary information for Chapter 11b, Avoidable Transfusions on the SHOT website (https://www.shotuk.org/shot-reports/report-summary-and-supplement-2021/). The incident investigation was comprehensive and corrective/preventative actions included staff education and improvements in systems. The education team worked together to raise awareness about WBIT and sent out hospital wide alerts, undertook training sessions and encouraged a challenge culture if the sample tubes were not being labelled at the bedside. Effectiveness of these interventions will only be evident with time and all staff involved should be informed of the improvements made with these interventions.

Another example of a report submitted in the ACE category related to a critical incident outside the hospital grounds which required a police officer to collect blood components from the hospital transfusion laboratory and transport them to the scene. Police officers are not GMP trained and there was no SOP in place for such events. Laboratory staff provided clear instructions which the police officer followed, including not to open the box and delivered the blood components to the clinician in charge at the scene of the critical incident. All blood components were accounted for, and traceability was provided. Following this incident an SOP was created and training initiated for outside agencies to safely transport blood components. Prompt actions by staff in this case ensured safe and timely provision of blood components during an emergency without compromising safety. This was recognised as an example of excellence. Such an SOP to cover outside agencies to safely transport blood components in emergencies is recommended and could help avoid delays.

Although the COVID-19 pandemic has created a lot of challenges in the NHS, it has also created opportunities for novel ways to provide transfusion training. One report submitted to ACE highlighted that staff training in their hospital for competencies relating to transfusion practice pre-pandemic was at 50% compliance using face-to-face educational sessions. Since the pandemic, the hospital has used virtual training sessions enabling staff to access training more flexibly which has increased the compliance of blood training to 75%. This innovative practice ensured continuity of training through challenging times. All healthcare organisations had to adapt quickly to the evolving challenges posed by the pandemic, switching to virtual platforms and exploring innovative methods of continuing staff training and competency-assessments. This was utilised effectively by many organisations.

Civility in the workplace

Excellent practice and patient safety in the NHS are reliant on teams or departments engaging together to promote a positive culture of civility and kindness. Civility is behaviour that helps to preserve mutual respect at work; it comprises behaviours that are fundamental to positively relating with one another, building relationships and empathy.

It is now recognised that individual team members interactions with each other can impact on patient 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 and Pearson 2013). Incivility in healthcare can cause breakdowns in communication and does not foster good team working

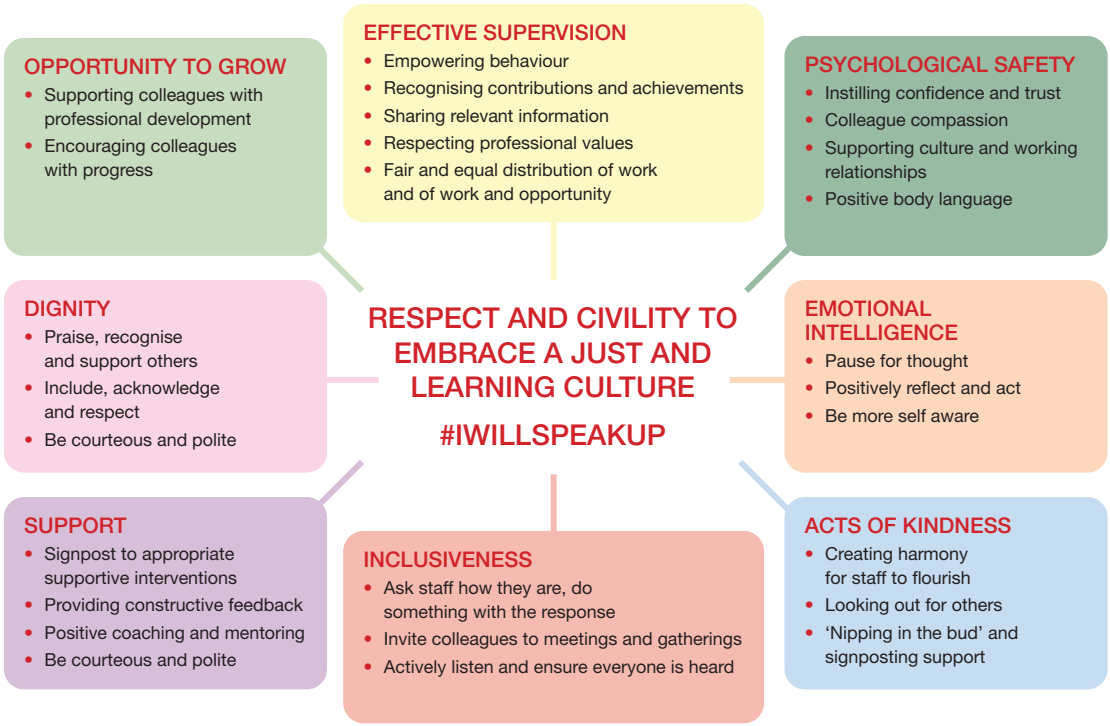
relationships, endangering patient safety. Good teamworking skills and good team relationships will achieve the best outcome for patients. Civility in the healthcare setting is crucial to reduce errors, reduce stress and encourage excellence (Civility saves lives 2022).

Johnson and Indvik (2001) identified 11 common uncivil behaviours:

1. Condescending and demeaning comments
2. Overruling decisions without giving a reason
3. Being disruptive in meetings
4. Giving public reprimands
5. Talking about someone behind their back
6. Giving others the silent treatment
7. Ignoring people
8. Not giving credit where credit is due
9. Sexually harassing employees
10. Giving dirty looks or negative eye contact
11. Insulting and yelling at others

Patient care is adversely impacted, and healthcare organisations suffer where there is not a culture of civility. There is also an impact on managers' time as they are required to deal with the grievance or investigation that can be associated with uncivil to disrespectful behaviour. NHS leaders and managers can make a difference in creating a culture based on civility where both the patient and staff experience are enhanced.

Figure 5.2: Respect and civility



Based on the infographic from Cheshire & Merseyside Health and Care Partnership https://www.cheshireandmerseysidepartnership.co.uk/civility-respect-and-the-importance-of-bystander-accountability/

Appreciative inquiry (AI)

AI is a collaborative, strengths-based, positive approach to change in organisations. The term 'appreciative inquiry' refers to both the principles and theory behind a strengths-based change approach as well as all the specific techniques used to bring about the positive change in the system. AI asks people to explore strengths and successes that already exist to facilitate change. This leads to extraordinary performance by reinforcing relationships and culture, creating common vision and direction, promoting learning and innovation, and energising collective action.

AI helps create an atmosphere of possibility, bringing enthusiasm and excitement back into teams and organisations. AI methods focus on the entire system, ensuring leaders, managers, employees, customers, and stakeholders all feel heard and acknowledged. The result is happier, more engaged employees with lower turnover, higher-performing employees, more collaboration, more creativity, and stronger teams and organisations (Cooperrider and Whitney 2000). AI is essentially a set of core principles that can potentially change existing patterns of conversation and ways of relating and give voice to new and diverse perspectives to expand what can be possible (Ludema et al. 2001). AI is usually described as using a four-stage version of the action research cycle, known as the '4D cycle' shown in the figure below and premised on the definition of a mutually agreed affirmative topic (Cooperrider and Whitney 2000).

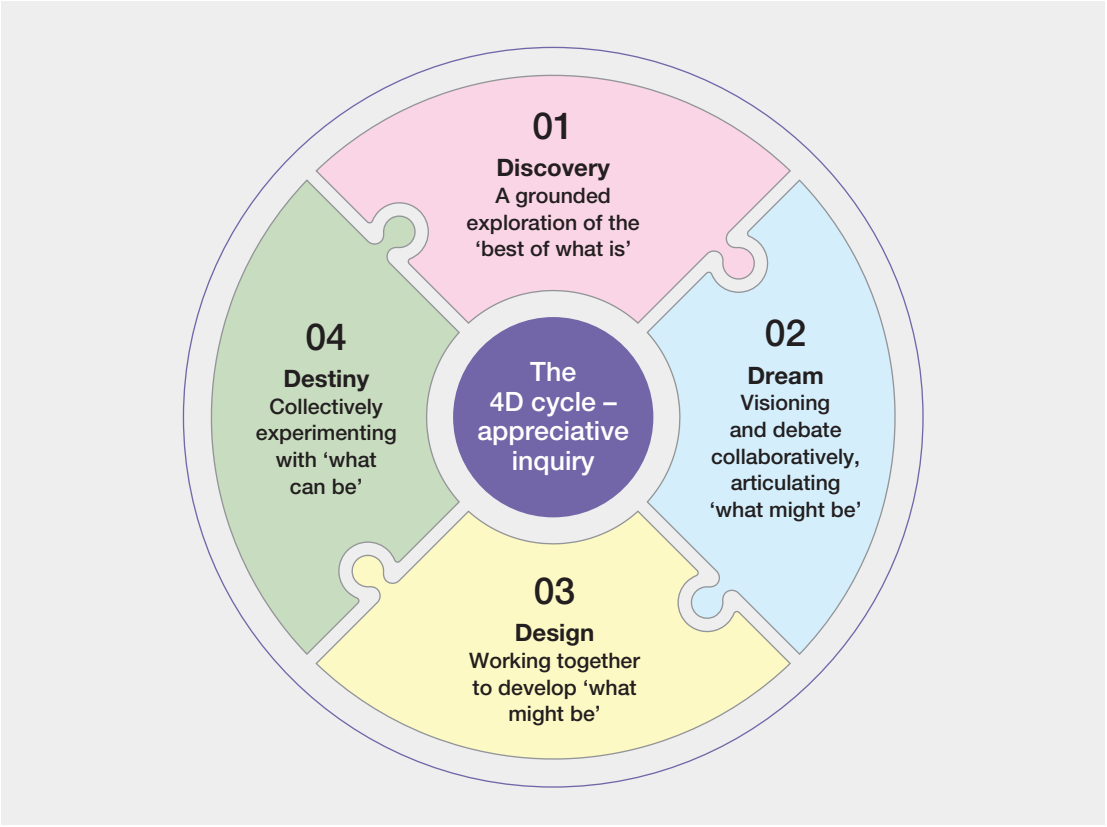


Figure 5.3: The 4D cycle for appreciative inquiry

AI provides a unique and valuable approach to making positive change in transfusion practices. It can help us look at established practices through a new lens and can help disrupt longstanding patterns of thinking and interaction and move them in a positive direction. AI can be used at individual, team, organisational and system levels. Such an approach can be applied in practice development, change management, incident investigations, workforce development, service redesign and delivery, thus potentially influencing transfusion practices in multiple ways. Using more established tools and approaches in healthcare and the assets-based approaches that AI provides will help build safer systems.

Psychological safety

Psychological safety in the workplace is a belief that one will not be punished or humiliated for speaking up with ideas, questions, concerns, or mistakes (Edmondson 2002). In a psychologically safe work environment, people accept the fact that they do not need to be the 'expert in the room'. People are willing to learn, to connect, and are not concerned with looking good (Lagace 2018). Healthcare leaders can build psychological safety in their organisations by creating the right climate, mindsets, and behaviours within their teams. Those who do this best act as catalysts, empowering and enabling other leaders on the team, even those with no formal authority, to help cultivate psychological safety by role modelling and reinforcing the behaviours they expect from the rest of the team (McKinsey and Company 2021). Positive team climate in which team members value one another's contributions, care about one another's well-being, and have input into how the team carries out its work is the most important driver

of psychological safety and most likely to occur when leaders demonstrate supportive, consultative behaviours, then begin to challenge their teams (Frazier et al. 2017). A systematic review of psychological safety literature published in 2020 identifies a list of enablers of psychological safety within healthcare teams (O'donovan and Mcauliffe 2020). This list can be used as a first step in developing observational measures and interventions to improve psychological safety in healthcare teams.

When staff feel psychologically safe, they perform better at work, co-operate better in teams, boost creativity, learning and quality of work relationships and hence safer patient care. A good reporting and learning culture results when staff feel psychologically safe. It is vital that this is embedded in clinical and laboratory transfusion teams to improve transfusion safety.

Conclusion

ACE reporting promotes learning from excellence. This enables transfusion teams and healthcare organisations to identify when things work well so that this is embedded in practice. Excellence can often be difficult to define. Staff work extraordinarily hard every day facing several challenges and there can be a tendency to think that 'they are just doing their job' or 'they should do that anyway'. But it is this 'ordinary excellence' that needs recognising so that gratitude can be shown, and shared learning can take place. It may be an individual member of staff who performs a task exceptionally well, goes above and beyond their usual role or does something in an innovative way. It may be an excellent episode of communication with a patient, relative or colleague or an exceptional teaching session. It could be an example of excellent team working which might be in an emergency or it could be an instance where teams have come together and improved systems when things have gone wrong. Learning from excellence can also be used as a quality improvement tool.

Civility and psychological safety in workplaces foster a great safety culture within teams, providing a safe environment for staff to raise concerns, challenge norms, report incidents and near miss events thus optimising learning and building safer systems. ACE reports submitted to SHOT have shown how staff have used clear communication, seamless collaboration and co-ordination, and supportive team working to ensure safe transfusions. Learning from such events will help embed good practices and improve patient safety. SHOT advocate incorporating such learning from excellence in all transfusion teams, such a culture of positive reinforcement, appreciative inquiry and learning from these reports should be shared widely within organisations to help improve patient safety in all areas.

ACE reporting reflects a proactive approach to patient safety and focuses on capturing and learning from episodes of excellence in transfusion to further improve the quality and safety of care provided. It also provides an opportunity to thank and recognise staff for excellence, which may improve resilience, culture, and morale.

SHOT
Serious Hazards of Transfusion

Recommended resources

ACE reporting – SHOT Definitions
ACE reporting – ACE Examples
https://www.shotuk.org/resources/current-resources/

TALK
https://www.talkdebrief.org/talkhome

Learning from Excellence
https://learningfromexcellence.com/

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6 Donor Haemovigilance

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Definitions:

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 donor or in 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) (BSQR 2005).

Abbreviations used in this chapter

AABB	Association for the Advancement of Blood & Biotherapies
ACS	Acute coronary syndrome
BSQR	Blood Safety and Quality Regulations
EBA	European Blood Alliance
ISBT	International Society of Blood Transfusion
IHN	International Haemovigilance Network
MRI	Magnetic resonance imaging
NHS	National Health Service
NHSBT	NHS Blood and Transplant
NIBTS	Northern Ireland Blood Transfusion Service
RTC	Road traffic collision
SAED	Serious adverse event of donation
SNBTS	Scottish National Blood Transfusion Service
STRIDES	STRategies to Improve Donor ExperienceS
UK	United Kingdom
VVR	Vasovagal reaction
WBS	Welsh Blood Service

Key messages

- The rate of SAED for January 2021 to December 2021 was 0.26 per 10,000 donations. The overall incidence of SAED remains low but the overall trend is upwards over the last 7 years
- Blood Services must ensure that all donors are aware of the importance of reporting all adverse events of donation so the donor can be appropriately managed, and the adverse events can be recorded, monitored and appropriate actions taken to improve donor safety

Recommendations

- Blood Services must ensure that blood donors are aware of any 'material risks' involved in donating blood as part of the consent process pre-donation
- Blood Services must ensure that donors are aware of the importance of reporting all adverse events of donation, especially those that occur after the donor has left the donation session
- All UK Blood Services to implement the 'severity grading tool for blood donor adverse events' developed in 2020 by the AABB Donor Haemovigilance Working Group and endorsed by ISBT, IHN and EBA

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

Introduction

The UK Blood Services rely entirely on the goodwill of blood donors to ensure an adequate supply of blood components to the NHS. It is imperative that the Blood Services do everything possible to facilitate the recruitment of new blood donors and the repeated return of regular donors. All donors should be fully informed about the blood donation journey, clearly understand the donation procedure and be aware of adverse events of donation prior to signing their consent forms.

For most donors the donation process is uneventful but as with any clinical procedure there are risks associated with blood donation. These are usually minor adverse events but there is a potential risk of more serious adverse events which may have lifelong consequences for the donor. European legislation (European Blood directives 2002/98/EC AND 2005/61/EC), which has been subsequently transposed into UK law through the BSQR, mandates that donors are made aware of these risks and that good governance processes exist to identify and mitigate risks, thus improving donor and donation safety. This chapter covers serious complications of blood donation reported in the UK in 2021.

UK Blood Services have implemented the 'Standard surveillance of complications relating to blood donations' (Goldman et al. 2016) and individually record and monitor complications relating to blood donations referred to as adverse events of donation. SAED are those which either result in donor hospitalisation, interventions, significant disability/incapacity persisting for >1-year post donation or rarely death.

The incidence of SAED for the UK Blood Services for 2021 was 0.26 per 10,000 donations. This is low; however, an upward trend is noted over the last 7 years which could reflect better reporting and recording of these events across all the four UK Blood Services.

Serious adverse events of donation

The UK Blood Services have ten SAED reporting categories. These are listed in Table 6.2.

Assigning severity rating and imputability scoring (the strength of the relationship between donation and complication) is challenging, especially when information is incomplete, history taking, and assessment are subjective and vary between clinicians. There are currently no uniformly agreed objective criteria to separate levels of severity or imputability and there is considerable variation in how this is recorded (Land et al. 2018).

Recording imputability status for donor events, whilst not a mandatory requirement under BSQR, is assessed and recorded for every SAED 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

Occasionally, it is clear that the reported complication is unrelated, or very unlikely to be related, to the donation event itself. For example, a donor developing a complication relating to gall stones requiring admission within 24 hours of donation. Hence the rate of SAED in the UK is calculated using all reported cases and by excluding those that are clearly not related to donation (Table 6.3).

Data

A total of 1,822,689 whole blood and component donations were collected by the four UK Blood Services in 2021. This is summarised in the Table 6.1 below:

Table 6.1: Cumulative donation data from the four UK Blood Services in 2021

Donations from 2021		NHSBT	SNBTS	NIBTS	WBS
Whole blood	Donations from male donors	711,925	64,392	20,653	37,981
	Donations from female donors	711,655	78,783	21,072	43,693
	Donations from new donors	131,938	9,161	2,792	6,470
	Donations from repeat donors	1,291,642	134,014	38,933	75,204
Apheresis	Donations from male donors	109,181	7,097	3,372	2,579
	Donations from female donors	9,067	402	407	430
	Donations from new donors	21,680	0	0	141
	Donations from repeat donors	96,568	7,499	3,779	2,868
Total number of donations in 2021		**1,541,828**	**150,674**	**45,504**	**84,683**

Total donations in the UK: 1,822,689

Table 6.2 summarises the number of SAED by category for all four UK Blood Services combined for 2021.

Table 6.2: SAED by category in 2021 (all SAED included here irrespective of imputability)

SAED category		Number of reported SAED
01.	Death within 7 days of donation	0
02.	Hospital admission within 24 hours of donation	9
03.	Injury resulting in a fracture within 24 hours of donation (including fractured teeth)	10
04.	RTC within 24 hours of donation	5
05a.	Problems relating to needle insertion persisting for more than one year (this mainly includes suspected or confirmed nerve and tendon injuries)	25
05b.	Problems relating to needle insertion requiring hospitalisation/intervention (this mainly includes vascular complications)	0
06.	ACS diagnosed within 24 hours of donation	1
07.	Anaphylaxis	0
08.	Haemolysis	0
09.	Air embolism	1
10.	Other event	0
Total reported SAED in 2021		**51**

Table 6.3 details the total number of whole blood and component donations and the total number of SAED reported for each of the four UK Blood Services during 2021. This equates to 0.28 SAED per 10,000 donations or 1 SAED per 35,739 donations when we include all SAED reported irrespective of imputability. Table 6.3 gives a summary of the total number of SAED excluding imputability scores of 0a and 0b for 2021. This equates to 0.26 per 10,000 donations or 1 SAED per 38,781 donations.

	NHSBT	SNBTS	NIBTS	WBS
Whole blood donations	1,423,580	143,175	41,725	81,674
Apheresis/component donations	118,248	7,499	3,779	3,009
Total donations	**1,541,828**	**150,674**	**45,504**	**84,683**
Total number of SAED reported in the calendar year 2021	43	5	0	3
Rate of total SAED per 10,000 donations (all submitted reports irrespective of imputability)		0.28		
Total number of SAED excluding those scored with an imputability of 'unlikely' or 'not related to blood donation'	40	4	0	3
Rate of SAED per 10,000 donations excluding those with imputability of 'unlikely' or 'not related to donation'		**0.26**		

Table 6.3: Summary of total donations for the four UK Blood Services and total numbers of SAED for 2021

Comparison of trends with previous years

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

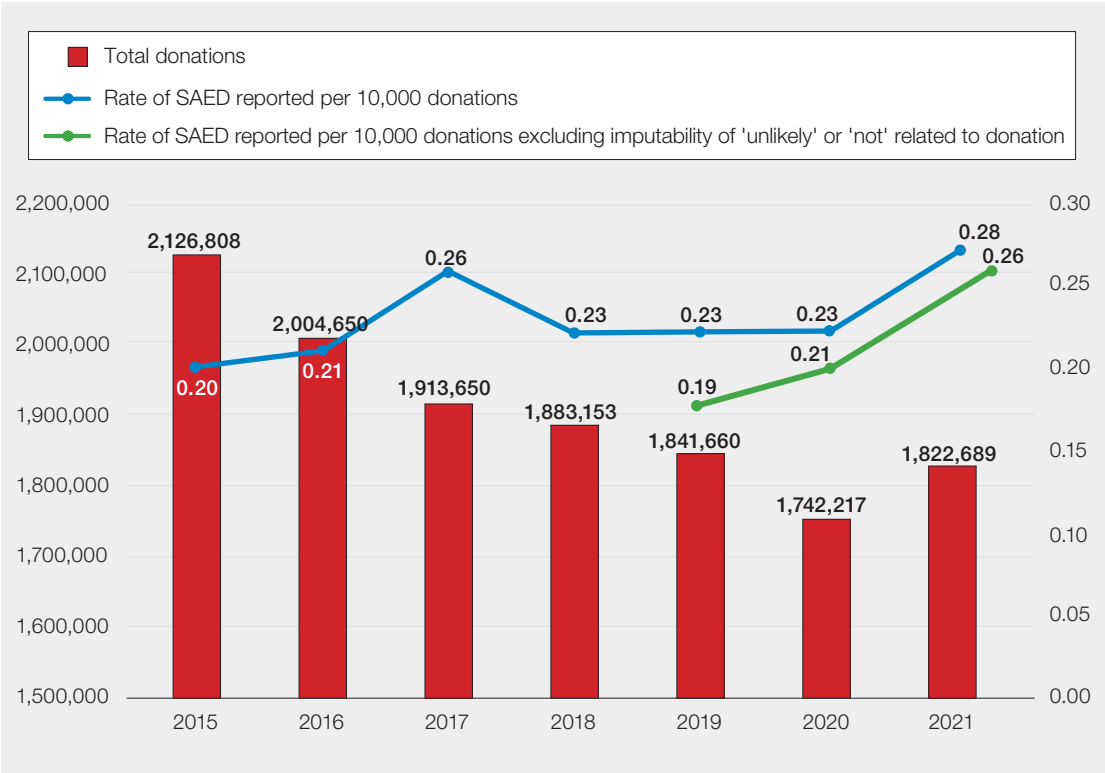
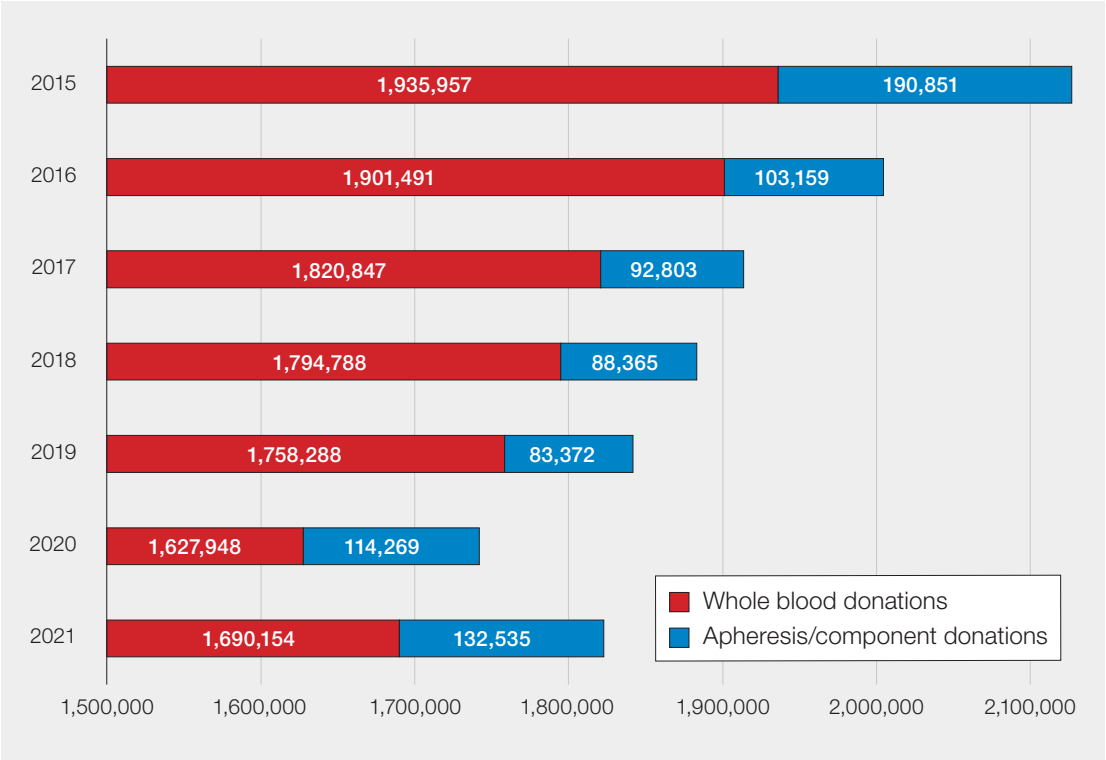


Figure 6.1: Rate of SAED reported per 10,000 donations in the UK from 2015-2021

Since 2015 there is an overall upward trend in the rate of SAED. Improved reporting by better informed donors who are now reporting SAED that occurred in years prior to 2021 (these are included in 2021's figures), and improved recording by UK Blood Services are key factors. Other contributory factors for the increasing trend in SAED reported include staff turnover, training challenges, and suboptimal measures implemented to reduce these severe events.

Figure 6.2: Trends in the number of donations collected across the UK 2015-2021



These numbers include COVID-19 convalescent plasma donations

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 (Link to document provided under 'Recommended resources') (Townsend et al. 2020). This helps rate severity of donor adverse events by grades 1-5 with 1 through 5 being roughly associated with mild, moderate, severe, life-threatening and death as described in Table 6.4. This tool will more accurately reflect the impact an adverse event has on a donor as it includes 'impact on activities of daily living' in the assessment. This may well lead to an increase in the number of SAED recorded in the UK.

Donor communications

It is essential that UK Blood Services collect data on all significant adverse events (immediate and delayed) related to donation. To achieve this, blood collection staff must be trained to log all donation-related adverse events in their organisations quality system.

Donors need to be aware of the importance of reporting adverse events that occur once they have left the donor centre (delayed events), so they can be given appropriate advice, signposted for appropriate management/follow up and the organisation can include this data in its quality statistics. Blood Services must ensure that appropriate follow up is given to all donors reporting an adverse event regardless of the mode of reporting: on donation clinic, via e-mail, in feedback/complaints and via the telephone contact centre. Py et al. (2016) found that the delayed adverse events are under-reported in standard donor haemovigilance systems and recommended that delayed reactions are included in all donor haemovigilance data.

It is not uncommon for a donor to report a significant delayed adverse event at their next attendance to donate, hence many months may have passed between the delayed adverse event and the Blood Service being made aware of it. Donors are also now reporting SAED which may have occurred in previous years. These events will be recorded in the year they are reported rather than in the year the

Table 6.4: Validated severity grading criteria for donor adverse events

Severity grade	General factors to consider in assigning severity. Donor adverse event (DAE) severity tool	DAE examples
Grade 1	No outside medical care (OMC) ***AND*** Short duration ≤2 weeks ***AND*** No limitation on activities of daily living (ADL) ***AND*** Resolved with no or minimal intervention	Arterial puncture, pressure bandage applied, resolved without intervention or sequelae Vasovagal event that resolves with comfort care and/or oral hydration Citrate reaction resolved with oral calcium or reduction in infusion rate
Grade 2	OMC, no hospitalisation ***OR*** Duration >2 weeks- ≤ 6 months ***OR*** Limitations on ADL for ≤2 weeks	Superficial thrombophlebitis resolved with oral antibiotics, no sequelae Vasovagal event that requires transport to ED for IV hydration Lacerations requiring sutures
Grade 3	Not life-threatening ***AND any of the following*** Hospitalisation ***OR*** Duration >6 months ***OR*** Limitations on ADL >2 weeks ***OR*** Require surgery ***OR*** Other serious complications (Category E)	Arteriovenous fistula requiring surgical repair Fracture, dental injury, or concussion Transient ischaemic attack and other cardiovascular events, which are not life-threatening
Grade 4*	Immediate medical intervention required to prevent death	Loss of consciousness with fall and intracranial bleed Anaphylaxis requiring intubation or tracheostomy
Grade 5*	Death	Death

*Grade 4 and Grade 5 are not shown in the severity grading tool of blood donor adverse events.

Based on the severity grading tool developed by the AABB Donor Haemovigilance Working Group (https://www.ihn-org.com/wp-content/uploads/2020/06/Tool_brochure_all_logos.pdf)

venepuncture occurred. Thus, both the donor and the Blood Service are at a disadvantage as this causes a delay in the donor seeking appropriate medical assessment which in turn may increase the likelihood of a donor developing long term complications impacting donor well-being and future donations.

Blood Services consent all donors prior to taking a donation by providing an information leaflet for donors which details the incidences of the variety of adverse events and requests that donors report any adverse events of donation and post donation illness information to the Blood Service. Donors are reminded of this request on booking a donation appointment, completion of a donation and Blood Services have this information on their websites. On occasion, however, some donors do not report delayed adverse events to the Blood Services promptly. Blood Services need to optimise their donor communications to try and reduce the numbers of adverse events that are reported long after the event itself. This helps to improve both donor health and donor retention.

Example of the information given to donors on the post donation thank-you card:

Thank you for giving blood today – the following notes are for your information.

- Have a drink and rest for at least 10 minutes
- For at least 2 hours, leave the dressing on your arm and do not smoke
- Today, drink plenty, avoid heavy lifting, unaccustomed exercise, using a sauna or steam room and alcohol

- If bleeding occurs, raise the arm and apply firm pressure on the site for at least 5 minutes
- If you feel faint or dizzy, lie down or sit with your head between your knees
- If you feel unwell, avoid hazardous activities
- If you become ill in the 2 weeks following your donation, please phone Welsh Blood Service on 0800 252266, 8:00am to 8:00pm Monday – Friday and 9:00am – 1:00pm on Saturdays
- At other times phone 01443 622000

Newman et al. (2003) obtained adverse reaction and donor arm injury information from 1000 randomly selected whole blood donors approximately 3 weeks after a whole blood donation. They found that adverse events and complaints after donation may be more common than previously thought and stated that a post-donation interview is a good tool for defining the blood donor's experience which can be used to evaluate and improve blood donor safety and comfort.

Tiwari et al. (2016) recognised that while blood donors experience both immediate and delayed adverse reactions, there is limited data on the incidence of delayed adverse reactions. They contacted donors 3 weeks after donation and concluded that delayed adverse reactions are more common than immediate adverse reactions and are of a different profile. They found that the post-donation interview provided an insight into donor experiences and was a valuable tool in donor haemovigilance.

Kaur et al. (2022) conducted a study to determine the incidence of delayed adverse reactions and explore how various epidemiological factors affect delayed adverse donor reactions. They concluded that donors do experience delayed adverse reactions which are often not reported to Blood Centres as they are mild. They note however that it is important that these delayed reactions are reported into the donor haemovigilance system so that preventative strategies can be formulated.

In practice conducting a post-donation interview with every blood donor in the UK is not feasible. It is therefore very important that Blood Services continue to inform and educate donors, making them aware that reporting all adverse events, immediate and delayed, is vital to ensure that appropriate advice and help can be offered in a timely manner and more data can be obtained on delayed adverse events to help formulate strategies to try and prevent them from occurring.

Update about STRategies to Improve Donor ExperienceS (STRIDES) study

Authors: Dr Amy McMahon, Scientific Study Coordinator, Cardiovascular Epidemiology Unit, Department of Public Health and Primary Care, University of Cambridge and Susan Mehenny NHSBT Lead – STRIDES Study & Our Future Health

The STRIDES study aims to improve donor experiences by finding an alternative intervention, or combination of interventions, to reduce VVR in whole blood donors. The STRIDES study is comparing four different interventions with current NHSBT practice to reduce VVR in blood donors including:

- Isotonic hydration before donation: 500mL isotonic drink vs. current 500mL plain water
- Time on donation chair after donation: 3-minutes before standing vs. current 2-minutes
- Modified applied muscle tension: new vs. current practice
- Psychosocial intervention: preparatory materials vs. current practice of nothing

To date, 1,241,439 donors are part of the STRIDES trial. In addition, 72,207 of those participants have provided additional blood samples for genetic and biochemical analyses and more in-depth questionnaire data relating to donor faints. The results of this study will determine if a change in current policy and strategies for faint prevention is required to safeguard all blood donors. The study is expected to be completed in autumn 2022 and some results expected to be released in 2023. Further information and updates can be found at the link provided in the 'Recommended resources' section.

Illustrative cases

Case 6.1: Delayed faint not declared until the next attendance to donate

A regular female donor in her 60s, who had given 46 donations previously, attended to donate again 8 months after her previous donation. At this attendance she declared that after her previous donation she was walking home and felt unwell, she became lightheaded which resulted in her falling and fracturing her elbow. She had not informed the Blood Service of this adverse event prior to her re-attendance as she was not sure if there was a causal link between her donation and the faint. She also did not wish to bother the Blood Service! This donor has since been withdrawn from further donation.

Discussion: Unlike immediate VVR or faint, the risk of a delayed faint occurring after the donor has left the session is not significantly higher in first time, inexperienced and younger donors compared to experienced, regular, and older donors. It is possible that experienced donors become complacent about following advice to increase their fluid intake following donation, thereby increasing their risk of a delayed reaction.

This case and the other SAED included in this chapter highlight the importance of ensuring blood donors are aware that they must feedback any post-donation information regarding adverse events or infections so that appropriate actions can be taken, and the donor advised appropriately. Post-donation information must be provided to all donors. This should include the risk of delayed reactions and advice on maintaining post-donation fluid intake, and avoidance of known precipitating factors such as overheating and prolonged standing. The mechanism for delayed faints remains poorly understood. Understanding the physiological basis of such reactions may lead to the development of appropriate interventions to reduce their likelihood. Prevention is important as blood donors who experience VVR are less likely to give blood again (Eder et al. 2012). Reducing adverse events improves donor retention. Therefore, it is important to understand and prevent adverse events related to blood donation and to improve blood donation safety.

Case 6.2: Tendon injury following venepuncture for blood donation

A female donor in her 50s, with one previous donation donated from the right (dominant) arm in September 2020. The donor described a sharp, severe pain at the insertion of the needle.

Although initially the pain seemed to be improving, it subsequently worsened, and the donor noted reduced function. The donor was referred and seen at a hospital outpatient clinic. An MRI scan demonstrated tendon injury. The specialist advised that the injury was secondary to venepuncture, to continue mobilising the arm and that recovery could take up to 2 years. The donor continues to have pain on flexion and reduced function/power in their right arm.

Discussion: As symptoms have persisted for more than a year, this event qualifies as a SAED (Problems relating to needle insertion lasting greater than 1 year).

Arm pain is a common event, occurring in around 10% of donors interviewed in one post-donation survey (Newman et al. 2003). This can be caused by nerve injury or non-neurological causes including haematoma formation, soft tissue injury or tendon injury. The donor's symptoms can help in the differential diagnosis. Tendon injury due to venepuncture can cause biceps tendonitis which presents with pain at the antecubital fossa exacerbated by supination of the forearm and flexion at the elbow. Reduced function with weakness affecting supination and flexion, as well as localised tenderness over the biceps tendon can occur (ASSH 2018). In contrast, pain due to nerve injury may result in sensory symptoms such as tingling, numbness or 'pins and needles' as well as motor symptoms such as weakness. Typically, the pain is described as sharp, burning, shooting or electrical, often radiating into the lower arm, hands, and fingers and occasionally into the upper arm.

Case 6.3: Suspected nerve irritation with persistent symptoms 12 months post donation

A first-time female whole blood donor in her 30s reported persistent ache and tingling in her donation arm and wrist 12 months post donation, following painful needle insertion.

During needle insertion into her left arm, she experienced sharp pain sensation from her forearm to her wrist. The donor did not mention the sharp pain during venepuncture to session staff as 'arm pain resolved during and immediately after donation'. She therefore made a full donation.

A few hours after leaving the session, she started to experience numbness in her left wrist and an 'electric shock sensation' from her forearm to her wrist on moving her arm. The donor reported this to Blood Service 2 days post donation and was appropriately advised on measures to take to alleviate symptoms by the clinical team and was also advised to call back in 3 weeks if no improvement. No further communications were received from the donor, and it was only an outbound call from the Blood Service a year later to discuss booking her next appointment to donate blood that the donor disclosed that she was still symptomatic and experiencing a dull ache in her left wrist which was also 'tender and tingly if touched'.

Due to persistent symptoms for at least 12 months, donor was advised by the clinical support team to seek medical review for further assessment and was withdrawn from future donations.

Discussion: Symptoms of nerve irritation may occur during venepuncture and can be due to direct injury to a nerve which is 'grazed' during venepuncture or compression on a nerve from surrounding haematoma or soft tissue swelling due to bruising (Goldman et al. 2016).

Up to 65% of donors report immediately apparent symptoms described as a sharp, lancinating burning or electrical pain that radiates to the lower arm or into the hand and fingers and in some cases also proximally (Newman et al. 2013). Symptoms of nerve irritation such as numbness, tingling, pins and needles, may develop and worsen over time or with certain positions and with certain arm motions.

It is recognised that in most cases, symptoms reported due to nerve irritation will usually resolve over a period of time. Resolution time is variable and could be days to weeks and months or even longer in rare cases. In rare cases, there may be residual long term or permanent symptoms in the affected donation arm. Nerve injuries are the most common cause of disability among donors. 70, 90, and 96% of venepuncture-related nerve injuries resolve within 1, 2 and 6 months, respectively. However, chronic disabling deficits have been reported at an incidence of 1 in 1.5 million phlebotomies. In 87% of patients who required ongoing care by a pain management specialist, some degree of permanent nerve damage continues to be experienced (Oven and Johnson 2017). Nerve injuries may not be completely avoidable because nerve anatomy is variable, and nerves cannot be palpated.

Minimising needle movement while in situ is probably also wise, however, taking the high anatomic variability into account, the risk of inadvertent nerve damage is still a possibility (Ramos et al. 2014).

Most donors will express some unusual discomfort and or symptoms such as severe sharp pain, numbness, paraesthesia or pins and needles because of nerve injury during venepuncture. This must be recognised and managed accordingly by staff when donors report such unusual symptoms during venepuncture or during donation and the donation discontinued with provision of appropriate post donation arm care advice to donor.

On this occasion, the donor did not report the symptoms she experienced during venepuncture and therefore went on to make a full donation. This could be because the donor was donating for the first time and self-deferred from donations.

It is therefore important for session staff to encourage all donors, especially first-time donors to report any unusual symptom during venepuncture and donation. Observation of donors for non-verbal clues of pain such as restlessness, facial expressions, and bracing is also important.

Recommended resources

Severity grading tool for donor adverse events developed by AABB Donor Hemovigilance Working Group and endorsed by ISBT, IHN and EBA
https://www.ihn-org.com/wp-content/uploads/2020/06/Tool_brochure_all_logos.pdf

STRategies to Improve Donor ExperienceS (STRIDES) study (ISRCTN10412338)
http://www.donorhealth-btru.nihr.ac.uk/studies/strides-study/

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EU directives: https://ec.europa.eu/health/blood_tissues_organs/blood_en [accessed 04 May 2022] then click Blood Legislation and guidelines to expand list and select the option below:

> Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC OJ L 33, 8.2.2003. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32002L0098 [accessed 04 May 2022].
>
> Commission Directive 2005/61/EC of 30 September 2005 implementing Directive 2002/98/EC of the European Parliament and of the Council as regards traceability requirements and notification of serious adverse reactions and events (Text with EEA relevance)

OJ L 287M, 18.10.2006, p. 350–358 (MT) https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32005L0061&qid=1648656281267 [accessed 04 May 2022].

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Kaur S, Mittal K, Kaur R, et al. Reporting of delayed adverse donor reactions in whole blood donors: Just the tip of an iceberg! *Transfus Clin Biol*. 2022;29(2):141-146. doi: 10.1016/j.tracli.2021.11.003.

Land K, Townsend M, Goldman, et al. (2018) International validation of harmonized definitions of complications of blood donations. *Transfusion* 2018:**58(11**)2589-2595.

Newman B, Pichette S, Pichette D, et al. Adverse effects in blood donors after whole-blood donation: a study of 1000 blood donors interviewed 3 weeks after whole-blood donation. *Transfusion*. 2003;**43(5)**:598-603.

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Py JY, Durieux S, Barnoux M, et al. Les effets indésirables retardés chez les donneurs de sang : des données de l'hémovigilance aux études spécifiques (Delayed adverse reactions to blood donation: From haemovigilance data to specific studies). *Transfus Clin Biol*. 2016;**23(4)**:233-239. French. doi: 10.1016/j.tracli.2016.07.007.

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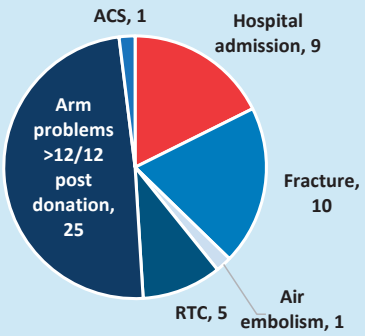
Townsend M, Kamel H, Van Buren N, et al. Development and validation of donor adverse reaction severity grading tool: enhancing objective grade assignment to donor adverse events. *Transfusion*. 2020;**60(6)**:1231-1242. https://doi.org/10.1111/trf.15830.

Serious Adverse Events following Blood Donation reported to the UK Blood Services in 2021

In 2021 the UK Blood Services collected approximately 1.8 million donations (whole blood and apheresis)- this includes plasma collected for fractionation at NHSBT. Fifty one serious adverse events of donation (SAED) have been reported last year (this includes all categories of imputability and equates to 1 in 35,739 donations). 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 2 years.

Breakdown of Serious Adverse Events in 2021

SAED Categories



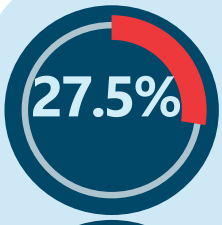
ACS=acute coronary syndrome
RTC=road traffic collision

SAED were seen in both female (25/51, 49%) and male donors (26/51, 51%).

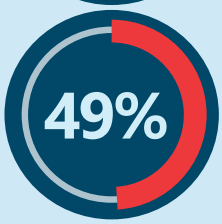
Five SAED were reported in first time donors, all whole blood with 3/5 of these being female donors.

There were no reports of anaphylaxis or haemolysis due to component donation reported in 2021. There was one suspected air embolism. No donor deaths reported relating to donation in 2021

All 10 fractures were related to vasovagal reactions (VVR), 3 immediate and 7 delayed reactions. 6/7 of these delayed VVR were in female donors. Two of these cases were in first time donors (both on session faints),

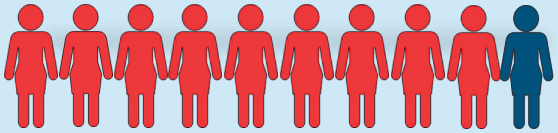


14/51 SAED were as a direct result of a delayed vasovagal reaction. The break down of these cases include 5RTC, 2 hospital admissions and 7 fractures.



25/51 SAED reported were related to persistent arm problems more than one year post donation. Only one was in an apheresis platelet donor while all others were whole blood donors. A suspected tendon injury accounted for one of these cases.

In general 9 /10 donors who suffer an SAED are withdrawn from future donations



Key Messages

Donors need a clear understanding of what, when and how to report adverse events. Blood Services must ensure that blood donors are aware of any 'material risks' involved in donating blood.

Vasovagal events, both immediate and delayed, resulting in donor hospitalisation or injury and nerve injuries post venepuncture continue to be the commonly reported SAED.

Whole blood and component donation is safe but complications do sometimes occur. The overall incidence of serious adverse events of donation (SAED) remains low. The rate of SAED in UK for 2021 is 0.26 per 10,000 donations taking into account all SAED where blood donation was deemed to have potentially contributed to the donor adverse event.

ERROR REPORTS

7 Human Factors in SHOT Error Incidents n=2569

Authors: Alison Watt and Emma Milser

Definition

Human factors and ergonomics (HFE) is the scientific discipline concerned with the understanding of interactions among humans and other elements of a system.

Key SHOT messages

- The term 'human factors' is not interchangeable with 'human error'. It broadly denotes the opposite because it refers to the factors that influence humans in their execution of tasks. It means the same as ergonomics, which incorporates how system and organisational factors, as well as design aspects, can affect human performance
- System and organisational factors – this phrase is used extensively and the simplest way to explain the meaning is to consider all the questions asked in the SHOT HFIT, particularly in conjunction with the tooltips on the website as they cover most of the system and organisational factors that are likely to contribute to adverse incidents

Recommendations

- The term 'human error' should no longer be used as a conclusion in any incident report and investigators should focus on finding the system and organisational factors that contributed to the incident
- Incidents should be investigated by staff trained in this process and protected time should be allocated for staff to receive training for incident investigation techniques and to carry out comprehensive incident investigations
- A tried and tested human factors-based framework should be applied to incident investigations. The SHOT HFIT questions may be used in addition, so that answers to the questions can be discovered during the investigation
- Human factors and ergonomics training should be provided to all staff, clinical and laboratory, to ensure a holistic approach to building safe systems and work towards error reduction

Action: Hospital risk departments, hospital transfusion committees, hospital transfusion teams

Abbreviations used in this chapter

AI	Artificial intelligence
BMS	Biomedical scientist
BSQR	Blood Safety and Quality Regulations
CCP	COVID-19 convalescent plasma
FFP	Fresh frozen plasma
GPG	Good practice guidelines
HFE	Human factors and ergonomics
HFIT	Human factors investigation tool
HSIB	Healthcare Safety Investigation Branch
IT	Information technology
MHRA	Medicines and Healthcare products Regulatory Agency
NHSEI	NHS England and NHS Improvement
PSIRF	Patient Safety Incident Response Framework
SAE	SAE Serious adverse event
SEIPS	Systems Engineering Initiative for Patient Safety
SOP	Standard operating procedure
YCFF	Yorkshire Contributory Factors Framework

Introduction

SHOT would like to emphasise the importance of recognising that the term 'human factors' does not equate to 'human error'. In fact, it means the opposite, as the discipline is related to understanding how humans interact with systems and processes. Ergonomics is the science applied to study the relationship between workers and their environments and means exactly the same as human factors and these principles must guide incident investigations. Investigators should look beyond the actions of the human to examine in more depth what system and organisational factors affected the decisions taken by the person or people involved in the event.

The new SHOT HFIT, introduced in 2021, is designed to encourage reporters to recognise that 'human error' is not an appropriate conclusion for an incident investigation. It has long been argued that the phrase 'human error' is a misnomer because it cannot exist as something that is observable in an incident or accident (Hollnagel 1983) and the activity leading to an error would usually be more accurately defined as a failure to achieve the intended outcome. SHOT is aware that the BSQR specification category of 'human error' exists, but reporters to the MHRA are also directed by the regulations to investigate incidents thoroughly to identify system or process improvements. The BSQR 2005 (as amended) mandates that reporters evaluate SAE to 'identify preventable causes within the process' (Regulation 12B (4a)). The Good Practice Guidelines for blood (GPG 2018) state 'Where human error is suspected or identified as the cause, this should be justified having taken care to ensure that process, procedural or system-based errors or problems have not been overlooked, if present. Appropriate corrective actions and/or preventative actions (CAPA) should be identified and taken in response to investigations.' (1.2.13). (Chapter 25, Medicines and Healthcare products Regulatory Agency (MHRA) Report).

In other words, even if it is concluded that an error is a result of a slip, or lapse in concentration in an individual human, it is likely that there is a process or system problem that contributed to the error, which can be identified and addressed. Attributing error to the actions of one person or team is not objective (Woods et al. 1994) so the use of the phrase 'human error' is likely to be misleading and best avoided (Hollnagel and Amalberti, 2001). SHOT recommends that the term 'human error' should no longer be used as a conclusion in any incident report and investigators should instead concentrate on finding the system and organisational factors that contributed to the incident.

Learning points

- Think beyond the person - human error is an outdated term and cannot be considered as a causal factor. Errors are unintended while deliberate acts of sabotage are not errors, they are deliberate harm events. Factors that led the human to make an error are the underlying causes of any incident, so every effort should be made to identify and resolve these system and organisational factors to prevent future problems
- The HFIT questions are designed to identify system and organisational factors that have contributed to an incident, so it may be beneficial to refer to these when trying to detect and understand causes beyond 'human error'

NHS organisations should develop systems that recognise and deal with people in a 'just' way, acknowledging through learning to support the changes required when people make errors. The fair treatment of staff supports a culture of fairness, openness and learning in the NHS by making staff feel confident to speak up when things go wrong, rather than fearing blame. Supporting staff to be open about mistakes allows valuable lessons to be learnt so the same errors can be prevented from being repeated. The framework of a just culture ensures balanced accountability for both individuals and the organisation responsible for designing and improving systems in the workplace. The NHS Improvement's 'A Just Culture guide' provides a powerful tool to help promote cultural change in organisations or teams where a blame culture is still prevalent (NHSEI 2021). Such a culture will help empower employees to proactively monitor practices at the workplace and ensure safety. Risk reduction will be achieved by focusing on human behaviours and redesigning systems. Promoting a just and learning culture was one of the main SHOT recommendations in the 2018 Annual SHOT Report (Narayan et al. 2019).

When examining adverse events, it is recommended that investigators should be fully trained in techniques for incident investigations and that appropriate time and resources are allocated to facilitate this training. In addition, a tried and tested human factors-based framework should be used. The SHOT HFIT questions may be used alongside that framework, so that answers to the questions can be discovered during the investigation. NHS England and NHS Improvement (NHSEI) are in the process of introducing a new Patient Safety Incident Response Framework (PSIRF) (NHSEI 2022).

SHOT
Serious Hazards of Transfusion

Patient Safety Incident Response Framework (PSIRF) (NHSEI 2022)

Contributed by Tracey Herlihey, Head of Patient Safety Incident Response Policy, NHS England and NHS Improvement

The PSIRF is supporting NHS providers to take a systematic, compassionate, and proportionate response to patient safety incidents, to achieve better learning and support continuous improvement.

PSIRF encompasses all patient safety incidents and supports development of an effective patient safety incident response system that integrates:

- Compassionate engagement and involvement of those affected by patient safety incidents
- Application of a range of system-based approaches to learning from patient safety incidents
- Considered and proportionate responses to patient safety incidents
- Supportive oversight focused on strengthening response system functioning and improvement

The framework is expected to be published by NHS England in June 2022, when NHS Trusts in England will begin preparing to transition from the Serious Incident Framework to PSIRF. Find out more on the PSIRF webpage (see 'Recommended resources').

Analysis of the SHOT HFIT

The number of error cases included in 2021 was 2569, which is comparable to 2020 (n=2623). Therefore, 81.3% of the total cases analysed in this Annual SHOT Report result from preventable error, rather than unforeseeable transfusion reactions, which is consistent with the 2020 error figure (81.6%).

These data represent the first year of the new SHOT HFIT which was based on the YCFF (Lawton et al. 2012). The YCFF was the first evidence-based framework of accident causation in hospitals developed following a systematic review of 83 research studies about the causes of patient safety incidents (Improvement Academy 2022). It is important to note that the SHOT HFIT is not a validated incident investigation tool, although it is adapted from the YCFF which is an evidence-based framework. SHOT suggests investigators have access to the SHOT HFIT questions when examining incidents, so that answers to the questions can be determined during the investigation, but it is recommended that this is done alongside a tried and tested incident investigation framework.

The HFIT questions were restructured for 2021 as the results from the original five years study of HFIT (2016-2020) showed reporters tended to give high scores to the staff involved. Various system and organisational factors contributing to these incidents may have been missed (Watt 2020). The expanded HFIT questions request more details about the contributory system and organisational factors and the scoring was revised to a five-point scale with guidance suggesting the scores were assigned by calculating the relative contribution thus:

0 – None, 1 – Barely, 2 – A little, 3 – Some, 4 – A lot, 5 – Fully.

The total scores assigned to each factor and the comparative percentages are shown in Figure 7.1. The analysis indicates that the new HFIT is encouraging scoring across a broader range of contributory factors. Where high scores have been attributed across all or several questions, they highlight the various systemic issues that contributed to a single incident.

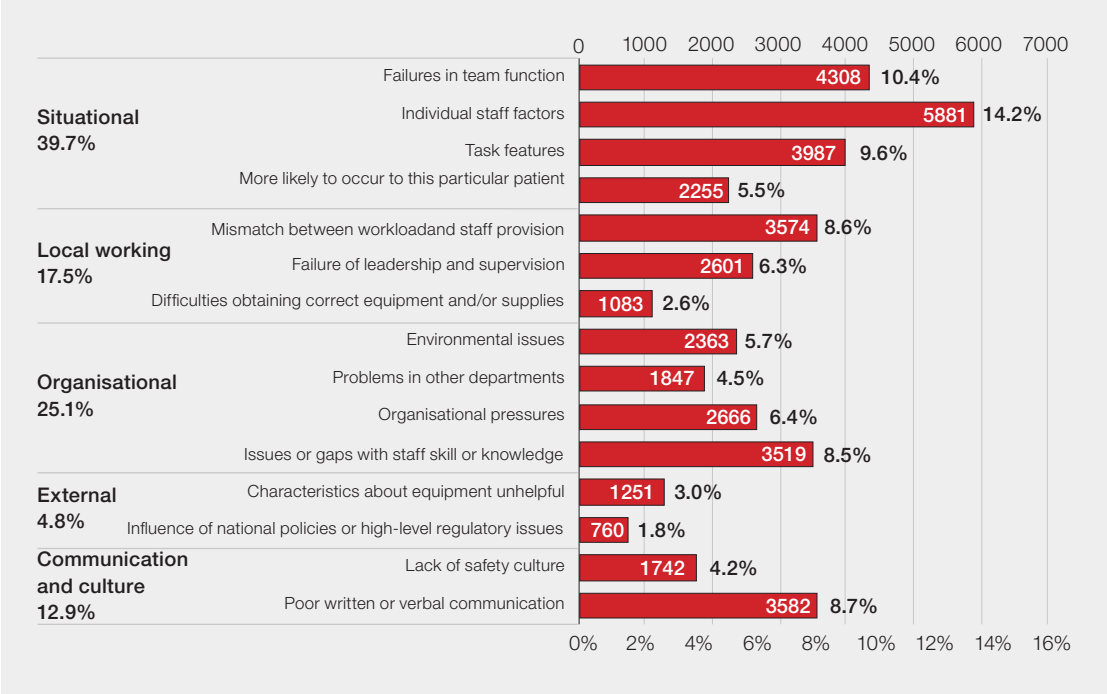


Figure 7.1: Comparative scores assigned for different system factors

The expanded HFIT introduced in 2021 reveals a greater breadth of factors that contribute to adverse incidents, so investigators can identify areas for system and organisational improvement

Figure 7.1 shows the highest scores were assigned to individual staff factors, which may be a sign that reporters are still focussing mainly on staff involvement. This question is designed to analyse specific issues with staff members, such as fatigue, stress, rushing, distraction, or inexperience. This question was amended slightly for 2022. The original question was 'To what extent did individual staff factors make this incident more likely?', this was amended to say, 'To what extent were there any reasons this incident was more likely to occur with the particular staff involved?'. A comparison was made of the scores given for each factor against a simple count of the number of cases assigned any score for the relative factors. A noticeable difference was seen for this question about individual staff factors, showing that reporters tended to assign comparatively higher scores which may indicate reporters are scoring

this question related to staff involvement slightly higher than other questions. SHOT is considering removing the requirement to assign quantitative scores and to simply ask if each factor is considered to have contributed at all.

The importance of systems thinking

It is important that a systems-thinking approach is taken when trying to learn from adverse events. Systems thinking is a holistic way to investigate factors and interactions that could contribute to a possible outcome.

Case 7.1: Limited scores assigned, but investigation shows a wider range of contributory factors could have been considered

A request was made for FFP and cryoprecipitate, but when the components were issued the compatibility labels were transposed. This was discovered during pre-transfusion checks on the ward. Only two scores were assigned for factors contributing to the incident: 2/5 for the extent to which the environment hindered work and 1/5 for organisational pressures playing a role in the incident. The most important contributory factors were listed as lack of concentration and distraction from external members of staff, but no scores were assigned to reflect these factors. The investigation report noted other factors that were also not fully reflected in the scoring, such as the staff member was busy and the procedure to issue only one component type at a time was not fully documented.

The incident was attributed mainly due to 'lack of attention to detail by staff member' and the individual was required to complete a reflective learning form. This meant that other system and organisational problems were not considered adequately. Scores in Case 7.1 could have been assigned to a broader range of contributory factors resulting in missed opportunities for learning. These included a mismatch between workload and staff provision, as the BMS was busy; problems with team leadership because colleagues were distracting the BMS who was crossmatching; difficulties caused by other departments, i.e., external staff also distracting the BMS, characteristics of the equipment because they were similar components and poor communication, as the SOP was unclear. Preventative measures that could have been considered included revising policies so that only one type of component is issued at a time, colleagues prohibited from distracting the BMS who is crossmatching and installing a doorbell to stop external distractions. The reflective learning outcome was that the staff member should seek help when busy, but if that has not been seen as a wider system problem related to staff leadership, then it is possible that other staff have not been empowered to seek help when needed. Reflective practice is a suboptimal intervention and can be perceived as punitive following any incident and is not an effective measure to prevent future recurrence of similar incidents. System level interventions including standardisation and IT solutions are sustainable solutions.

In previous Annual SHOT Reports the importance of a combined Safety-I and Safety-II approach has been detailed, and recently the concept of Safety-III as a safety management principle has been introduced (Leveson 2020). Safety-III is based on systems theory, and 'it spans the entire lifecycle but puts particular focus on designing safety in from the very beginning of system concept definition.' The simplest description of Safety-III is freedom from unacceptable losses, which in a transfusion context would equate to freedom from adverse incidents. The goal of Safety-III is to eliminate, mitigate or control hazards, because incidents can result from inadequate control or enforcement of safety-related aspects. Hence the focus is on preventing hazards, but also on learning from events, accidents, incidents, and audits of how the system is performing (Aven 2022).

Table 7.1 Definitions of Safety (Leveson 2020)

Safety-I	Safety-II	Safety-III
As few things as possible go wrong	As many things as possible go right	Freedom from unacceptable losses as identified by the system stakeholders. The goal is to eliminate, mitigate, or control hazards, which are the states that can lead to these losses (i.e., adverse incidents)

Learning point

- To improve safety in healthcare, it is vital to apply human factors and ergonomics principles as well as systems thinking. This will help address organisational and other system issues and help design safer systems so that hazards are eliminated, mitigated, or controlled. NHS Patient Safety Syllabus training programme has recently been introduced that covers these aspects (see link under 'Recommended resources' at the end of this chapter

Effect of the COVID-19 pandemic

A search of terms related to COVID-19 identified 161/2569 (0.6%) cases that had some link to the pandemic. This is a relatively small percentage, and the pandemic was not necessarily identified as a key contributory factor in these incidents, but it could be argued that most of these adverse events would not have occurred if not for the prevalence of COVID-19 in 2021.

Case 7.2: Pressures caused by COVID-19 pandemic contribute to error with CCP

A patient was due to receive a second dose of CCP, but FFP was issued in error and placed in a yellow CCP trial bag. The porter received an electronic request to collect 'plasma'; CCP was not specified. The unit was administered without any of the staff involved noticing that FFP had been issued in error. The hospital was experiencing an overwhelming number of COVID-19 cases and many staff were unfamiliar with the component. Staff in all ward areas were under pressure and overwhelmed physically and emotionally. It was a difficult time to oversee and implement any changes and face-to-face training could not be undertaken, so a training video had been created to help staff, but uptake was likely to have been variable.

This case reveals how difficult it was for staff to work during the height of the COVID-19 pandemic. It demonstrates challenges faced when implementing new processes which the pandemic itself required, such as the introduction of CCP as a new component. HFE methods can be applied to lessons learned from responses to the COVID-19 pandemic (Wooldridge et al. 2022). Scores for the HFIT questions in this case were given across the full range of contributory factors and highlighted key system and organisational problems, such as the CCP storage drawer being near to the FFP drawer and that the IT systems did not warn against selection or administration of FFP versus CCP. Preventative actions included relocation of CCP to another freezer, plus photographs of both components with an indication of the correct unit to transfuse for incorporation in the training video and circulated directly to staff. IT failings were not addressed, potentially because effecting major IT amendments might be outside the remit of the incident investigators. The BMS was required to complete training and a reflection log, which is unlikely to have been an effective corrective action and may be seen as punishment for an error that was driven by system and organisational problems.

Conclusion

The new format of the revised HFIT has helped SHOT reporters and incident investigators to focus on underlying system failures instead of stopping at the classic outcome of blaming 'human error'. The foreword of a valuable new open access book telling the story of the patient safety movement discusses medical errors and states the causes would not be '…rogue clinicians or even incompetent ones, but rather the very designs of healthcare delivery, itself, in which even the best of the workforce get trapped … the myriad interactions of those delivery system designs and the frailties of unaided human minds and manipulations – the human factors that set up normal people for the familiar 'oops' of daily life.' (Leape 2021).

The patient safety syllabus, launched in 2019 and updated in 2021, was developed for all NHS staff to help identify risks proactively to prevent errors before they occur (HEE 2021) and emphasises the need for all staff to have basic awareness of human factors.

An essential learning outcome within the patient safety syllabus is to understand the hierarchy gradient and its effects. In healthcare, mistakes that are potentially harmful or fatal to patients are often the result

of poor communication between members of a team. This is particularly important in high-risk areas such as operating theatres or during any intervention, and the ability to challenge colleagues who are in authority when something does not seem right or is clearly wrong, is crucial (Green et al. 2017). It is further recognised that patient safety can be compromised where there is failure or reluctance to challenge poor practice or culture. Flattening the hierarchy within teams and organisations, empowering staff to speak out safely with confidence that concerns will be investigated is essential; without this a just culture cannot thrive.

Incident investigations must be systematic and thorough, proportionate to the risk and impact and identify systems-based corrective and preventative actions. Fostering a strong and effective safety culture that is 'just and learning' is vital to ensure a reduction in transfusion incidents and errors, and to improve patient safety. The framework of a just culture ensures balanced accountability for both individuals and the organisation responsible for designing and improving systems in the workplace. The NHS Improvement's 'A Just Culture guide' provides a powerful tool to help promote cultural change in organisations or teams where a blame culture is still prevalent (NHSI 2021). Such a culture will help empower employees to proactively monitor practices at the workplace and ensure safety. Risk reduction will be achieved by focusing on human behaviours and redesigning systems.

Recommended resources

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/tools-and-resources/the-yorkshire-contributory-factors-framework.html

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/

NHSEI: A just culture guide
https://www.england.nhs.uk/wp-content/uploads/2021/02/NHS_0932_JC_Poster_A3.pdf

Case Study reworked using updated HFIT and SEIPS framework
https://www.shotuk.org/wp-content/uploads/myimages/HFIT-and-SEIPS-Supplementary-material-2020.pdf

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8 Adverse Events Related to Anti-D Immunoglobulin (Ig) n=341

Author: Jennifer Davies and Nour Almozain

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 red cells or platelets.

Abbreviations used in this chapter

BSH	British Society for Haematology
cffDNA	Cell-free fetal deoxyribonucleic acid
CI	Confidence interval
EPR	Electronic patient records
FMH	Fetomaternal haemorrhage
HFIT	Human factors investigation toolkit
IBGRL	International Blood Group Reference Laboratory
Ig	Immunoglobulin
IT	Information technology
LIMS	Laboratory information management system
NHSBT	National Health Service Blood and Transplant
NICE	National Institute for Health and Care Excellence
NPEx	National Pathology Exchange
PSE	Potentially sensitising event
PV	Per vaginal
RAADP	Routine antenatal anti-D Ig prophylaxis

Key SHOT messages

- Non-invasive prenatal testing for fetal D-type should be made available to all D-negative women in the UK during pregnancy. The service is available from organisations in the UK, including the IBGRL at the NHSBT in England and the Exeter Genomics Laboratory
- Anti-D Ig should be administered prior to patient discharge to avoid delays and omissions of anti-D Ig
- Formal incident investigation should take place where errors in the management of anti-D Ig and RAADP have been identified. These should be discussed at relevant governance meetings

Recommendations

- IT systems, including LIMS, EPR systems, integration systems (such as NPEx) and electronic blood-tracking systems should be used to their full potential to support safe and appropriate management of anti-D Ig and RAADP. System providers should work with subject matter experts and IT departments within organisations to develop and implement functionality designed to support good practice

Action: Suppliers of all hospital IT systems, subject matter experts, IT departments

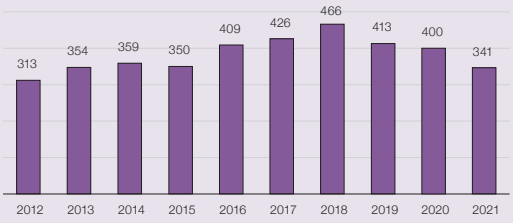
- Where IT systems are not yet available, or do not include decision support for good practice, checklists, such as the SHOT anti-D aide memoire, should be readily accessible in transfusion laboratories and clinical areas. These should also be embedded in processes relating to the management of pregnancy in D-negative individuals

Action: Maternity services, gynaecology services, laboratory management

Headline data 2021

Number of reports n=341
Deaths n=0
Major morbidity n=0

Anti-D Ig reports by year



Demographic data

Male n=0
Female n=341
Adults n=338
Paediatric n=3

Potential for major morbidity n=228

Late/omitted RAADP n=55
Late/omitted anti-D Ig following a PSE (including delivery) n=172
Unknown n=1

Introduction

Appropriate and timely administration of anti-D Ig post sensitising events and RAADP reduces the risk of development of immune anti-D resulting from pregnancy (BSH Qureshi et al. 2014; NICE TA156 2008; NICE NG140 2019; NICE NG126 2019). BSH guidelines and NICE guidance should be reflected in local policies. 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. In this chapter 341 cases have been analysed, 338/341 (99.1%) related to pregnancy and 3/341 (0.9%) involved the transfusion of D-positive platelets.

SHOT data over the years demonstrate that errors in anti-D Ig and RAADP management occur in both the clinical and laboratory setting. The management of anti-D Ig and RAADP is complex, involving healthcare professionals in primary care and secondary care. It involves consideration of many aspects of the clinical picture, including patient D-type, fetal D-type predicted by cffDNA screening, immune anti-D status, gestation period, and requires coordination between several staff groups. Errors can occur at any stage of the process, from identification of the requirement for anti-D Ig or RAADP, ordering, prescription, laboratory release, storage and administration of anti-D Ig.

Deaths n=0

There were no deaths reported in the cases analysed for 2021 related to anti-D Ig errors.

Major morbidity n=0

No cases related to major morbidity were noted as a direct result of anti-D Ig errors. However, delays, omissions, under-dosing and failures to perform follow up testing after a 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. More information regarding the clinical outcomes resulting from failures in anti-D Ig and RAADP management can be seen in Chapter 25, Immune Anti-D in Pregnancy. The impact of anti-D Ig and RAADP errors should not be underestimated.

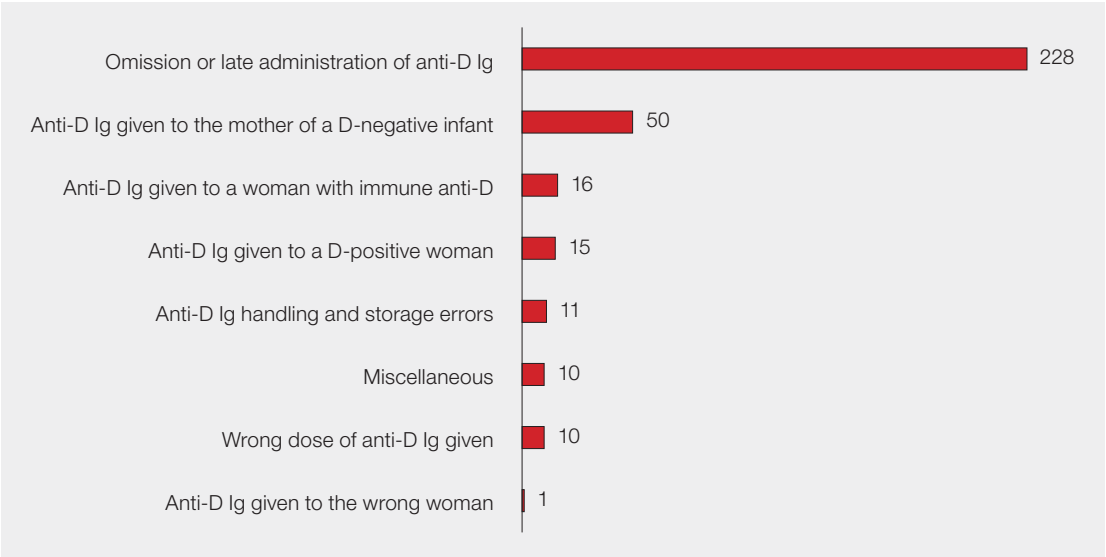
Overview of cases n=341

Omission or late administration of anti-D Ig or RAADP accounted for the majority of cases analysed 228/341 (66.9%), 98/228 cases (43.0%) were related to PSE, 74/228 (32.5%) to post-delivery, 55/228 (24.1%) involved RAADP, and in 1/228 (0.4%) case the reason for anti-D Ig was not recorded. Patient discharge prior to administration of anti-D Ig was implicated in 63/228 (27.6%) of these cases and

49/228 (21.5%) were a result of flawed decision making.

The distribution of the remaining anti-D Ig errors can be found in Figure 8.1.

Figure 8.1: Distribution of anti-D Ig related error reports in 2021 (n=341)



Note: Miscellaneous cases included 4 failures to complete follow up post FMH greater than 4mL, and 6 failures in sample taking or testing processes

Errors in the clinical setting accounted for 271/341 (79.5%) of cases and laboratory errors accounted for 70/341 (20.5%) cases. In 301 cases the stage of the process that the error originated was recorded, 254/301 (84.4%) of these noted the error at a single point and 47/301 (15.6%) noted errors at multiple points in the process.

Table 8.1: Location of clinical anti-D Ig errors n=271

Location	Number of reports	% of clinical reports
Delivery suite	70	25.8%
Community setting	33	12.2%
Out-patient department	25	9.2%
Antenatal clinic	23	8.5%
Maternity ward	21	7.8%
Emergency department	15	5.5%
Gynaecology ward	11	4.1%
Other	35	12.9%
Unknown	38	14.0%
Total	**271**	**100%**

A root cause analysis, or other equivalent formal investigation had been completed in 187/341 (54.8%) of cases, with 110/341 (32.3%) of reporters stating no investigation had been completed. This information was not available for 44 cases. Where information was provided regarding incident review by maternity governance, 141/341 (41.3%) reported that the cases were discussed, with 153/341 (44.9%) stating no discussion had taken place. Lack of formal investigations and no discussion of these cases at a governance level indicate missed opportunities for identification of the causes of errors and implementation of effective corrective and preventative actions.

The COVID-19 pandemic was implicated in 20 cases, 16 of these related to omission or late administration of anti-D Ig or RAADP. The impact of the pandemic on errors was varied and included mothers being unable to attend clinics because they had COVID-19 or were self-isolating, clinics being cancelled to reduce attendances, changes to patient mixes in wards, misunderstanding of changes to policies related to the use of anti-D Ig, cancellation of training and educational activities, staff re-deployment and early discharge of patients to reduce potential risk of exposure.

Case 8.1: Patient discharged before being given anti-D Ig

The patient had a PV bleed at 38+6 weeks gestation. She attended maternity triage the same evening and a sample was taken for a Kleihauer test. A standard dose of anti-D Ig was issued by the laboratory. Kleihauer tests are not routinely completed overnight at this hospital, a standard dose should be given with a follow up once Kleihauer result is available, if more anti-D Ig is required. However, the patient was sent home without the standard dose being given because the doctor was waiting for the Kleihauer result before giving any anti-D Ig. The midwife was asked to write the patients details in the follow up diary to be contacted the next day, which she did. Unfortunately, the midwife on duty the following day overlooked this in the diary. The patient was therefore not contacted. The anti-D Ig was found in the blood refrigerator during subsequent checks. The patient had not been given a date or time to attend for anti-D Ig administration by the discharging doctor, neither had she been contacted by the midwives. The anti-D Ig was administered but beyond the required 72-hour period.

A standard minimum dose of anti-D Ig should be administered before the patient is discharged from the hospital to ensure that it is given within the recommended 72-hours. FMH requiring additional doses, as indicated by laboratory testing, such as Kleihauer tests, is uncommon, and administration of anti-D Ig should not be delayed whilst waiting for test results.

Human factors

A review of the HFIT responses can be found in the supplementary information on the SHOT website (https://www.shotuk.org/shot-reports/report-summary-and-supplement-2021/).

Cell salvage and anti-D Ig n=2

There were 2 cases where incorrect doses of anti-D Ig were administered following the use of cell salvage, both resulting in under-dosing. In 1 case, the incorrect dose was selected by the biomedical scientist. In the 2nd case, the use of cell salvage was not communicated to the transfusion laboratory and a standard dose of 500IU was given.

Case 8.2: Failure to inform the transfusion laboratory of cell salvage reinfusion

A D-negative mother delivered by emergency caesarean section, and cell salvage was used during the procedure. The transfusion laboratory was not informed that cell salvage had been used for this patient. The patient received 515mL of salvaged blood and baby was D-positive so she should have been given 1500IU anti-D Ig. However, because the transfusion laboratory staff were unaware that cell salvage had been used only 500IU anti-D Ig was issued to the patient. This was discovered retrospectively by the transfusion practitioner after receiving the cell salvage data collection form.

Non-invasive prenatal testing n=52

Fetal D-typing using cffDNA screening is a highly accurate non-invasive method supporting the appropriate use of anti-D Ig and RAADP, reducing exposure to blood products for D-negative women carrying D-negative fetuses (NICE 2016). However, 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 results. Anti-D Ig should be given when results are inconclusive.

Fetal cffDNA screening for D should now be now considered standard practice. The service is provided by specialist laboratories in the UK, including the IBGRL and the Exeter Genomics Laboratory. Maternity services currently not offering cffDNA screening for D routinely should be actively working towards implementation.

It is important to investigate, and report results that are discrepant with cord D-type to the referral laboratory and to SHOT. NHSBT report that the false negative rate has remained below 0.1%. Between September 2019 to April 2021, the false predicted D-negative rate has remained at 0.06%. The reasons for incorrect results could be varied and have been covered in the NHSBT information sheet (NHSBT 2022). Fetal DNA in maternal plasma represents a very small fraction of the total DNA in plasma and

this increases during pregnancy. In some cases, the amount of fetal DNA may be too low to detect, especially in early pregnancy which can cause a false negative result. Errors in testing and wrong blood in tube could also lead to false negative results. False positive results may, on rare occasions, be caused by presence of genes which are not expressed on red cell surface (i.e., the phenotype does not reflect genotype). Some blood group genes are inactivated by mutations distinct from the blood group gene itself. Other causes of false positive results may be due to either extraneous contamination of the blood sample or extraneous contamination of testing reagents (despite existing precautions taken to prevent this), testing errors, WBIT or due to vanishing twin (Vanishing twin syndrome is the name given to a type of miscarriage that usually happens in early pregnancy with twins or triplets, when one embryo miscarries and the pregnancy continues. Vanishing twin is the term given to the baby that doesn't fully develop). Where a fetal D-positive result has been reported but the cord blood tests D-negative, this should be reported to the testing laboratory and SHOT. Investigations at the local level could include WBIT (mother or cord) and weak D (cord sample). Anti-D Ig prophylaxis should be given as appropriate. All cases of apparent false negative cffDNA results should be reported to the testing laboratory, along with blood samples from mother and baby. They should also be reported to SHOT. Reporting to the referral laboratory ensures that accurate data on the sensitivity and specificity of the screening assay is available and can be used in the informed consent process during antenatal care.

Errors related to cffDNA screening were identified in 52 cases (Table 8.2), 29/52 (55.8%) occurred in the laboratory and 23/52 (44.2%) in the clinical setting. In 37/52 (71.2%) anti-D Ig was administered unnecessarily to women carrying fetuses predicted to be D-negative.

Table 8.2: Errors in cffDNA screening n=52

SHOT reporting category	Cause of error	Number of cases	% of cffDNA errors
Anti-D Ig given to the mother of a D-negative infant	False positive cffDNA result	13	25.0%
	Failure to check the cffDNA result	20	38.5%
	Misinterpretation of cffDNA report	4	7.8%
Omission or late administration	False negative cffDNA result	5	9.6%
	Misinterpretation of cffDNA result	6	11.5%
	Failure to check the cffDNA result	2	3.8%
	cffDNA result from previous pregnancy used	2	3.8%
Total		**52**	**100%**

Case 8.3: Failure to review cffDNA results leads to unnecessary administration of anti-D Ig

The patient was admitted to the labour ward assessment unit following a PSE. The patient was D-negative and the fetus was predicted to be D-negative. An FMH test was carried out by the transfusion laboratory and no further anti-D Ig was recommended for the PSE. The cffDNA results were available to view on the electronic patient record but were not viewed the day of the event and 500IU anti-D Ig was given to the patient unnecessarily.

Near miss anti-D Ig cases n=15

There were 15 near miss cases analysed in 2021, errors were mainly prevented by robust pre-administration checks by clinical staff and infants fortuitously being D-negative.

Digital solutions to ensure patient safety

Previous Annual SHOT Reports have recommended review of procedures and processes as a means to improve practice. Whilst these recommendations are still applicable, compliance is inherently reliant on the knowledge, skills, experience and understanding of the individuals involved. Systems should be designed with consideration of human factors, including barriers to prevent unsafe practice based on the principles of the intervention hierarchy to truly improve practice. The advancement of digitalisation in healthcare has accelerated, particularly during the COVID-19 pandemic and in line with government strategies (DHSC 2018; Scottish Government 2018; Welsh Government 2021; Government of Ireland

2020), presenting opportunities to improve the management of anti-D Ig and RAADP by building functionality into clinical and laboratory IT systems that support good practice. IT has been proven to reduce risk of error and support good practice relating to the management of blood component transfusion (Murphy et al. 2019; Staples et al. 2020; Goodnough and Hollenhorst 2019), it is incumbent on IT providers to now develop their systems to support similar functionality for anti-D Ig and RAADP.

The SHOT SCRIPT user survey identified improved management of anti-D Ig as one of the top ten functions that laboratory users would like to see in the LIMS that it does not currently support. A follow up survey with LIMS suppliers noted a paucity of functionality within LIMS to support safe practice. SCRIPT have recommended that suppliers explore improvements in functionality in their LIMS to support safe release of anti-D Ig dependent on test results within the patient record. Transfusion service managers should work with the LIMS supplier to ensure that current functionality is utilised to its full potential. The SCRIPT survey results can be accessed on the SHOT website (https://www.shotuk.org/resources/current-resources/script/).

Electronic transmission of cffDNA results to hospital LIMS, using integration systems such as the NPEx would streamline this process, reducing risk of transcription errors and increasing visibility of results. The SCRIPT supplier survey identified that the majority of LIMS already supported interfacing via NPEx, with the remainder engaged in pursuing interoperability. This functionality should be explored and expedited by transfusion laboratory and referral laboratory service managers.

EPR systems provide opportunities for electronic clinical decision support, for the management of anti-D Ig and RAADP, using algorithms based on information within the patient record relating to pregnancy, D-status and cffDNA screening results. EPR providers should review the functionality within their systems that could be harnessed to support safe practice, working with subject matter experts to ensure this is used to its full potential. EPR and electronic blood-tracking systems should provide functionality that can be harnessed to support safe administration and traceability of anti-D Ig and RAADP.

Conclusions

Current IT systems may not have the functionality to provide robust electronic decision support, organisations should continue to ensure that systems, educational activities, processes and procedures support good practice in anti-D Ig management. When developing IT systems to support the management of anti-D Ig, human factors must be considered to reduce risk of workarounds and technology complacency. However, the age of digitalised healthcare has arrived and we must embrace the opportunities that this has provided for us to truly improve the future management of anti-D Ig and RAADP.

Recommended resources

Anti-D Immunoglobulin (Ig) Administration to avoid sensitisation in pregnancy - an aide memoire SHOT 2020
https://www.shotuk.org/resources/current-resources/

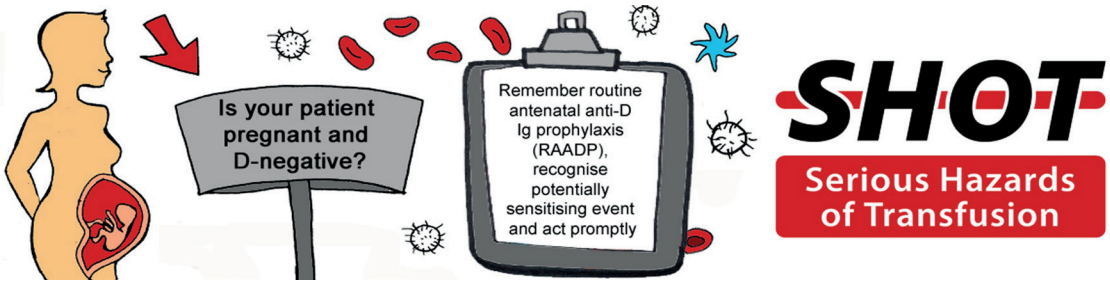
SHOT Bite No 2: Anti-D Ig Administration
https://www.shotuk.org/resources/current-resources/shot-bites/

SHOT Video: Anti-D Ig and Immune anti-D (part 1 and part 2)
https://www.shotuk.org/resources/current-resources/videos/

Blood assist app to cover anti-D following transfusion
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/)

cffDNA testing centres
Exeter Genomics Laboratory (https://www.exeterlaboratory.com/genetics/non-invasive-cell-free-fetal-rhesus-d-rhd-genotyping/)

IBGRL (NHSBT)
https://ibgrl.blood.co.uk/services/molecular-diagnostics/fetal-rhd-screen/



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Incorrect Blood Component Transfused (IBCT) n=266

9

Authors: Simon Carter-Graham and Nicola Swarbrick, Jennifer Davies 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
BMS	Biomedical scientist
BSH	British Society for Haematology
CAPA	Corrective and preventative action
CMV	Cytomegalovirus
DOB	Date of birth
ED	Emergency department
FFP	Fresh frozen plasma
Hb	Haemoglobin
HLA	Human leucocyte antigen
HSCT	Haemopoietic stem cell transplant
HSIB	Healthcare Safety Investigation Branch
IBCT	Incorrect blood component transfused
ID	Identification
IT	Information technology
LIMS	Laboratory information management system
MHP	Major haemorrhage protocol
NHS	National Health Service
NM	Near miss
PPE	Personal protective equipment
PPID	Positive patient identification
Sp-ICE	Specialist Services electronic reporting using Sunquest's Integrated Clinical Environment
SOP	Standard operating procedure
SRNM	Specific requirements not met
WCT	Wrong component transfused

Key SHOT messages

- All ABO-incompatible cases reported in 2021 were related to plasma components. No ABO-incompatible red cell transfusions were reported in 2021. Transfusion of ABO-incompatible red cells can be fatal
- Available LIMS functionality and algorithms should be used to their full potential to meet patients' specific requirements
- LIMS alerts should be relevant, understandable to the user, not easily overridden and actionable. These should be regularly reviewed and updated where appropriate
- Clear, timely and comprehensive communication between all teams and hospitals involved in patient care is vital to ensuring safe transfusions
- Reporting and investigating near miss error expediates early risk identification and provides valuable opportunities to improve transfusion safety
- SOP need to be simple, clear, concise and explain the rationale for each step. This will facilitate staff engagement and increase compliance
- Positive patient identification must be carried out prior to obtaining the pre-transfusion blood sample and before administering any blood component

Recommendations

- Incident investigations must be systematic and thorough, proportionate to the risk and impact, identifying systems-based corrective and preventative actions

Action: Risk management departments, governance groups, transfusion service managers, transfusion practitioners

- LIMS should be configured to support safe release of all blood components, including ABO/D compatibility, red cell antigen matching, irradiated, CMV-negative and other specific requirements

Action: Transfusion service managers, LIMS suppliers

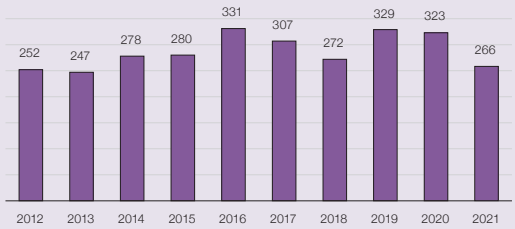
- Collection of blood components must include checks to ensure correct blood components are collected for the right patient. Electronic checking systems and smart refrigerators should be used to support safe practice

Action: Transfusion service managers, risk management departments, hospital transfusion teams

Headline data 2021

Number of reports n=266
Deaths n=0
Major morbidity n=3

IBCT reports by year



Demographic data

Male n=116
Female n=144
Unknown n=6

Adults n=226
Paediatric n=31
Unknown n=9

Blood component data

Red cells n=205
Platelets n=23
Plasma n=15
Multiple components n=19
Granulocytes n=3
Cryoprecipitate=1

Introduction

SHOT acknowledges the pressures clinical and laboratory staff have faced, and continue to face, during these challenging times as a new 'normal' begins to be realised. The Annual SHOT Report highlights areas where practices can be enhanced throughout the transfusion process to improve patient safety.

IBCT events have the potential to cause major morbidity or death and are often due to multiple errors in the transfusion process. These errors accounted for 266/3161 (8.4%) of all reports to SHOT in 2021 representing a decrease in both number and proportion of reports from 2020 (323/3214 (10.0%)). The total number of IBCT-WCT reports has slightly increased in 2021 (87 in 2020 to 93 in 2021), however there has been a substantial decrease in the number of IBCT-SRNM reports from 236 in 2020 to 173 in 2021. This decrease could partly be attributed to the decision at SHOT to stop creating duplicate reports for cases where more than one patient was affected (i.e., 1 report per patient), however, this only accounted for 29 additional SRNM reports in 2020.

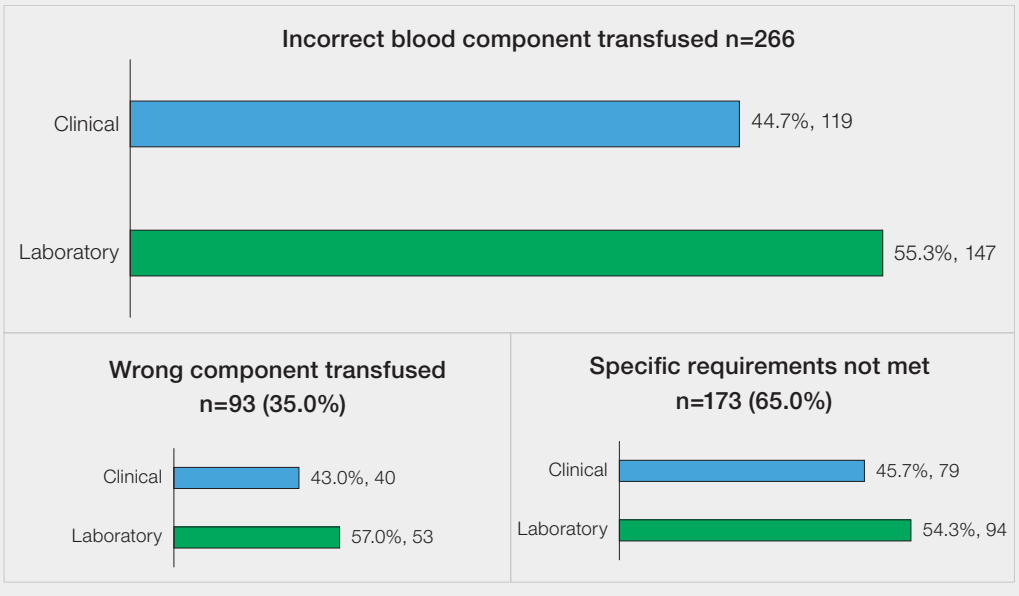
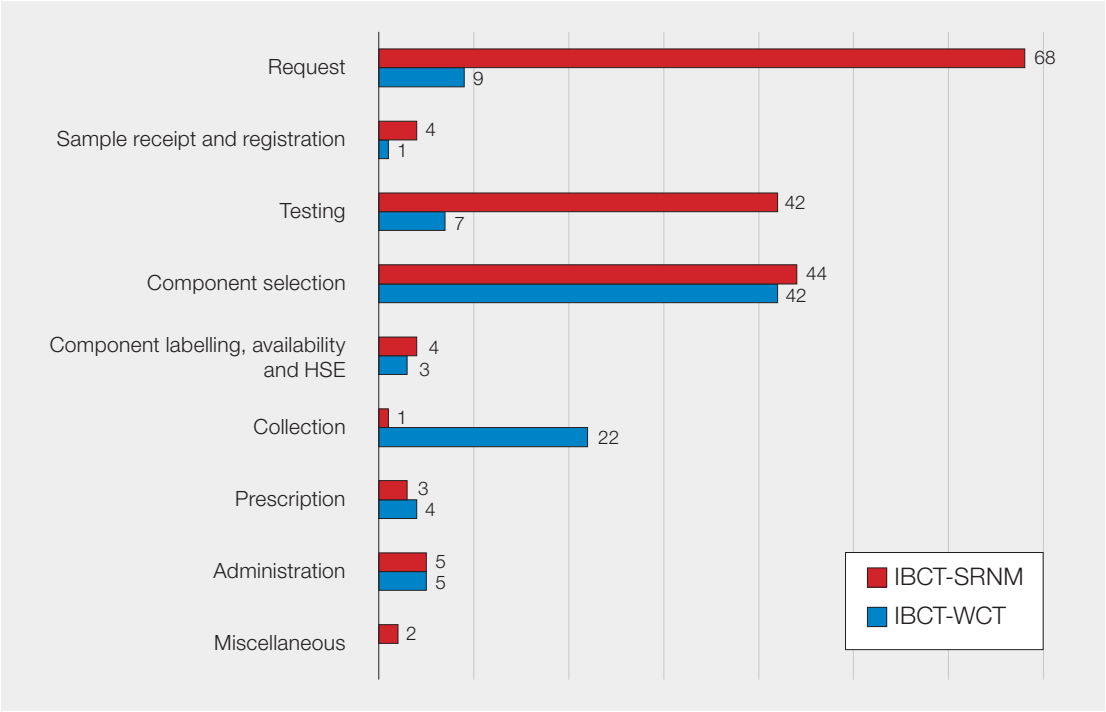


Figure 9.1: Overview of reports where an incorrect blood component was transfused in 2021 n=266

The majority of clinical errors occurred at the request step of the transfusion process with 77/119 (64.7%) reports followed by 23/119 (19.3%) at collection. There were 10/119 (8.4%) administration errors and 7/119 (5.9%) prescription errors.

In the laboratory the majority of errors occurred at the component selection, 86/147 (58.5%) and testing, 49/147 (33.3%) stages.

Figure 9.2: Total IBCT errors categorised by the step where the error occurred n=266



IBCT-WCT=incorrect blood component transfused-wrong component transfused; IBCT-SRNM=IBCT-specific requirements not met; HSE=handling and storage errors

Patient identification errors and omissions continue to be of concern. In the clinical IBCT-WCT errors reported, 6/40 (15.0%) events were caused by not properly identifying the patient. Patient misidentification in the transfusion laboratories have also been reported in 4 cases of IBCT-WCT and IBCT-SRNM each, all of these were mainly at the sample receipt and registration stage. In addition, there was one report where patient identification at testing was stated as the primary error. Accurate patient identification is fundamental to patient safety. One of the main SHOT recommendations in the 2019 Annual SHOT Report was that organisations must review all patient identification errors and establish the causes of patient misidentification (Narayan et al. 2020). Recognising gaps in existing processes, use of electronic systems, empowerment of patients and staff will reduce these errors.

Undertaking PPID must be done at each step of the transfusion process when at the patient's bedside. This should be done using the ID band attached to the patient and wherever possible the patient should be included in the process. In emergency situations the patient's ID band, containing the core identifiers, must be used to confirm PPID prior to administering the transfusion.

Not performing these checks at critical points such as pre-transfusion blood sampling or administration increases the risk of error and of an ABOi transfusion which could result in the death of the patient. Blood is a 'living transplant' and should be treated with the same attentiveness as the transplant of a solid organ, administration of controlled drugs or provision of chemotherapy.

When PPID is not performed properly it is crucial not to simply attribute fault to the staff member for the omission, but to investigate system factors allowing these errors to happen, for instance poor transfusion policies, inability to print an ID band in a timely manner, poor training and lack of staff or skill mix.

Deaths related to transfusion n=0

There were no deaths reported in the IBCT category related to transfusion error.

Major morbidity n=3

There were 3 cases of major morbidity, all resulting from errors originating in the laboratory where K-positive red cells were issued to women of childbearing potential who later developed anti-K.

There were a further 5 cases of K-positive red cells being transfused to this patient group, with 4/5 cases due to K-positive emergency red cells being issued in error. In all these cases there was a potential for sensitisation leading to major morbidity.

ABO-incompatible (ABOi) transfusions n=3

ABOi transfusions have the potential to cause severe clinical consequences including patient death.

In 2021 there were 3 ABOi transfusions all resulting from laboratory errors. There were no cases related to red cell transfusions in 2021, all 3 were to plasma transfusions. Table 9.1 provides an overview of each case as provided by the reporters and these are detailed further below.

Case 9.1: ABOi error related to convalescent plasma

A male in his 60s with a blood group of A D-positive was issued a unit of O D-positive CCP in error by the transfusion laboratory. The LIMS alerted the BMS to the ABO discrepancy, but this was overridden, and the unit issued. The nurse administering the CCP noted the ABO discrepancy but believed O plasma could be transfused to group A recipients. Within 17 minutes of the transfusion commencing the patient began complaining of loin pain and the transfusion was stopped and patient was medically reviewed. It was felt the loin pain was consistent with previous medical history and given pain relief. The pain settled and the transfusion was restarted. Following administration of the CCP unit the patient complained again of loin pain, and the ABO discrepancy was detected. The patient was monitored closely and fully recovered.

This case emphasises the role LIMS flags and alerts can play in preventing the issue of ABOi blood components, but that conversely excessive alerts can result in alert fatigue with the potential to lead to patient harm. The primary error occurred at the component selection stage, and efforts must be made to clearly differentiate stock based on blood group and component type.

Case 9.2: ABOi error due to misunderstanding of instructions on LIMS

A MHP was initiated for a male in his 40s following transfer from an outlying hospital where he had received group O D-negative emergency red cell units. Blood grouping results indicated a mixed field population of both O and A, and D-negative and D-positive red cells. The ABO/D group was entered into the LIMS as A D-positive, with a note in the patient record stating to crossmatch and issue group O D-positive components until the group could be confirmed by further samples. A request was made to the transfusion laboratory for FFP and group O FFP was selected and issued as per instructions. The patient received 3 units of ABOi FFP. There was no mention of clinical harm to this patient.

This case reiterates the importance of clear instructions for component selection and should have differentiated between red cells and other blood components.

Case 9.3: ABOi error due to miscommunication during handover

A telephone call was received in the transfusion laboratory requesting two units of cryoprecipitate for a male in his 40s. During the same telephone call two units of cryoprecipitate were also requested for another patient. Both patients were group A.

The telephone order was taken during handover between the day and night shifts. In an informal conversation between the two BMS staff the day shift BMS mentioned that there were only two units of group A cryoprecipitate remaining in stock and the night shift would need to order more group A or find out if another group (group O) would be a suitable substitute.

The night shift BMS misunderstood the day shift BMS and thought they had been instructed to issue group O to the second patient and proceeded to issue group O cryoprecipitate units to the patient.

The laboratory IT system warned the BMS that the units they were issuing were 'incompatible'. At this point the BMS acknowledged and overrode the warning to proceed with the product issue. No harm was detected in the patient.

This case enforces the importance of clear handover procedures, and the use of appropriate LIMS alerts which are not easily overridden and are appropriate to the task.

Commentary

These cases were all related to incorrect plasma component selection by the laboratory, of which 2 involved staff inappropriately overriding LIMS flags which should have acted as safety mechanisms to the prevent the issue of ABOi components. Each of the errors could have been prevented by robust pre-administration checks and better understanding of ABO compatibilities and substitutions for all staff involved in the transfusion process.

Previous SHOT recommendations (Bolton-Maggs et al. 2018) have outlined the importance of all staff in the transfusion process having awareness of ABO and D blood group compatibility principles in relation to red cells and plasma. The use of technologies such as the Blood Assist app, developed by the Patient Blood Management Team at NHS Blood and Transplant, can aid in supporting safe and appropriate blood component administration (see 'Recommended resources').

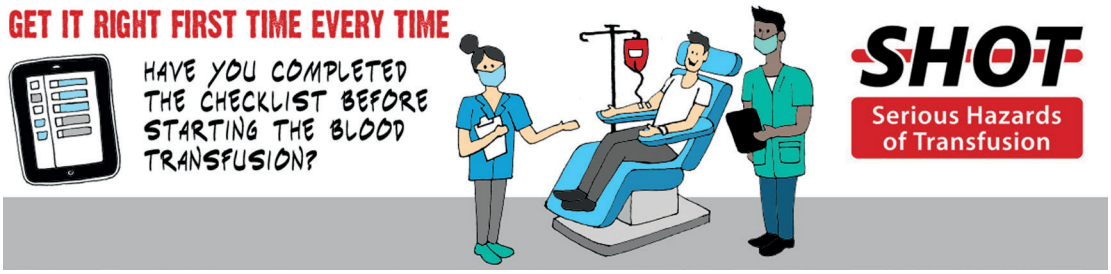
A recent HSIB national learning report on 'Never Events' highlighted the importance of reporting and investigating significant safety events by NHS organisations without apportioning blame or liability, using a recognised systems-based approach such as the Systems Engineering Initiative for Patient Safety (SEIPS) (HSIB 2021). In 2020, one of the ABOi cases reported to SHOT was worked through using the new SHOT human factors investigation tool (HFIT) (incorporating the Yorkshire Contributory Factors Framework) and SEIPS model to illustrate the benefits of applying human factors principles and systems thinking to incident investigations. Both these re-worked investigation reports can be accessed online (https://www.shotuk.org/shot-reports/report-summary-and-supplement-2020/).

There were 5 cases of NM ABOi which are discussed later in the chapter.

SHOT
Serious Hazards of Transfusion

	Case 9.1	Case 9.2	Case 9.3
Component transfused	CCP group O 	FFP group O 	Cryoprecipitate group O 
Patient group	Group A	Group A	Group A
Primary error	Component selection	Component selection	Component selection
Where did the error originate?	Laboratory	Laboratory	Laboratory
No. of units	1 unit	3 units	2 units
IT warning flags in place	Yes, overridden	Manual note in LIMS, not heeded	Yes, overridden
When was error detected	Within 20 min as patient complained of loin pain	By laboratory staff post transfusion	By laboratory staff post transfusion
Patient impact and outcome	Minor morbidity, patient recovered	No reaction	No reaction
Urgency	Emergency	Routine	Urgent
In hours/out-of-hours	08:00-20:00	08:00-20:00	20:00-24:00

Table 9.1: ABO-incompatible transfusions in 2021 n=3



ABOi transfusions involving plasma components

ABOi plasma reports received by SHOT from 2012 to 2021 were analysed to determine patient and plasma blood groups involved and the extent of patient harm.

A total of 29/88 (33.0%) ABOi errors involved plasma. In 26/29 (89.7%) group O plasma was transfused to non-group O patients. There were 9/29 (31.0%) events that occurred in paediatric patients. No ABOi plasma events directly caused major morbidity, haemolytic events, or death.

Plasma components (e.g., cryoprecipitate and CCP) should be compatible with the ABO group of the recipient to avoid potential haemolysis caused by donor anti-A or anti-B. ABO group identical FFP should be given whenever possible; if not possible, FFP of a different ABO group may be acceptable as per BSH guidelines (BSH Green et al. 2018). 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. Group AB plasma is haemolysin free and may be used if the patient's group is unknown but is in short supply and should only be used for non-AB recipients if absolutely essential. It is important to recognise that these decisions must be taken after considering the clinical indication, urgency of the transfusion request and availability of appropriate components. Only those instances where plasma components of the wrong ABO group were transfused inadvertently are reportable to SHOT.

Haemolysis after the transfusion of ABOi plasma is rare but is of particular risk to infants (JPAC 2013). A standardised titration method with an agreed definition of a safe low-titre component is likely to prevent the most severe haemolytic reactions. Guidelines for the Blood Transfusion Services in the UK recommend that 'there should be a procedure in place to collect and review testing and patient outcome data and to implement changes in policy in the light of continuing clinical experience with the plasma containing blood products issued'. The risk of haemolysis due to passively transfused anti-A and anti-B is small but present and should be considered in any situation in which relatively large volumes of incompatible plasma is transfused (including platelet components). It is important to recognise that, although testing for high-titre ABO antibodies in blood donors may reduce the risk of HTR in 'out of group transfusion', it cannot be eliminated through this route.

In two large retrospective studies of trauma patients, no differences in mortality were observed between those who received ABO-identical or compatible plasma versus those who received ABO-incompatible plasma (Seheult et al. 2020; Dunbar and Yazer 2017).

Clinical IBCT events n=119

There were 119 cases reported in 2021 which is a decrease from 149 in the 2020 Annual SHOT Report.

Clinical IBCT-WCT events n=40

This is a slight decrease in cases from 43 in the 2020 Annual SHOT Report.

The majority of WCT errors 22/40 (55.0%) occurred at the point of collection of the component from the storage area, where the wrong unit was selected for the patient. This step must only be carried out by a trained and competency-assessed healthcare worker but in 5/22 (22.7%) reports this was not the case. The staff member is required to take documentation containing the patient's core identifiers to the designated storage device. This must be checked against the laboratory-generated label attached to the blood component (BSH Robinson et al. 2018) before the component is transported to the clinical area. Details about how many of these collections were from storage devices with IT control was not available.

Whilst the primary error occurred at collection for these incidents, there were additional missed opportunities to detect and rectify the error prior to administration had the pre-administration checklist been applied or used correctly. There were 12/40 (30.0%) reports where a checklist had not been used. In 27/40 (67.5%) of cases the checklist had indeed been utilised but not properly, with all the relevant checks not being completed. In 1 report there was no information about the use of a checklist. A pre-administration checklist is vital in identifying errors before the component is transfused, this has been promoted by SHOT recommendations and the CAS alert: 'Safe Transfusion Practice: Use a bedside checklist' (Department of Health 2017).

Of the remaining cases 9/40 (22.5%) errors were made with the request, 5/40 (12.5%) at administration and 4/40 (10.0%) at prescription. The majority of WCT errors occurred between 08:00-20:00, 23/40 (57.5%). The urgency of the transfusion was classed as elective in 17/40 (42.5%) of reports, with 12/40 (30.0%) emergency and 11/40 (27.5%) urgent. There were 6/40 (15.0%) paediatric cases.

Learning points

- All staff involved in the transfusion process must be up to date with relevant transfusion theoretical training and be competent in whichever part of the process they are involved in
- On arrival in the clinical area, the blood component should be checked by the member of staff who requested the collection to ensure it is for the correct patient

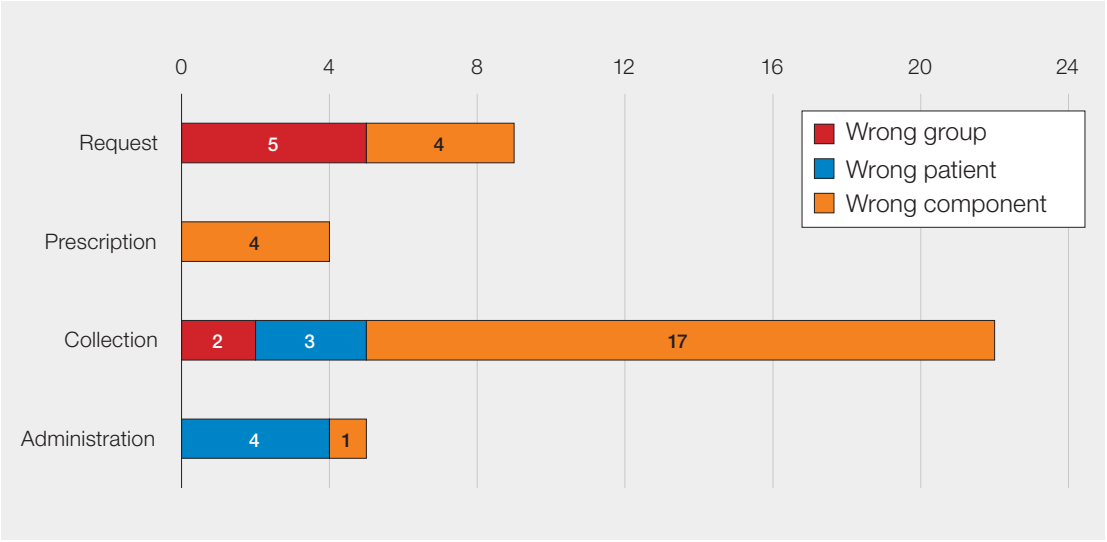


Figure 9.3: Categorisation of clinical IBCT-WCT errors by transfusion step where the primary error occurred (n=40)

Learning points

- Staff should ensure local processes are followed to ensure collection of the correct component from the laboratory or the satellite storage area
- All the final checks must be carried out by the patient's side immediately prior to administration using a pre-administration safety checklist
- While the use of an electronic blood transfusion system facilitates safe transfusion practice, clinical staff should avoid an over reliance on these systems when undertaking PPID and the final pre-administration check

Illustrative cases

Case 9.4: Patient given red cells instead of platelets

A male patient in his 60s with acute myeloid leukaemia, neutropenic sepsis and a low platelet count of 15x10^9/L was admitted to a medical ward. A platelet transfusion was prescribed. Nurse 1 went to the platelet agitator, but it was not operational at the time (nurse had not been informed of this), the patient had red blood cells in the issue refrigerator, so these were collected instead of the platelets. The nurse checked the unit with a colleague but not at the patient's bedside. Nurse 2 read the prescription and questioned if this was the correct component as she was concerned that it had been prescribed to be administered over 30 minutes. Nurse 1 sought the advice of the prescribing doctor (but did not show the doctor the unit of red cells) and was reassured platelets can be transfused over 30 minutes. The patient raised his concerns about what he was being given due to the colour of the component, but despite this, Nurse 1 started the transfusion without Nurse 2 present to complete the checks. Nurse 1 realised she had made an error after 10 minutes and the transfusion was stopped. There was no harm to the patient.

In this case the ward staff had not been informed that the platelet storage device was not operational, the nurse's transfusion training and competency-assessments were up to date, but there remained a lack of knowledge about platelet transfusion. They had never been asked to collect or administer platelets in the past and did know what they looked like. The nurse was unwell before starting the shift but came to work anyway as there were already staffing issues in the hospital. The final pre-administration checks were not carried out at the patient's side and the hospital did not use a pre-administration bedside checklist, which should have picked up the omission. It appears also that the patient's concerns were dismissed. There were multiple missed opportunities where the error could have been identified and multiple factors contributed to this error, including ineffective training and competency-assessment of staff, inappropriate supervision, and suboptimal pre-transfusion checks.

Learning points

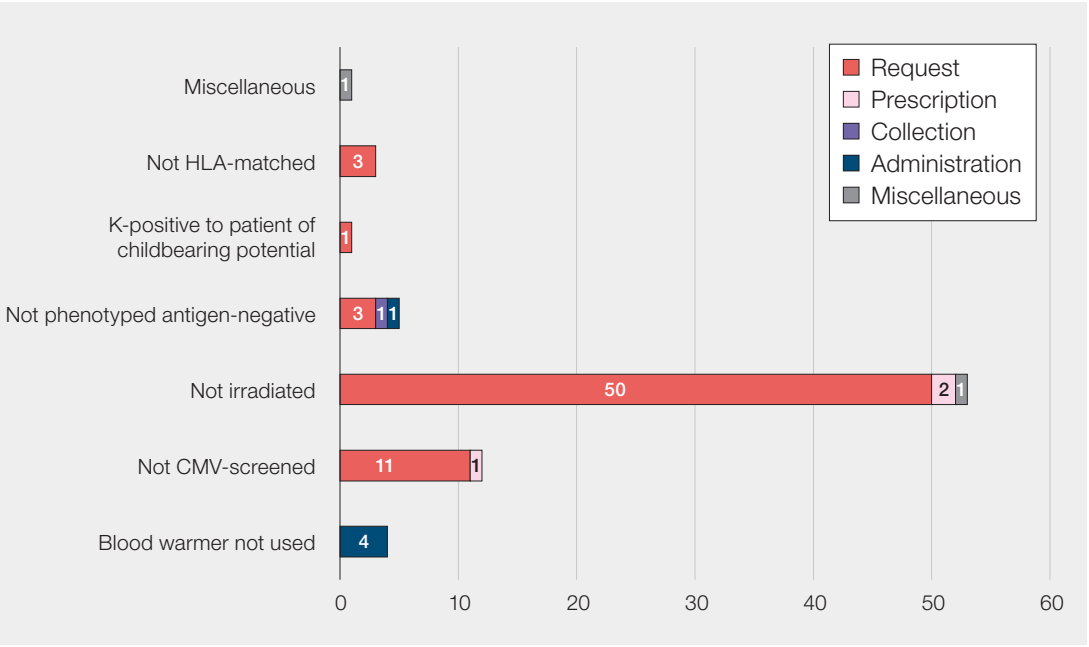
- Systems for collection of blood components should include fail safes which prevent collection of the wrong component
- A robust checking process at the administration step immediately prior to transfusion remains a critical step to support safe transfusion
- Training and competency-assessment for collection and administration must cover all blood components and ABO compatibility

Clinical SRNM events n=79

This is a marked reduction from the 106 events in the 2020 Annual SHOT Report.

The most common error in this category was failure to provide irradiated components 53/79 (67.1%), which has been the case for several years (Elliot et al. 2021). There has been a slight increase in the numbers of cases where the requirement for CMV-negative components was missed 12/79 (15.2%) compared to 9 reports in 2020. An incorrect phenotype was transfused in 5/79 (6.3%) of cases and there were 4/79 (5.1%) reports of a blood warmer not being used when required.

Figure 9.4: Clinical IBCT-SRNM errors and transfusion step where the primary error occurred (n=79)



HLA=human leucocyte antigen; CMV=cytomegalovirus

The most common point in the ten-step process where the error occurred was at the request stage 68/79 (86.1%). In 20/68 (29.4%) of these cases there was a communication failure between the clinical area and the laboratory where the clinical staff were aware of the need for the specific requirements but did not request them or where the transfusion laboratory was not informed of the requirement in a timely manner.

There were 53/79 (67.1%) cases where the requirement for irradiated components was missed and in 31/53 (58.5%) cases the patient had a previous diagnosis of Hodgkin's lymphoma which was either not on the patient's records or not communicated to the laboratory team. This is an increase from 21 cases in the 2020 Annual SHOT Report. Reasons for these omissions were the same as in previous years where there was a lack of knowledge of the requirement, poor communication through shared care and clinical electronic systems not being updated.

Errors occurred at administration in 5/79 (6.3%) cases. These included 4 instances of a blood warmer not being used and 1 case where the unit was not phenotyped as per patient requirement.

There are opportunities to detect omissions at several steps in the transfusion process, but only if staff complete their part of the process correctly. The use of an aide memoire for specific requirements on the reverse of written request forms, prescription forms, on electronic request systems or at the final pre-administration check may help reduce the numbers of SRNM reports (see 'Recommended resources').

Illustrative cases

Case 9.5: Non-irradiated component administered despite the patient highlighting the specific requirement to the administering nurse

A female patient in her 60s with acute myeloid leukaemia was admitted to a haematology ward for chemotherapy (purine analogue). As she had symptomatic anaemia, neutropenic sepsis and a Hb of 76g/L she was transfused two units of red cells and 1 unit of platelets. The units issued and transfused did not meet the specific requirements as they were not irradiated.

Fludarabine had been prescribed and issued from pharmacy without an irradiated components registration number, which should have been the correct process for ensuring a patient receives irradiated components if a transfusion is required. The transfusion laboratory was not informed that the patient required irradiated components and as there was no flag on the LIMS to alert the BMS to the irradiation requirements, standard units were issued.

The patient asked staff to check that the components had been irradiated but this was not acted upon. Nursing staff did not accurately complete the pre-transfusion checks when administering the transfusion and it was commenced. A pre-administration bedside checklist had been used ineffectively and it was recorded that specific requirements had been met when they hadn't. They had also failed to respond to alerts on the ward handover and the electronic prescription which highlighted the need for irradiated components. Staff had assumed that the components were irradiated but did not check.

The error was detected after the transfusion was complete and the patient had no clinical reaction.

Case 9.6: Requirement for irradiated red blood cells missed

A male patient in his 50s with non-Hodgkin's lymphoma in shared care was prescribed bendamustine. The transfusion laboratory in hospital 1 had been informed about the need for irradiated blood components. Patient attended hospital 2 where the transfusion laboratory was not aware of the specific transfusion requirement. Irradiated blood components were not requested appropriately on the transfusion request form and as the LIMS had not been updated with the irradiated blood requirement this was not flagged in the transfusion laboratory. Two units of non-irradiated red cells were issued. The nurses checking the first unit at the patient's side were unaware that irradiated red cells were required as it was not on the prescription, and the whole unit was transfused. It was only on checking the second unit by a junior member of the clinical team who had recently attended transfusion training, which had detailed specific requirements for patients treated with bendamustine, that the error was discovered. The second unit was not transfused and returned to the laboratory.

Learning points

- Where possible the patient should be asked if they are aware of any specific requirements at the time of giving consent for transfusion and during pre-administration checks
- Communication of specific requirements to the laboratory is key to provision of appropriate components
- The transfusion laboratory should ensure that the specialist blood product requirements are flagged on the laboratory IT system appropriately
- The need for specific requirements should be documented on the patient's prescription and if it is not clear, then the blood should not be given until the requirements of the patient have been established

Patients should be viewed as partners in their care. This promotes a proactive approach to safety with better communication skills, particularly regarding one's expectations and risk situations (potential and actual). It also reinforces the notion of shared responsibility. The recognition of patients and their relatives as full members of the care team facilitates them to identify any situation that may impact their safety. This approach helps develop a shared responsibility between patients and healthcare professionals which will complement vigilance that professionals may lack (due to blind spots, fatigue, or other unexpected circumstances) and avoid a blame culture.

Laboratory errors n=147

In 2021 there has been a slight decrease in reports of incorrect blood components transfused from 174 in 2020 to 147 in 2021. There has been a 20.5% increase in WCT from last year from 44 to 53. There has been a 27.7% reduction in SRNM events from last year from 130 to 94.

In 28/53 (52.8%) of WCT events, the error occurred outside of normal working hours, with 18/53 (34.0%) reports stating the error occurred when there was a lone worker. In 41/94 (43.6%) SRNM events the error occurred outside of normal working hours, with 29/94 (30.9%) of reports stating the error occurred when there was a lone worker. In proportion to the number of units issued during core working hours versus out-of-hours, it is clear that a disproportionally high proportion of IBCT events occur when there is a lone member of staff. Factors which may influence this include insufficient training and knowledge for lone working, distractions, multitasking, increased workload, and decision fatigue. Previous SHOT recommendations have detailed the need to examine current lone working conditions to reduce distraction where possible. Staff should not be allowed to work alone until they have passed a robust competency-assessment. Staff capacity planning should be regularly reviewed to ensure staff numbers and skill mix meet the demands of the service. Transfusion laboratories should have written protocols in place which define the responsibilities of all staff in dealing with urgent requests (BSH Milkins et al. 2013).

Laboratory IBCT-WCT events n=53

Table 9.2: Laboratory WCT errors in 2021

Error subcategory	Sample receipt and registration	Testing	Component selection	Component labelling, availability and handling and storage error
				
Number of error reports	**1**	**7**	**42**	**3**

Laboratory IBCT-WCT are discussed in more detail in Chapter 14, Laboratory Errors.

The majority of IBCT-WCT laboratory errors occurred during the component selection stage, 42/53

(79.2%). Most IBCT-WCT reports involved the issue of the component with the wrong ABO/D group (39/53), and issue of the wrong component type (9/53).

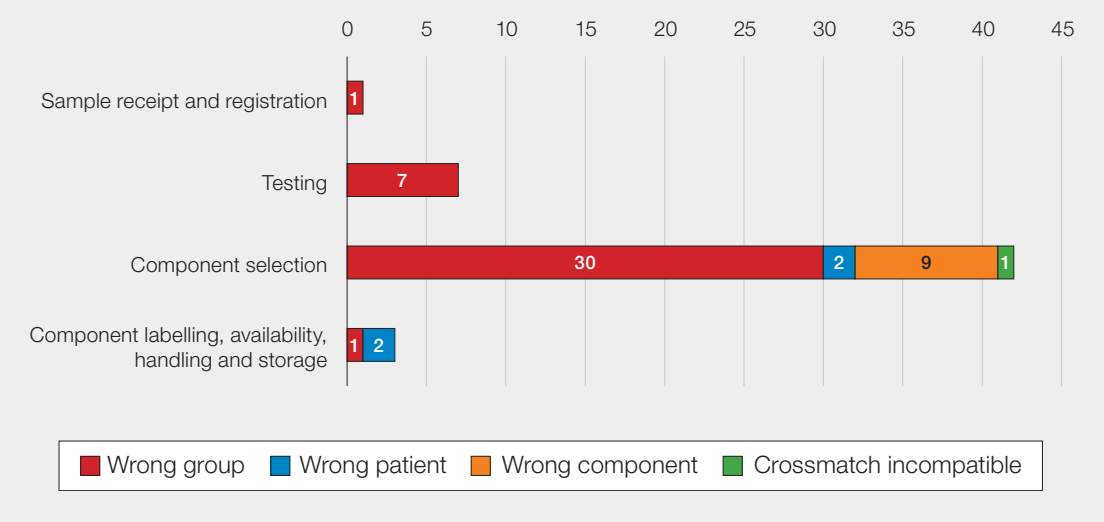


Figure 9.5: Laboratory WCT errors by transfusion step (n=53)

Cases of incorrect ABO/D group being transfused to solid organ and HSCT recipients persist. These are discussed further in Chapter 24, Transfusion Errors in Transplant Cases.

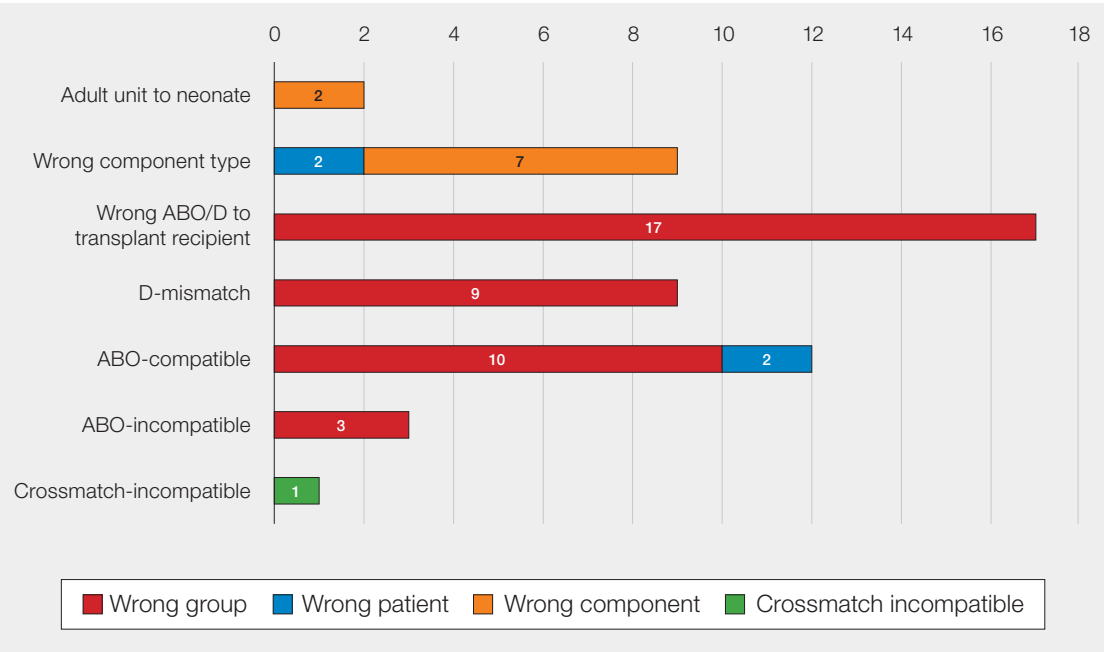


Figure 9.6: Laboratory WCT errors by category (n=53)

Poorly configured LIMS not reflecting current guidelines, or staff not heeding information readily available in LIMS can lead to patient harm. Component selection errors should be prevented at the point of selection. Staff selecting and collecting the blood components must be able to differentiate easily between the various component types from stock or issue refrigerators. Following transplant, patient's new requirements should be updated on the LIMS in a timely manner, which should include appropriate LIMS alerts that are not easily overridden.

Learning points

- LIMS should be kept up to date with the patient's blood group requirements, and clear instructions and algorithms to support selection of appropriate blood components
- LIMS alerts should be relevant, appropriate, and not easily overridden. Where overrides are required there should be a clear audit trail of the justification

Details about additional cases can be found in the supplementary information on the SHOT website (https://www.shotuk.org/shot-reports/report-summary-and-supplement-2021/).

Laboratory IBCT-SRNM events n=94

Table 9.3: Laboratory SRNM errors in 2021

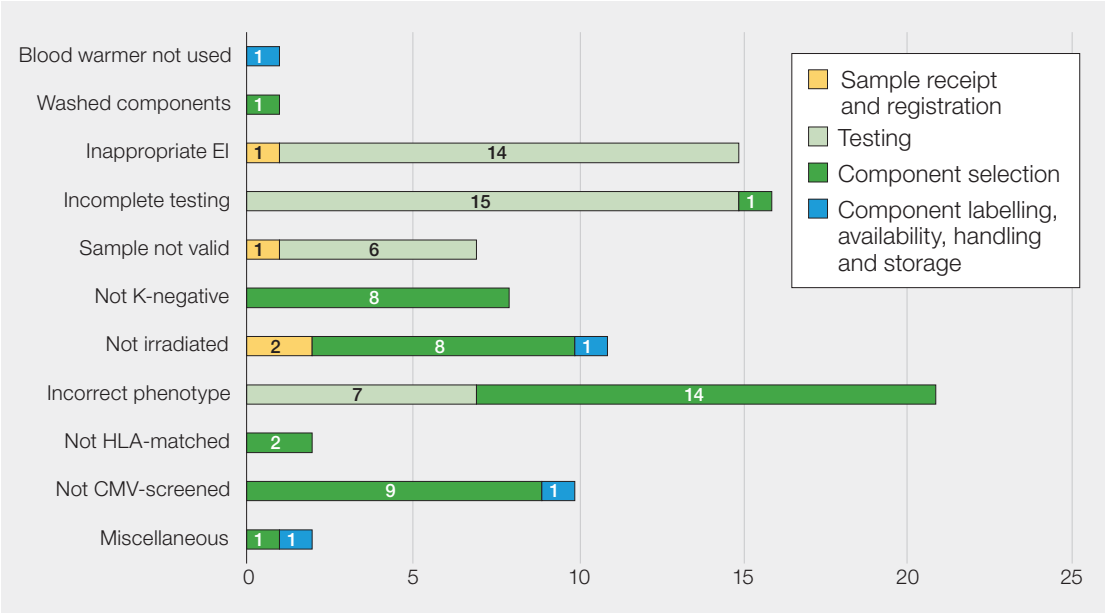
	Sample receipt and registration	Testing	Component selection	Component labelling availability and handling and storage
				
	4	42	44	4

Laboratory IBCT-SRNM are discussed in more detail in Chapter 14, Laboratory Errors.

Most laboratory errors related to SRNM occurred during component selection (44/94, 46.8%) or testing (42/94, 44.7%). Incomplete testing includes cases where blood has been transfused prior to resolution of serological testing (e.g., antibody identification not completed, analyser not within quality control or incorrect testing methodology used). Details of the laboratory SRNM errors can be found in Figure 9.7.

Of the 94 SRNM reports, 52/94 (55.3%) stated that staff had not followed the SOP correctly.

Figure 9.7: Laboratory errors resulting in SRNM (n=94)



Footnote: Where the blood warmer was not used, transfusion laboratory knew patient had cold agglutinins and would normally add a sticker to unit if warmer is needed. Clinical staff should have been informed before collection of unit as they would need to source warmer pre transfusion

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

Incidents have been grouped based on the specific requirement that has not been met

Case 9.7: Beta thalassaemia on request not investigated

A woman in her 60s attended the ED requiring a blood transfusion. The patient told ED staff they had beta thalassaemia and presented their antibody card from the Blood Service. The request received in the laboratory stated 'Beta thalassemia major, regular RBC transfusion and intra op femoral nailing', but the BMS did not investigate this further and two standard red cells were issued by two different members of staff over the following hours which did not meet extended phenotype and red

cell antibody requirements. A further blood request was received by a third BMS who determined that further investigation was needed. Sp-ICE was checked, which detailed presence of known antibodies and an extended phenotype.

All available clinical information must be used to inform specific transfusion requirements for patients. In this case further information had been provided by the clinical area and this should have prompted the BMS to investigate further and provide appropriate red cell units.

Case 9.8: Antigen-negative requirements missed due to cognitive bias

A woman in her 40s with known anti-e and anti-C requiring a blood transfusion due to multi organ failure received red cells not antigen-matched for known red cell antibodies. The BMS received a request for two red cell units for this patient, and upon seeing the patient's DOB and assumed that, as the patient was of childbearing potential, they should receive R1R1 (c-E-) red cells in accordance with local policy, rather than identifying that patient required R2R2 (C-e-) red cells due to presence of anti-C and anti-e red cell antibodies. LIMS warning flags were in place but were not heeded. C and e-positive red cell units were serologically crossmatched and issued. There was no clinical reaction in the patient following blood transfusion.

LIMS should be updated with antigen-negative requirements and algorithms and alerts should be built to alert staff where there is inappropriate blood component selection. In this case, while the LIMS flag was in place, it was not very clear and not robust enough to prompt appropriate action.

The BMS made assumptions based on the patient's date of birth rather than their specific requirements for antigen-negative units, which led to the selection and issue of inappropriate red cells. LIMS functionality should support safe decision making for component selection and specific requirements.

Learning points

- All essential testing should be resolved prior to issue of red cells. Further advice from senior colleagues should be sought if in doubt
- If the antibody identification is yet to be completed, then concessionary release should be considered to avoid transfusion delays
- LIMS functionality should support safe decision making for component selection and specific requirements

Near miss cases n=145 (87 clinical, 58 laboratory)

Definition:

A near miss event refers to any error which if undetected, could result in the determination of a wrong blood group or transfusion.

There was a total of 5 NM ABOi transfusions in 2021 which is a reduction from the 20 cases in the 2020 Annual SHOT Report. Of these 4/5 originated in the clinical area and 1/5 in the laboratory. All the clinical cases involved red blood cells. The errors were picked up by vigilant nurses carrying out their proper checks, two errors were detected at the final bedside check and one when the unit was checked on arrival to the ward with the porter. In the final case the transfusion practitioner was in the blood issue room at the time as she wanted to check the HCA's collection technique. She noticed that the paperwork the HCA was holding did not match the name on the unit and an error was avoided.

Clinical NM IBCT-WCT n=66

As in previous years the most common near miss in this category was at the collection stage of the process with 39/66 (59.1%) of reports. Of these errors 26/39 (66.7%) were identified by effective pre-administration checks and by check at arrival of the component in the clinical area in 7/39 (17.9%) of cases.

At the administration step of the transfusion process there were 21/66 (31.8%) errors. These were detected by an electronic tracking system in all but 1 case.

Clinical NM IBCT-SRNM n=21

There were 19/21 (90.5%) events where the patient could have potentially received non-irradiated components. The majority 15/21 (71.4%) of errors had been made at the request stage and 10/15 (66.7%) of these were detected by nurses during the final pre-administration checks.

As an example of excellent care, in 1 report an attentive nurse asked the patient as part of the pre-administration checks, if they had any specific requirements. This prompted the patient to produce a card which showed they needed to have irradiated components. The patient had forgotten, and this had not been discussed with them during the consent process.

Laboratory NM IBCT-WCT n=22

The most common laboratory IBCT-WCT NM errors occurred during component selection 14/22 (63.6%). Component selection NM errors included issue of D-mismatch components (7/14), incorrect ABO but compatible (2/14), and ABO requirements not met for post HSCT patients (5/14). Of these, 11/14 stated the error was IT-related, and 6 stated that LIMS alerts were either not heeded or were overridden.

Case 9.9: Post-HSCT issued incorrect ABO/D platelets

A male post-HSCT patient in his 60s who now grouped as O D-negative was issued B D-positive platelets by the BMS. The post-HSCT comments for this patient were on the 4th page of the LIMS record, and the BMS did not check all the available comments. The error was detected at the bedside.

Comments and notes for selection of appropriate ABO group for component transfusions for HSCT patients should be clear and succinct and supported by algorithms in the LIMS.

Case 9.10: D group incorrectly transcribed from LIMS onto request form

An ABO/D group was transcribed from the LIMS incorrectly onto the transfusion request form of a woman in her 50s by a BMS as B D-positive, but the patient was in fact B D-negative. The newly qualified BMS, who should have been under supervision, was rostered to work on a late shift due to extremely low staff levels. The BMS issued three red cells units, with the LIMS alerting to the incorrect D group, but alarms were overridden by the BMS. The error was detected during the pre-administration checks.

Laboratory NM IBCT-SRNM n=36

The most common laboratory IBCT-SRNM NM errors occurred during component selection (27/36, 75.0%), with 18/27 not meeting irradiation requirements, and 7/27 not meeting CMV requirements. There were 23/27 NM IBCT-SRNM errors detected during pre-administration checks, emphasising the importance of the pre-administration checklist (See Recommended resources).

Of these IBCT-SRNM events, 27/36 reports stated that the error was IT related with failure to update the LIMS (9/27) and failure to heed LIMS warnings (14/27) being most frequently stated.

Case 9.11: Red cells issued not meeting CMV or irradiation requirements (CMV local requirement)

A request form received in the laboratory for a child <10 years old stated a requirement of CMV-negative and irradiated components. The BMS did not update the LIMS with this information. At the point of issuing the red cell units the BMS thought they remembered this patient's specific requirements from earlier in the day and issued standard components. The report stated that the BMS was rushing to get work completed as they were lone working out-of-hours without a break in 6 hours with a high workload reported. The error was detected at the bedside.

Assumptions and rushing to complete tasks can result in errors.

COVID-19 pandemic

This year the pandemic was implicated in 9 clinical cases where errors were made. In each report issues such as staff shortages, working in unfamiliar areas, with new documentation, PPE and the use of radios for communication were identified. There were 4 COVID-19 positive patients who received incorrect or unsuitable components (2 non-irradiated, 1 non-CMV negative and 1 patient given FFP instead of platelets). In every case some of the above issues were implicated.

From the laboratory perspective COVID-19 was mentioned as a contributory factor in 9 cases and included: reduced staffing levels, additional pressures on remaining staff and staff recovering from COVID-19, pressures on ability to effectively train staff, redeployment of staff into unfamiliar areas and reorganisation of workspaces which all contributed to errors.

Conclusion

It is encouraging to see a reduction in the number of ABOi transfusions especially red cells reported this year. Important lessons can be learnt from errors made at all steps in the transfusion process, clinical and laboratory. If these are identified immediately prior to administration, they will prevent the most serious transfusion incident, unintentional transfusion of an ABO-incompatible blood component. This can lead to patient harm or even death. There continues to be strong evidence supporting a pre-administration patient-side checklist and/or electronic identification systems to improve identification of errors at the final step of the transfusion process. Checks should be embedded in each stage of the transfusion process to ensure that appropriate components are transfused.

Clear communication of specific requirements to the laboratory is essential in order to meet patient's requirements, and when received should be updated on LIMS with appropriate flags to alert laboratory staff to errors in selection.

Where information is available and not entered into the LIMS, or where information is available on the LIMS but not heeded, both have the potential to lead to patient harm. Laboratories should ensure they are using their LIMS functions to their full potential, in particular where algorithms for specific patient groups could significantly improve patient safety. Gender, age, specific clinical conditions and location should all be considered for LIMS algorithms and functionality.

Pre-administration checks detected 39/58 (67.2%) of NM laboratory IBCT errors, with 27/58 (46.6%) stating a formal bedside checklist was used to identify the error. In the clinical area pre-administration checks detected 55/88 (62.5%) of NM errors and a formal bedside checklist had been used in 42/88 (47.7%) of reports. This supports the importance of a robust pre-administration checking system to help detect errors. Such checklists can be an effective safety tool in clinical and laboratory settings. They strengthen compliance with guidelines, improve human factors and reduce the incidence of adverse events.

Factors contributing to transfusion errors have been repeatedly shown to be assumption, inattention, distraction, poor supervision, inexperience, high workload, inadequate staffing and staff fatigue – all commonly seen in high pressure clinical and laboratory environments. It is time to look at a full systems approach which utilises the resources available in a way that makes it more difficult to make errors and supports staff in the busy environments in which they work. Technology (better LIMS, electronic patient identification systems) must help to engineer solutions which compensate for human limitations, and the use of IT must be capable of reducing reliance on human interventions in making systems safer rather than adding to the burden. Finally, despite all the above measures, it is important to remember that patient care is ultimately delivered by humans who are having to work in increasingly complex and hurried environments. Care involves multiple team members, often across teams, working at a faster pace, with higher caseloads, and resource constraints. In most of the near-miss and safety events reported, several cognitive factors are contributory. Factors included attention channelled on a single issue, overconfidence or confirmation bias, inadequate vigilance, errors made based on inaccurate information, and distractions. For all safety critical steps, it is vital to make critical information more conspicuous, decreasing diversions of attention, and reducing the number of secondary tasks when staff are carrying out complex tasks. Hence, in addition to the measures described, the only satisfactory

improvement tool in some cases may be to allow our colleagues to slow down and do less, have more time to think and therefore be able to deliver high quality patient care. Patients and family members should be considered as partners in care supporting a pro-active approach to safety.

Recommended resources

A just culture guide:
https://www.england.nhs.uk/wp-content/uploads/2021/02/NHS_0932_JC_Poster_A3.pdf

Use of checklists: Can Checklists Prevent Human Error?
https://www.exida.com/Blog/can-checklists-prevent-human-error

SHOT Video: ABO-incompatible transfusion events: Insights learned from SHOT Reports 2010-2019
SHOT Video: Transfusion errors in haemopoietic stem cell transplant recipients
https://www.shotuk.org/resources/current-resources/videos/

Safe Transfusion Checklist
https://www.shotuk.org/resources/current-resources/

SHOT Bites No. 1a and 1b: Incident investigation
SHOT Bite No. 9: Component Compatibility
SHOT Bite No. 10: Why 2 Samples?
SHOT Bite No 12: Cognitive Bias
SHOT Bite No. 17: Near Miss
SHOT Bite No. 19: Human Factors
SHOT Bite No. 20: IBCT-SRNM
https://www.shotuk.org/resources/current-resources/shot-bites/

SHOT Webinar: Near Miss and Incident Investigation
SHOT Webinar: Laboratory and IT
SHOT Webinar: Human Factors
https://www.shotuk.org/resources/current-resources/webinars/

SHOT Safety Notice 02: Ensuring patient specific transfusion requirements are met
https://www.shotuk.org/resources/current-resources/safety-notices/

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/)

Good practice guidelines
https://www.edqm.eu/en/good-practice-guidelines-for-blood-establishments

CQC Learning from Never Events
https://www.cqc.org.uk/news/stories/learning-never-events

CAS alert – Safe transfusion practice: use a bedside checklist
https://www.cas.mhra.gov.uk/ViewandAcknowledgment/ViewAlert.aspx?AlertID=102663

HSIB National Learning Report: Never Events
https://www.hsib.org.uk/investigations-and-reports/never-events-analysis-of-hsibs-national-investigations/

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10 Handling and Storage Errors (HSE) n=244

Authors: Heather Clarke and Nicola Swarbrick

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	**MOH**	Massive obstetric haemorrhage
LIMS	Laboratory information management system	**NM**	Near miss

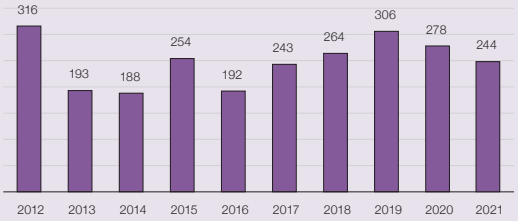
Key SHOT messages

- A detailed and robust process must be in place and followed for the use of infusion pumps, to ensure that the correct rate and time is set as prescribed for the transfusion. The process should include a second check of the pump set up before the transfusion is commenced
- Errors have been reported with staff choosing the wrong blood giving sets. These should be easily identifiable from other solution giving sets with distinct packaging to avoid incorrect selection
- Patient monitoring during transfusions is essential to prevent excessive time to transfuse errors and to avoid potential patient harm. Effective handovers between shifts will help ensure timely completion of transfusions. Blood transfusion training and competency-assessments of clinical staff should include awareness of potential impact of these errors

Headline data 2021

Number of reports n=244
Deaths n=0
Major morbidity n=0

HSE reports by year



Demographic data

Male n=108
Female n=119
Unknown n=17

Adults n=201
Paediatric n=15
Unknown n=28

Blood component data

Red cells n=204
Platelets n=21
Plasma n=10
Multiple components n=6
Other n=3
Unknown n=0

Introduction

There were 244 cases reported in 2021. HSE errors accounted for 278/3214 (8.6%) errors in 2020 (Narayan et al. 2021) and for 244/3161 (7.7%) in 2021. The reduction in the total number of HSE is multifactorial and could reflect a reduction in the number of transfusions during the COVID-19 pandemic during 2021 or under-reporting due to staff pressures. This could be also due to the decision to stop duplicating reports where multiple patients were affected. Clinical errors accounted for 190/244 (77.9%) and laboratory errors for 54/244 (22.1%). The distribution between clinical and laboratory errors are illustrated in Figure 10.1.

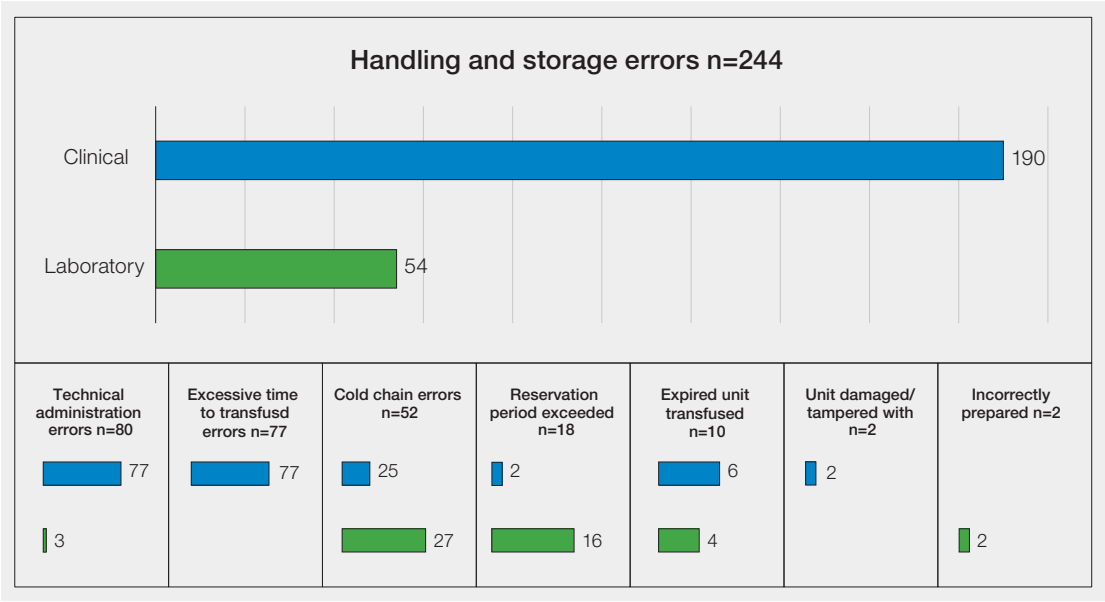


Figure 10.1: Breakdown of 2021 handling and storage error (HSE) reports (n=244)

3 cases were categorised as 'miscellaneous' (1 clinical error, 2 laboratory errors)

Deaths related to transfusion n=0

There were no deaths reported that related to errors associated with HSE in 2021.

Major morbidity n=0

There were no HSE cases reported in 2021 that resulted in major morbidity.

Clinical errors n=190

The number of clinical errors has seen a slight rise (2.7%) from the previous year (185 in 2020) and there has been an increase (16.7%) in technical administration errors (77/190 in 2021 from 66/185 in 2020) and also a slight decrease (4.9%) in excessive time to transfuse errors (77/190 and 81/185 in 2020). Technical administration errors have been further categorised below in Table 10.1.

Technical administration error	Number of cases
Administration pump error	42
Giving set error	26
Inappropriate rate	4
Same venous access used	1
Drug added	1
Miscellaneous	3
Total	**77**

Table 10.1: Clinical technical administration errors n=77

Of the 42 administration pump errors, 36 reported that the prescription was correct, but the pump had been set incorrectly.

Of the 26 giving set errors 23 were due to a blood giving set not being used. Inappropriate giving sets were reported to have been used and in 1 case, the set used was stated as having no filter.

Excessive time to transfuse errors mostly occurred during routine hours (08:00-20:00) 48/77 (62.3%) which is a slight decrease from last year. The majority of these were routine requests (34/48), however there were 7/48 incidents of urgent or emergency requests. Routine hours would normally see higher staff levels which should ensure increased patient monitoring, however staffing levels in the hospitals generally have been reduced across the board in 2021 due to COVID-19 sickness and self-isolation requirements. Yet again it has been reported that 34/77 cases (44.2%) had no incident investigation performed, with the most common reason given being that the error was not deemed serious enough to warrant an incident investigation. This lack of full investigation may explain why the problem is persisting and increasing. In 24/77 (31.2%) excessive time to transfuse incidents, cases were identified retrospectively during the traceability process or during routine audits and a further 18/77 (23.4%) were identified by laboratory staff. Only 31/77 (40.3%) of these incidents were reported by the clinical staff, which demonstrates a potential lack of awareness of the importance of not exceeding the permitted time to transfuse and the possible harm to patients among clinical staff.

There has been a slight decrease in incidents of expired units being transfused, but there were still 6 clinical incidents reported. It is imperative that clinical staff check the expiry date and time to make sure that the blood component can be completely transfused before expiry. Transfusion laboratories must make sure that the post-thaw expiry date and time for plasma components is clearly visible for clinical staff so that this can be adhered to.

Case 10.1: Cryoprecipitate transfused after the permitted 4 hours post-thaw expiry time

A request for two adult pools of cryoprecipitate was received in the laboratory at 10:35. The units were thawed and issued at 11:10 and were ready for collection with a post-thaw expiry time of 15:10. The first unit was collected at 15:01 and transfused at 15:25. The second unit was then attempted to be collected but was no longer available as it had expired and was subsequently wasted by the laboratory. On investigation the electronic blood-tracking system was active and permitted the removal of the unit as it had not expired at the time of collection, but staff involved failed to check the expiry time on the unit prior to commencing the transfusion.

Laboratory errors n=54

There has been a 40.0% decrease in the number of laboratory errors from the 2020 Annual SHOT Report, 54 errors in 2021 compared to 90 in 2020. There were 4 cases reported where the laboratory had issued blood components for transfusion that had expired and 3 of these involved the LIMS allowing the issuing of expired units or a unit with no expiry.

Case 10.2: Expired unit of emergency group O issued and transfused

A unit of red cells was requested by maternity theatres due to a MOH at 01:24. The porter came to the laboratory to collect a unit of red cells and the laboratory staff member on-call selected the first O D-negative unit from the stock refrigerator not noticing that the unit had expired at 23:59 the previous day.

On investigation, the laboratory had a relatively new LIMS and the on-call laboratory staff member was unfamiliar with issuing un-crossmatched units in an emergency. The incorrect procedure was performed and the expired red cell unit was issued. The incident investigation identified that the LIMS did not block the user from changing an expired unit's location to 'Flying Squad'.

Half of the laboratory HSE reports were related to cold chain errors, 27/54 (50.0%) reports in 2021. This has decreased considerably from 68/90 (75.6%) in 2020. The largest cause of cold chain errors identified was refrigerator/equipment failure 12/27 (44.4%) of which 9 involved temperature monitoring systems, followed by inappropriate return to stock 6/27 (22.2%), transport and delivery 5/27 (18.5%), inappropriate storage 3/27 (11.1%) and finally 1 incident of incomplete cold chain.

Learning points

- The LIMS must ensure that expired blood components are prevented from being issued
- When blood components expire whilst issued to a patient, the LIMS or electronic blood-tracking system should alert the laboratory staff so that they take appropriate actions. These include returning the units from the storage location and setting the expired components for wastage
- Laboratory temperature monitoring systems must have a detailed and robust process for alerting the appropriate staff, and staff acknowledging and actioning any alerts/alarms. Staff should respond to the issues with adequate corrective and preventative actions as necessary to ensure safe storage of blood components

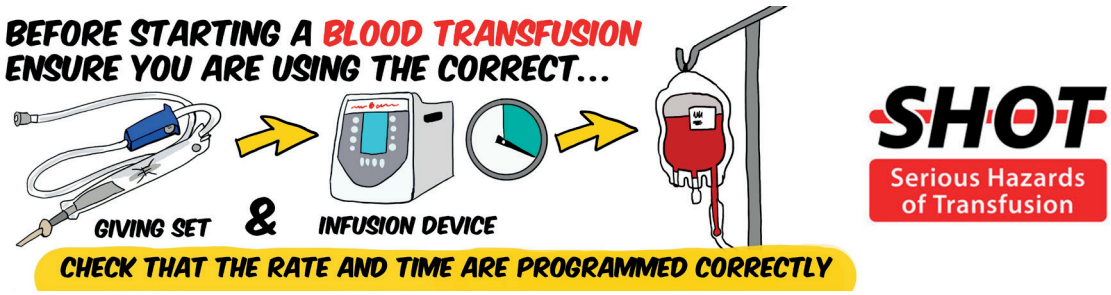
Near miss (NM) HSE cases n=140

There were 140 NM HSE cases which is an 8.5% increase in the number of cases reported in 2020 (n=129), 107/140 (76.4%) originated in the clinical area and 33/140 (23.6%) in the laboratory. The NM HSE cases primarily involved cold chain errors 101/140 (72.1%), which is an increase from 59/129 (45.7%) in 2020, followed by 17/140 (12.1%) cases of reservation period exceeded and 13/140 (9.3%) cases where expired units were almost transfused to patients. There is a much larger number of NM incorrect storage errors, 75/140 (53.6%) than actual errors, 10/244 (4.1%). As seen in 2020 this shows that there is a need for increased awareness among staff about correct component storage and actions to be taken if appropriate conditions are not met. Staff should be vigilant and return blood components to the transfusion laboratory when they are found outside of recommended conditions.

Conclusion

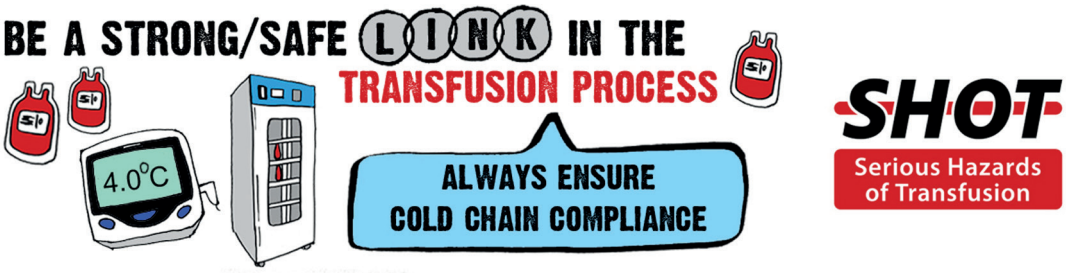
Collaboration and good communication between clinical and laboratory staff will ensure the safety of all the blood components that are transfused to patients. Laboratories can further ensure this by meticulous blood stock control ensuring that suitable components are supplied in a timely manner. Blood components which are no longer, or may soon be no longer appropriate for transfusion, are not available for clinical use. The need for further transfusion education around the appropriate rate and duration of transfusion is highlighted by this year's Annual SHOT Report. These errors are probably also due to reduced levels of staffing in the clinical area and potential impact on adequate patient monitoring.

The overall findings remain consistent with previous Annual SHOT Reports. 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 (BSH Robinson et al. 2018). By embedding these policies in working practice, safer patient care overall can be achieved.



Recommended resource

Patient Blood Management - Blood assist app provides information on appropriate giving sets, safe rates and duration of transfusion.
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/)



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Avoidable, Delayed or Under/ Overtransfusion (ADU) and Incidents Related to Prothrombin Complex Concentrate (PCC) n=347

11

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

Abbreviations used in this chapter

AAA	Abdominal aortic aneurysm
ADU	Avoidable, delayed or under/overtransfusion
AF	Atrial fibrillation
AML	Acute myeloid leukaemia
APML	Acute promyelocytic leukaemia
ATD	Adult therapeutic dose
BMS	Biomedical scientist
BP	Blood pressure
BSH	British Society for Haematology
CAS	Central alerting system
CT	Computed tomography
CVST	Cerebral venous sinus thrombosis
DIC	Disseminated intravascular coagulation
DOAC	Direct acting oral anticoagulant
EHP	Expert haematology panel
ERCP	Endoscopic retrograde cholangiopancreatography
ED	Emergency department
EVD	External ventricular drain
FBC	Full blood count
FFP	Fresh frozen plasma
GI	Gastrointestinal
GP	General practitioner
Hb	Haemoglobin
HSE	Handling and storage errors
ICH	Intracranial haemorrhage
ICU	Intensive care unit
ID	Identification
INR	International normalised ratio
IT	Information technology
ITP	Immune thrombocytopenia
IUT	Intrauterine transfusion
IV	Intravenous
LIMS	Laboratory information management system
MH	Major haemorrhage
MHP	Major haemorrhage protocol
MHRA	Medicines and Healthcare products Regulatory Agency
NCA	National comparative audit
NHS	National Health Service
PCC	Prothrombin complex concentrate
SOP	Standard operating procedure
TACO	Transfusion-associated circulatory overload
UK	United Kingdom
VITT	Vaccine induced thrombotic thrombocytopenia
VKA	Vitamin K antagonist

Key SHOT messages

- Delays in blood component transfusion and PCC administration are often multifactorial, including staffing issues, and impact on patient safety
- Avoidable transfusions could be reduced by improved management of haematinic deficiency
- Many men and women >50 years of age could receive emergency group O D-positive units rather than group O D-negative
- Avoidable errors continue to be made in paediatric prescribing and administration

Recommendations

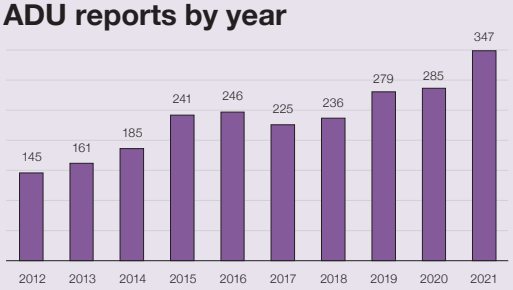
- Safe staffing levels must be ensured in hospitals both in clinical areas and transfusion laboratories and capacity plans must be reviewed regularly

Action: Hospital chief executive officers, medical directors, nursing directors, transfusion laboratory managers, pathology leads, hospital transfusion committees

Headline data 2021

Number of reports n=347
Deaths n=9
Major morbidity n=12

ADU reports by year



Demographic data

Male n=166
Female n=173
Unknown n=8

Adults n=296
Paediatric n=33
Unknown n=18

Blood component data

Red cells n=250
Platelets n=37
Plasma n=14
Multiple components n=22
PCC n=18
Granulocytes n=1
Cryoprecipitate n=1
Unknown n=4

Overview of ADU Cases

- Delayed transfusions n=179
- Avoidable transfusions n=116
- Under or overtransfusion n=34
- Incidents related to PCC n=18

Deaths related to transfusion n=9

There were 9 transfusion-related deaths, all due to delays. The imputability for all the deaths was 1: 'possibly related'. The cases are described in Chapter 11a, Delayed Transfusions.

Major morbidity n=12

There were 12 cases with major morbidity.

- Delays n=7
- Under transfusion n=2
- Over transfusion n=1
- PCC n=2

Near miss cases n=12

- Delayed transfusion n=1
- Avoidable transfusion n=4
- Under or overtransfusion n=6
- PCC n=1

Problems with MHP activations n=51

There were 51 cases with reported activation of the MHP (25 of these occurred out-of-hours)

- 28 delays (2 deaths possibly related)
- 17 avoidable use of O D-negative red cells
- 2 undertransfusion
- 4 overtransfusion

Human factors questions - impact of staffing issues

Human factors questions for reporters were modified for 2021. In answer to the question 'To what extent was there a mismatch between workload and staff provision around the time of the incident?' 91 reports noted this was 'fully', 'a lot' or 'some', and the majority, 56/91 (61.5%) impacted delayed transfusion, including 1 possibly related death (Table 11.1).

	Delays	Avoidable	Under or over	PCC
Fully n=9	7	0	1	1
A lot n=36	26	7	2	1
Some n=46	23	17	6	0
Total n=91	**56**	**24**	**9**	**2**

Table 11.1: To what extent was there a mismatch between workload and staff provision around the time of the incident?

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/

UKTLC: Capacity planning guidance May 2021
https://www.shotuk.org/resources/current-resources/uktlc/

11a Delayed Transfusions n=179

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

Definition:

Where a transfusion of a blood or blood component was clinically indicated but was not undertaken or was significantly delayed or non-availability of blood components led to a delay with impact on patient care (not restricted to emergency transfusion).

Key SHOT messages

- Errors have been reported at all steps in the transfusion pathway and delays in provision of transfusion support to patients are incremental along the patient journey including transfers between wards or hospitals
- Communication issues continue to contribute to delays at all points of the transfusion pathway
- Reports where major haemorrhage protocols were not activated or not followed appropriately continue to be reported
- Staffing issues with poor patient to staff ratios in the clinical areas contribute to delays in administration of blood components. Staffing challenges in the transfusion laboratories are also contributory
- Paediatric major haemorrhage is rare and staff are often unfamiliar with the necessary procedures

Recommendations

- All actions recommended in the SHOT CAS alert 2022 must be completed to address preventable transfusion delays and ensure patient safety
- MHP are activated following rapid identification of actual, or suspected, major haemorrhage, with or without traumatic coagulopathy. These must be acted upon promptly like any other resuscitation calls to ensure effective treatment is delivered without any delays to bleeding patients
- Equipment (bleeps, pagers, printers) must be checked on a regular basis to prevent them contributing to delays in emergencies
- Hospitals who care for children should have a paediatric major haemorrhage protocol and ensure the relevant paediatric clinical and laboratory staff receive appropriate education and training

Action: Hospital transfusion committees, all transfusion staff

Introduction

Delayed transfusions continue to cause concern and the number of reports increase year on year (Figure 11a.1). These concerns resulted in publication of a CAS national alert, 'Preventing transfusion delays in bleeding and critically anaemic patients', with actions for hospitals including review of their policies and procedures (SHOT 2022). These actions should result in a reduction in delayed transfusion. Although there was a shortage of blood sample tubes in 2021 no cases of delay were reported in relation to this

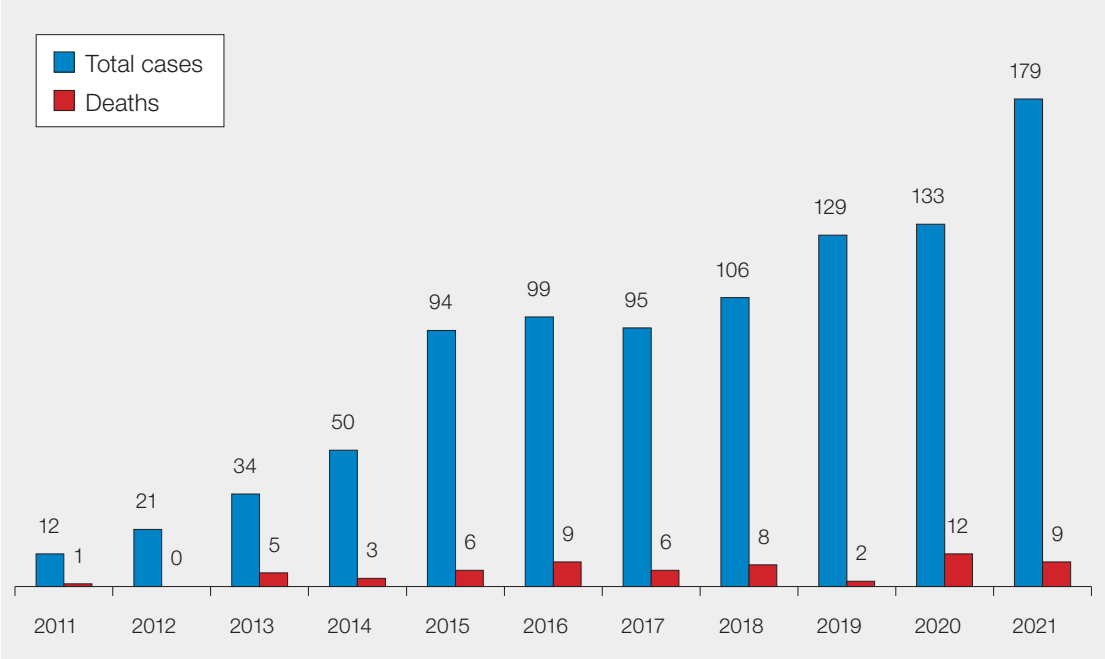


Figure 11a.1: Delayed transfusion reports and deaths by year 2011 to 2021 (n=952, deaths n=61)

Deaths related to transfusion n=9

Nine deaths were reported where the delay played a part, including 1 death in a premature infant with severe anaemia (Case 22.1 in Chapter 22, Paediatric Cases). Imputability in all these cases was 'possible'. There were 12 deaths reported in 2020.

Case 11a.1: Urgent need for blood during surgery - pager failure

Theatre staff needed blood during repair of an AAA for a man in his 80s but could not contact the BMS due to pager failure. The delay was 30 minutes and was thought to have contributed to the patient's death.

Major haemorrhage drills should include testing of communication channels and equipment. Clinical staff must be able to reach transfusion laboratory staff in case of emergencies.

Case 11a.2: Delayed transfusion contributes to death due to myocardial ischaemia

A man in his 80s with myocardial ischaemia and anaemia, Hb 63g/L, received a first unit of red cells but the second was delayed for 12 hours contributing to his death. There were several issues:

- *The request form had incorrect details so was rejected*
- *The revised request form could not be found when the porter came to collect the unit. The porter did not inform the clinical area of this*
- *A further collection form had to be sent*
- *All these factors and poor communication contributed to the delay. It is important that transfusion requests are completed accurately to avoid delays – 'Get it right first time every time'*

Case 11a.3: An unexpected death from sickle cell disease

A young man with sickle cell disease had a routine ERCP with removal of a biliary stent and went home. The next day he was admitted with fever and treated for biliary sepsis (Klebsiella was grown from the blood culture). His bilirubin remained high over the next 3 days and on day 5 he developed a sickle cell crisis with an acute chest syndrome. He rapidly deteriorated and was admitted to the intensive care unit. He developed multiple organ dysfunction and died. The review noted failure to act on the deteriorating condition in a timely manner (failure to escalate the deteriorating early warning scores) and failure to initiate prompt transfusion after recognition of deterioration. The patient was admitted to a general medical ward where staff were not familiar with sickle cell disease, and was

not managed by the haematology team directly. The coroners report suggested earlier transfusion should have been considered.

The above resulted in a recommendation from the All-Party Parliamentary Group on sickle cell and thalassaemia report (Sickle Cell Society 2021) 'No one's listening' that all NHS organisations must ensure that haematology teams are informed whenever a sickle cell patient accesses or is admitted to the hospital to ensure the patient's clinical history is known and advice can be passed on regarding their care. Staff managing the patient in this case were unfamiliar with sickle cell disease and failed to seek input from the haematology team regarding his management in a timely manner. There was no delay in the provision of blood once the haematology team were notified and a decision was made to proceed with an emergency automated red cell exchange. The APPG report includes several key recommendations that are critical to ensure safe and timely provision of care for sickle cell patients. One of the main recommendations is to ensure all healthcare professionals in the UK are trained and are familiar with management of patients with sickle cell disorder. Training should cover diagnosis, presentations, management, acute complications (such as pain, acute chest syndrome, stroke) and ongoing care and featuring direct contributions from sickle cell patients.

Learning point

- Care of patients with sickle cell disease is complex and specialised. Urgent referral to haematology locally and liaison with a specialist centre is recommended to optimise care (Sickle Cell Society 2018; BSH 2016; Trompeter et al. 2020; Sickle Cell Society 2021)

Case 11a.4: Confusion between two patients needing transfusion in the ED

Emergency red cell units were given to the wrong patient resulting in delay of blood to the intended patient and inappropriate use of emergency blood to the transfused patient. ED staff had not been able to talk to the BMS who was on the telephone about another transfusion issue. The intended recipient, Patient 1, a male in his 90s, had a Hb of 47g/L and died 15 hours after the initial request with the delayed transfusion cited as contributory. Two units of emergency blood were issued 10 minutes after the doctor requested them but were transfused to Patient 2, a woman in her 70s needing urgent surgery who had the major haemorrhage protocol activated in theatre later. Patient 1 received two units about 4.5 hours later, and two more 4 hours later. There were additional issues with unlabelled samples, wrong paperwork and training of porters.

Learning points

- Communication issues frequently contribute to delayed transfusions. It is important to be concise, clear, and provide all necessary patient identification information to the transfusion laboratory including urgency of transfusion
- Failure to label samples correctly, errors in safety checks pre transfusion, wrong paperwork, and poor training all contribute to delays. It is vital to get it right first time to avoid such delays

Additional case studies for deaths possibly related to transfusion can be found in the supplementary information on the SHOT website (https://www.shotuk.org/shot-reports/report-summary-and-supplement-2021/).

Major morbidity n=7

Seven patients suffered major morbidity related to the transfusion delays, 4 patients died due to other causes and 3 patients recovered (these were all associated with MHP activation and communication failures).

Case 11a.5: Delayed transfusion resulted from looking at the wrong result

A man in his 50s was admitted with difficulty breathing and had a Hb of 58g/L falling to 48g/L 2 days later. The MHP was activated, and he was transfused and required admission to the ICU which might have been avoided if he had been transfused in a timely way. The doctor had looked at the wrong Hb result on the computer (101g/L from a different date).

Case 11a.6: Slow provision of components due to lack of clear communication

A man in his 50s was admitted with upper GI bleeding. MHP was initiated but red cells did not arrive in the expected time frame from the laboratory (within 15 minutes). Emergency red cell units from a satellite refrigerator were transfused and a second MHP call was initiated in view of ongoing bleed and patient deterioration. It was identified that a lack of clarity about the urgency of the MHP call resulted in a delay in provision of the blood components.

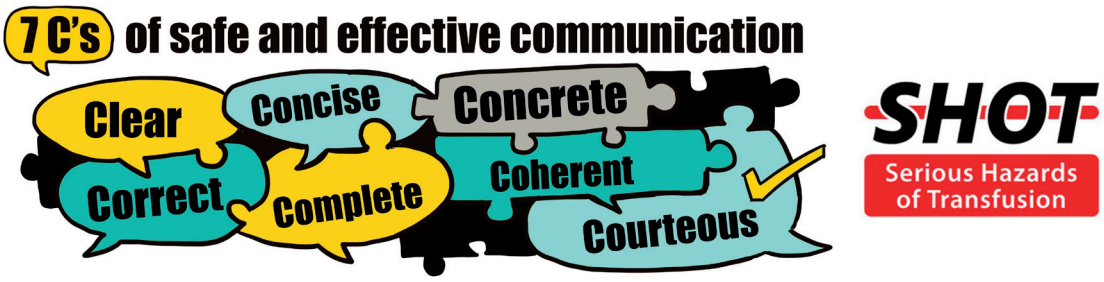
Case 11a.7: Patient struggled with breathing overnight due to delayed transfusion

A man in his 60s with cirrhosis suffered a peritoneal bleed with a Hb of 49g/L. Delay was caused by three factors: the first sample was unlabelled; a new antibody was present in the second sample (2 hours later) so was sent to the Blood Service out-of-hours for crossmatch. Although the blood was ready for transfusion by 02:00 it could not be transfused until 06:45 due to lack of ward staff. The patient struggled to breathe overnight.

Learning points

- Clinical staff at the site of a major haemorrhage alert should only have to telephone a single emergency number and have a standard script covering all essential information. Then the call can be cascaded from switchboard to other essential services. This will avoid staff dealing with the emergency being delayed by unnecessary calls
- Labelling errors must be avoided especially in emergency situations to avoid transfusion delays

A further case where the patient suffered major morbidity is discussed in Chapter 14, Laboratory Errors (Case 14.2).



Staffing and logistic issues resulting in delay

Case 11a.8: Delayed transfusion due to staff shortage (1)

A postnatal woman was seen by a doctor on a Sunday and was noted to have a Hb of 64g/L. She was symptomatic so a transfusion was requested. Blood was issued in the afternoon and confirmed by the transfusion laboratory. On review the following day the team were told that the blood was not given because the ward staff were too busy, and this was not escalated. Her Hb was now 55g/L and so further blood was requested and transfused.

Case 11a.9: Delayed transfusion due to staff shortage (2)

A woman being given palliative care had a Hb of 68g/L and a unit of red cells was requested. There was a delay of 5 days due to having staff shortages and avoiding transfusion overnight. The transfusion was eventually given with help from a neighbouring ward.

Learning point

- Staffing and workload issues have been reported as contributory factors to transfusion delays. Safe staffing levels appropriate to the workload must be in place so that necessary transfusions are not delayed. Contingency plans must be in place so that staff competent in providing transfusion support are available especially in case of emergencies

Case 11a.10: Delay in urgent transfusion caused by lack of labels in the remote refrigerator printer

A man with gastrointestinal bleeding came to theatre, shocked with hypotension and tachycardia and a Hb of 70g/L. He was eligible for electronic issue, but staff were unable to release blood from the electronically controlled refrigerator as there was no paper in the printer for the compatibility tags. Staff had to wait for the transfusion laboratory staff to come to theatre to put the labels in. During the first telephone call requesting help the staff were told the transfusion laboratory staff were in the middle of handover. The second telephone call was made by the anaesthetic consultant who said they needed someone to 'come now'. The label printer did not generate a local nor remote alert when empty and was designed to count a specified number of printed labels. It was supposed to send a remote alert when it reached a low threshold. Access to the printer was open to anyone, and is easily knocked, resulting in misalignment of the feed.

Case 11a.11: Incomplete testing results in delayed intrauterine transfusion

A severely anaemic fetus required intrauterine transfusion. A unit was requested on the basis of previous maternal antibodies (anti-c and anti-E) but the current sample displayed an additional antibody (anti-Jk^{a}) meaning the selected unit was incompatible. The hospital BMS had not completed the maternal antibody identification panels. A further unit had to be sourced from elsewhere in the country and there was a delay of 24 hours.

Case review identified that the hospital BMS required complete retraining in the manual section, was having difficulty understanding written English, and that there were staff shortages that were being addressed. The BMS has been successfully retrained and competency demonstrated. At the time of this incident the transfusion laboratory was on the hospital's risk register due to lack of staff in general and experienced staff in particular. They have continued to recruit and retain staff and are constantly reviewing and updating their training packages.

Lone working out-of-hours was identified in 4 reports as contributing to laboratory delays. One of these was a patient with sickle cell disease needing exchange transfusion for whom the wrong group had been ordered. They had to be admitted overnight.

Learning points

- Laboratory staff working in transfusion should be adequately trained and competency-assessed
- All lone workers should be adequately supported through their training and competency-assessment to ensure they are equipped with adequate skills and knowledge. Laboratory management have a responsibility to ensure all staff members are competent before exposing them to lone working

Delays associated with the Blood Services

Unavoidable delays

The presence of irregular antibodies may require samples to be sent to the Blood Service for investigation and crossmatch. Delays in provision of suitable blood components was noted for 14 cases. Patients with autoimmune haemolysis may have severe anaemia and require urgent transfusion, such as 1 case where the Hb was 34g/L so concessionary release was agreed for one red cell unit and two more became available from the Blood Service 5 hours later. Patients should not die from anaemia or bleeding.

Learning points

- Laboratory staff should liaise with clinicians and consider the urgency. The laboratory should have a policy for concessionary release of best matched red cells
- There should be clear communication between the hospital transfusion laboratory and the Blood Service about the urgency of request and any expected delays in provision to allow concessionary release

Avoidable delays

In 5 cases errors occurred at the Blood Service.

Case 11a.12: Red cells sent to the wrong hospital

An elderly man required transfusion to treat anaemia due to chemotherapy. The Blood Service used a taxi to send crossmatched and stock red cells but to the wrong hospital. A new crossmatch was arranged as the units would have been out of temperature control with another taxi transfer. The transfusion was delayed until the next day.

Case 11a.13: Miscommunication results in cancelled crossmatch and overnight admission of the patient

An elderly woman was found to have irregular antibodies. The sample was sent to the Blood Service laboratory for investigation on a morning transport run. Later the Blood Service laboratory was contacted both by telephone and email from the hospital to note that the patient required transfusion the following morning. Overnight the request was cancelled following discussion between the hospital BMS (who had not received a handover about this) and the Blood Service staff. This was a miscommunication. The patient had to be rebled and was admitted overnight. The email was found in the 'deleted' folder.

There were errors at both the hospital (handover not done and order not completed on the computer system) and the Blood Service laboratory (information poorly displayed or not accessible).

Case 11a.14: Hospital staff unable to contact the on call BMS at the Blood Service

The Blood Service laboratory could not be contacted on multiple occasions in the middle of the night when platelets were required urgently for an elderly patient with thrombocytopenia and haemoptysis. There was a 4-hour delay.

Investigation at the Blood Service identified that the hospital services telephone was diverted to the on-call colleague's work telephone which was out of order at the time. This was incorrect procedure as this was already known and the BMS had requested calls be diverted to their personal telephone, but the latest rota had not been updated with this information. This highlights the importance of having robust contingency plans for communication between clinical and laboratory staff in case of emergencies. Communication methods must be reliable with clear processes in place for escalation.

Additional case studies can be found in the supplementary information on the SHOT website (https://www.shotuk.org/shot-reports/report-summary-and-supplement-2021/)

Learning points

- Errors anywhere along the transfusion pathway including Blood Service errors can contribute to delays in transfusion
- Human factors also impact staff working in the Blood Services. Training in this should be provided and human factors/ergonomics should be used in system design to reduce the risk of errors

Delays associated with major haemorrhage n=28

See the supplementary information on the SHOT website (https://www.shotuk.org/shot-reports/report-summary-and-supplement-2021/) for details.

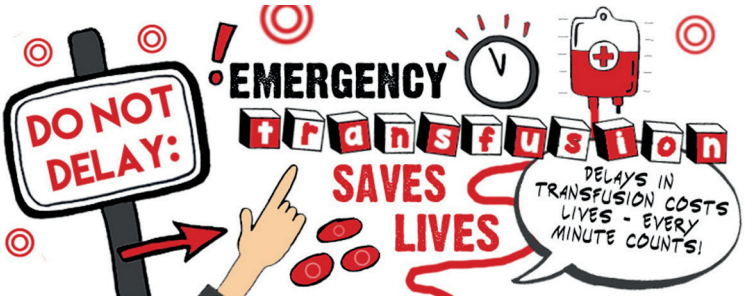
Near miss cases n=1

Case 11a.15: MHP activated for the wrong patient

Activation of the MHP for Patient 1 from the delivery suite was the incorrect patient. This should have been for Patient 2, so there was potential for delay in issuing the correct blood group for the patient in an emergency situation. However, this was recognised very quickly by clinical staff so did not result in significant delay.

Conclusion

The urgent provision of blood components and/or blood products is vital for life threatening bleeding and severe anaemia. Delays in provision and transfusion of blood components puts patients at risk and may contribute to death. Transfusion delays continue to be reported and multiple factors are usually contributory. Communication failures were identified in 48.0% of reports as a continuing problem leading to or compounding delay. Failures in team function contributed to some extent in 50.3%, and workload issues are also identified in a third of reports. Individual patient factors were much less likely to contribute. Staffing shortages are a widespread problem across the NHS and have been identified as a contributory factor in many cases of delayed transfusion reported in 2021. Urgent actions are needed to ensure safe staffing in clinical areas and laboratories and staff should escalate these issues to their managers and review their capacity plans. The recommended actions as per the SHOT CAS alert will help address preventable transfusion delays and improve patient safety. Patients should not die or suffer harm from avoidable delays in transfusion.



SHOT
Serious Hazards of Transfusion

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/

UK Transfusion Guidance in Response to the Shortage of Blood Collection Tubes
https://www.shotuk.org/resources/current-resources/

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11b Avoidable Transfusions n=116

Authors: Paula Bolton-Maggs, Catherine Booth 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.

Key SHOT messages

- For a patient with anaemia, unless there is haemodynamic instability, pause and investigate before transfusing. The definitive treatment will be correcting the underlying cause
- If a patient's results are unexpected or outwith expected trends, consider whether they fit the clinical picture. If not an emergency, repeat before acting on them
- Unless the patient is critically unstable due to bleeding, speak to the transfusion laboratory before accessing emergency group O red cells (or at least before removing multiple emergency units)
- Caution must be exercised when acting on Hb results from point-of-care machines. Ideally the result must be confirmed with a venous sample if time allows

Recommendations

- Avoidable transfusion in patients with haematinic deficiency puts them at risk of TACO. Clinical staff should be familiar with full blood count results that suggest deficiencies of iron (microcytosis), or B12 or folate (macrocytosis)
- Local transfusion training should include the indications for group O emergency red cells and how to check if group-specific or crossmatched units are available
- Laboratories should have a mechanism for alerting other pathology departments to erroneous results – a diluted sample withdrawn by biochemistry should trigger review of haematology samples taken at the same time

Action: Hospital transfusion teams, UK medical schools, transfusion laboratory managers

Introduction

There were 116 reports of avoidable transfusion compared to 110 in 2020.

Deaths related to transfusion n=0

There were no deaths reported related to avoidable transfusions.

Major morbidity n=0

There were no cases of major morbidity related to the transfusion.

Haematinic deficiency n=6

Six people were transfused for haematinic deficiency: 1 had B12 deficiency, the others had iron deficiency (4 female, 2 male). Two were found to be iron deficient preoperatively and this was not corrected resulting in the need for perioperative transfusion.

Case 11b.1: Avoidable transfusion for B12 deficiency

Two units of red cells were given to a patient with B12 and folate deficiency. His Hb was 39g/L with macrocytosis. He was referred by his GP with pancytopenia. He had symptomatic anaemia and a single unit transfusion would have been reasonable, but the administration of the second unit could have been avoided.

Pancytopenia is a characteristic feature of B12 or folate deficiency.

Case 11b.2: Avoidable transfusion for iron deficiency

A woman with symptomatic iron deficiency had a Hb of 27g/L. She was transfused three red cell units, and her post-transfusion Hb was 56g/L. She was stable with no overt bleeding or cardiovascular compromise, but she went on to receive two more red cell units. Iron replacement was not considered. The locum haematology consultant did not review the patient's latest Hb or iron results before authorising the extra two units.

Case 11b.3: Avoidable transfusion of group O D-negative emergency blood in an iron deficient patient

A man admitted to the ED with gastrointestinal bleeding was found to have a Hb of 49g/L, with a ferritin of 2micrograms/L. Four units of red cells were requested with no clinical details and urgency was also not indicated. The laboratory staff liaised with the haematology registrar who approved issue of one unit of red cells following discussions with the gastroenterologist. It was agreed that transfusion was appropriate to stabilise prior to endoscopy. In the meantime, the treating team had transfused emergency O D-negative red cells, but the laboratory staff were not updated. After two units the Hb was 68g/L. The first unit of group O blood was justifiable, but as a male, he could have received O D-positive red cells.

Learning points

- Haematinic deficiencies can be detected before severe anaemia develops and transfusions are indicated only in patients with haemodynamic instability
- All relevant clinical information must be provided to the transfusion laboratory to enable issue of appropriate blood components. The urgency of the transfusion must be stated clearly
- Hospitals need to review policies for use of emergency group O D-positive rather than D-negative for appropriate patients

The recently published NCA on medical use of blood found that 20% of patients receiving transfusion were found to have iron deficiency once investigation was complete (NCA 2022). This indicates that cases with avoidable transfusions for haematinic deficiency are significantly under-reported to SHOT contrary to published guidance (NICE 2015, Royal College of Pathologists 2019).

Errors due to verbal handover n=13

Four unnecessary transfusions were given as a result of incorrect verbal handover of treatment plans and in 3 of these there was no prescription for the transfused components. In another 5 patients a decision to transfuse was made based on incorrect results given verbally. Four patients were transfused based on handover of previous treatment plans, when subsequent medical reviews had identified that transfusion was no longer necessary.

Handover is a safety critical point in the working day. It is essential that accurate and timely information is communicated between members of staff to ensure continuity of care. This information should be documented in a standardised format where possible to ensure clarity and limit any interpretation errors. Structured, standardised communication methods overcome barriers and foster a safety culture. Change in shifts is a particularly risky time for such errors if staff taking over do not independently check the plan or relevant results.

Avoidable transfusion of group O D-negative units in patients with major haemorrhage n=17

Sixteen were due to clinical errors and 1 to laboratory error. In 15 cases the MHP was activated but in 2 it was not.

Crossmatched units were available for 8, and group-specific red cells could have been provided for another 2.

Communication issues were reported for 5/17 cases and in another none of the traceability paperwork was completed for any of the emergency blood including the prescription.

Case 11b.4: Confusion caused by duplicate hospital numbers

A woman in her 30s was admitted for elective surgery. The surgical team requested that blood be available but when they needed it, it was not ready because the BMS expected a second group sample (which was not necessary as she had a group record with another hospital number). The woman was bleeding heavily so the MHP was called and emergency group O D-negative was used. She was transfused three units of blood, four units of FFP and two pools of cryoprecipitate.

The reporting organisation had three sites; two sites use the same hospital number. This caused confusion for this patient who had more than one hospital number which was not noticed by the BMS.

The outcome from this case was to change the LIMS so that it linked patients by NHS number in the background so patients with two hospital numbers could be easily identified and blood issued.

Case 11b.5: Errors in procedure

An elderly man with neutropenic sepsis (myelodysplasia) was transferred from a ward to the coronary care unit. He developed hypotension and an initial Hb check done was 58g/L. The MHP was activated and although a repeat Hb was 73g/L he received two units of group O D-negative red cells based on the erroneous Hb result. O D-negative red cells were used despite the fact that crossmatched red cells were available. There were several errors noted in this case such as prescription errors, incomplete information on the traceability records with no patient ID information and acting on erroneous Hb results. The first Hb result may have been from a diluted sample.

Use of O D-positive units would have been appropriate n=13

Eight of these were male and 5 were females over 50 years of age who could have received group O D-positive units.

Avoidable transfusion of platelets n=17

These included 6 cases where the platelet count was above the threshold for platelet transfusion, 2 cases with spurious low counts due to clumping, another with a clot in the sample and 3 patients with immune thrombocytopenia. Others included platelets ordered for the wrong patient, platelets given the night before an invasive procedure by mistake, wrong blood in tube and cancelled surgery after platelets were transfused.

Learning points

- Thrombocytopenia is infrequently associated with bleeding and platelets should only be transfused according to guidelines (BSH Estcourt et al. 2017)
- Platelet transfusions are not indicated for ITP except in serious bleeding
- Clinical staff should be aware of platelet thresholds above which transfusion of platelets is not appropriate
- Unexpected low platelet counts should be repeated, and a blood film reviewed

Case 11b.6: Did the platelet transfusion contribute to thrombosis?

A patient with COVID-19 VITT and post thrombolysis intracranial haemorrhage with mass effect required an EVD. Platelet count originally was 16x10^9/L and increased to 46 after 2 ATD of platelets. Haematology advice to the ICU consultant and neurosurgeon was to proceed with EVD because

- *Platelet count of >80x10^9/L was not achievable*
- *The patient was unlikely to bleed given that he had VITT and was prothrombotic (i.e., thrombocytopenia would not translate into a higher risk of bleeding)*
- *There was a reasonable possibility that a platelet transfusion might cause thrombosis*

The neurosurgical registrar insisted on an additional ATD of platelets before surgery but was unwilling to wait for a check of the platelet count prior to theatre. The FBC was checked at 18:15 immediately after return to ICU from theatre. The platelet count was 33x10^9/L, with no increment following the third unit. The patient did not bleed. Subsequent postoperative head CT/CT venogram at 22:40 showed no worsening of bleed but there was a new CVST (not present on 01:34 scan), that subsequently progressed despite adequate anticoagulation. The patient recovered slowly and was discharged to another hospital.

The reporter wrote 'given the mechanism of VITT, there is a high probability that the platelet transfusion(s) directly contributed to the new CVST'.

Later review noted that:

- This is a new disease process and correct treatment remains unclear
- Current guidelines suggest platelet count >100x10^9/L is needed for neurosurgery (although this is contentious)
- It cannot be said with certainty that the additional platelet transfusion was the sole cause for sinus thrombosis in this patient

As a result, the incident has been downgraded from moderate harm. In addition, the ICU consultant noted that the right sided venous thrombosis is on the same side as the infarct and hydrocephalus with mass effect had occurred. It is reasonable to suggest that raised pressure probably affected venous flow and increased the risk of thrombosis from mechanical means (and prior to platelet transfusion) (i.e., thrombosis is multifactorial).

The patient was discharged to another hospital 3 weeks later and continued to suffer extensive and progressive arterial and venous thrombosis despite therapeutic anticoagulation with argatroban.

Commentary: VITT was first reported in 2021 (Greinacher et al. 2021, Pavord et al. 2021, Perry et al. 2021, Schultz et al. 2021). This case occurred in May 2021. This is a new condition and the guidance for management is evolving over time. Intravenous immunoglobulin and non-heparin anticoagulants are recommended (Scully et al. 2021). An expert haematology panel (EHP) was convened on 22 March 2021 meeting several times a week (Chevassut et al. 2021), collecting information from reported cases (Pavord et al. 2021) and giving advice on management. The EHP has a 'live' guidance document found here https://b-s-h.org.uk/media/20499/guidance-version-22-20210903.pdf. This notes that it is not

clear whether platelet transfusions should be given or not, and that they may be indicated to cover neurosurgery. There is also guidance from the intensive care society found here: https://www.ics.ac.uk/Society/COVID-19/PDFs/Management_VITT_Guidance.

This guidance is also unclear about platelet transfusion but states this: 'Platelets only for surgery or major bleed'. They suggest caution: 'There are theoretical reasons to try and avoid platelet transfusions in case they could exacerbate the pathological disease process, analogous to thrombotic thrombocytopenic purpura, however there is no evidence that giving platelets does actually cause any harm at this stage.' This is their conclusion: 'Note: It is unclear whether platelet transfusions will exacerbate the condition, the risk/benefit in supporting platelets <50x10^9/L on anticoagulation who a secondary cerebral bleed and not requiring procedure is unknown and therefore clear advice cannot be offered at the time of writing'.

All cases of suspected VITT should continue to be reported centrally so that more can be learned from study of as many cases as possible.

Case 11b.7: Inappropriate transfusion for immune thrombocytopenia

An elderly man with ITP on a background of chronic lymphocytic leukaemia received 50mL of platelets before transfusion was stopped as his platelet count was 1258x10^9/L. His previous count 2 weeks before was 13x10^9/L but he had been treated with eltrombopag. The plan was to review the count before proceeding with platelet transfusion but that was overruled by a doctor.

ITP is not treated with platelet transfusions unless there is serious bleeding (which is rare). Treatment guidelines recommend immune suppression and use of thrombopoietic mimetic agents such as eltrombopag (Thachil et al. 2018, Provan et al. 2019). This patient showed a very good response.

In 1 case, the patient received a platelet transfusion in error following a wrong blood in tube incident. This was investigated thoroughly and appropriate corrective and preventative actions were taken. This case has been described in the supplementary information on the SHOT website (https://www.shotuk.org/shot-reports/report-summary-and-supplement-2021/) as well as in Chapter 5, Acknowledging Continuing Excellence in Transfusion (ACE) acknowledging the thorough and effective incident investigation.

Learning points

- When a patient has thrombocytopenia, it is important to find out the cause before requesting a platelet transfusion, particularly to exclude a spurious result
- Some causes of thrombocytopenia are associated with thrombosis rather than bleeding, including VITT and thrombotic thrombocytopenic purpura (similar mechanisms)

Avoidable transfusion of plasma components n=8

In 4 cases, patients received plasma components although coagulation tests were normal with no bleeding. Two cases related to errors involving COVID-19 convalescent plasma (1 patient received CCP instead of FFP, and the other received CCP after recovery from COVID-19. This patient had initially been randomised to receive CCP which was delayed due to sample errors but was given CCP prior to discharge which was deemed unnecessary). One patient received cryoprecipitate after an erroneous low fibrinogen was recorded due to interference in the test by dabigatran (Kanda et al. 2021). In the final case the respiratory team wanted INR <1.5 to perform a pleural tap. The FFP was transfused after the procedure had taken place.

As with transfusions in iron deficiency, these cases will most likely represent the tip of the iceberg in relation to unnecessary plasma transfusions. In the recently published NCA of use of FFP in neonates and children, more than 75% of FFP transfusions given to neonates were to correct abnormal coagulation results, in the absence of bleeding or surgery (NCA 2021). This is contrary to BSH guidelines (BSH New et al. 2016).

Learning points

- Use of FFP in non-bleeding patients with normal coagulation tests must be avoided
- There is no evidence to support prophylactic use of FFP in non-bleeding patients with pre-procedural abnormal standard coagulation tests (BSH Green et al. 2018)

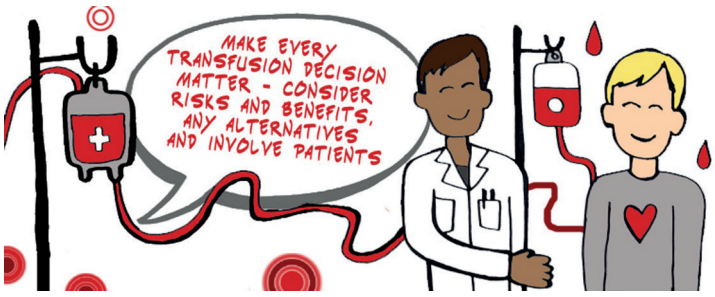
Near miss cases n=4

The 4 near miss cases are detailed in the supplementary information on the SHOT website (https://www.shotuk.org/shot-reports/report-summary-and-supplement-2021/).

Conclusion

Unnecessary or excessive transfusion continues to be reported in patients with haematinic deficiencies, suggesting a reactive response in transfusing to correct anaemia rather than investigating and treating the cause (BSH Fletcher et al. 2022). Errors continue to occur due to decisions based on inaccurate results from clotted or diluted samples, platelet clumping, wrong blood in tube or point-of-care machines. Unexpected results should be confirmed on a repeat sample unless the patient is unstable due to bleeding. Shift changeover is a particularly dangerous time for communication errors. Transfusions should not be prescribed or administered based on verbal handover alone without confirmation in the patient's notes and after review of any relevant results. Staffing pressures, working in unfamiliar areas or on call and multiple competing priorities contribute to this.

Group O units can be lifesaving in an emergency, but O D-negative should be preserved for women of childbearing potential and robust systems are needed to ensure a switch to group specific or crossmatched units as soon as these are available.



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Recommended resources

New e-learning resources:

Anaemia
Includes modules 'Anaemia - the only introduction you need', 'Anaemia in primary care patients' and 'Anaemia in hospital patients'
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/

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

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Under or Overtransfusion n=34

11c

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

Definition:

A dose/rate inappropriate for the patient's needs, excluding those cases which result in transfusion-associated circulatory overload (TACO). Infusion pump errors leading to under or over transfusion (if it did not lead to under/over transfusion then it is reportable under handling and storage errors (HSE).

Key SHOT messages

- Volume calculation for transfusions in paediatric patients continues to be a concern. Clinical staff involved in prescribing/authorising blood components for children must be familiar with calculating and prescribing correct doses
- Hb increment following transfusions should be checked and used to guide further transfusion support

Recommendations

- Hospitals should ensure their paediatric transfusion guidelines are updated to include calculations in g/L and not g/dL
- Staff who authorise paediatric transfusion should be trained so that they know how to calculate the correct dose of all components

Action: Hospital transfusion teams, Royal College of Paediatrics and Child Health

- Transfusion essentials must be included in the paediatric curriculum and staff should have access to regular and relevant updates. A close liaison with the hospital transfusion committee is vital to ensure that learning is optimised from reported events and trends

Action: Royal College of Paediatrics and Child Health, hospital paediatric clinical leads

Introduction

In this category with a total of 34 reports, 6 were under and 28 were overtransfusions. This is an increase compared with 2020 when 25 cases were reported. Errors in paediatric prescribing or administration resulted in 12 cases of overtransfusion in children.

The following themes emerged:

- Incorrect volume calculation in paediatrics
  - 2 cases where calculations using g/dL were used with Hb result in g/L, so volume was out by a factor of 10
  - Absence of appropriate checks: failure to notice when calculated volume exceeded adult therapeutic dose, and a 15kg child's weight mis-transcribed as 46kg

- Correct volume prescribed for paediatric patients, but complete unit administered
- Overtransfusion in sick/bleeding patients who are hypotensive where other causes for low BP were not considered and no interim Hb checks made

Deaths related to transfusion n=0

There were no deaths reported relating to under or overtransfusion in 2021.

Major morbidity n=3

Case 11c.1: Overtransfusion for GI bleeding

A woman in her 60s, weight 46kg, died following a GI bleed from a duodenal ulcer. Four units of red cells were requested because of a falling Hb (113 to 88g/L over 5 hours). After three units had been transfused over a 3-hour period her Hb was 203g/L. The overtransfusion did not contribute to the patient death.

Staff were not expecting this degree of Hb increment from three units of red cells with a baseline Hb of 88g/L but perhaps the low body weight had not been taken into consideration.

Case 11c.2: Unexpected bleeding during elective surgery

The patient suffered a major haemorrhage due to bleeding from an unidentified source during an elective laparoscopic inguinal hernia repair. The MHP was called 7 hours after the start of surgery. After about 11 hours in theatre the wound was packed, and the patient was transferred to the ICU. The bleeding could not be stopped and the patient died. This was a complex case where slow, insidious bleeding gradually worsened into a state of cardiovascular collapse due to major haemorrhage and DIC.

This was reported as undertransfusion because it was thought that this patient with active bleeding and worsening clinical status received fewer units of FFP (four units) and platelets (one ATD) than indicated for major bleeding (total 17 units of red cells) with evidence of DIC. This relative undertransfusion did not contribute to death.

Case 11c.3: Concealed blood loss after caesarean section

A woman underwent caesarean section and lost 1.3L of blood during the surgery which appeared to have been successfully managed with surgical techniques and two units of red cells. However, 8-9 hours after the delivery, she became very unwell and was taken back to theatre with suspected internal bleeding. A large amount of blood was found in her abdomen, and it was difficult to stop the bleeding and repair its source. She required a hysterectomy. The MHP was activated, and several components transfused. The patient lost 7.3L of blood in total and was transferred to the ICU for ongoing monitoring.

Undertransfusion in this case was due to delay in staff not recognising the extent of the internal bleeding following surgery. The patient had also improved partially following the initial top up transfusion which falsely reassured the treating team.

Paediatric cases

As in previous years errors in prescribing were notable and recorded in 9/12 overtransfusions. In the other 3 cases administration errors resulted in transfusion of more than had been prescribed.

Two children with malignant disease died but this was not related to the transfusion errors.

In 2 cases the wrong formula was used resulting in 10-fold error (calculated in g/dL rather than g/L). Hb has been measured in g/L rather than g/dL for several years. Calculations are available in the paediatric transfusion guidelines (BSH New et al. 2016).

All were transfusions of red cells except 1 infant who received an excess of platelets.

Learning point

- Prescribing errors for blood components in children are common. Hospitals should review their paediatric transfusion guidelines and ensure they contain updated units and calculations

Additional paediatric cases of overtransfusion have been covered in detail in Chapter 22, Paediatric Cases, as well as in the supplementary information on the SHOT website (https://www.shotuk.org/shot-reports/report-summary-and-supplement-2021/).

Under or overtransfusion in relation to major haemorrhage n=6

There were 6 cases, 4 of overtransfusion including 2 cases of haemorrhage during surgery for abdominal aortic aneurysm. An obstetric case is discussed above.

In another case with intra-abdominal bleeding following percutaneous coronary intervention there was extreme haemodynamic instability with multiple peri-arrest episodes intraoperatively which necessitated massive transfusion. Multiple (14) red cell units were transfused but relatively fewer plasma and platelet components (four FFP, two platelets). On reflection of the MH incident and in retrospect it seems that a different combination of volume resuscitation may have been more appropriate therefore limiting the number of red cell units given. The patient made a full recovery and was discharged 3 days later. Undertransfusion was reported in the surgical case described above (Case 11c.2).

In a further case the MHP was activated in the absence of any bleeding. The woman in her 60s had known history of anaemia and on admission to the ED was unwell with a reduced level of consciousness and had very low Hb (26g/L). However, eight units of emergency O D-negative red cells were prescribed by a consultant and transfused within an hour, and she received four units of FFP. CT confirmed no active bleeding. The post-transfusion Hb was 139g/L. This was also avoidable use of group O D-negative units. With such a low Hb in an unwell patient, a more controlled red cell transfusion was appropriate with one or two units sufficient to bring Hb to acceptable levels.

Learning points

- Blood loss may be difficult to estimate during major haemorrhage especially in covert bleeding
- It is helpful to obtain regular measurements of Hb to guide transfusion support to help avoid under and overtransfusion
- Blood gas analysers may be used for this if they are quality assured for this purpose and the sample is handled correctly

Near miss cases n=6

Case 11c.4: Misreading the blood count results

A prescriber erroneously interpreted a patient's platelet count as his Hb (the last three results were 89, 68 and 66) so booked him into for a two-unit red cell transfusion the same day. Blood was taken for a repeat blood count, film and a crossmatch sample was also taken. An IV cannula was inserted, and he waited for his transfusion. The blood was placed in the blood refrigerator on the ward. A nurse asked why the patient was having a blood transfusion when his Hb was 141g/L which was when the prescriber realised their error. The patient did not receive any blood.

Five other cases are described in the supplementary information on the SHOT website (https://www.shotuk.org/shot-reports/report-summary-and-supplement-2021/).

Conclusion

Paediatric cases continue to be overrepresented in this category with calculation or administration errors resulting in overtransfusion. Measures are needed to improve transfusion safety in children and neonates. This is a role for paediatricians as well as the hospital transfusion team.

Blood loss in major haemorrhage in adults can be difficult to assess. Regular monitoring of blood parameters is recommended and should be performed. Blood gas analysers may be used for this as long as they are quality assured for this purpose and the sample is handled correctly.

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Recommended resources

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

Key information from the BSH paediatric guidelines
https://www.shotuk.org/resources/current-resources/paediatric/

Reference

BSH New HV, Berryman J, Bolton-Maggs PHB, et al. Guidelines on transfusion for fetuses, neonates and older children. *Br J Haematol.* 2016;**175(5)**:784-828.

Incidents Related to Prothrombin Complex Concentrate (PCC) n=18

11d

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)

Key SHOT messages

- PCC administration is an emergency treatment used for reversal of oral anticoagulants (warfarin and DOAC) and should be started within an hour of the decision being made before the patient is transferred to other wards or departments
- PCC does not affect heparin treatment and should not be used for its reversal. Use protamine sulphate for heparins with advice from a haematologist
- The ED should ensure they have clear instructions for PCC administration and have 24-hour access to it
- The use of fixed dose PCC simplifies management and can reduce the time to treatment
- Medical and nursing staff working in the ED should be trained in the prescription, reconstitution, and administration of PCC

Recommendation

- All ED must have a protocol for use of PCC with clear instructions for dose, reconstitution, and administration. Staff should be appropriately trained in using PCC
- Use of PCC should be regularly audited for timeliness and appropriateness

Action: Medical directors of acute Trusts/Health Boards

- The haemostasis task force of the BSH should consider guidance on the use of a fixed dose of PCC for emergency treatment

Action: Haemostasis task force of the BSH

Introduction

PCC incidents mainly occurred in an elderly population aged 70 years or more, median age 82 years. There were 3 younger patients, 1 a teenager. There were 11 reports of delayed infusion, and 1 inappropriate treatment for a patient receiving heparin. Other issues were inappropriate infusion rates and confusion over the dose.

All patients (except 1) were taking anticoagulants, either warfarin or apixaban/edoxaban; 1 patient was on low molecular weight heparin and was prescribed PCC when the instruction from the haematologist was to give protamine sulphate. This patient in his 80s had COVID-19 pneumonitis and severe epistaxis. Six patients had intracranial haemorrhage and 1 was admitted with head injury.

The SHOT CAS alert released in 2022 also addresses preventable PCC delays. One of the recommended actions was for all healthcare organisations to ensure their transfusion policies and procedures include agreed criteria where rapid release of PCC is acceptable without the initial approval of a haematologist.

Deaths related to transfusion n=0

There were no deaths reported that were related to the PCC incidents.

Major morbidity n=2

Case 11d.1: PCC delay because of need to weigh the patient

A woman in her 80s on apixaban for AF, with upper GI bleeding was in the ED and received red cells. Confusion was caused by the requirement for her weight, and she was not well enough to get off the trolley. This hospital had a fixed dose policy but shared on call haematology staff with another NHS organisation who use a weight-based dose. It was not clear if she received the dose but was put on an end-of-life pathway and died unrelated to the PCC issues.

She was described as having major morbidity and was very unwell.

Case 11d.2: Difficulties in accessing PCC resulting in delayed administration and extension of ICH

An elderly patient on apixaban presented to the ED following trauma with a head injury at 17:31. The report of a head CT at 22:25 showed ICH. PCC was requested. On this site the transfusion laboratory was shut after midnight, so PCC was kept in the emergency drugs cupboard with access restricted to the site manager and pharmacists. The PCC could not be found in the emergency drugs cupboard. The on-call pharmacist was contacted who recommended discussion with the transfusion laboratory at the main site. The main site BMS offered to transport the PCC but to prevent further delay the clinician chose to transfer the patient to the main site where PCC was issued (06:42). A repeat CT scan the next day showed extension of ICH.

This demonstrates the potential impact of delay in administration of PCC in ICH and the importance of replenishing emergency stock to ensure 24/7 availability of these emergency products.

Delays n=11

Delays were caused by poor communication, transfer of patients between departments or setting inappropriately long infusion times. Patients with intracranial bleeding experienced delays of 4, 6 and 8 hours.

Case 11d.3: **Off licence use of PCC**

A teenager was very unwell and admitted to the intensive care unit with an initial diagnosis of APML. The patient had coagulation disturbances and was prescribed PCC 3000IU but received 1000IU. FFP, platelets and cryoprecipitate were also given which were appropriate for AML with coagulopathy, however there is no literature to suggest PCC is indicated or appropriate in this setting.

The two commercial preparations of PCC available are currently only licensed for reversal of vitamin K antagonists. There is published evidence for benefit in haemorrhage in patients on DOAC (Hitchcock et al. 2021, Milioglou et al. 2021, Milling et al. 2021, Nederpelt et al. 2021), however there are specific reversal agents for DOAC (Cuker et al. 2019, Gomez-Outes et al. 2021) demonstrated to be of benefit in ICH (Vestal et al. 2022). PCC carry a risk of thrombosis and are relatively contraindicated in the setting of disseminated intravascular coagulation.

PCC (two different products available) have been used off label in a variety of other settings (Tanaka et al. 2021), particularly cardiac surgery (Katz et al. 2022, Santana and Brovman 2022).

Case 11d.4: Long delay in treatment for ICH with staffing and communication issues

A patient on warfarin presented with frontal ICH. CT confirmed this diagnosis 21 hours after admission. After rapid discussion with the haematologist at 17:00, PCC was requested and issued at 17:40. This plan was not communicated to the ward staff until 21:00. The ward was very busy and short-staffed with many sick patients. The need for additional staff was escalated without success. The patient was difficult to cannulate, and the PCC was given at 01:50 the next morning (about 8 hours from the decision) and with a slow rate as 1500IU took over 1 hour and 50 minutes to administer.

Additional factors included unfamiliarity of staff with PCC prescription and administration.

Learning points

- Medical and nursing staff working in emergency departments and medical/surgical admissions units should be trained in the use of PCC so that it can be administered without delay for specific anticoagulant reversal in the face of major haemorrhage
- The staff should be aware of the indications and also have clear information about how to administer it
- PCC should be rapidly accessible, and consideration given to keeping a stock in the ED (note that this blood product must be fully traceable)
- Immediate reversal of anticoagulant should take place (and certainly within an hour) especially in cases of suspected ICH

Commentary

Fixed dose PCC

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). More recently haemostatic efficiency was shown. In an open-label, multicentre, randomised clinical trial, patients with non-intracranial bleeds requiring VKA 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. 2021). 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.

Use of PCC for DOAC reversal

PCC may also be used for DOAC (Sweidan et al. 2020). Canadian authors recommend the specific antidote idarucizumab 5g for a patient on dabigatran. For a patient on a Xa inhibitor (apixaban, rivaroxaban), PCC 2000IU is recommended; if significant bleeding persists after 1 hour, a second dose of 2000IU of PCC should be considered. While not approved in Canada, a specific antidote to Xa inhibitors, andexanet alfa, has also been used in these situations as a continuous infusion (Callum et al. 2021).

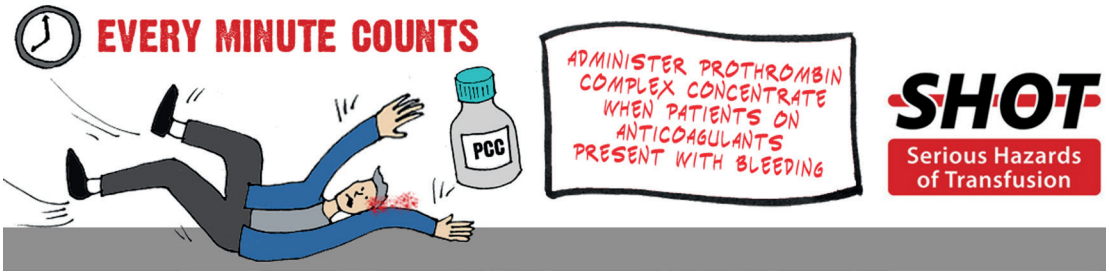
Reversal of oral anticoagulation in patients with ICH has been reviewed noting the importance of rapid treatment (Kuramatsu et al. 2019). A meta-analysis of reversal agents (PCC, idarucizumab and andexanet) for bleeding related to DOAC evaluated 60 studies with 4735 patients. Mortality of those with ICH was 20%; effective haemostasis was achieved in 75-81% and was similar for all agents and a particularly high thromboembolism rate was noted for andexanet (Gomez-Outes et al. 2021). New agents are in development including ciraparentag, a small molecule that works against several anticoagulant agents (Ansell et al. 2022).

Near miss cases n=1

An elderly woman had her weight incorrectly recorded resulting in an inappropriately high dose of PCC. Fortunately, this was recognised, and the prescription revised down to the correct dose.

Conclusion

PCC is an important treatment for immediate reversal of vitamin K antagonists and other oral anticoagulants and should be given immediately once a decision is made to reverse anticoagulant effect. All clinical 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, reconstitute, and administer PCC. Delays can contribute to patient death.



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12 Near Miss (NM) Reporting n=1155

Author: Shruthi Narayan and Debbi Poles

Definition:

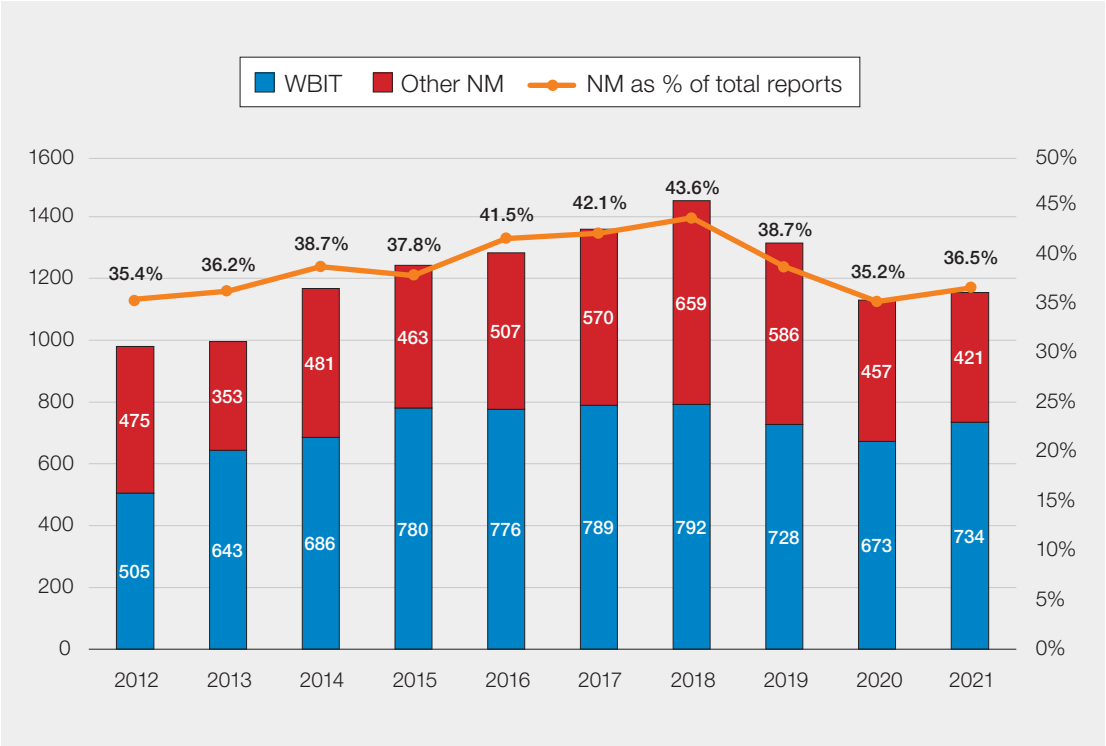
A 'near miss' event refers to any error which if undetected, could result in the determination of a wrong blood group or transfusion of an incorrect component, but was recognised before the transfusion took place.

Abbreviations used in this chapter

BMS	Biomedical scientist	**NM**	Near miss
cffDNA	Cell-free fetal deoxyribonucleic acid	**PPE**	Personal protective equipment
NHS	National Health Service	**WBIT**	Wrong blood in tube

Near miss events account for the largest proportion of the events/reactions reported to SHOT (1155/3161, 36.5%) and after a decrease in reporting numbers over the previous 2 years, 2021 has seen a slight increase in reporting again, with 25 more reports than in 2020 (n=1130). The proportion of WBIT reports has also increased, with other categories of NM reports continuing to decrease.

Figure 12.1: A decade of near miss and WBIT reports 2012-2021



WBIT=wrong blood in tube; NM=near miss

Effective incident investigations help to identify weaknesses in healthcare systems. These inform measures to be taken to help reduce risk and improve safety. Investigating near misses is a very powerful tool in

an effective quality management system. Near misses happen more often than serious events meaning the opportunities for learning are numerous and are available at little or no cost.

Reporting and investigating near misses can highlight otherwise overlooked hazards and risks supporting a proactive approach to transfusion safety. Taking near misses seriously saves time, money and lives. Investigating close calls also means investigating and rectifying potential hazards. It is vital that adequate measures are taken after identifying the risks. The most in-depth incident investigation is useless without acting on its findings. The near miss will just happen again; except this time, it might not be a near miss. Encouraging reporting and educating staff on its necessity is recommended for building a strong safety culture.

Discussion of near miss errors in other categories

Near miss cases have been reviewed and discussed in each relevant chapter for this Annual SHOT Report, and Table 12.1 shows the chapters that include near miss events according to SHOT definitions.

		Discussed in chapter	Number of cases	Percentage of cases
Incorrect blood component transfused (IBCT)	Wrong component transfused (WCT)	Chapter 9	88	7.6%
	Wrong blood in tube (WBIT)	Chapter 12a	734	63.5%
	Specific requirements not met (SRNM)	Chapter 9	57	5.0%
Handling and storage errors (HSE)		Chapter 10	140	12.1%
Right blood right patient (RBRP)		Chapter 13	109	9.5%
Adverse events related to anti-D Ig (Anti-D Ig)		Chapter 8	15	1.3%
Avoidable, delayed or under/overtransfusion (ADU)		Chapter 11	12	1.0%
Total			**1155**	**100%**

Table 12.1: Categorisation of all near misses according to SHOT definitions n=1155

WBIT incidents continue to be the largest subset of near miss cases, 734/1155 (63.5%) of all near miss events and as such are analysed and reported separately in this chapter.

12a Near Miss – Wrong Blood in Tube (WBIT) n=734

Author: Paula Bolton-Maggs, April Molloy 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.

Key SHOT messages

- Failure to adhere to safe procedures remains the major cause of WBIT
- 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
- Use the sample circle, identify the patient fully and label the sample at the bedside

Figure 12a.1
The sample circle

All samples must be labelled at the patient side using positive patient identification.

Unlabelled blood samples MUST NOT leave the SAMPLE CIRCLE.

Unlabelled blood samples outside the circle should be disposed of.

Recommendations

- Accurate patient identification is fundamental for patient safety and patient identification errors must be avoided during blood sampling. This practice must be reinforced with all staff by mandatory transfusion training and be audited regularly
- Blood sample tubes must be labelled next to the patient and systems should be in place to facilitate this
- Hospital transfusion policies should include guidance for safe labelling of transfusion samples including cord blood

Action: Hospital chief executives, medical directors, nursing and maternity leads, hospital transfusion teams, all transfusion staff

Introduction

WBIT samples continue to be a problem with an increase in reports in 2021 (n=734) compared to 2020 (n=673). Cases from maternity departments make up a third of the reports. Sampling cord blood from the placenta is often done away from the patient's side, with risks of mislabelling, and this is a target area for improvement.

What errors lead to WBIT?

There were 265 incidents where the intended patient was bled but the tube labelled with another patient's details, 115 where an unintended patient was bled and 354 where it was not possible to determine either way.

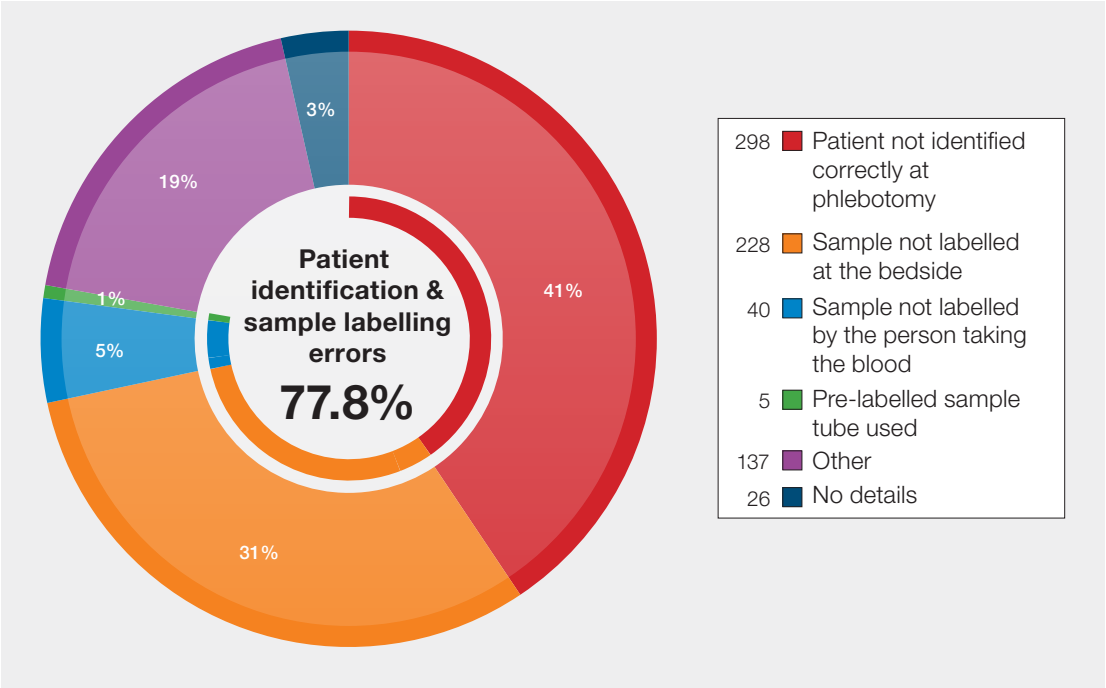
WBIT errors result from two main causes: failure to identify the patient correctly and labelling the blood samples away from the patient (total: 526/734, 71.7% of cases, Figure 12a.2). These errors frequently occur together: 125/734 (17.0%) had both these errors. Additional errors were identified in 440/734 (59.9%).

Maternity cases were reported for 257/734 (35.0%) similar to 2020. These included 33 errors involving neonates:

- Mother and cord mix ups n=16/33 (3 were investigated because the baby's group was not consistent with that predicted from cffDNA)
- Confusion in sampling from twins or triplets n=9/33
- Other reasons n=8

Overall, 526/734 (71.7%) were attributed to failure to identify the patient at the time of sampling or the sample was not labelled at the bedside.

Figure 12a.2: Primary errors leading to WBIT (n=734)



ABO-incompatibility

In 599 cases blood group data were provided. These data show that 278/599 (46.4%) could have received ABO-incompatible components with a risk of serious harm or death.

Table 12a.1: Potential for ABO-incompatible transfusion

		Blood group of the component that might have been transfused as a result of the WBIT					
		A	B	AB	O	Compatible	Incompatible
Patient blood group	A	54	33	11	133	187	44
	B	38	8	5	29	37	43
	AB	7	7	3	12	29	0
	O	142	39	10	68	68	191
	Totals	**241**	**87**	**29**	**242**	**321**	**278**

Who takes the samples?

As in previous years many errors are noted for midwives. Comparative data are available for all transfusion samples taken across the Oxford University Hospitals NHS Foundation Trust which cover a population of about 800,000 people and 7500 deliveries per year. As shown in Figure 12a.3, doctors and midwives are overrepresented compared with Oxford. Although other large hospitals use electronic systems (e.g., Norfolk and Norwich University Hospitals NHS Foundation Trust, King's College Hospital NHS Foundation Trust and University Hospital Southampton NHS Foundation Trust) they do not use them across all wards and departments so are unable to provide comprehensive comparative data.

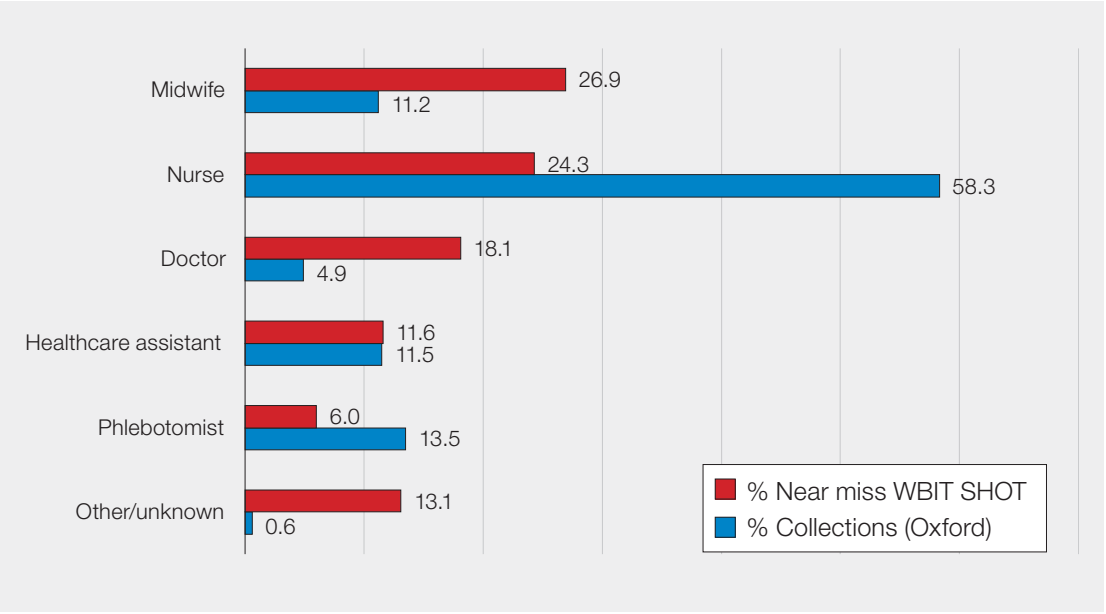


Figure 12a.3: Percentage of different healthcare professionals who took blood samples

WBIT=wrong blood in tube

The pattern of error varies in the different professional groups. WBIT attributable to phlebotomists are mostly caused by failure to identify the patient correctly. Three patients had been given the wrong request form and then their identity was not properly established. Other reasons noted included distraction, patients not being where they were expected to be on the ward, patients having similar names, assumptions that they had found the correct patient, staff shortages, unrealistic training expectations on an already short-staffed workforce and busy wards.

Midwives had a higher proportion due to sample not being labelled at the patient's side. In all groups there were cases reported with both errors.

Hospitals were asked whether they had a two-sample policy for patients receiving their first transfusion: 685/734 (93.3%) did, and 36/734 (4.9%) did not (13 did not answer); 269/685 (39.3%) were detected as a result of the two-sample policy. In 76 cases it was the second sample that was the WBIT.

There is paucity of information at a national level regarding the staff groups involved in taking transfusion samples. Previous Annual SHOT Reports have included data of staff groups involved in transfusion sampling provided by the Oxford Hospitals group for illustration, but this may not be truly representative across all NHS Trusts and Health Boards. Understanding patterns of errors in different clinical situations will help identify targeted interventions to improve practice. British Society for Haematology guidelines (BSH Robinson et al. 2018) must be followed to ensure safe practice.

Maternity cases

Case 12a.1: The cord blood sample was shown to be unrelated to the mother

Fetal genotyping in pregnancy predicted the baby to be D-negative. However, the cord and Kleihauer samples at delivery typed as D-positive. Samples from both mother and baby were referred to the Blood Service for investigation because of this apparent discrepancy. The two maternal samples pre and postnatal were from the same person, but the cord sample did not share at least one allele with the mother indicating that the cord was not related to the mother. The cord was female, and the baby was predicted to be male. The cord sample was from the placenta which was not sampled at the patient's bedside. The mother received anti-D immunoglobulin inappropriately. This maternity department is reviewing their procedures for sample taking and labelling for cord samples

Sampling the neonate's umbilical cord after the placenta had been removed to the sluice area and labelling this sample away from mother and baby was identified as a risk in several reports.

Case 12a.2: A WBIT in the setting of major haemorrhage identifies several errors

A major haemorrhage procedure was activated for a woman with a postpartum haemorrhage. Samples were sent to the transfusion laboratory with a request for two units of red cells. Two samples arrived in the same bag. The patient received two units of emergency group O D-negative red cells.

- *The switchboard operator did not wait to receive all the information, in particular the extension number to be used during the emergency. A bleep message using the extension number from labour ward from a call received earlier was sent erroneously. There was then a delay in the BMS establishing the correct contact number*
- *Maternal samples were taken by Midwife 1 and then handed to Doctor 1 who completed the details on the hospital transfusion request form and pre-transfusion sample. The mother was bleeding profusely, and Doctor 2 had to attend to her*
- *WBIT: one pre-transfusion sample was group O D-positive, but the other sample and the patient's transfusion history indicated that the patient was O D-negative (retrospectively known that one sample was the cord sample). The cord sample was taken by Midwife 2 but was not labelled immediately after the sample was taken. Doctor 2 then completed the details on the cord sample bottle with the mother's details (but no indication that this was the cord sample) and sent this to the transfusion laboratory with the other pre-transfusion sample (in the same bag)*
- *No patient identification details were completed on the traceability record that was returned to the transfusion laboratory. However, the donor number for the unit was documented in the transfusion record (which had patient identification details attached)*

The review noted the need for improved methods for labelling of cord samples and this was to be added to the agenda of a future hospital transfusion committee meeting.

Cases from other departments

Case 12a.3: Wrong practice was the norm, lack of safety culture in the organisation

An elderly man was admitted for surgery. A first sample was sent for grouping (O D-positive) and later two more were sent. Both these later samples were taken at the same time but labelled 15 minutes apart and were found to be a different group (A D-positive) compared to the first one. The newly qualified nurse (transfusion training had been suspended due to lack of resources) who took the sample had filled out the request forms later at the computer away from the patient. She selected the wrong patient details. She noted that 'the practice I have witnessed throughout my training and in our hospital is that blood sampling labels are not completed at the bedside, an action by many professionals, doctors and nurses. The ward was busy, and I was rushing to help the demand.' She was working in a different healthcare organisation from the one where she trained suggesting this poor practice was embedded in other hospitals.

Learning points

- Staff learn by watching and copying their peers and this can result in a drift into poor practice
- Workload and staffing contribute to workarounds that may not be safe
- Electronic identification systems are only safe when used correctly
- When the cord sample gives a result different from that predicted by cffDNA sampling, full investigation is needed
- Staff need to challenge unsafe practices and be aware of making assumptions and accepting established norms that are not based on guidelines

An international prospective study identified the same non-compliance errors or protocol violations in 260 WBIT reported from 36 centres in 11 countries (Dunbar et al. 2022). It was notable that in 43 cases the electronic positive patient identification was either not used when available or was used incorrectly. In this study 78% of samples were taken by nursing staff. Most WBIT errors had more than one contributing factor, mean 2.3 range 1 to 6.

Human factors

A review of the human factors questions related to WBIT can be found in the supplementary information on the SHOT website (https://www.shotuk.org/shot-reports/report-summary-and-supplement-2021/).

Impact of COVID

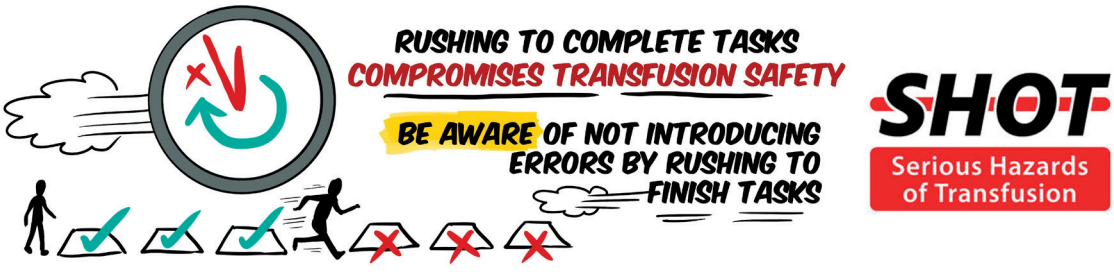
The COVID-19 pandemic continues to impact staffing levels and patient numbers within the NHS. This year 32 WBIT were attributed to COVID-19 due to either staffing pressures, increased workload, or issues with PPE, for example, glasses steaming up due to PPE leading to transcription errors.

Conclusion

The number of reported WBIT has increased in 2021. These are potentially dangerous errors as many could have resulted in ABO-incompatible transfusions. Failure to identify the patient correctly at the time of phlebotomy and failure to label the blood samples next to the patient continue to be the main factors contributing to these errors similar to previous Annual SHOT Reports. These poor practices should be addressed urgently to improve transfusion safety.

Maternity departments and clinics are particular high-risk areas. The HSIB published a report about a WBIT full blood count sample from a maternity unit where there was no patient harm (HSIB 2019). This illustrated many reasons why these errors can occur ('work as done' may not reflect 'work as imagined' in protocols) and recommended the use of electronic systems for patient identification and blood sample labelling. Additional recommendations for organisations from the HSIB report include human factors training, adequate staffing, provision of appropriate equipment and reduction in distractions.

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

SHOT Bite No. 17: Near Miss
SHOT Bite No. 19: Human Factors
https://www.shotuk.org/resources/current-resources/shot-bites/

SHOT Safe Transfusion Checklist
https://www.shotuk.org/resources/current-resources/

Reference

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Right Blood Right Patient (RBRP) n=216

13

Authors: Terrie Perry and Nicola Swarbrick

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

BSH	British Society for Haematology	**IT**	Information technology
CAS	Central alerting system	**LIMS**	Laboratory information management system
CCP	COVID-19 convalescent plasma	**NM**	Near miss
DOB	Date of birth	**RBRP**	Right blood right patient
IBCT	Incorrect blood component transfused	**PID**	Patient identification

Key SHOT messages

- Staff should utilise a pre-administration bedside checklist as recommended by the Department of Health in 2017. Where local policies stipulate a two-person check, this should be done independently
- Positive patient identification with accurate details on sample labels and requests will reduce RBRP errors
- Collection of blood components is a critical step in the transfusion process and checks as recommended below must be carried out to ensure safe transfusions

Recommendations

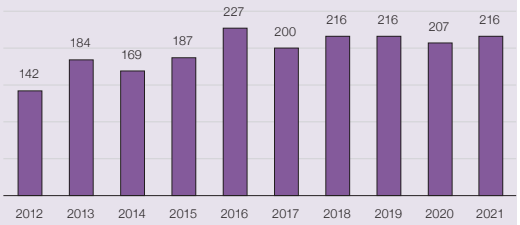
- A checklist should be incorporated into blood component collection procedures to avoid any critical check being missed (for example the PLEDGE aide memoire (Narayan et al. 2021))
- Samples must be labelled accurately at the patient side using positive patient identification
- Transfusion laboratory staff should use the laboratory exit check (Narayan et al. 2020) when issuing blood components to reduce component labelling errors

Action: All staff in transfusion

Headline data 2021

Number of reports n=216
Deaths n=0
Major morbidity n=0

RBRP reports by year



Demographic data

Male n=115
Female n=92
Unknown n=9

Adults n=189
Paediatric n=16
Unknown n=11

Blood component data

Red cells n=166
Platelets n=20
Plasma n=9
Multiple components n=19
Other n=2

Introduction

There were 216 cases reported in 2021, slightly more than in 2020. Clinical errors accounted for 164/216 (75.9%), laboratory errors for 51/216 (23.6%), and 1 miscellaneous case where the patient gave the incorrect identity details on admission. Clinical errors increased from 68.6% in 2020 and laboratory errors decreased from 31.4%. Transposed compatibility tags were implicated in 15 cases and there were 33 compatibility label patient ID errors.

Deaths related to transfusion n=0

There were no deaths related to the transfusion.

Major morbidity n=0

No patient suffered major morbidity as a result of these errors.

Overview of RBRP errors

The majority of laboratory reports were due to component labelling, handling and storage errors, 30/51 (58.8%) with 23/30 due to component labelling errors, of which 14/23 were transposed labels. Sample receipt and registration errors accounted for 18/51 laboratory reports, with 14/18 resulting in patient ID errors on the compatibility labels.

The majority of clinical RBRP reports were due to patient ID errors at sample taking (77/164, 47.0%), with 69/77 due to PID errors on the sample tube and 3/77 PID errors on the request form. Administration errors accounted for 29/164 of clinical RBRP reports, with 12/29 due to patient being transfused without a wristband.

Of the 51 primary laboratory errors, 37 were not spotted at collection or administration. Of the 164 primary clinical errors, 66 were missed by the laboratory, 52 were not picked up at the collection stage and 93 missed at the administration stage (of these there were 41 errors related to prescriptions and wristbands or no bedside checks).

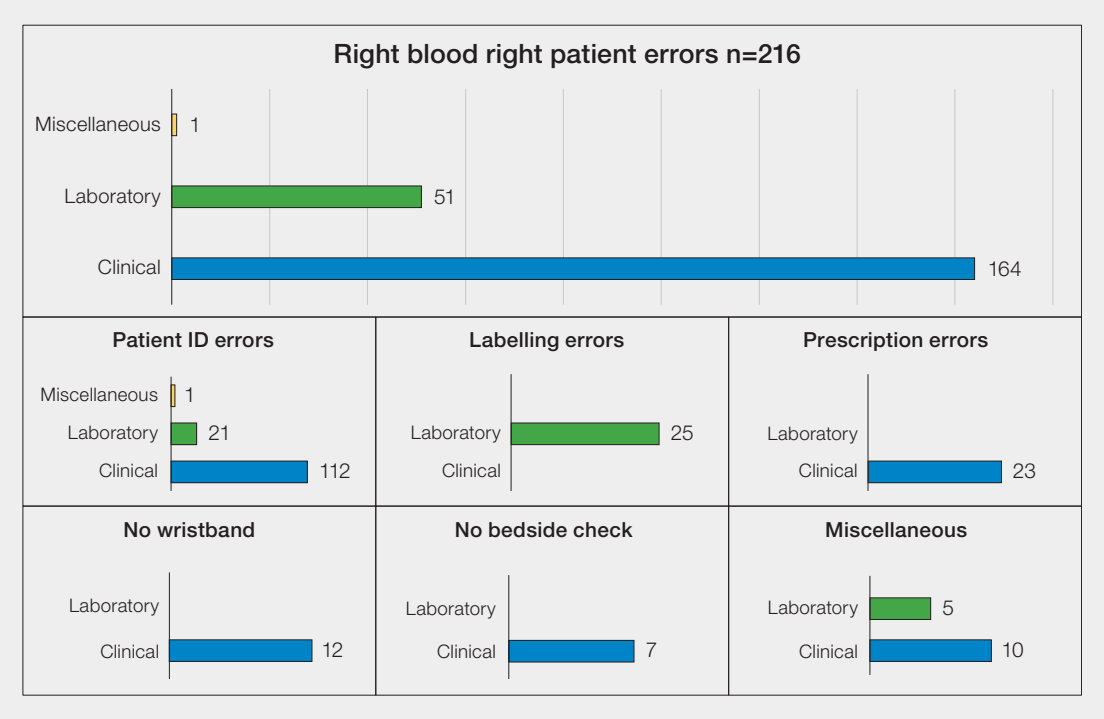


Figure 13.1: Breakdown of 2021 RBRP reports (n=216)

The majority of errors occurred at sampling, 77/216 (35.6%) followed by component labelling, availability and HSE, 30/216 (13.9%) and administration, 29/216 (13.4%). (Figure 13.2). This is an increase from 2020 where sampling errors accounted for 45/207 (21.7%) of RBRP errors.

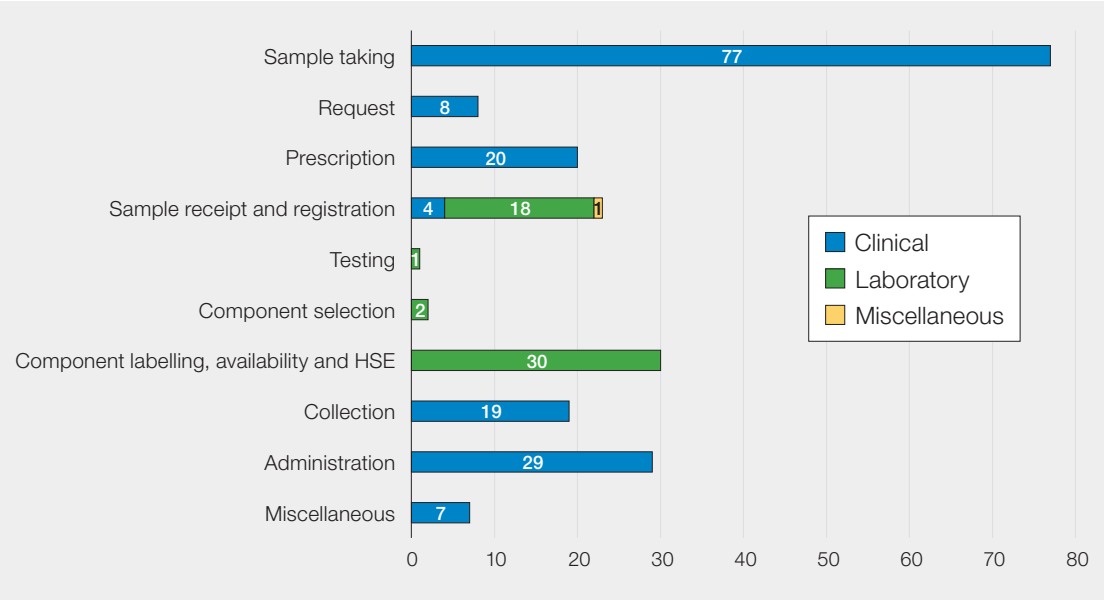


Figure 13.2: RBRP classified by the stage when the primary error occurred in 2021 (n=216)

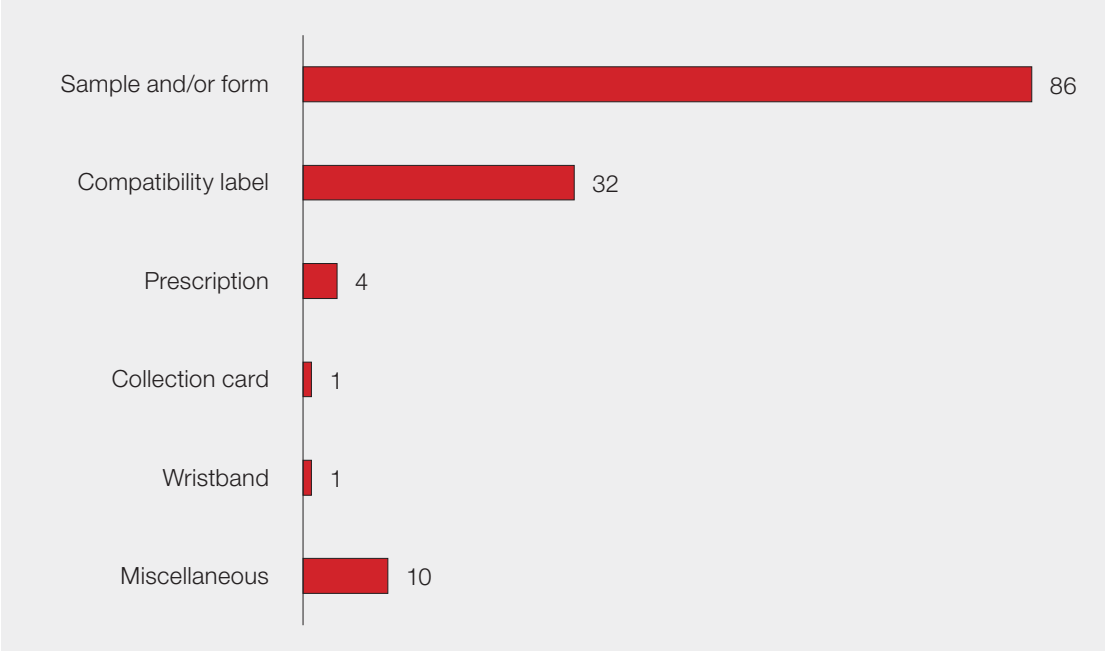
HSE=handling and storage errors

PID errors n=134

PID errors accounted for 134/216 (62.0%) of all RBRP errors. Patient identification errors occurred throughout all stages of the transfusion process, with 86/134 (64.2%) due to errors with sample tubes and request forms. These included both clinical errors where patient details were wrongly transcribed onto samples and request forms, and laboratory errors where laboratory staff entered data incorrectly into LIMS (Figure 13.3).

Most of these were due to transposed numbers, misspelt names and DOB being inaccurately recorded. Sampling errors have increased from 21.7% in 2020 to 35.6% this year.

Figure 13.3: Details of patient identification errors (n=134)



Data demonstrates the majority of RBRP errors occur at the sample taking step. This number may be higher as some investigations implicate the laboratory for errors at sample receipt and registration, but the primary error may have been at the sampling stage.

Case 13.1: Error in sample labelling not noticed by laboratory or clinical staff

A specimen was received in the transfusion laboratory for an elderly man with surname ending M on the sample and request form. Following processing of the sample 20 blood components were issued and transfused. A further sample and request form were received a few days later with surname ending N but the discrepancy was not noticed by laboratory staff and 1 ATD platelets were issued and transfused. Further samples were received ending N and the discrepancy was then noticed by the laboratory.

Hand-written names on sample bottles are sometimes hard to read and laboratory staff can miss those small errors which should have been detected. These errors should also be detected at collection and the bedside with relevant checklists and good practice.

Case 13.2: Clerical error leads to wrong DOB on all documentation

The DOB for a male in his 60s was incorrect on the patient wristband, compatibility label and prescription. At the patient ID stage of administration, the nurse asked the patient for their DOB but misheard. Electronic PID allowed the transfusion as the wristband and component label matched. The patient had been incorrectly clerked.

A well-executed bedside checklist of some sort (be it electronic or paper) is always required and the wristband and patient themselves are very much part of this. Never assume that the wristband is correct as clerking errors do occur.

Bedside checklists

In 2017 the CAS alert: 'Safe Transfusion Practice: Use a bedside checklist' (Department of Health 2017) was issued in response to SHOT recommendations. A bedside checklist was used in 136/216 (63.0%) RBRP cases and stated as 'not used' in 39/216 (18.1%). In 6/216 (2.8%) cases a checklist was stated as not used/not available. In 35 cases no information was provided.

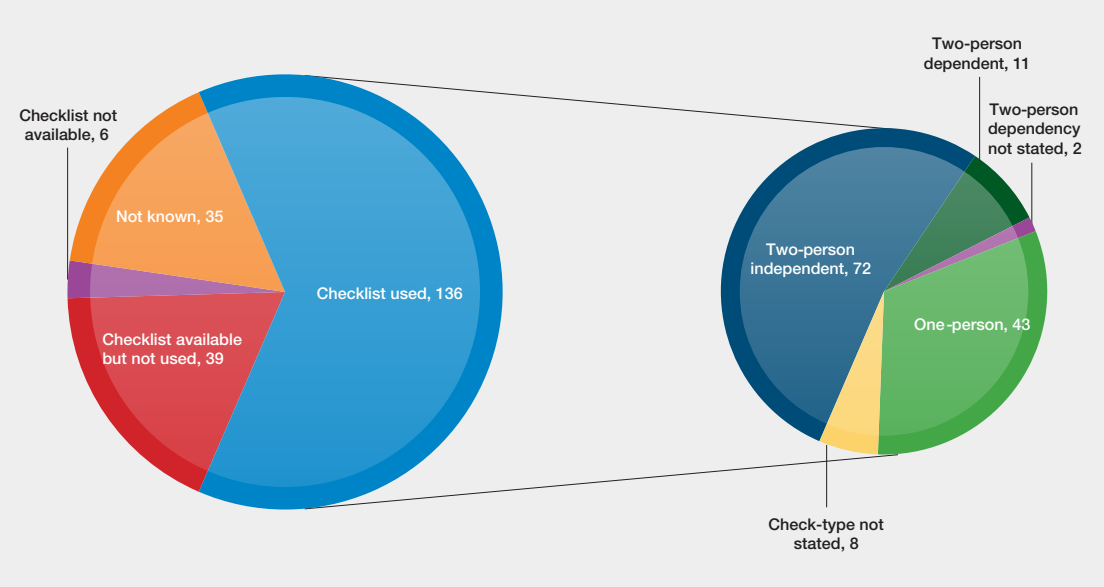


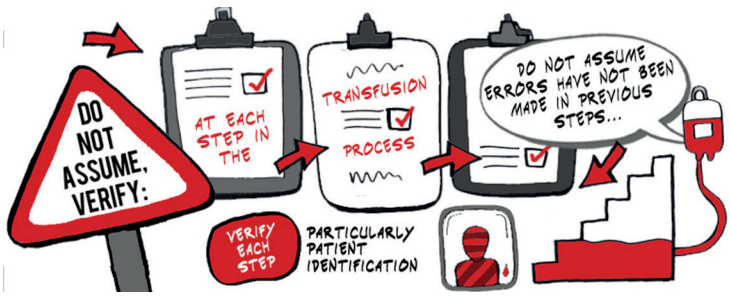
Figure 13.4: The presence of a pre-administration check, and type of check in RBRP errors

In the 136 reports which stated a bedside administration checklist was used, most had a two-person check, 85/136 (62.5%) and the majority of these, 72/136 (52.9%) used a two-person independent check (Figure 13.4). Data regarding dependency of checks was not consistently reported.

SHOT recommends that local blood transfusion policies are aligned with national guidelines and if local policy requires a two-person checking procedure, each person should complete all the checks independently (double independent checking) (BSH Robinson et al. 2018). See 'Recommended resources' at the end of this chapter for an educational video produced by SHOT and NHS Blood and Transplant patient blood management teams.

Learning points

- Care at clerking of the patient, labelling of samples and requests and inputting of data into LIMS will prevent many RBRP errors
- A checklist at the collection of the blood component from the refrigerator/storage area will prevent most RBRP errors from reaching the patient
- Pre-administration bedside checks must be carried out robustly to be effective in picking up RBRP errors



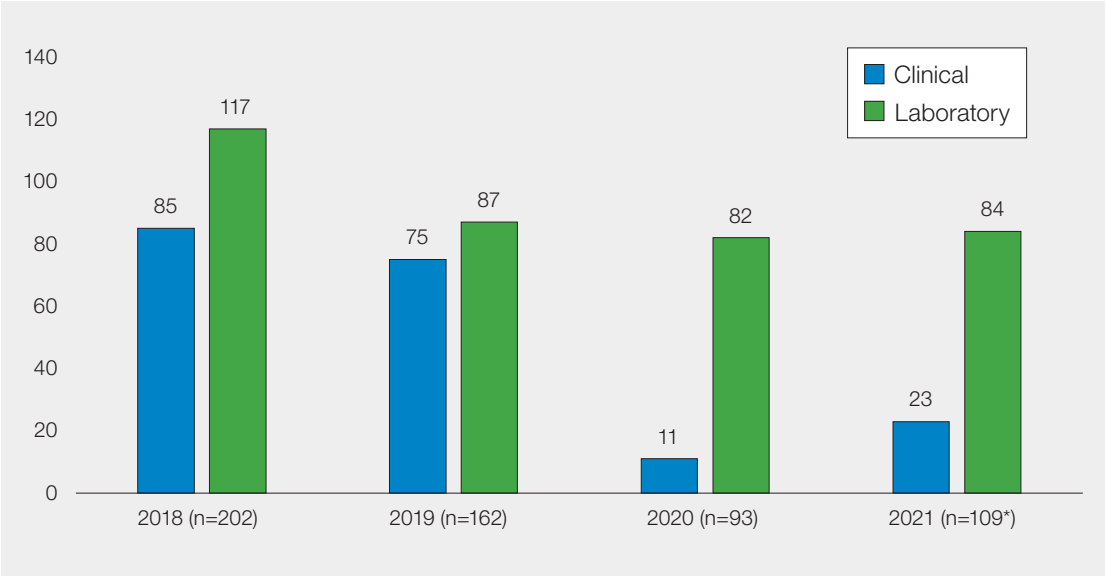
SHOT
Serious Hazards of Transfusion

Near miss cases n=109

There were 109 near miss RBRP incidents, 23/109 (21.1%) originating in the clinical area and 84/109 (77.1%) originating in the laboratory (2 miscellaneous cases). This constitutes a drop in laboratory errors from 2020 (88.2% to 77.1%) and an increase in the clinical area (11.8% to 21.1%).

Most near misses 94/109 (86.2%) were detected when collecting blood or at the bedside, and 80/109 (73.4%) using a formal bedside checklist.

Figure 13.5: RBRP near misses 2018-2021



**Total includes 2 miscellaneous cases not reflected on the figure*

A collection check provides the opportunity to detect any errors prior to the blood being transported to the patient. The fact that the majority of errors are being detected at the bedside may indicate that the collection check is not as robust as it could be.

Conclusion

Pre-administration patient side safety checks can pick up RBRP errors but these have to be carried out correctly to be effective. RBRP errors can potentially result in patient harm, these incidents were 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. As in previous years, many of the incident investigations and questionnaires do not find or state the main causal and contributory factors. Several reports mentioned clerking errors due to misinformation provided by patients themselves or from ambulance teams or completely new entries on Trust/Health Board systems. Sampling and labelling errors continue to be reported. Lack of appropriate checks at collection of blood components meant that there were missed opportunities to pick up some of the RBRP errors.

While the collection process may differ between establishments, there are essential checks that must made at this point which could reduce the number of RBRP (and IBCT) incidents. This has been discussed in previous Annual SHOT Reports and collection checks should follow BSH guidelines (BSH Robinson et al. 2018).

Recommended resources

SHOT Video: The Pre-administration Blood Component Transfusion Bedside Check 2020
https://www.shotuk.org/resources/current-resources/videos/

References

BSH Robinson S, Harris A, Atkinson S, et al. The administration of blood components: a British Society for Haematology Guideline. *Transfus Med* 2018;**28(1)**:3-21. http://onlinelibrary.wiley.com/doi/10.1111/tme.12481/full [accessed 05 May 2022].

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Narayan S (Ed), Poles D, et al. On behalf of the Serious Hazards of Transfusion (SHOT) Steering Group. The 2020 Annual SHOT Report (2021). https://www.shotuk.org/shot-reports/ [accessed 05 May 2022].

Laboratory Errors n=573 (389 transfused errors and 184 near miss)

14

Authors: Nicola Swarbrick, Peter Baker and Heather Clarke

With contributions from Jennifer Davies and Shruthi Narayan

Abbreviations used in this chapter

AAA	Abdominal aortic aneurysm
ABOi	ABO-incompatible
AML	Acute myeloid leukaemia
BMS	Biomedical scientist
BSQR	Blood Safety and Quality Regulations
CAPA	Corrective and preventative action
CL	Component labelling, availability and handling and storage
EQA	External quality assessment
Hb	Haemoglobin
HSE	Handling and storage errors
LIMS	Laboratory information management system
MHP	Major haemorrhage protocol
MHRA	Medicines and Healthcare products Regulatory Agency
QMS	Quality management system
RCA	Root cause analysis
SOP	Standard operating procedure
SRNM	Specific requirements not met
SRR	Sample receipt and registration
UKAS	United Kingdom Accreditation Service
UKNEQAS	UK National External Quality Assessment Scheme
UKTLC	UK Transfusion Laboratory Collaborative

Key SHOT messages

- Final checking of the unit before issuing is important. The use of label verification in LIMS or electronic blood-tracking systems helps to optimise safety
- LIMS alerts should be relevant, appropriate, not easily overridden and have an audit trail
- Communication between clinical teams and the laboratory, and between clinical teams in shared care patients is vital to ensure provision of appropriate blood components
- Manual input of patient information and blood grouping results is prone to error. Independent checking processes should be in place where IT solutions are not available
- Release of red cells in a major haemorrhage situation should not be delayed whilst awaiting Hb results, or where recent Hb is within normal limits

Recommendations

- Laboratories should have training programmes and regular competency-assessments that ensure staff have the appropriate knowledge and skills commensurate to their role
- Laboratories should have a schedule for regular LIMS upgrades in accordance with manufacturers recommendations and contractual requirements. The operational LIMS should include all available functionality to support safe practice, where deficiencies are noted a roadmap for upgrade and/or development should be in place and regularly reviewed by the laboratory management and the LIMS supplier
- The LIMS should be used to its full potential to support transfusion safety, transfusion service managers should work with the LIMS supplier to ensure that all functionality is available and operational to support safe laboratory transfusion practice
- Laboratories should have capacity plans in place that include all aspects of transfusion practice. These should be reviewed regularly and have appropriate escalation processes when safe staffing levels are not met
- Interoperability between patient administration systems and LIMS reduces the risk of errors in manual registration of patient information. Transfusion service managers should work with the LIMS supplier and IT departments to explore options for interfacing

Action: Transfusion laboratory managers, pathology leads

Introduction

The number of events involving laboratory errors and near misses decreased by 10.3% to 573 of 3161 total reports from 639 in 2020. Reported laboratory errors have been reducing since 2018 which may reflect improvements in laboratory processes. Conversely, this could be due to under-reporting as a result of staffing issues during the COVID-19 pandemic. There were 389 laboratory errors where a component was transfused, and 184 near misses.

In 2021, the highest proportion of errors occurred within the component labelling, availability, handling, and storage steps, 122/389 (31.4%), followed by testing, 114/389 (29.3%) and component selection, 91/389 (23.4%) categories. This highlights key areas of weakness that need more care, attention, and knowledge to ensure safe transfusions. Figures 14.1 and 14.2 illustrate at which stage in the laboratory the error occurred.

In 99/389 (25.4%) of laboratory error reports, the error occurred where staff were lone working. Adequate, appropriate training and support must be given to staff before beginning lone working.

Process instructions within SOP must be clear and concise to ensure they can be followed correctly.

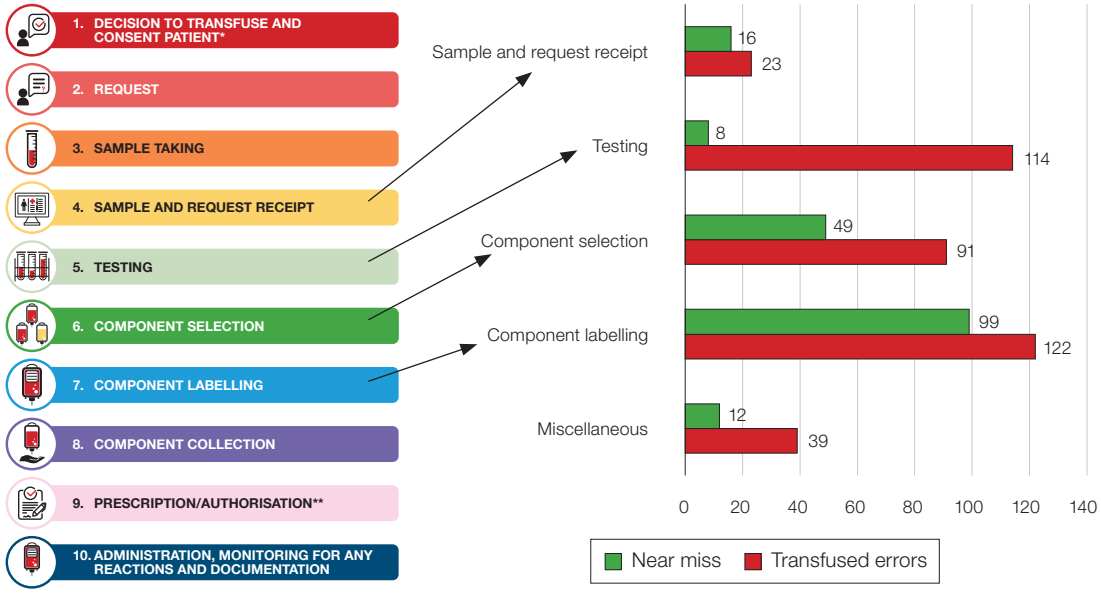


Figure 14.1: Laboratory errors (events and NM) related to the 10 steps

Of the 39 miscellaneous laboratory errors reported 29/39 were related to anti-D Ig errors and 10/39 were due to delays in provision of blood components. The anti-D Ig errors were reportedly due to cffDNA results not being checked, communication failures, incorrect advice from the laboratory to the clinical area and LIMS flags being missed by laboratory staff. The delays were reportedly due to laboratory communication errors and equipment failures.

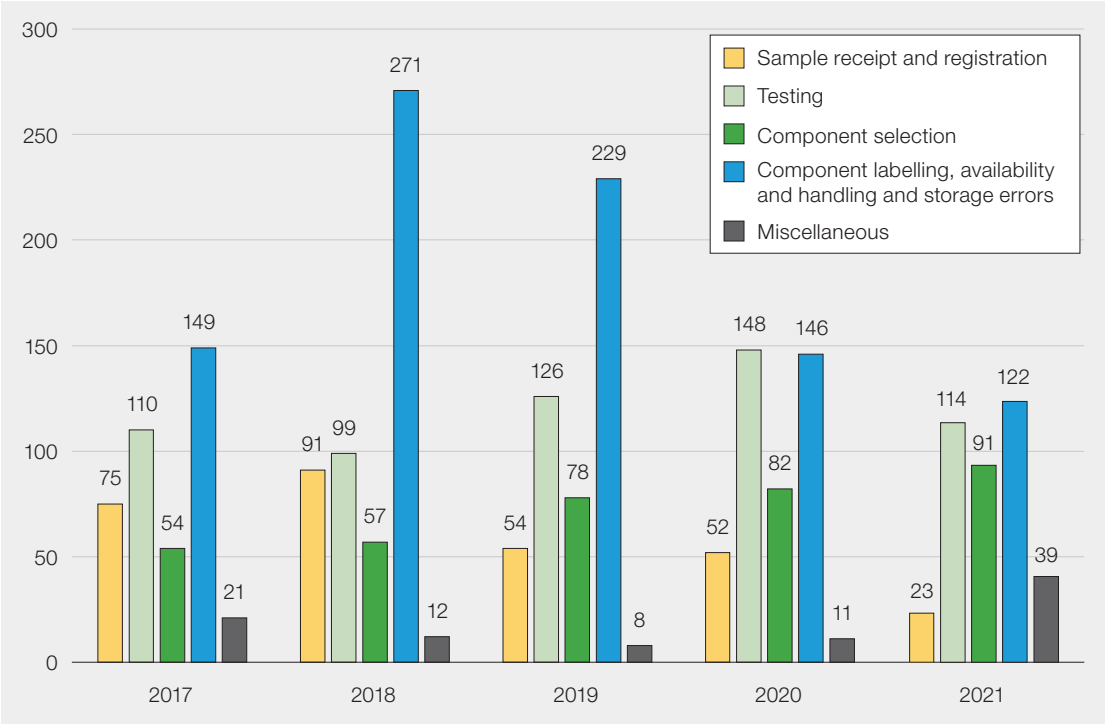


Figure 14.2: Laboratory errors 2017–2021 categorised by step where the error occurred

Deaths related to transfusion n=0

There were no deaths reported relating to laboratory errors.

Major morbidity n=6

There were 6 cases of major morbidity related to laboratory errors; 3 cases of sensitisation to anti-K in females of childbearing potential and 3 errors which resulted in avoidable transfusion delays.

There were 3 cases of preventable alloimmunisation of anti-K to women of childbearing potential following transfusion of K-positive units. In 2/3 cases, reports stated that the LIMS alerted the BMS to the requirement for K-negative, but these were overridden. Females of childbearing potential (<50 years) should receive K-negative red cells unless they are unavailable in an emergency (BSH Milkins et al. 2012). Laboratories should take all steps possible (including the application of LIMS flags which are not easily overridden) to prevent sensitisation to the K antigen and so prevent increased risk for the fetus in future pregnancies.

Case 14.1: Transfusion of K-positive red cells resulted in antibody formation

A female patient in her 20s was transfused two red cell units post miscarriage, one of which was K-positive. The LIMS alerted the BMS to the requirement for K-negative units, but alerts were not heeded and were overridden, with the LIMS allowing users to skip past alerts. This incident occurred towards the end of a night shift. This patient became pregnant again, with anti-K titre of 128, where the partner was Kk. cffDNA results indicated the fetus was K-negative.

Decision fatigue can lead to errors that result in patient harm.

Case 14.2: Lack of provision of emergency stock red cell units

An elderly patient in his 80s was admitted with Hb 110g/L, which had fallen to 92g/L the following day. The patient became hypotensive with rapid deterioration, and an arterial blood gas result indicated the Hb had fallen further to 70g/L. One unit of emergency O D-negative red cells was requested urgently, but the BMS refused the request as they felt this was not appropriate given that there were no obvious signs of blood loss. The BMS suggested to contact the consultant haematologist, which did not happen. By the time the BMS had a confirmed Hb result of 50g/L and contacted the ward to state group specific red cells could be released, the patient had already died. Post-mortem results identified the patient died due to a bleeding duodenal ulcer.

This case highlights that covert bleeding cannot be quantified and transfusion support must be guided by the patient's clinical status. Gastrointestinal bleeding can be deceptive, the severity is often masked, diagnosis may be delayed; hypotension and tachycardia are important clinical signals. Transfusion delays must be avoided. Haematocrit and haemoglobin levels in bleeding patients are not reliable indicators of blood loss (BSH Hunt et al. 2015), and red cells should be readily available for immediate use for life-threatening bleeding.

ABOi cases

There were 3 ABOi cases reported in 2021, all of which were laboratory errors related to selection of plasma components. In all 3 cases group O plasma was issued and transfused to group A patients. In 2/3 cases the LIMS alerted the laboratory staff to the incompatibility, but this was overridden. These cases are discussed in detail in Chapter 9, Incorrect Blood Component Transfused (IBCT) Cases 9.1, 9.2 and 9.3.

Transplant cases

For further details of laboratory errors in patients who had received a transplant, please see Chapter 24, Transfusion Errors in Transplant Cases.

Trends in error reports

The highest proportion of errors occurred within the IBCT-SRNM category, 94/389 (24.2%), which is similar to previous years. The highest proportion of near miss events involved RBRP events, 84/184 (45.7%).

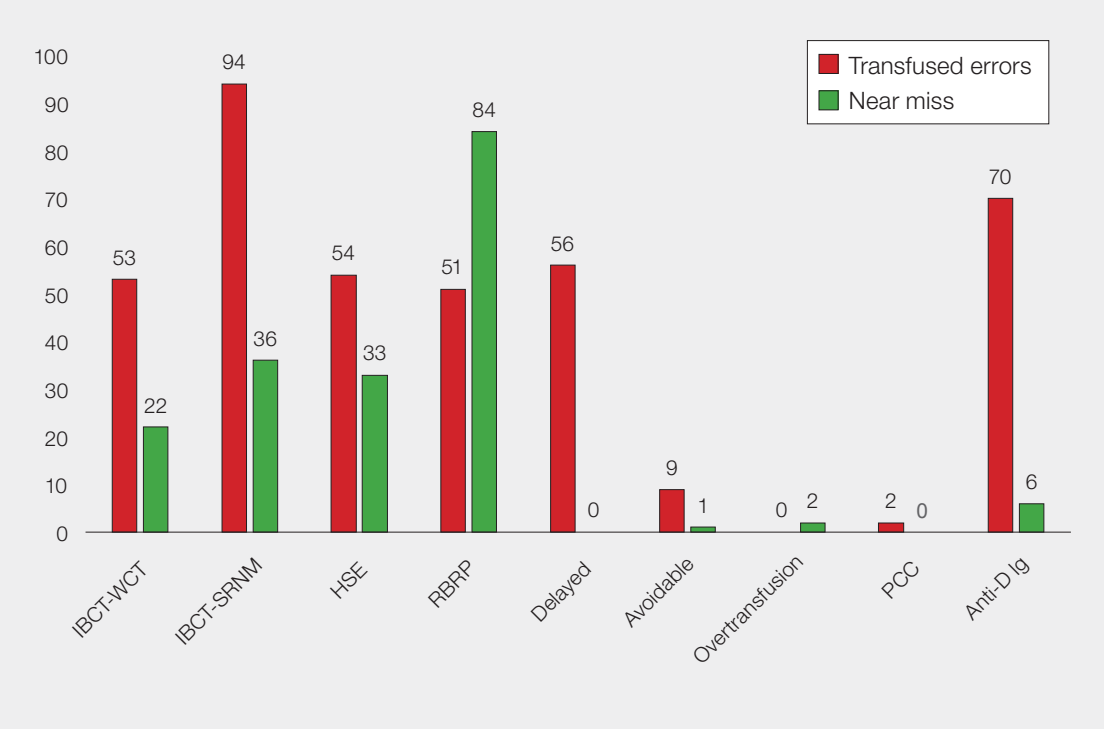


Figure 14.3: Laboratory incidents and near misses by category of outcome (n=573)

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

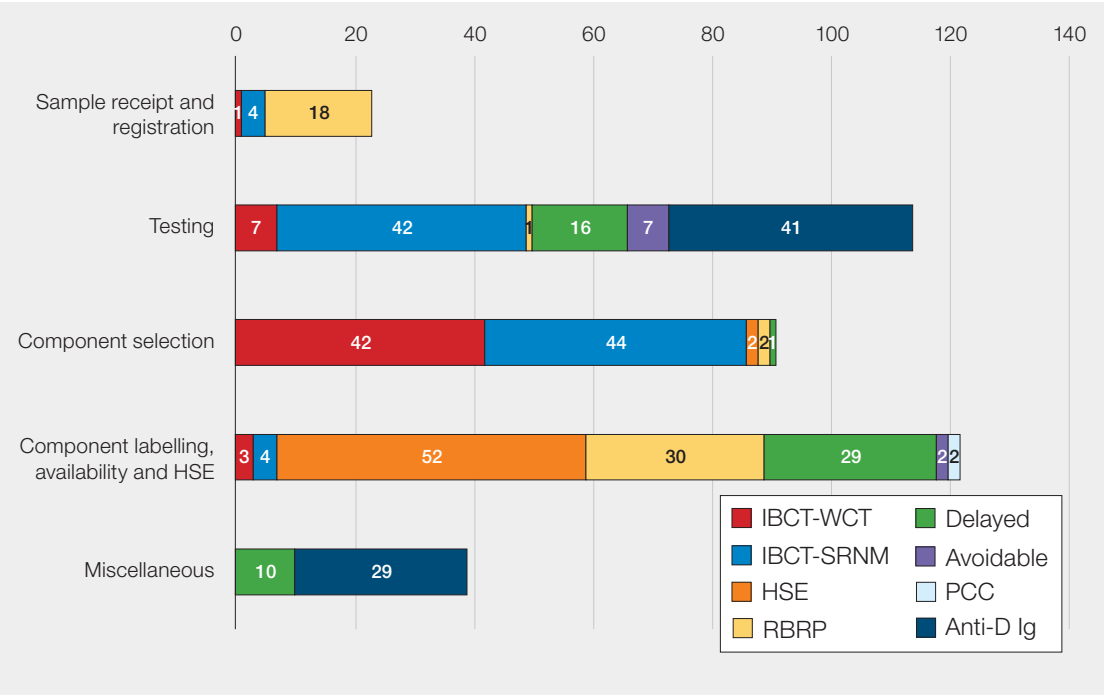


Figure 14.4: SHOT laboratory data showing at which stage in the transfusion process the primary error occurred (n=389)

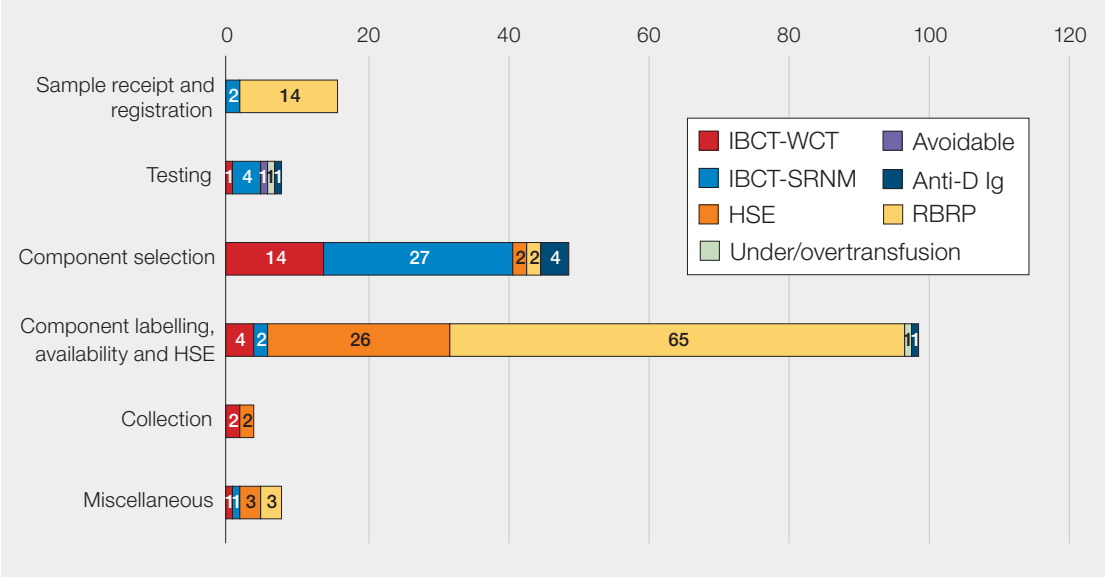
IBCT-WCT=incorrect blood component transfused-wrong component transfused; IBCT-SRNM=IBCT-specific requirements not met; HSE=handling and storage errors; RBRP=right blood right patient; PCC=prothrombin complex concentrate; Ig=immunoglobulin

It is concerning that similar patterns and themes are observed in laboratory reports, and sustained improvements have not been made to laboratory practices. A safety-II approach to incident investigation and review of laboratory procedures could help identify potential gaps which can be rectified, and also areas of good practice which may be able to be applied elsewhere (Hollnagel et al. 2015).

Near miss cases n=184

There has been a decrease in NM laboratory errors since 2020, from 200 to 184. The pattern of laboratory near miss errors is consistently highest at the component labelling, availability, handling and storage stages, 99/184 (53.8%), and component selection stage, 49/184 (26.6%).

Figure 14.5: SHOT near miss laboratory errors showing at which stage in the transfusion process the primary error occurred with outcome (n=184)



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

The largest group of single errors occurred in the RBRP category, 84/184 (45.7%) of which 56/84 (66.7%) were related to labelling errors. Of these 31/56 (55.4%) were reports of transposed labels between units. Where possible label verification systems should be implemented to prevent release of units with labelling errors. The recent SCRIPT survey indicated that 100% of UK LIMS suppliers had a label verification process available (see 'Recommended resources').

In 14/84 (16.7%) RBRP NM events, the error occurred at the sample receipt and registration stage, with 12/14 due to demographic data entry error, leading to incorrect details present on compatibility labels at issue. Where there is manual processing of transfusion requests, steps should be taken to verify that the details on the sample/request form and LIMS concur before authorisation of results and issue of units.

There were 49/184 (26.6%) laboratory NM events that occurred at the component selection stage with IBCT-SRNM, 27/49 (55.1%) and IBCT-WCT, 14/49 (28.6%) being the largest categories. Component selection errors consisted of 18 reports not meeting irradiated requirements and 6 reports not meeting CMV requirements for pregnant females. Not heeding LIMS alerts (14/49), not updating LIMS to reflect specific requirements (4/49), and LIMS unable to prevent inappropriate issue (3/49) reiterates the importance of LIMS in preventing incorrect component selection. Triggering a LIMS alert means a component selection error has already occurred, and efforts must be made to minimise these errors at the point of selection by the BMS.

The laboratory NM error was detected at the administration stage in 127/184 (69.0%) of cases. There were 96/127 (75.6%) that had a pre-administration check, which indicates the importance of safety checklists in detecting transfusion errors.

In 126/184 (68.5%) of laboratory NM errors, the reports stated that the event occurred due to failure to follow policy. Whilst policies and procedures are critical aspects for safe laboratory practice, fail safes and barriers to poor practice should be embedded in the system to actively reduce the risk of error. Investigation of near miss events provides opportunities for laboratories to identify effective corrective and preventative actions that can be implemented to support good practice. Near misses are sometimes referred to as 'good catches' as an actual error was prevented. A review of the 'good practice' that prevented an actual error may present an improvement action that can be embedded into the system.

Errors by step in the transfusion process in the laboratory

Sample receipt and registration (SRR) n=39 (23 transfused errors and 16 near misses)

The majority of SRR events occurred when demographic data was incorrectly entered onto LIMS. Electronic transfer of patient information from central patient administration systems to LIMS avoids the requirement for manual registration in the laboratory. Transfusion service managers should collaborate with local IT departments to ensure that electronic transfer of patient data to the LIMS is implemented wherever possible. Where manual registration is necessary staff performing this role should be protected from distractions and second checking systems should be in place, which may be incorporated at later stages in the process.

Case 14.3: Incorrect inputting of surname for patient who later required MHP activation

A group and screen sample was received in the transfusion laboratory for female in her 50s. The name was inputted incorrectly into the LIMS, but the error was not detected during processing checking points. The MHP was activated for the patient and red cells, platelets and FFP were all issued with incorrect details on the labelling. The error was not detected at administration checking, and units were transfused.

Although second checking processes used in the laboratory for manual processes often identify errors in patient data, this case is an important reminder that independent checks can fail to highlight discrepancies. Transfusion service managers should strive to ensure that processes are in place to 'get it right first time', utilising IT systems wherever possible.

Getting it right first time (GIRFT) is a national programme designed to improve the treatment and care of patients through the in-depth review of NHS services, which are used to support change. The GIRFT national pathology report, published in September 2021 (GIRFT 2021), aims to improve patient care by ensuring the right test is carried out at the right time, with the right answer for each patient. To help achieve this GIRFT have developed The Clean Framework, designed to help laboratories to widen their diagnostic pathways into an end-to-end service which includes 'Clean in' (pre-analytical stage), 'Clean through' (the analytical stage) and 'Clean out' (post-analytical stage).

The Clean Framework for pathology is designed to improve quality, develop data interoperability between NHS systems and maximise efficiency to improve the diagnostic service delivery.

Learning points

- Staff responsible for receipt and registration of samples must confirm patient identification match on the sample, request form (if relevant) and LIMS
- Staff responsible for sample receipt and registration should be protected from distractions
- There should be independent checks of sample ID against LIMS prior to authorisation of results and again prior to issue of components

Testing n=122 (114 transfused errors and 8 near misses)

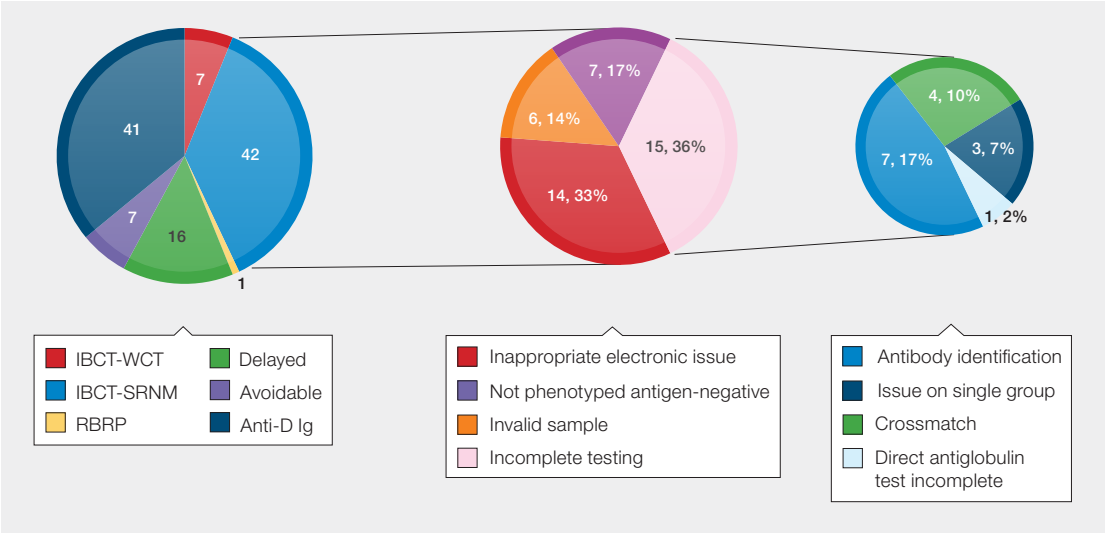
Laboratory testing errors increased significantly in 2020 compared to previous years, but encouragingly have reduced by 26.5% from 166 in 2020 to 122 in 2021. The majority of these adverse events were procedural errors in the categories IBCT-SRNM (42/114) and anti-D Ig (41/114). IBCT-SRNM errors were largely due to inappropriate electronic issue of red cells (15/42) and issue of components with incomplete testing (16/42). There were 4/114 cases where neonatal and maternal sample testing was not completed prior to issue of components.

Of the 67 ADU laboratory error reports, testing was stated as the main fault in 23 reports which led to 7/23 avoidable, and 16/23 delays. The errors contributing to reported transfusion delays were related to laboratory equipment failure, or incorrect or delayed haematology laboratory results being reported on LIMS.

There were 4 cases reported where neonatal testing and crossmatching with maternal sample were not completed appropriately.

During the first 4 months of life ABO antigens may be poorly expressed on red cells and the corresponding ABO antibodies may not have yet developed, making confirmation by 'reverse grouping' unreliable. Maternal IgG ABO antibodies may be detected in neonatal plasma. Wherever possible, samples from both the mother and infant should be tested for ABO and D grouping, an antibody screen should be performed on the larger maternal sample, and a direct antiglobulin test (DAT) on the infant's sample. Because of the significant risk of 'wrong blood in tube' errors due to misidentification, the infant's blood group should be verified on two separate samples (one of which can be a cord blood sample) as recommended for adult patients, providing this does not delay the emergency issue of blood. If there are no atypical maternal antibodies and the infant's DAT is negative, top-up transfusions can be given without further testing during the first 4 months of life (BSH New et al. 2016).

Figure 14.6: Laboratory testing errors by reporting category (n=114) and SRNM testing errors by subcategory (n=42)



IBCT-WCT=incorrect blood component transfused-wrong component transfused; IBCT-SRNM=IBCT-specific requirements not met; RBRP=right blood right patient; Ig=immunoglobulin

IBCT-SRNM testing errors n=42/114

Case 14.4: Error inputting group into LIMS

A group and screen sample was received for a female in her 70s. The patient could not be positively identified (unconscious and unable to communicate) and so was given an unknown patient ID. The sample was processed, and the patient had a forward group A, but no reverse group to confirm, therefore the LIMS required a manual overall ABO D interpretation. The BMS entered the group as A D-positive, when in fact the patient was A D-negative. There was no information available as to whether a manual confirmation of group was carried out. The patient was transfused D-positive red cells. The patient was subsequently discovered to require irradiated cellular components, but this was not identified prior to administration.

Manual input of test results into the LIMS should include a verification process that crosschecks the reaction patterns for the assay against the interpretation of the result.

Case 14.5: Neonatal crossmatch without antibody screen

Neonatal red cells were requested for a newborn infant. The BMS checked the LIMS and confirmed that the mother had a negative antibody screen and units were issued and transfused. It was subsequently detected that the maternal antibody screen was 5 days old, and therefore did not meet BSH 2016 guidelines (BSH New et al. 2016) requiring a sample to be ±72 hours from delivery.

Anti-D testing errors n=41/114

Anti-D Ig errors accounts for 41/114 of testing errors, with 16/41 errors related to cffDNA testing. Of these cases, 15/16 were errors related to prediction of fetal D-type, with 10/16 cases cffDNA testing incorrectly predicted D-positive, and 5/16 cases incorrectly predicted D-negative.

Case 14.6: Postnatal patient incorrectly given anti-D Ig after BMS used cffDNA result from previous pregnancy to determine newborn's blood group

A D-negative postnatal patient was transfused anti-D Ig following delivery of a D-negative infant after the BMS used the cffDNA result from a previous pregnancy to confirm the infant's D group, rather than the current cord group result. The EDD date of this pregnancy was exactly 1 year from the EDD of the most recent previous pregnancy.

Care must be taken to ensure the cffDNA result for the current pregnancy is being used to determine suitability for anti-D Ig.

Case 14.7: Miscalculation of FMH post delivery resulted in excessive anti-D Ig administration

A BMS tested a post-natal maternal sample for FMH, but during the calculation entered an incorrect FMH value and the bleed estimate was tenfold larger than the actual value. The actual bleed was 6.4mL, but the estimated bleed was 64mL. The BMS issued 9000IU anti-D Ig to cover this bleed.

Learning points

- Inappropriate electronic issue can be reduced by implementing appropriate LIMS rules
- Where neonatal blood components are required mother and/or baby samples must meet guidelines for antibody screen testing ±72 hours of delivery
- Ensure cffDNA results are for the current pregnancy, and available results should be entered into the LIMS in a timely manner to avoid unnecessary anti-D Ig issue
- Laboratories should have contingency plans in place for equipment failure to avoid delays in the provision of blood components

Component selection n=140 (91 transfused errors and 49 near misses)

Errors related to component selection mainly involved IBCT-SRNM (44/91, 48.4%) and IBCT-WCT (43/91, 47.3%).

Component selection errors in IBCT-SRNM included issuing units which were not antigen-negative as per patient requirement (14/44), K-positive red cells to patients of childbearing potential (8/44) of which 3/8 patients have subsequently developed anti-K, units not tested seronegative for CMV (8/44) and non-irradiated blood components where required (8/44).

Component selection errors in IBCT-WCT included issuing components of the wrong ABO/D group (30/43), of which 17/30 were errors related to patients post HSCT. Other component selection errors included wrong component type (9/43), units issued to the wrong patient (2/43) and incorrectly selecting units which were not crossmatched (1/43).

Component selection should be appropriately controlled by a robust LIMS system where specific requirements based on patient characteristics including age, sex, antibody status and clinical status are incorporated into IT rules and alerts, which are not easily overridden.

There were 8 cases of K-positive units to women of childbearing potential in 2021 in total, with 3 women who went on to develop anti-K.

Learning points

- Understanding of ABO compatibility for red cells and plasma components should be included in training and regular competency-assessment for BMS staff
- LIMS functionality should include decision support for appropriate selection of blood components based on patient characteristics including ABO/D type, age, sex, antigen, and antibody status
- LIMS alerts should be relevant, appropriate, and not easily overridden
- Transfusion laboratory staff should have a good understanding of grouping serology and how this applies to component selection

Case 14.8: Incorrect D group issued to patient – multiple influencing factors

A confirmed B D-negative patient was issued two B D-positive red cells via electronic issue. The BMS selected the incorrect D group red cells and proceeded to assign them to the patient record on the LIMS. The LIMS alerted the user to the D-incompatibility, but this was overridden. The BMS signed a laboratory issue checklist to say the units had been checked as compatible. Theatre staff waiting in the transfusion department were pressurising the BMS to prepare the units urgently. The units were collected and transfused in theatre without checking the D-status of the units and the patient.

Component labelling, availability and HSE n=220 (122 transfused errors and 98 near misses)

The component labelling, availability and handling and storage stage are the final steps in the transfusion process before the units are issued for the patient, and therefore the final stage where errors and discrepancies can be identified.

Handling and storage errors accounted for 52/122 transfused errors, with 27/52 related to cold chain errors including 12/27 refrigerator failures, 7/27 inappropriate return to stock episodes, and 4/27 inappropriate storage events. There were 16/52 errors where the dereservation period (time a component is reserved for a patient) was exceeded at the point of transfusion. In 24/122 cases, errors were related to compatibility labelling, and 29/122 due to delays. The source of delays included communication errors between clinical and laboratory staff, and misidentification of the urgency of the transfusion request.

Case 14.9: Red cell units out of temperature-controlled environment not quarantined correctly and mistakenly returned to stock and issued

Two red cell units were placed into a temperature monitored cool box for a MHP and were returned unused to the laboratory after 5 hours 21 minutes. These units should have been discarded but were instead quarantined in the laboratory refrigerator, without clear handover to next staff member. These units were returned into routine stock, issued, and transfused to other patients with no patient harm occurring.

Learning points

- Laboratory staff should pause, and review the compatibility label at the point of labelling
- There must be clear instructions for both clinical and laboratory staff to follow where the cold chain of the blood components has not been maintained

PAUSE

An overview of the laboratory data indicates that final checks of the units before they leave the laboratory could prevent errors and NM events. SHOT is introducing the PAUSE concept, encouraging laboratory staff to pause and recheck at this final critical step before the component is released for transfusion, this will help ensure that that all previous steps have been completed correctly and that unit is safe for issue to the clinical area.

At the point of unit release laboratory staff should ask themselves:

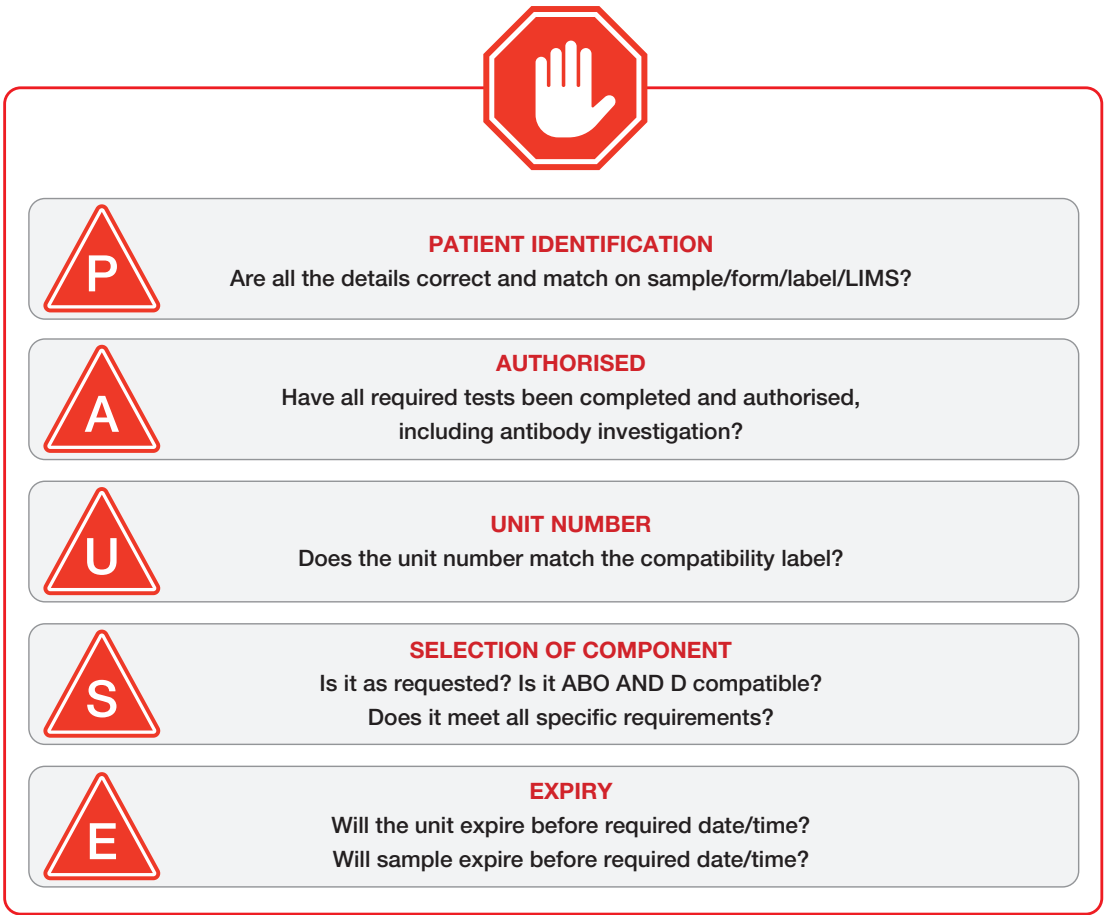


Figure 14.7: The PAUSE checklist prior to release of blood components from the transfusion laboratory

Further laboratory learning

Importance of structured handovers in the transfusion laboratories

Effective transfer of information relating to patient care helps ensure safe patient care. While a formal handover is an established and well reported process in the clinical setting, it is not so well established in transfusion laboratories. Blood transfusions occur within many hospital specialities and across clinical and laboratory staff shifts, making robust handover critical for safe practice.

Failure to adequately transfer information relating to pending or ongoing provision of blood components during shift handover in the laboratory can have an adverse impact on patient care.

Between 2015-2020, laboratory incidents involving handover were mainly associated with IBCT-SRNM and delays in provision of blood components for transfusion, with 16.6% of these cases involving major haemorrhage situations. Handover was found to be insufficient in most cases, no handover was completed in 29.5% of cases, inadequate written handover accounted for 14.8% cases, and inadequate verbal handover for 5.7% of cases (Tuckley et al. 2022).

Lack of clear communication and comprehensive handover has been shown to be causative of, or contributory to laboratory errors, particularly delays. Information vital for safe transfusion is missed in a high proportion of urgent cases where there is increased pressure and communication may not be ideal. Handover should be considered a task that is built into routine laboratory practices, ensuring effective transfer of information and appropriate follow up actions are taken. SHOT have created a handover template which can be adopted in laboratories to formalise this process (See 'Recommended resources').

Case 14.10: Transfusion delays due to lack of handover by laboratory staff

An elderly male had a delay of over 24 hours for his transfusion due to lack of handover within the transfusion laboratory regarding this patient's red cell units requiring transport to the satellite refrigerator. The BMS forgot to add the need to organise transport for these units on the laboratory handover log.

Handover is a safety critical point in the working day. Transfusion laboratories should implement a written handover log to support clear communication, as recommended in the 2020 Annual SHOT Report (Narayan et al. 2021).

Cognitive bias as a source of error in transfusion laboratories

Cognitive biases are flaws or distortions in judgment and decision-making (Tversky et al.1974). These are inconsistently reported and therefore challenging to quantify but cognitive biases are increasingly recognised as contributors to patient safety events. Whilst the contribution of cognitive biases to errors has not been systematically captured or analysed, cases reviewed have highlighted that these are under-recognised and need addressing to reduce errors (O'Sullivan et al. 2018). The following cases highlight the importance of recognising and mitigating impact of cognitive bias in day-to-day transfusion practice.

All staff need to be aware of the potential for such biases, and be trained to recognise, and if possible, prevent them through simple interventions. These include formally 'slowing down', using checklists, use of flowcharts and 'metacognition' (considering alternatives). Such strategies help mitigate the effect of cognitive bias in healthcare and improve patient safety.

Alert fatigue in transfusion laboratories

IT has become integral to day-to-day working in the laboratory. LIMS alerts are designed to ensure transfusion safety and accuracy of transfusion decisions. However, it is important to recognise that laboratory transfusion staff can get overwhelmed by multiple alerts resulting in 'alert fatigue' i.e., users inundated with constant reminders that are meant to be helpful but are more of a nuisance. This results in staff tendency to ignore notifications when they become too frequent with the potential for errors and impact on transfusion safety. Staff can overcome alert fatigue, identify, and respond to critical issues in real time, and reduce risk continuously over time if these alerts can be transformed into relevant and actionable intelligence.

Between 2016-19 over 10% of SHOT reports stated the source of error was overriding alerts (Swarbrick et al. 2022).

A structured, proactive approach is suggested to address this by using the following practices:

1. Regularly review and reduce redundant alerts

2. Make all alerts contextual and actionable

3. Ensure appropriate escalation and that correct individuals and teams are notified

4. Apply human factors principles when designing alerts (e.g., format, content, legibility, and colour of alerts). Consider having tiered alerts according to severity, consistently throughout laboratories, so that attention is drawn to those more clinically consequential thus allowing staff to maintain situational awareness and responsiveness

5. Improve the culture of safety in transfusion by creating a shared sense of responsibility between users and developers, paying careful attention to safe IT implementation, and engaging leadership in IT planning, implementation, and evaluation

LIMS alerts should be driven by evidence, well-designed logic, ensuring that an alert will only be triggered appropriately and only provides recommendations that are relevant to the laboratory staff decision at that point. Ultimately, when it comes to LIMS alerts, less is often more.

COVID-19 pandemic

COVID-19 was mentioned as a contributory factor in 9 cases and included: reduced staffing levels, additional pressures on remaining staff and staff recovering from COVID-19, pressures on ability to effectively train staff, redeployment of staff into unfamiliar areas and reorganisation of workspaces which all contributed to errors.

Pre-existing staffing issues were highlighted in the key findings of the 2019 UKTLC transfusion laboratory survey, which also detailed the high level of inexperienced staff who require training, and the overall increased level of vacancies (Bolton-Maggs et al. 2019).

Conclusion

Transfusion laboratories have a crucial role in ensuring safe and timely provision of suitable blood components for patients. A trained, competency-assessed workforce with the right skill mix is vital to support the needs of patients across all clinical disciplines. Training in human factors and understanding of cognitive bias will help improve process-based safety.

Multiple UKTLC surveys have highlighted staffing challenges, lack of appropriately trained scientists, increasing out-of-hours' workload which need to be addressed urgently to ensure transfusion safety.

The COVID-19 pandemic has worsened pressures on scientific and technical staff, requiring staffing shortages to be urgently addressed.

Effective, clear communication at multiple levels of the multidisciplinary, interprofessional team caring for patients is critical for this life-saving therapy to be effective and safe for patients.

It is also important to embed a learning culture in healthcare organisations - to support learning at an individual and organisational level, organisations need to create an environment that embeds learning into the way they do things and to continually adapt and transform. This will ensure that learning is optimised from all experiences, adverse events, and instances of excellent care.

Use of IT supports safe transfusions, but it must be set up and used correctly to be safe.

UKTLC update

Haemovigilance reporting continues to show laboratory-based errors with 389 transfused errors and 184 near misses reported this year (639 in 2020). Of the 389 transfused errors 56.3% involved IT. Laboratory errors have shown a decrease and the UKTLC aims to support the reduction of laboratory-based errors with supporting materials. The UKTLC standards from 2014 (Chaffe et al. 2014) are being updated and a 2022 revision is due to be released to provide laboratories with guidance for staffing, education, culture and IT. Further resources to support implementation of the standards and capacity plan examples will be available later this year on the UKTLC page of the SHOT website.

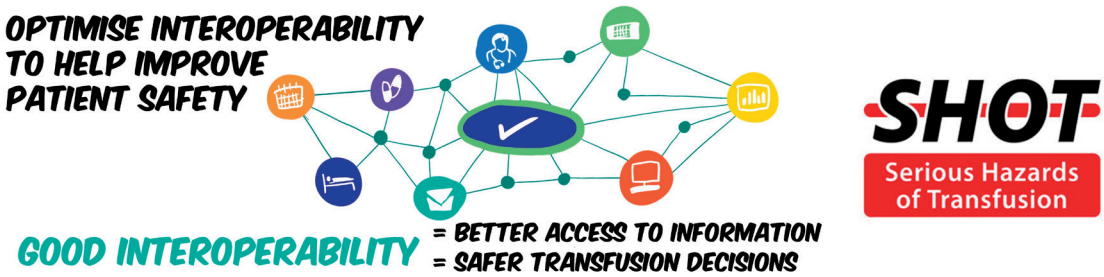
UK NEQAS update

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, errors caused by sample or result transposition, and/or data transcription into the UK NEQAS website continue to be the leading cause of penalty during EQA exercises. Participants made many of these such errors in nine out of the ten pre-transfusion testing exercises distributed during 2021. In exercise 21E6, a laboratory submitted a reaction pattern which did not match the anti-S present in the sample but appeared to match the pattern for anti-S if using a previous batch of screen and panel antigrams. In exercise 21R10, a participant submitted results identical to those in the previous exercise, and upon enquiry, it was confirmed that the samples from 21R8 had been used erroneously. 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 data entry of results of manual testing of clinical samples into a LIMS, or in the event of LIMS downtime.

During two exercises, 21R2 (Patient 3 anti-K+Fy^{a}) and 21E6 (Patient 3 anti-c+K), several laboratories excluded the presence of anti-K on the basis of negative reactions with K-positive cells in an enzyme panel. Whilst the K antigen is generally resistant to enzyme treatment, not all examples of anti-K react with enzyme treated red cells in a standard two-stage enzyme test, and anti-K should not be excluded on a negative reaction with a K-positive cell using this test alone. However, anti-K that is detectable by IAT will react in an enzyme IAT, and this technique can be useful in differentiating between anti-K and specificities where the corresponding antigen is denatured by enzyme treatment.

The results of EQA exercises also continue to show laboratories missing clinically relevant antibodies in the 'patient' plasma samples and also, conversely, recording confirmed specificities for antibodies not present in the samples. In exercise 21E3, one participant did not notice that the analyser had flagged an 'incorrect liquid level' and had not dispensed plasma into the test well; the participant missed the anti-D in two patient plasma samples as a result. A second participant in this exercise did not record the presence of anti-E for Patient 2 (anti-D+E), and a third recorded the presence of anti-C^{w} as a confirmed specificity for Patient 1 (anti-D). To avoid misidentification, every antibody investigation should include a systematic process for exclusion and positive identification of antibody specificities, and all positive reactions should be accounted for before a conclusion is reached. BSH guidance for inclusion of antibody specificities requires that 'the plasma is reactive with at least two examples of reagent red cells expressing the antigen and non-reactive with at least two examples of reagent red cells lacking the antigen. In a sample already containing anti-D, two examples of very rare D-negative C^{w} positive cells would be required to confirm the presence of anti-C^{w}. These are just two examples of antibody specificities either overlooked or confirmed when not present in the sample; the first instance having the potential to cause a haemolytic transfusion reaction, and the second possibly causing delays to transfusion where further testing of patients or donors is carried out unnecessarily.



Recommended resources

SCRIPT user and supplier report summaries
https://www.shotuk.org/resources/current-resources/script/

SHOT Bite No. 12: Cognitive Bias
https://www.shotuk.org/resources/current-resources/shot-bites/

SHOT Video: ABO-incompatible transfusion events
SHOT Video: Learning from transfusion laboratory errors
https://www.shotuk.org/resources/current-resources/videos/

The UKTLC capacity plan guidance
https://www.shotuk.org/resources/current-resources/uktlc/

An example handover document
https://www.shotuk.org/shot-reports/report-summary-and-supplement-2020/

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15 Errors Related to Information Technology (IT) n=374

Authors: Jennifer Davies, Alistair McGrann and Megan Rowley

Definition:

This chapter includes transfusion adverse events that relate to LIMS as well as other IT 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 and includes cases where IT systems could have prevented errors but were not used.

Abbreviations used in this chapter

ABOi	ABO-incompatible
BSH	British Society for Haematology
EBMS	Electronic blood management system
EPR	Electronic patient record
HTC	Hospital transfusion committee
HTT	Hospital transfusion team
Ig	Immunoglobulin
IT	Information technology
LIMS	Laboratory information management system
NHS	National Health Service
SCRIPT	SHOT Collaborative Reviewing and reforming IT Processes in Transfusion
UK	United Kingdom

Key SHOT messages

- Gaps in the interoperability of IT systems continue to cause errors in clinical transfusion practice
- Transcription errors made in the manual transfer of data between sources continues to result in avoidable incidents
- There is a disconnect between LIMS users and LIMS suppliers regarding functionality, system upgrades and interoperability with other systems that should be addressed by collaborative working to improve safe laboratory practices
- Fragmentation of the patient's electronic record across multiple digital systems makes clinically important information difficult to discover and act upon, particularly in increasingly busy working environments

Recommendations

- IT should be used to its full potential to support safe transfusion practice as well as guiding appropriate clinical decision-making relating to transfusion of blood components
- Healthcare organisations should ensure that collaborative working is in place between subject matter experts from clinical and laboratory departments together with hospital-based IT departments to ensure systems functionality and interoperability are optimised. The support of IT suppliers should be sought to further enable improvement across the range of transfusion activities

Action: NHS Trust/Health Board leaders, IT department managers, transfusion service managers, clinical service managers, IT suppliers

Background

The pandemic has had and continues to have profound consequences for the NHS severely disrupting healthcare. Digital tools have played an important role mitigating some of the challenges arising, with adoption being accelerated by necessity. Notable successes include the widespread deployment of video conferencing in support of social distancing. Over a million meetings a week are now conducted using Microsoft Teams across the NHS each week (NHS Digital 2021).

Digital infrastructure continues to be recognised politically as an important component of healthcare reform. The current Secretary of State for Health and Social Care has publicly stated the aim for 75% of all UK adults to be signed up for the NHS mobile app by March 2024 and to decrease the number of NHS organisations without an EPR from 20% to 10% by December 2023 (BMJ 2022).

Given the proliferation of digital systems in healthcare provision in the UK (DHSC 2018, Scottish Government 2018, Welsh Government 2021, Government of Ireland 2020), the need for the integration and interoperability of such systems becomes increasingly pressing. This year's incident reports continue to show that manual transcription of information between systems leads to preventable errors. In addition, opportunities to utilise information to support clinical decision making are being missed as information is not presented in a suitable accessible manner. For example, clinical information in the EPR that is essential to support decisions around transfusion is not always accessible to all those involved in decision-making. To make information available in non-interoperable systems, manual transfer of information from one system to another results in significant data integrity problems. This manual transfer is usually done either using verbal reports, paper records or transcription from one IT system to another. The choice of where and how information is stored varies from one organisation to another and the lists of systems to check for information is expanding to the point that a comprehensive review of all systems for possibly relevant information becomes impracticable for healthcare teams under increasing pressure.

In essence healthcare activity is increasingly reliant on practitioners aggregating information from an increasing number of disparate digital sources using manual steps that are vulnerable, amply demonstrated by successive years of SHOT reporting, to transcription errors. Much of the requirement regarding data aggregation is mundane, repetitive data entry work.

SHOT Collaborative Reviewing and reforming IT Processes in Transfusion (SCRIPT)

The SCRIPT group was formed by the laboratory and IT SHOT working expert groups in 2019. The main driver was to improve transfusion safety through improved IT systems and practices. SCRIPT aimed to identify gaps in practices, barriers for IT, recognise areas for improvement and begin a constructive dialogue between transfusion stakeholders and IT providers. Further goals included identifying training needs, promoting subject matter experts, and supporting and maintaining a community of practice within transfusion IT.

An initial online user survey was sent to registered SHOT reporters to gather data from transfusion professionals working in hospitals. SHOT requested that a single response was submitted per transfusion laboratory on behalf of all the hospitals/facilities that they supply blood to. Reporters were requested to submit their responses following discussion with members of the HTT, HTC and IT department, to get a holistic picture of transfusion IT throughout the hospital. The survey included questions relating to LIMS, EBMS, electronic temperature monitoring systems, electronic clinical systems, system functionality and barriers to improving systems. A summary of the findings can be accessed on the SHOT website (https://www.shotuk.org/resources/current-resources/script/). The key findings from the initial survey were:

- Several upgrades are offered for LIMS systems that transfusion services do not have the financial resources or time to implement consistently
- There was a general lack of knowledge of other electronic systems used within the hospital. For systems to be interoperable, communication should extend beyond the immediate users and the needs of the wider hospital considered where possible
- Many reporters indicated a desire for greater transparency from suppliers and increased support

- There were barriers to implementing new electronic systems for transfusion, mainly lack of resources and engagement from the Trust/Health Board
- There was a clear need for more training and resources for IT experts. A specialist role for IT experts in transfusion should be created

LIMS is a vital electronic system for transfusion laboratories, not only for controlling test results and issuing blood components, but also for interfacing with other electronic systems in the clinical area. The initial survey revealed problems with upgrades, as detailed in the key findings, and respondents noted that they would like to see:

- Increased interoperability of the LIMS with other systems (EPR, other pathology LIMS, pharmacy systems)
- Improved algorithms based on BSH guidance for sample validity, specific requirements based on age/gender, electronic issue, and remote issue, dereservation times, prevention of ABOi emergency unit release, antigen-matching between patient and component, apheresis platelets, COVID-19 convalescent plasma release, haemopoietic stem cell transplant compatibility, removal of flags, automated flags from other systems, logic for anti-D Ig release
- Improved functionality of flags and alerts

The SCRIPT team followed on from the initial survey with a survey designed to understand the current state of LIMS in the UK by speaking directly with the suppliers. The LIMS suppliers survey contained questions relating to LIMS support, functionality, and interoperability, particularly aspects identified by the responses to the initial user survey. An online survey was completed by a SCRIPT team member with representatives from the LIMS providers via virtual meeting or telephone contact between September and December 2021. There were 10 transfusion LIMS providers identified by the initial survey, all of whom were included in the supplier survey. Suppliers were asked about the specification of the current LIMS; the questionnaire did not cover details of any previous versions of the LIMS.

There was excellent participation from the suppliers, with all 10 suppliers identified from the SCRIPT user survey engaging in the survey process. The SCRIPT team would like to extend their thanks to the suppliers for engaging in this process. A summary of the findings can be accessed on the SHOT website (https://www.shotuk.org/resources/current-resources/script/) and is provided below, further details of the results can be provided on request to the SHOT office.

Interoperability with other IT systems

LIMS generally provided processes for interoperability with other IT systems. LIMS suppliers should work together with transfusion laboratory management, hospital IT departments and suppliers of other clinical IT systems to maximise interoperability within organisations and improve patient safety. Where interfacing with other systems is already present in organisations, suppliers and transfusion service managers should work together, with other relevant stakeholders, to ensure that electronic data flow is used to its full potential.

Upgrades to LIMS

Suppliers provide upgrades to LIMS which generally have no cost implications. The SCRIPT user survey noted that many organisations are not upgrading their LIMS due to cost related to implementation, time, and resource constraints. LIMS suppliers and transfusion service managers should initiate conversations to review the current LIMS version and upgrade where necessary. LIMS suppliers provide resources to support validation of upgrades which should be utilised as appropriate, and in accordance with local validation recommendations.

Functionality, rules, and algorithms

Although the majority of LIMS included rules and algorithms that supported good practice, several deficiencies were noted across a range of safe practice requirements. Suppliers should review their LIMS

to ensure that rules and algorithms support current national good practice requirements. Suppliers and transfusion service managers should work together to ensure that rules and algorithms in local LIMS are configured correctly to support good practice. Upgrading LIMS to current versions will ensure that the functionality of rules and algorithms is optimised.

Anti-D Ig management

There is a general lack of control around release of anti-D Ig in LIMS. Suppliers should review current UK guidelines and include rules and algorithms in the LIMS to support good practice.

Communication

There was a marked disparity between responses to the SCRIPT user survey and those in the supplier survey, particularly in respect to interoperability and functionality. This is potentially a result of many users having outdated versions of LIMS, a lack of understanding of LIMS configuration or lack of IT expertise within the laboratory. LIMS suppliers should work with transfusion service managers and IT departments to improve understanding, update systems, and ensure the LIMS is used to its maximum potential.

Errors related to IT in 2021

The number of reports related to IT is stable and Table 15.1 shows the distribution of errors across categories. This does not include near miss reports. The themes continue to be similar to previous years with IT flags, alerts, and warnings accounting for most errors.

Primary reporting category	Number of cases 2021
Incorrect blood component transfused (IBCT-WCT)	41
Specific requirements not met (SRNM)	116
Right blood right patient (RBRP)	109
Avoidable, delayed and under or overtransfusion (ADU)	41
Handling and storage errors (HSE)	67
Total	**374**
Anti-D Ig	25
Total including anti-D	**399**

Table 15.1: Source of cases containing errors related to IT

Further detail on IT errors can be found in individual case reports in this Annual SHOT Report.

Conclusion

The use of technology in healthcare provides an opportunity to support safe transfusion practice and reduce the risk of error. For clinical users the accessibility of patient data in a single system is key to providing safe care, however healthcare IT systems may be discrete, and integration may be challenging. When choosing electronic patient record systems, healthcare providers should ensure that interoperability with other systems is included in the user requirement specification. LIMS should support safe transfusion practice in the laboratory setting, including interfacing to other healthcare IT systems and should be regularly upgraded. Where system alerts are used in clinical and laboratory IT systems these must be appropriate and unambiguous to reduce risk of alert fatigue. IT systems have been shown to improve transfusion safety and efficiency (Murphy et al. 2019; Staples et al. 2019) and provide barriers to errors caused by human factors. However, it must be remembered that IT systems do not replace the knowledge and skills of healthcare staff. IT systems are subject to planned and unplanned downtimes and healthcare providers must have robust contingency plans for this and be able to provide continuity of the quality of care expected when the systems are unavailable. Teamwork is key to implementation and maintenance of effective electronic systems that support safe transfusion practice, this includes subject matter experts from the clinical, laboratory, IT suppliers and interfacing fields. With the inexorable march of new technology in healthcare in the UK it is incumbent on system providers to ensure that all relevant standards and best practice guidelines for transfusion are supported by their systems.

Recommended resources

SHOT SCRIPT resources
https://www.shotuk.org/resources/current-resources/script/

SHOT Laboratory and IT webinar 2020
https://www.shotuk.org/resources/current-resources/webinars/

SHOT Bite No. 13: Information Technology and Transfusion (2020)
https://www.shotuk.org/resources/current-resources/shot-bites/

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REACTIONS IN PATIENTS

16 Febrile, Allergic and Hypotensive Reactions (FAHR) n=318

Authors: Catherine Booth and Janet Birchall

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

ATD	Adult therapeutic dose	**IV**	Intravenous
BSH	British Society for Haematology	**MB**	Methylene blue treated
FAHR	Febrile, allergic and hypotensive reactions	**PAS**	Platelet additive solution
FFP	Fresh frozen plasma	**PICC**	Peripherally inserted central catheter
Hb	Haemoglobin	**SABRE**	Serious adverse blood reactions and events
IHN	International Haemovigilance Network	**SD**	Solvent detergent treated
ISBT	International Society for Blood Transfusion		

Key SHOT messages

- Use the patient's symptoms and signs to differentiate allergic from febrile reactions, as they require different investigation and treatment
- Do not give antihistamine or a steroid to treat or prevent febrile reactions
- Anaphylactic transfusion reactions are unpredictable and can occur in any setting. All staff involved in administering transfusions should be trained in recognition and management of severe allergic reactions
- The possibility of a febrile or allergic reaction should be explained to patients/guardians when taking consent for transfusion

Recommendations

- Give appropriate targeted treatment and if needed, use preventative cover for future transfusion (BSH Tinegate et al. 2012), as indicated below:

Table 16.1: Targeted treatment for febrile and allergic transfusion reactions

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 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. SD-treated plasma

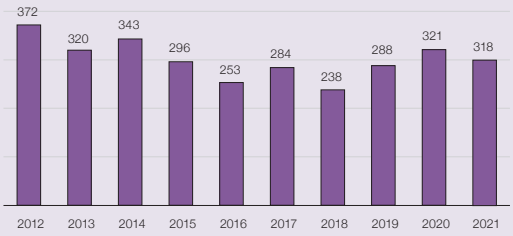
- Transfusion teams should audit appropriateness of treatment given for acute transfusion reactions and take relevant actions

Action: Hospital transfusion teams

Headline data 2021

Number of reports n=318
Deaths n=0
Major morbidity n=74

FAHR reports by year



Demographic data

Male n=145
Female n=173
Adults n=272
Paediatric n=42
Unknown n=4

Blood component data

Red cells n=179
Platelets n=96
Plasma n=19
Multiple components n=23
Granulocytes n=1

Introduction

Reactions are classified according to the ISBT/IHN definitions, which are summarised below in Table 16.2, available online (ISBT/IHN 2011) and have been adopted by the BSH (BSH Tinegate et al. 2012). Mild reactions are not reportable to SHOT.

Table 16.2: 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*

As the reporting categories on SABRE can cause confusion, the SHOT definitions document has been updated for 2022 to clearly map which category to select when submitting a report.

Total number of FAHR reactions n=318

Although the number of reactions reported is similar to 2020, this was still more than 10% higher than in previous years. This is due to an increase in the reports of febrile reactions, while allergic reactions remain stable.

Deaths related to transfusion n=0

There were no deaths related to the transfusion reactions in 2021.

Major morbidity n=74

The ISBT/IHN classification of a severe reaction has been used to define major morbidity.

Reactions are categorised in Table 16.3.

	Moderate	Severe	Total
Febrile	158	16	174
Allergic	58	50	108
Mixed allergic/febrile	20	6	26
Hypotensive	8	2	10
Total	**244**	**74**	**318**

Table 16.3: Classification of FAHR in 2021

NB: in 20 of the 74 reactions classified as severe this was primarily because the patient was admitted or kept in overnight or re-presented to the hospital after discharge

Excluded reports n=150

There were 468 cases initially reported as FAHR. Of these, 140 cases were withdrawn, and 10 cases were transferred to other SHOT reaction categories. This resulted in 318 FAHR cases for analysis and inclusion in the Annual SHOT Report. Of the withdrawn cases, 65/140 (46.4%) were withdrawn as they were mild reactions, which have not been reportable to SHOT since 2012. The remaining reports were withdrawn as clinical details suggested the reaction was not related to the transfusion, or did not fit the criteria for reporting to SHOT (for example, reactions to anti-D Ig which are only reportable to the MHRA yellow card scheme).

Reactions in IgA deficient patients n=4

There were 4 reactions reported in patients who on subsequent investigation were discovered to have severe IgA deficiency with anti-IgA antibodies. All occurred within the first 15 minutes of transfusion. Of these, 3 were febrile reactions; 2 of these patients had marked systemic upset, with other features including hypertension, breathlessness, myalgia and vomiting. The 4th case was an anaphylactic reaction involving bronchospasm and hypotension in a patient under anaesthesia.

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. Transfusion should be carried out in a setting where there is immediate access to skilled clinical help (Latham 2019).

Anaphylactic reactions n=32

Anaphylaxis is a serious systemic hypersensitivity reaction that is usually rapid in onset. It is characterised by potentially life-threatening compromise in airway, breathing and/or the circulation, with or without typical skin features or circulatory shock (Resuscitation Council UK 2021).

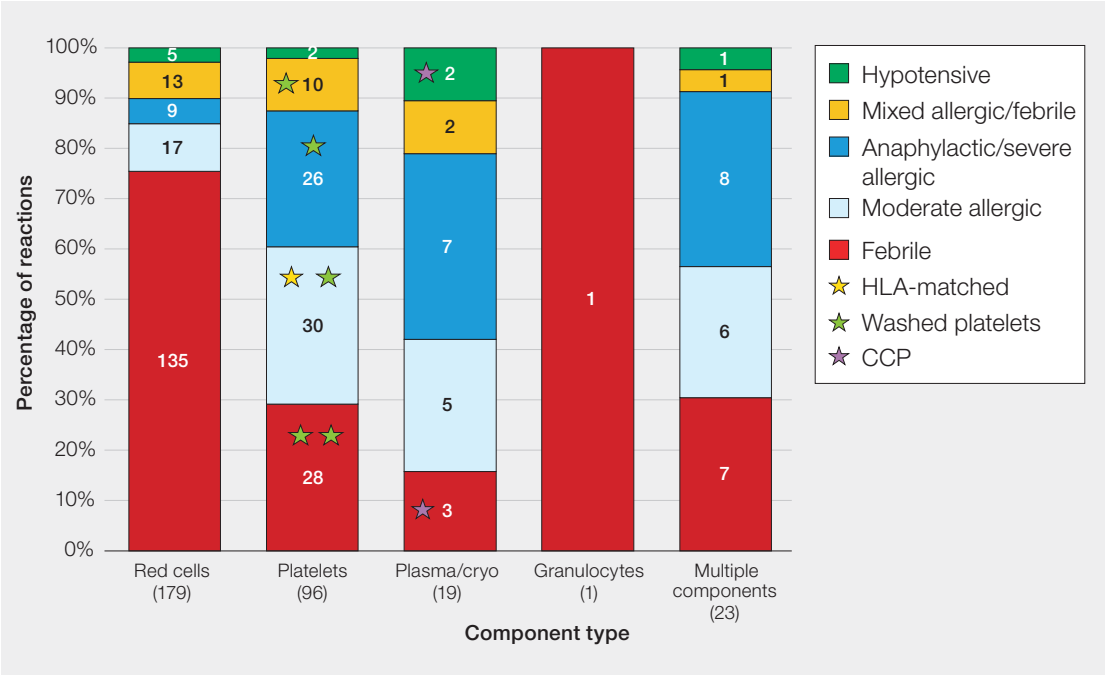
There were 32 reactions reported which required the use of adrenaline. In 15 cases the transfusions were routine, and 5 occurred in an outpatient or day care setting. Children were disproportionately represented: 10/32 (31.3%) cases were in patients under 18 years. There was 1 unnecessary transfusion (a fourth unit of platelets given to a patient with an intracranial haemorrhage who was taking aspirin), and 1 patient was subsequently discovered to have IgA deficiency (see above).

This highlights the importance of close monitoring and observation of patients receiving transfusions. Staff should be able to recognise any complication and act promptly.

Type of reaction by component

This remains similar to previous Annual SHOT Reports; see Figure 16.1. Red cells are usually associated with febrile-type reactions, 135/179 (75.4%), whereas plasma components and platelets more commonly cause allergic reactions, 12/19 (63.2%) and 56/96 (58.3%) respectively. There were 2 reactions reported with the use of COVID-19 convalescent plasma. None were reported in association with solvent-detergent treated FFP or methylene blue treated components.

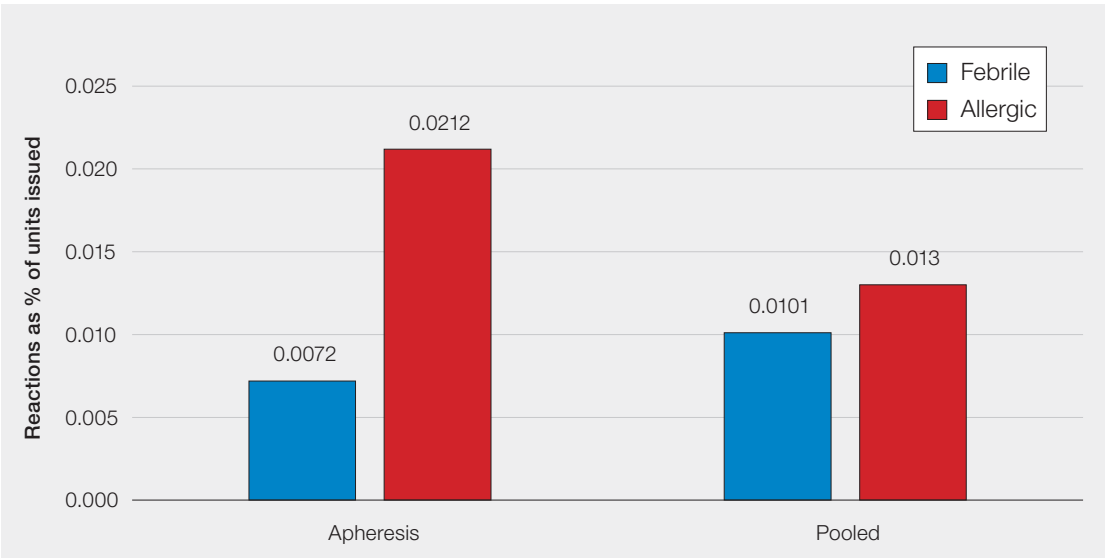
Figure 16.1: Reactions by component type



HLA=human leucocyte antigen; CCP=COVID-19 convalescent plasma; cryo=cryoprecipitate

The overall incidence of reactions of all types combined is greater for apheresis 48/145,920 (0.03%) than for pooled 35/137,932 (0.025%) platelet components (there were 13 cases that did not specify the type of platelets). Fewer allergic reactions continue to be reported in association with pooled platelets in PAS than apheresis platelets, which is linked to the lower plasma content (Figure 16.2) (Estcourt et al. 2017).

Figure 16.2: Incidence of reactions as a percentage of platelet units issued



Analysis of reactions remains comparable to previous years in the following characteristics (Table 16.4):

Table 16.4: Characteristics of FAHR

Recipient or transfusion characteristic	Percentage
Age distribution	84% of patients were aged 18 years or over
Gender	46% male and 54% female cases
Urgency of transfusion	63% were given routinely
Timing of transfusion	73%* occurred within standard hours
Location	62% were on wards and 17% in outpatient/day case units

**Higher % of cases than previous years likely associated with fewer cases reported as unknown*

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; see Table 16.5. In addition to no evidence of benefit, the repeated use of steroids may further suppress immunity in already immunocompromised patients and increase the risk of side effects such as infection.

	Number	Medication stated	Antihistamine and/or steroid
2021	174	155/174 (89.1%)	61/155 (39.4%)
2020	166	140/166 (84.3%)	58/140 (41.4%)
2019	146	130/146 (89.0%)	62/130 (47.7%)
2018	103	88/103 (85.4%)	39/88 (44.3%)
2017	140	121/140 (86.4%)	46/121 (38.0%)
2016	124	102/124 (82.3%)	51/102 (50.0%)
2015	142	101/142 (71.1%)	57/101 (56.4%)
2014	144	97/144 (67.4%)	42/97 (43.3%)

Table 16.5: Reported treatment of febrile reaction

In 2023, as part of the annual participation benchmarking exercise for 2022, SHOT will provide feedback on the proportion of reactions from each Trust/Health Board where the SHOT working experts judged that alternative treatment might have been more beneficial. This will give a means of benchmarking and can be used to target local quality improvement initiatives.

SHOT have produced a quick-reference guide to aid classification and immediate management of febrile and allergic reactions (Figure 16.3), which can also be found in SHOT Bite No. 5: FAHR (see 'Recommended resources').

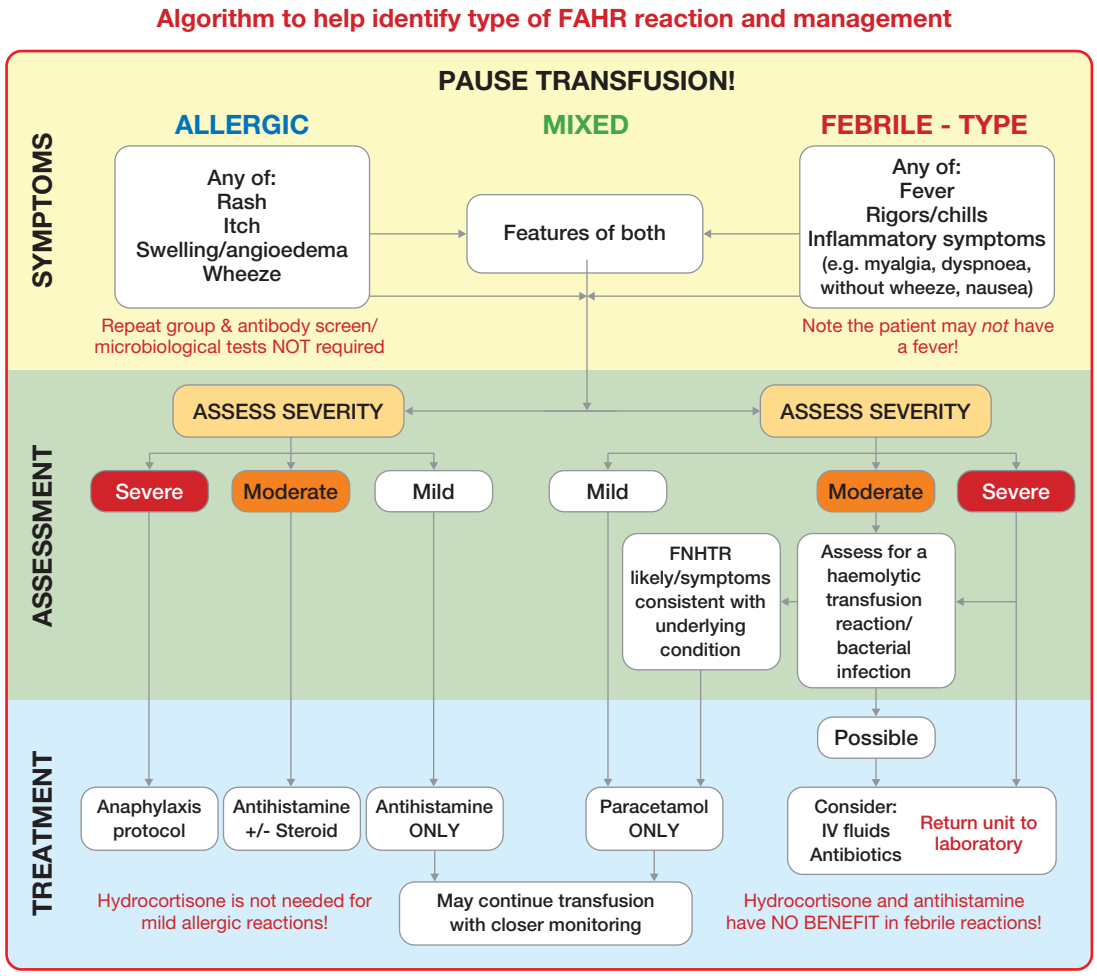


Figure 16.3: Algorithm for classification and management of febrile and allergic reactions

Subsequent management

A plan for subsequent treatment of febrile reactions was only given in 18 cases, likely reflecting that many patients are not expected to need further transfusion. While only 3 reports explicitly gave a plan to use antihistamine with or without steroids to treat a subsequent pure febrile reaction (Table 16.6), a further 4 stated 'premedication'. The use of washed blood components in 9/18 (50.0%) was the most frequently chosen management for future transfusions.

Table 16.6: Planned treatment of subsequent febrile reactions

	Number where treatment stated	Antihistamine +/- steroid stated
2021	18	3/18 (16.7%)
2020	33	7/33 (21.2%)
2019	42	7/42 (16.7%)
2018	27	8/27 (29.6%)
2017	22	5/22 (22.7%)
2016	21	9/21 (42.9%)
2015	9	7/9 (77.8%)
2014	24	9/24 (37.5%)

Illustrative cases

Case 16.1: Allergic reaction to an unnecessary platelet transfusion

A man in his 50s was transfused one ATD of apheresis platelets to cover a PICC insertion in interventional radiology. He developed peri-orbital and lip swelling and a rash. He was treated with IV hydrocortisone and chlorphenamine with resolution of his symptoms.

BSH guidelines (BSH Estcourt et al. 2017) recommend that platelet transfusions should not be used routinely prior to PICC insertion, regardless of the patient's platelet count.

Case 16.2: Future transfusion plan fails to account for reaction type

A woman in her 80s with transfusion-dependent anaemia required one unit of red cells following two large nose bleeds. Her Hb was 68g/L with a stated target Hb of >90g/L. Midway through transfusion she developed pyrexia (temperature 38°C from baseline 36.5°C), rigors and vomiting. The transfusion was stopped. Investigations revealed no evidence of a serological reaction. On review, frequent transfusion reaction investigations had been performed previously due to similar symptoms. The patient was given a plan for premedication with paracetamol, chlorphenamine, hydrocortisone and furosemide for future transfusions.

The choice of premedication appears to be a scatter-gun approach to cover all possible eventualities. This patient suffered recurrent febrile-type reactions, which would be best managed by premedication with paracetamol. If reactions persist, this might be an indication for washed red cells. The history suggests numerous abandoned transfusions, causing wastage of a precious resource, inconvenience to the patient and additional workload for both clinical and laboratory teams.

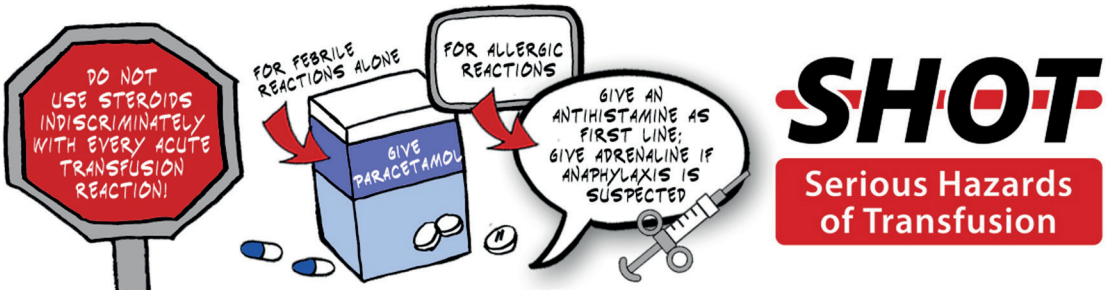
Learning points

- The risk of an acute reaction to transfusion should be a part of the evaluation process when making the decision to transfuse. Patients should be warned of the possibility of a reaction during consent
- 'Premedication' is not a one-size-fits-all cocktail suitable for all eventualities. Treatment of transfusion reactions and prophylaxis for those with recurrent reactions must be tailored to the type of reaction (allergic versus febrile) and its severity

Conclusion

Febrile, allergic and hypotensive reactions are an unavoidable and largely unpredictable risk of transfusion. While most are minor, anaphylaxis can be life-threatening and this underlines the need to ensure that transfusion is only given when clinically indicated and there is fully informed patient consent. There is continuing suboptimal management of acute transfusion reactions, particularly the inappropriate use of antihistamine and/or steroids to treat febrile reactions (in 39.4% of cases). The key message remains the need to use the patient's symptoms and signs to distinguish febrile from allergic reactions and to tailor management accordingly.

SHOT is planning to feedback on appropriateness of reaction management in the annual participation summary to all Trusts/Health Boards, beginning at the next Annual SHOT Report (2022 cases). This will provide benchmarking data and can be used to target local quality improvement initiatives.



Recommended resources

SHOT Bite No. 5: FAHR
https://www.shotuk.org/resources/current-resources/shot-bites/

SHOT Video: FAHR
https://www.shotuk.org/resources/current-resources/videos/

References

BSH Estcourt LJ, Birchall J, Allard S, et al. on behalf of the British Committee for Standards in Haematology. Guidelines for the use of platelet transfusions. *Br J Haematol.* 2017;**176**(3):365-394.

BSH Tinegate H, Birchall J, Gray A, et al. Guideline on the investigation and management of acute transfusion reactions. Prepared by the BCSH Blood Transfusion Task Force. *Br J Haematol.* 2012;**159(2)**:143-153.

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17 Pulmonary Complications n=161

Author: Tom Latham

Abbreviations used in this chapter

ISBT	International Society of Blood Transfusion	**TAD**	Transfusion-associated dyspnoea
RC	Revised consensus (TRALI criteria)	**TRALI**	Transfusion-related acute lung injury
TACO	Transfusion-associated circulatory overload	**WEG**	Working expert group

Key SHOT messages

- Classification and nomenclature of pulmonary complications are evolving. When using these terms, staff need to be precise in clarifying what is meant when the terminology is used
- Preventable risk factors, in particular fluid overload, are often identifiable regardless of the final classification. Structured incident investigation may be useful to ensure that risk factors and preventative actions are identified

Classification of pulmonary reactions: clear reflection or confusing rabbit hole?

> 'When I use a word,' Humpty Dumpty said, in rather a scornful tone, 'it means just what I choose it to mean-neither more nor less.' 'The question is,' said Alice, 'whether you can make words mean so many different things.' 'The question is,' said Humpty Dumpty, 'which is to be master-that's all. – Lewis Carroll

The overview chapter this year focuses on current challenges and controversies in classifying pulmonary complications of transfusion and discusses the rationale for the decision to consolidate non-TACO pulmonary complication cases into a single chapter in the Annual SHOT Report.

Pulmonary complications of transfusion contribute significantly to transfusion-related morbidity and mortality. In this year's Annual SHOT Report, there were 18 deaths in patients who were reported to have pulmonary complications thought to be at least possibly due to the transfusion. Gaining a better understanding of why some patients develop respiratory deterioration after transfusion is therefore a priority for transfusion safety. Patients with pulmonary complications post transfusion are often complex with multiple pathologies being present simultaneously, and it is difficult to disentangle the contribution of the underlying disease, the fluid load of the transfusion, and biologically active mediators in the transfusion (including leukocyte antibodies but with the possibility of other undiscovered agents).

Organisation into categories is a natural approach to understanding complex phenomena, aiming to reduce cognitive load by grouping together cases with features of interest in common and to provide a concise terminology for discourse and record keeping. The generally accepted approach for pulmonary reactions is to classify as either TACO, TRALI or TAD. In recent years there has been much work internationally to standardise definitions. The ISBT TACO criteria have undergone international validation and have been found to be useful, perhaps underpinned by the idea that fluid overload is a pathologically defined concept even though clinical recognition may be challenging. The RC TRALI criteria have been more controversial and yet to be validated. It remains to be seen whether they will be adopted

internationally, but it does not appear that the goal of reaching a consensus of what is understood by 'TRALI' has yet been achieved. TAD remains a diagnosis of exclusion for cases which do not meet TACO or TRALI criteria, and thus does not represent a pathologically defined entity. A classification as TAD is dependent on the definition chosen for TRALI and TACO and whether there is sufficient clinical information available to apply the definitions.

All categorisations are to some extent artificial constructs, and this is particularly evident for pulmonary complications, where there is no naturally apparent dividing line and no gold standard diagnostic investigation. The usefulness of categorisations to a user depends on whether they preserve the features which the user is interested in. However, different users have different needs. For example, *haemovigilance practitioners* need to identify trends which could identify emerging safety concerns and monitor the effectiveness of preventative recommendations. *Blood Services* need to identify concerns with blood products and to identify donors who may need deferral in order to preserve safety of the blood supply. *Clinicians* need simple indicators based on clinically measurable or observable features to identify prevention and treatment interventions. *Researchers* need objective and precisely defined criteria so that work is reproducible and which either maximises the probability of including phenomena of interest or minimises the probability of including cases where the object of study is not present. There is a conflict between a precisely defined classification losing information which is of interest to a particular group, or a more conceptual categorisation leading to unclear communication because of differences of interpretation.

In this year's Annual SHOT Report, the pulmonary WEG have attempted to escape between the horns of the dilemma by consolidating pulmonary cases which do not meet ISBT TACO criteria into a single chapter and accepting that it is probably most helpful to view a complex object from multiple angles rather than to force cases into mutually exclusive classes in a single classification system. The approach is to acknowledge that all factors that could have contributed to the reaction probably interact rather than trying to work out which was the most important factor. Classification of cases using the RC TRALI schema will be important for international comparison. There does not seem to be a clear separation between cases classified using this schema but perhaps this will become clearer with larger numbers of cases either through international collaboration or historical review of cases. The number of cases with leukocyte antibodies remains low, with only 1 case this year, but it remains important to continue to monitor leukocyte antibodies to monitor the effectiveness of TRALI prevention strategies.

The technical details of classification can sometimes seem arbitrary and of little interest to non-specialists. By consolidating cases and returning the focus to identifying preventable factors, it is hoped that it will be easier to see the bigger picture. One message does emerge from the new approach, which illustrates the benefit of using parallel approaches. The strict application of ISBT TACO criteria ensures that fluid overload was present in cases included in the TACO chapter with high confidence. The recurring conclusion from this year and previous reports is that recognition and prevention of fluid overload is often incomplete. Complementary to this conclusion is the finding from the non-TACO chapter that risk factors or features suggesting fluid overload were present in over half of the remaining pulmonary cases, and therefore preventative messages could potentially be extended more widely. Cases may often be difficult to classify because of missing information or subjectivity of interpreting definitions, but preventative actions may nevertheless be identifiable.

TACO is still the main cause of death from transfusion and much work is being done on prevention. This should be extended to all pulmonary complications. Use of TACO checklists and structured investigation of incidents remains the main focus of prevention, although there is further work needed on assessing whether mitigating actions were sufficient. Only 12/40 cases where a checklist was completed had all mitigating actions performed. It will not be possible to prevent all respiratory deteriorations with a temporal relationship to transfusion but at least those that can be prevented may be identified through pre-transfusion checks. Future goals might be to improve understanding of which patients with inflammation are sensitive to fluid, how to prevent any adverse impact, and identify which reactions to investigate for leukocyte antibodies.

17a Transfusion-Associated Circulatory Overload (TACO) n=131

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† of 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 17a.2 for details of required and additional criteria for a surveillance diagnosis

Abbreviations used in this chapter

BSH	British Society for Haematology	**NCA**	National comparative audit
CT	Computed tomography	**NT-pro BNP**	N-terminal-pro B-type natriuretic peptide
Hb	Haemoglobin	**TACO**	Transfusion-associated circulatory overload
HDU	High dependency unit	**TRALI**	Transfusion-related acute lung injury
WEG	Working expert group		

Key SHOT message

- Patients who develop respiratory distress during or up to 24 hours following transfusion where transfusion is suspected to be the cause must be reported to SHOT. The TACO definition criteria can be used as guidance, but this should not be restrictive. SHOT pulmonary WEG can transfer cases between categories

Recommendations

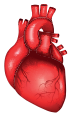
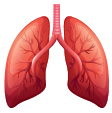
- A formal pre-transfusion risk assessment for TACO should be undertaken whenever possible for all patients receiving blood transfusion (especially if older than 50 years or weighing less than 50kg) and appropriate mitigating actions taken
- Use weight-adjusted red cell dosing to guide the appropriate number of units required, for all non-bleeding adult patients, ideally using tools which also highlight inappropriate transfusion (Grey et al. 2018, NCA 2017)

Action: All staff authorising transfusion

- A structured review and incident investigation should be undertaken for every case of TACO to optimise organisational and individual patient-safety measures

Action: Trust/Health Board governance and clinical risk departments, all staff investigating transfusion incidents

The TACO pre-transfusion risk assessment infographic (Figure 17a.1) was updated in the 2020 Annual SHOT Report to make it suitable for incorporation into clinical documents. No further update was required this year.

TACO Checklist	Patient Risk Assessment	TICK
	Does the patient have a 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 can be 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	
Monitor vital signs closely, including oxygen saturation	

Name (PRINT):	
Role:	
Date:	**Time (24hr):**
Signature:	

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.

TACO=transfusion-associated circulatory overload

Figure 17a.1: TACO pre-transfusion checklist

Introduction

The traditional hypothesis for the pathophysiology of TACO is increased hydrostatic pressure in the pulmonary capillaries which surround the alveoli which results in a transudate and increased interstitial pressure. This is forced into the alveoli causing pulmonary oedema which compromises normal lung function, leading to hypoxia. Other mechanisms have been proposed. These include a TRALI-like response where inflammatory cells disrupt the endothelial barrier resulting in the passage of transudate and exudate. The interstitium becomes widened and epithelial layer of the alveolus is disrupted allowing the passage of inflammatory cells and exudate resulting in pulmonary oedema. Mechanical destruction (barotrauma) may cause increased permeability and dysfunction of the capillary endothelial layer. The increased intra-capillary pressure disrupts the endothelial glycocalyx of the capillary allowing transudate and exudate to penetrate the epithelial barrier of the alveolus. Storage lesions such as the presence of microparticles or cell-free haemoglobin may induce vasoconstriction of the capillary resulting in transudate and exudate which disrupts the epithelial barrier of the alveolus (Bosboom et al. 2019). The emerging complexity of the mechanism of transfusion-related pulmonary oedema creates significant difficulties for definitive categorisation for haemovigilance purposes, and increasingly strengthens the hypothesis that pulmonary complications of transfusion may not be mutually exclusive.

Although the pathophysiology of TACO is not fully understood, the evolving understanding of risk factors for TACO and the development of tools to mitigate risks has been a significant advance in recent years. This chapter describes the demographics of patients reported to have TACO, haemovigilance categorisation, and the adoption of TACO risk-reduction strategies, and highlights areas requiring further focus.

Deaths related to transfusion n=11

TACO resulted in the death of a patient in 11 reported cases. With exception of 1 case the imputability level was low (possibly related to transfusion). There were fewer deaths compared to the previous reporting year (18 in 2020) which was significantly affected by COVID-19. This was likely to have been influenced by the severity of underlying illness of those with COVID-19 and as such were more likely to die.

Major morbidity n=23

There were a similar number of cases that resulted in major morbidity compared to the previous reporting year (25 in 2020). This may reflect a continued increased number of patients with severe respiratory comorbid disease due to COVID-19 but fewer that resulted in the patient's death, as COVID-19 related deaths began to fall. TACO remains the leading cause of transfusion-related combined mortality and major morbidity.

Table 17a.1: Demographic overview of cases

Demographic	Number of reports
Deaths (imputability 3)	0
Deaths (imputability 2)	1
Deaths (imputability 1)	10
Major morbidity outcome	23
Age	Range: 2-97 years (four age under 18 years) Median: 75 years
Gender	76 female: 55 male
Body weight (adults)	Female (n=38): average 65.2kg (38.0-118kg) Male (n=33): average 75.2kg (51.0-125.6kg)
Top four medical specialties where TACO was reported	Acute medicine 16.0% (21), haematology 14.5% (19), emergency medicine 12.2% (16), general medicine 10.7% (14)
Bleeding patients (indication code R1 or 'massive bleeding' indicated	28
Non-bleeding patients (other indication codes or not stated)	103

Commentary

TACO is more commonly reported in the elderly, non-bleeding patients but is seen across all age groups and is consistent with the data from previous years. There were 4 cases in the under-18 age group, (age 2 to 16 years). TACO was reported more in adult female patients compared to male. Weight was provided in 38 adult female cases, with an average of 65.2kg (38.0-118kg). Weight was provided in 33 adult male cases, with an average of 75.2kg (51.0-125.6kg). This difference may account for the apparent higher incidence of TACO in female patients and underlines the risk of TACO in lower-weight patients and the importance of weight-adjusted red cell dosing. Adult medical specialties and haematology continue to be the most common specialties where TACO is reported, and this should be considered when delivering TACO education and mitigation plans.

Analysis by definition criteria

Cases reported in 2021 were assessed using the surveillance criteria in Table 17a.2. It should be noted that the criteria are for the purposes of reporting and surveillance and do not constitute a clinical diagnosis for the purpose of real-time interventions for the medical management of a patient presenting with respiratory compromise during or following transfusion. However, the surveillance criteria should help promote recognition of TACO.

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

Table 17a.2: TACO surveillance definition (adapted from Wiersum-Osselton et al. 2019)

Figure 17a.2 shows the number of accepted TACO cases versus the number of TACO surveillance criteria met. The majority of cases met four criteria. Only 2 cases met all five criteria where a pre- and post-transfusion BNP sample had been taken. This is a useful biomarker to demonstrate left atrial hypertension. In previous years, cases were accepted that did not fully meet the criteria due to missing data but were otherwise clinically compelling cases. A decision has now been taken to not include these cases and instead transfer them to the non-TACO category for separate analysis.

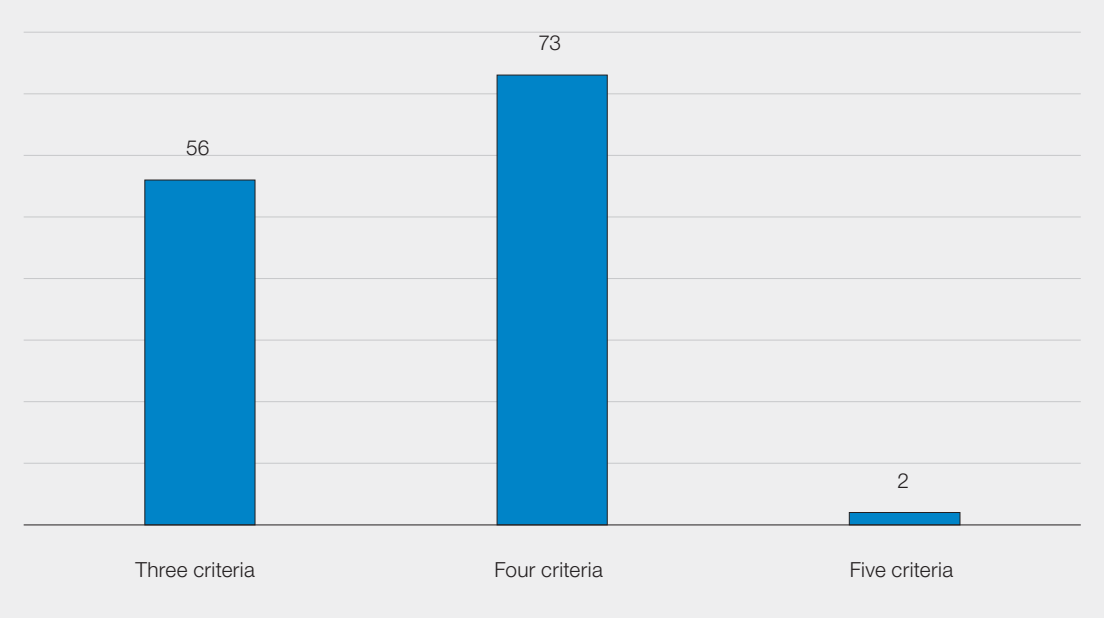
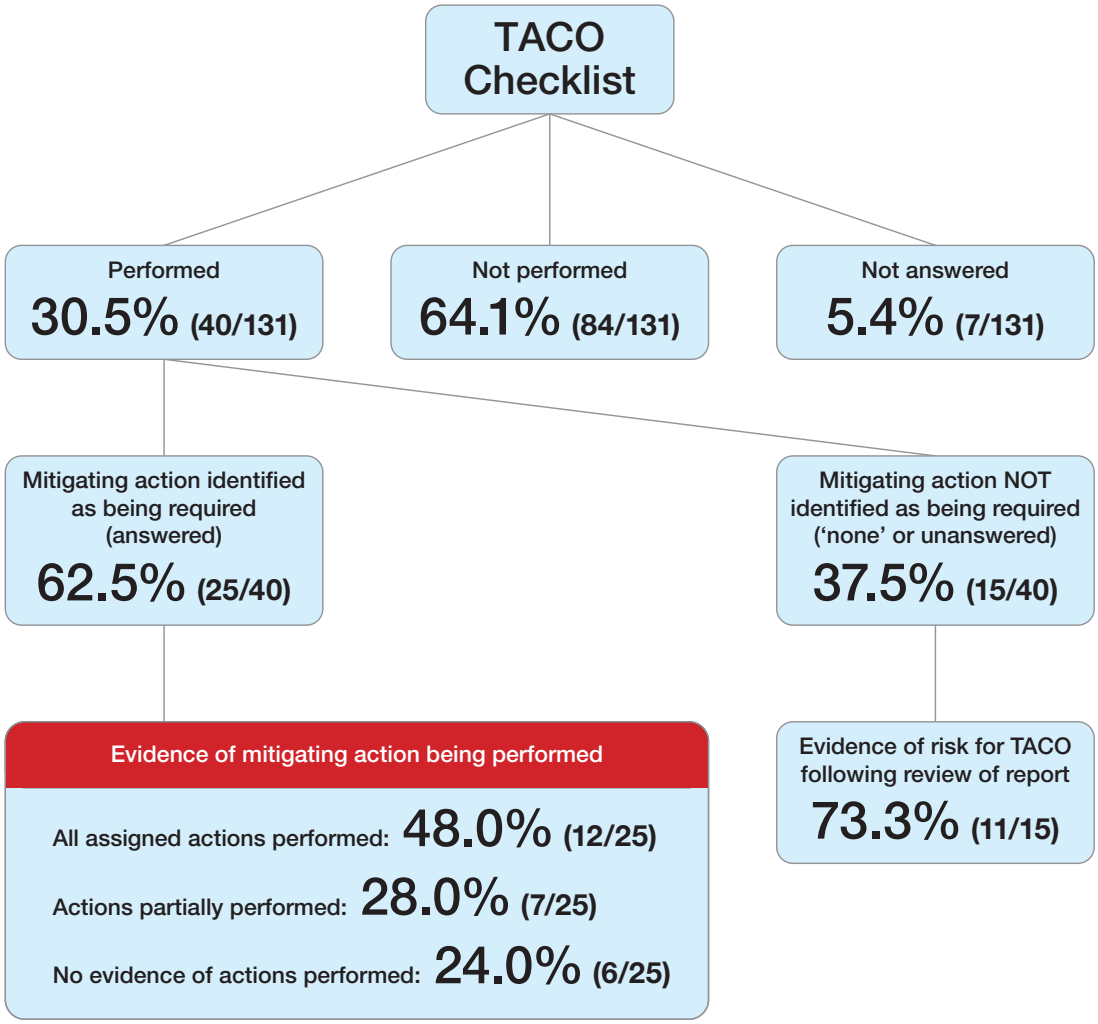


Figure 17a.2: Number of surveillance criteria versus number of accepted TACO cases

Use of the TACO checklist

The recommendation for a formal pre-transfusion TACO risk assessment was introduced in the 2015 Annual SHOT Report (Bolton-Maggs et al. 2016). A question regarding the use of the TACO risk assessment and mitigating actions was added to the SHOT questionnaire for the 2019 reporting year. An overview is shown in Figure 17a.3.

Figure 17a.3: Use of the checklist to identify patients at risk of TACO and implementation of mitigating actions



TACO=transfusion-associated circulatory overload

The TACO checklist was reported to have been used in only 40/131 (30.5%) cases. It is disappointing that the checklist is not universally utilised as there may have been missed opportunities to reduce the risk of TACO. This has been a SHOT recommendation since 2016 and is also highlighted in the BSH guideline on the administration of blood components (BSH Robinson et al. 2018). Where a TACO checklist was performed 25/40 (62.5%) this demonstrated the need for a mitigating action and in most cases appropriate actions were taken. There were 6 cases where assigned actions had not been performed and 7 where the actions were only partially complete. Where a TACO checklist was performed and it was determined a mitigating action was not required, a review of these reports showed that 11/15 (73.3%) did in fact have at least one risk factor for TACO. It is important to recognise that while the TACO risk assessment does not guarantee avoidance of TACO, it can provide a means of identifying patients at risk. This helps apply strategies to reduce it and help make safe transfusion decisions.

TACO cases with evidence of excessive red cell volume to meet the target Hb

The recommendation for weight-adjusted red cell dosing with tools to identify inappropriate transfusion for non-bleeding patients was introduced in the 2017 Annual SHOT Report (Bolton-Maggs et al. 2018). Analysis of the 2021 data shows that this is not sufficiently implemented in practice and is contributing to overtransfusion in some reported cases of TACO. There were 20 cases involving red cell transfusions that reported a body weight, a pre- and post-transfusion Hb level and the number of units transfused. In 3/20 (15.0%) of cases transfusion was not required because the Hb was already within the target range. There were 2/20 (10.0%) cases that received more than the calculated weight-adjusted dose, and in 3/20 (15.0%) cases, the post-transfusion Hb target was exceeded.

Case 17a.1: Omitted TACO risk assessment led to overtransfusion and TACO, with no structured investigation performed

*A male patient in his 70's weighing **64kg** was admitted to a medical ward with **severe symptomatic microcytic hypochromic anaemia (Hb 47g/L).** His pre-transfusion CT scan showed some pulmonary fibrosis and a small pleural effusion. He had **severe left ventricular systolic dysfunction**, **renal impairment**, **peripheral oedema** and was on a **regular diuretic**. He was initially transfused uneventfully with two units of red cells. A TACO risk assessment was not performed and a fluid balance chart was not in place. His post-transfusion Hb was 65g/L. He was then given a third unit of red cells. There were no signs of active bleeding. He became wheezy, hypertensive, tachycardic, pyrexial and had rigors. His oxygen saturations reduced to 75% and he had peripheral pitting oedema. His post-transfusion chest X-ray showed consolidation thought to be caused by aspiration pneumonia and new bilateral infiltrates consistent with pulmonary oedema. He received oxygen via continuous positive airway pressure, a diuretic, hydrocortisone, bronchodilator and antibiotics. He was transferred to HDU and later recovered. The local procedural review identified single unit with review and not transfusing blood for iron deficiency as preventative actions.*

This patient had multiple risks for TACO (in **bold** above). A TACO risk assessment/checklist was not performed but would have identified these, and there were no reported mitigations put in place. A single unit red cell transfusion followed by intravenous iron would have sufficed to treat this patient's severe symptomatic anaemia. Three units of red cells was excessive in a relatively low weight patient with no active bleeding. TACO was almost inevitable in this scenario. Although a local review took place it did not identify all strategies to avoid TACO. The TACO structured investigation tool (see recommended resources) would have also highlighted the need for single unit transfusion and review, weight-adjusted red cell dosing, fluid balance chart, increased measurement of oxygen saturation, a prophylactic diuretic in addition to his regular medication (if not contraindicated). These measures would have helped mitigate the risk for this transfusion episode and help in planning future transfusions. It also represents an opportunity to improve practice and reduce risk for all future patients.

Learning points

- Excessive volume of red cell transfusion to meet a target Hb level remains a significant factor in cases of TACO, in non-bleeding patients. This can be minimised by weight-adjusted red cell dosing, and medical management of anaemia where possible. The calculation below helps estimate the volume of red cells required to meet the target Hb (Norfolk 2013)

  [target Hb (g/L) - pre-transfusion Hb (g/L)] x weight (kg) x 0.4mL red cells = volume of red cells (mL) required to meet target Hb

  (The volume of a unit of adult-specification red cells in the UK is 220-340mL)

- A significant number of reported TACO cases do not appear to have had a TACO checklist performed, and/or TACO risk-reduction measures not implemented where risk was identified. This should be embedded into the procedure for the request and authorisation of transfusion
- Every case of TACO is an opportunity to improve practice and reduce risk for other patients. Structured incident investigation allows implementation of effective corrective and preventative actions

Conclusion

The continued adoption of the TACO checklist is encouraging though analysis of the data shows it is still under-utilised. The data suggests that there is lack of structured investigation following cases of TACO and this results in missed opportunities to mitigate the risk of TACO and to improve transfusion safety for all patients. The TACO structured investigation tool was launched last year in the 2020 Annual SHOT Report and continues to be a recommendation this year. The pulmonary reactions questionnaire in the SHOT database (Dendrite) has been updated to include a question as to whether it was performed

and what gaps and preventative actions were identified. This will inform the degree to which it is being adopted and will also provide important data regarding the implementation of risk-reduction measures.

Recommended resources

Example of weight-adjusted red cell dosing implemented in clinical practice
www.rcdcalculator.co.uk

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 Bite No. 11: Respiratory Symptoms During Transfusion
https://www.shotuk.org/resources/current-resources/shot-bites/

SHOT Video: TACO
https://www.shotuk.org/resources/current-resources/videos/

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Pulmonary Complications of Transfusion: Non-TACO (n=30)

17b

Authors: Tom Latham and Shruthi Narayan

Acknowledgements: All members of the pulmonary WEG

Definition:

Cases where there was respiratory deterioration temporally related to transfusion which may not be due to the patient's condition and which do not meet SHOT surveillance criteria for TACO.

Abbreviations used in this chapter

AF	Atrial fibrillation
ARDS	Acute respiratory distress syndrome
ATD	Adult therapeutic dose
ATRA	All-trans-retinoic acid
BNP	B-type natriuretic peptide
CCU	Critical care unit
CLL	Chronic lymphocytic leukaemia
COPD	Chronic obstructive pulmonary disease
CXR	Chest X-ray
FAHR	Febrile, allergic and hypotensive reactions
FFP	Fresh frozen plasma
GI	Gastrointestinal
Hb	Haemoglobin
HDU	High dependency unit
ISBT	International Society of Blood Transfusion
ICU	Intensive care unit
IV	Intravenous
RC	Revised consensus (TRALI criteria)
TACO	Transfusion-associated circulatory overload
TAD	Transfusion-associated dyspnoea
TRALI	Transfusion-related acute lung injury
UCT	Uncommon complications of transfusion
WEG	Working expert group

Key SHOT message

- The understanding and nomenclature of pulmonary complications is evolving. Cases submitted are reviewed by the SHOT pulmonary WEG (which includes pulmonologists) to assess the reports for imputability, causality and categorisation.
- Regardless of final categorisation, preventable risk factors for established causes such as fluid overload are identifiable in many cases

Recommendations

- Patients who develop respiratory distress during or up to 24 hours following transfusion, where transfusion is suspected to be the cause, must be reported to SHOT with as much detail (clinical and laboratory aspects) as possible

Action: All staff involved in transfusion

- A structured incident review should be undertaken for all cases of respiratory deterioration after transfusion. This will ensure optimum organisational and individual patient safety measures are in place to protect patients from TACO as far as possible

Action: Trust/Health Board governance and clinical risk departments, all staff investigating transfusion incidents

Introduction

As noted in the overview chapter, all pulmonary complication reports which do not meet the ISBT TACO criteria have been consolidated into a single chapter this year. Categorisation of pulmonary complications following transfusion remains a complex area with ongoing international collaboration for validation of definitions and data collection. Often, the interpretation of the cases submitted is limited by the available clinical information including results of relevant investigations. Transfers of cases submitted between categories (FAHR, TACO, TRALI, UCT etc.) reflect the challenges involved in interpreting these real-life cases. By consolidating cases together, it is hoped that preventable factors can be identified regardless of the final classification, which will always to some extent be arbitrary.

The SHOT pulmonary WEG continues to attempt applying the new proposed RC TRALI definitions to those cases reported under TAD to see if it helps categorise these reactions (Table 17b.1). As there are have been few cases with positive leukocyte antibodies for many years, these cases have been reported as 'antibody-positive' in addition to the RC classification. There was 1 case classified as TRALI type II with risk factors for ARDS and 1 case with worsening respiratory status in the 12 hours prior to transfusion, categorised as transfused ARDS.

Cases classified as TAD represent cases which do not fit TRALI or TACO criteria, either because clinical features do not meet criteria or because there was insufficient information to classify. As in the previous years, cases included under TAD have been subdivided based on adequacy of the clinical information available. TAD-C (those with complete or adequate clinical information) and TAD-IC (those with insufficient clinical information).

Figure 17b.1 summarises the categorisation and transfers of pulmonary complication cases submitted this year.

Table 17b.1 Summary of classification using the revised consensus criteria

Table 7 Comparison table to assist with pulmonary reaction classification

	TRALI Type I	TRALI Type II	ARDS	TRALI/TACO	TACO	TAD
Hypoxemia	Present	Present	Present	Present	May be present but not required	May be present but not required
Imaging evidence of pulmonary edema	Documented	Documented	Documented	Documented	May be present but not required	May be present but not required
Onset within 6 hr	Yes	Yes	Yes	Yes	Yes*	No*
ARDS risk factors	None	Yes—with stable or improving respiratory function in prior 12 hr	Yes—with worsening respiratory function in prior 12 hr	None, or if present, with stable or improving respiratory function in prior 12 hr	Not applicable	Not applicable
LAH†	None/mild	None/mild	None/mild	Present or not evaluable	Present	May be present but not required

*Some definitions of TACO allow onset up to 12 hours posttransfusion. However, our current recommendation is that 6 hours be used. If pulmonary edema occurs greater than 6 hours following the transfusion and is clinically suspicious for a temporal association with transfusion, the case should be classified as TAD as is currently done in many hemovigilance systems.

†LAH is difficult to assess. When LAH is suspected, we recommend using objective evaluation to determine if it is present. Objective criteria include imaging (e.g., echocardiography) or invasive measurement (e.g., pulmonary artery catheter pressure measurement). However, clinical judgment is often required and, if this is needed, should be used for case classification as follows: TRALI and/or TACO = respiratory insufficiency at least partially explained by hydrostatic lung edema resulting from cardiac failure or fluid overload or unable to fully assess the contribution of hydrostatic lung edema resulting from cardiac failure or fluid overload; TACO = respiratory insufficiency explained by hydrostatic lung edema resulting from cardiac failure or fluid overload.

Reproduced from Vlaar et al. 2019

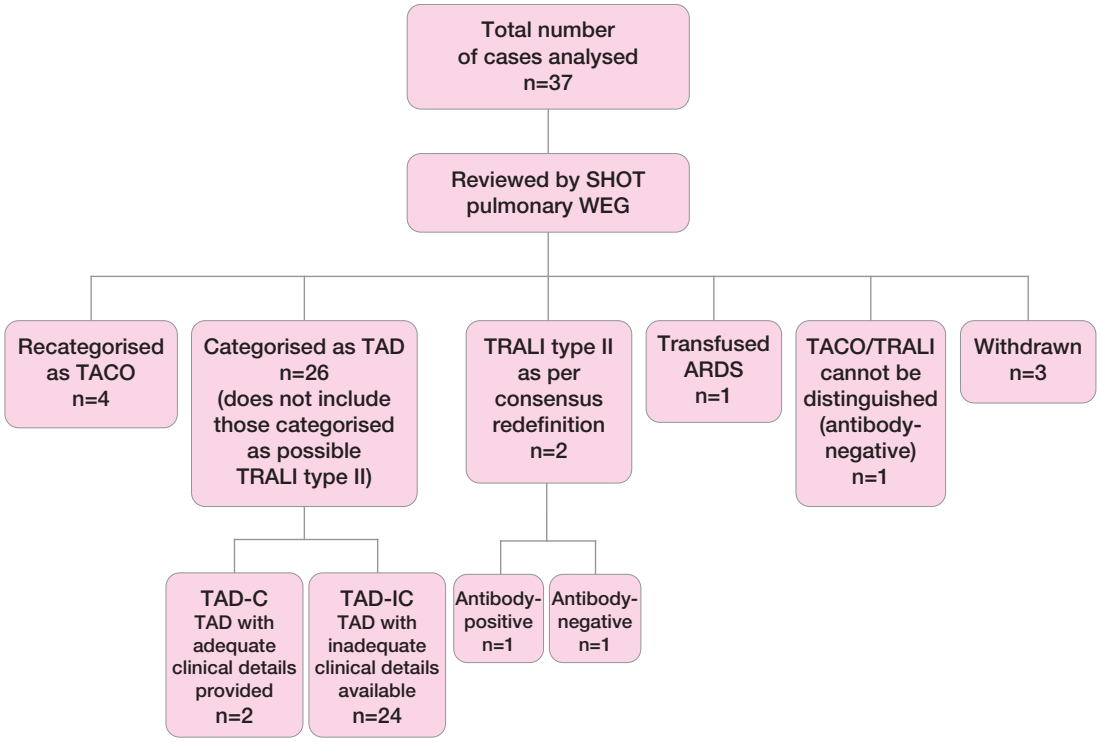


Figure 17b.1: Summary of transfers and categorisation of cases included under TAD

WEG=working expert group; TACO=transfusion-associated circulatory overload; TAD=transfusion-associated dyspnoea; TRALI=transfusion-related acute lung injury; ARDS=acute respiratory distress syndrome

Most cases included as TAD had incomplete clinical and laboratory information (TAD-IC). This could either be due to lack of availability or accessibility of the information when the reporter was submitting the case or that all the relevant investigations were not done as part of patient management.

Many cases had identifiable factors which could explain the respiratory deterioration. These are summarised in Figure 17b.2.

There was only 1 case of antibody-associated TRALI, which was considered as probably contributing to the patient's death.

There were 3 patients with COVID-19 pneumonitis. Interpretation of the clinical and radiological picture in patients with COVID-19 pneumonia who developed worsening respiratory status <24 hours after administration of any blood component continues to be a challenge. Multiple factors could contribute to the deterioration in these patients, ranging from worsening of the COVID-19 pneumonitis (sudden respiratory deterioration with ARDS is well recognised in these patients), to other factors such as thromboembolism and cardiac effects of COVID-19. Secondary bacterial infections and other rare events such as pneumothorax and pneumomediastinum can also cause respiratory deterioration (Pooni et al. 2020). Imputablity has been attributed as being 'possible' in these cases.

Figure 17b.2: Summary of possible explanatory factors for non-TACO pulmonary complications

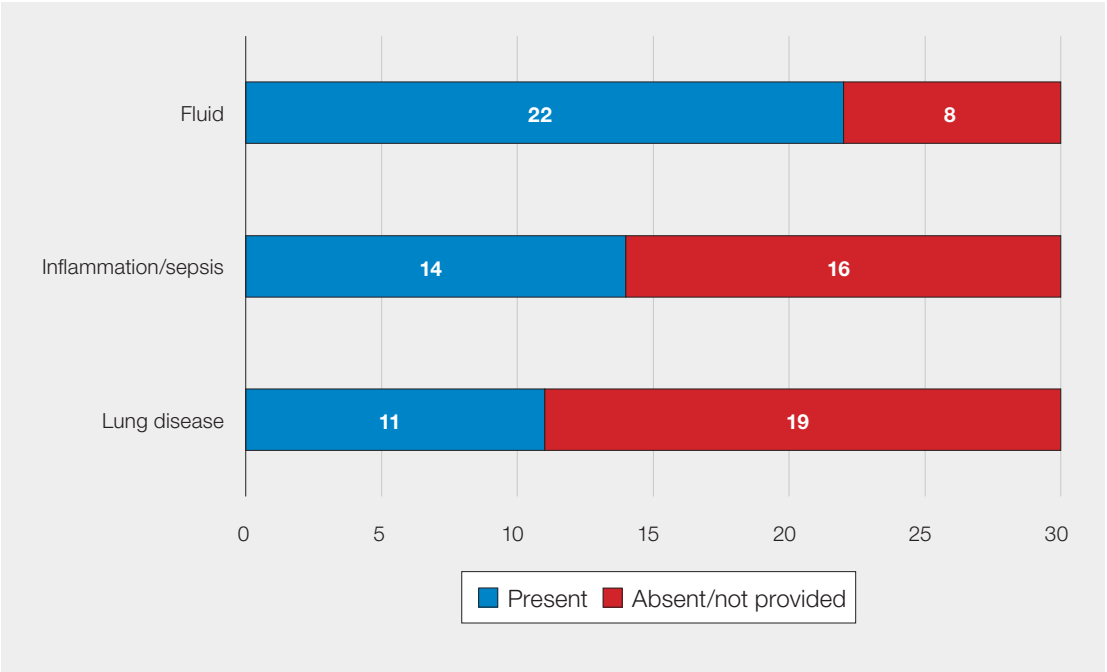
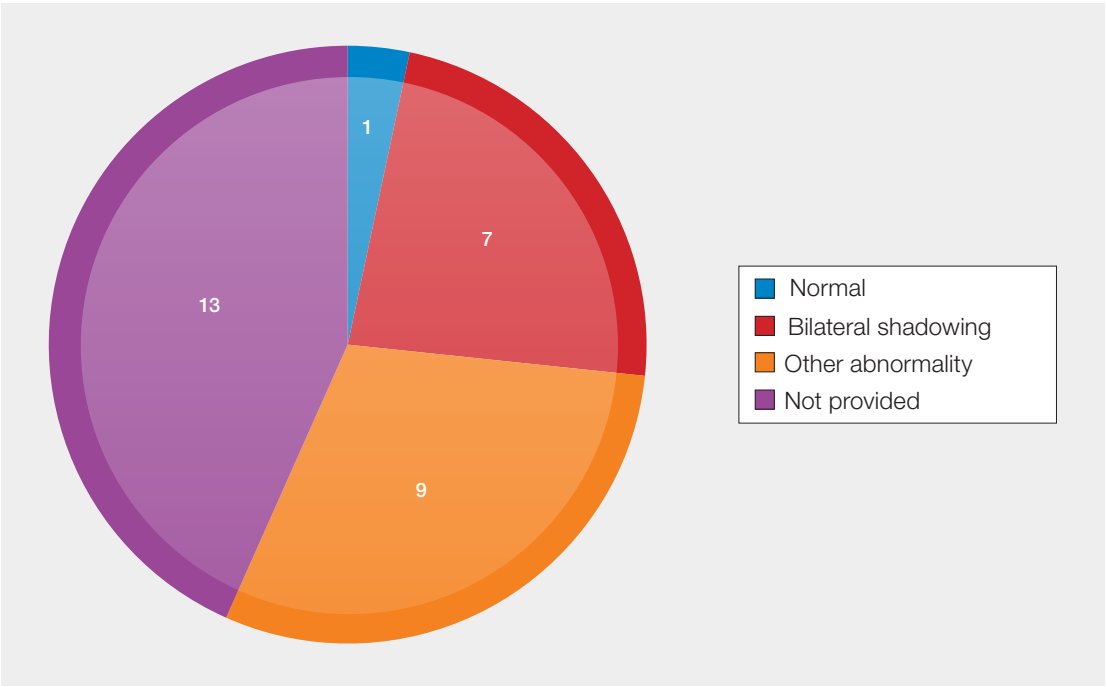


Figure 17b.3: Summary of imaging findings for non-TACO pulmonary complications



Deaths related to transfusion n=7

There were 7 transfusion-related deaths, 2 were categorised as having an imputability of probable, and the other 5 were all possibly related to the transfusion.

Pulmonary complications contribute significantly to transfusion-related deaths reported in the UK. Table 17b.2 summarises all pulmonary complication deaths this year. In particular, the table summarises features (pre-existing patient factors, aspects of the transfusion and features of the reaction) which could support fluid or the underlying disease causing a respiratory deterioration. The table also notes the challenges in applying definitions.

It is notable that in all cases where death occurred, patients had some risk factors for, or features of, fluid overload. In 3 cases, the patients had advanced liver disease. Pulmonary complications are common

in liver disease, with multiple underlying mechanisms, many of which, including fluid overload, may be exacerbated by transfusion.

A full narrative description of all cases which caused death can be found in the supplementary information on the SHOT website (https://www.shotuk.org/shot-reports/report-summary-and-supplement-2021/).

Table 17b.2: Summary of pulmonary complication deaths

Case	Category	Imputability	Blood components transfused	Feature or risks for fluid overload	Underlying disease	Imaging	Difficulty classifying
1	TACO/ TRALI antibody-negative	2	3 red cell units	Rise in BNP, heart failure on 200mg frusemide	Autoimmune haemolysis	Bilateral CXR changes	Imputability of heart disease, between RC and SHOT class
2	TRALI type II antibody-positive	2	2 red cell units, 4 FFP, 1 ATD platelet	Large volume transfusion over 3 hours	Myelodysplasia, sepsis	Bilateral CXR changes	Imputability of antibody
3	TRALI type II	1	1 red cell unit	Cirrhosis, anaemia Hb 47g/L	Cirrhosis, anaemia Hb 47g/L	Bilateral pulmonary oedema, effusions	Difference between SHOT and RC class
4	TAD-IC	1	1 red cell unit	History of AF, heart failure, cirrhosis	Cirrhosis, COPD	Perhilar consolidation	Does not fit TRALI/ TACO
5	TAD-IC	1	3 FFP	Alcoholic liver disease	COVID-19, GI bleed	Not supplied	Limited clinical detail
6	TAD-IC	1	1 red cell unit	Decompensated heart failure anaemia Hb 79g/L	COVID-19	Not supplied	Limited clinical detail
7	TAD-IC	1	1 red cell unit	Renal impairment, cardiac impairment, low albumin, positive fluid balance	GI bleed	Not supplied	Limited clinical detail

Major morbidity n=2

Both cases included here are those where patients needed admission to HDU/ICU/CCU following respiratory deterioration post transfusion. They subsequently recovered.

Table 17b.3: Summary of pulmonary complication major morbidity cases

Case	Category	Imputability	Blood components transfused	Features or risks for fluid overload	Underlying disease	Imaging	Difficulty classifying
1	TAD-C	1	2 ATD platelets, 1 red cell unit	Cardiac and renal impairment, IV fluid, response to diuretic	Lymphoma, sepsis	Unilateral consolidation	Does not meet TACO/ TRALI criteria
2	TAD-C	1	4 red cell units		GI bleed, CLL, COVID-19	Bilateral pulmonary oedema	Antibody-negative, definition of 'stable respiratory state'

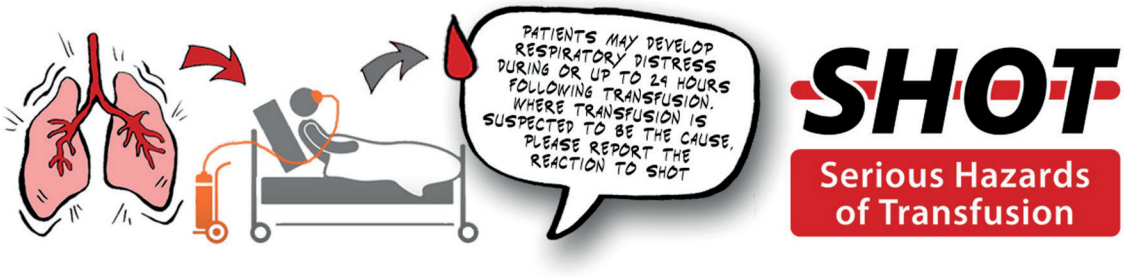
Learning point

- All cases with post-transfusion pulmonary complications must be reported to the Blood Service so that further investigation can be done as appropriate to help classify these cases. Regardless of final classification, many cases have identifiable risk factors which may have compromised the ability of the patient to tolerate the transfusion

Conclusion

As illustrated in the cases included here, most patients with pulmonary complications are very unwell with multiple ongoing issues and it is often difficult to establish whether the transfusion contributed to the deterioration or whether the deterioration was coincidental. Consolidation of cases into one chapter and incorporating the RC TRALI criteria has led to a proliferation of classes, which will be helpful for international comparison but there is not always a clear dividing line between cases assigned to different classifications.

There is still much work that needs to be done to understand pulmonary complications, and identify common themes which will inform future preventative and management strategies. Some of the uncertainty revolves around whether there may be undiscovered mediators in the transfusion which contributed to the reaction, which will always be impossible to rule out. What is apparent however is that there are often identifiable features, particularly for fluid overload that could indicate patients at higher risk of transfusion. These factors are identifiable across categories and it is probably more helpful to acknowledge that all factors coexist and interact rather than to make subjective decisions about which was the most important in order to assign cases to a single category. It is hoped that consolidating cases in to a single chapter will help to assess pulmonary complication cases holistically, and a retrospective review of cases is planned for this year.



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Haemolytic Transfusion Reactions (HTR) n=44

18

Authors: Tracey Tomlinson and Anicee Danaee

Definitions:

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 reactions
DAT	Direct antiglobulin test
DHTR	Delayed haemolytic transfusion reactions
EPO	Erythropoietin
Hb	Haemoglobin
HT	High-titre
HTR	Haemolytic transfusion reactions
IV	Intravenous
IVIg	Intravenous immunoglobulin
LDH	Lactate dehydrogenase
Sp-ICE	Specialist Services electronic reporting using Sunquest's Integrated Clinical Environment

Key SHOT messages

- As seen in previous years, cases of hyperhaemolysis remain under-reported. It is important that there is communication between clinical teams and the transfusion laboratory to ensure these cases are reported to SHOT
- Whilst most cases of hyperhaemolysis are seen in patients with sickle cell disease, this can occasionally occur in other patient groups and a low index of suspicion is necessary
- It is important that patients are monitored for signs and symptoms of haemolytic transfusion reactions both during and following the transfusion episode

Recommendations

- Patients must be informed about the risks of transfusion reactions including delayed reactions and know when and how to seek medical help. These discussions should be part of consent pre transfusion

Action: All clinical staff involved in transfusion

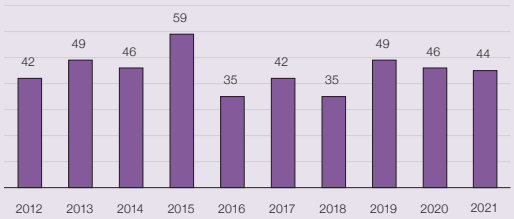
- When submitting reports to SHOT, it is important to record the treatment received by patients with hyperhaemolysis as this remains an evolving field

Action: Haemovigilance reporters

Headline data 2021

Number of reports n=44
Deaths n=1
Major morbidity n=10

HTR reports by year



Demographic data

Male n=11
Female n=33
Adults n=39
Paediatric n=4
Unknown n=1

Blood component data

Red cells n=43
Platelets n=1
Plasma n=0
Multiple components n=0
Other n=0

Number of cases n=44

A total of 44 cases have been included, 14 acute, 23 delayed reactions and 7 cases of hyperhaemolysis. The total number of reactions reported is comparable to 2020 (46 cases) and 2019 (49 cases).

All but 1 reaction occurred following red cell transfusions. One single case followed the transfusion of platelets, and this was also the only case in which the reaction was attributed to ABO antibodies. This case is described in the AHTR section.

Age range and median

The age range was 1 to 92, with a median age of 57. This is shown in Figure 18.1, broken down further by gender. HTR were reported in 4 paediatric patients. In 33/44 (75.0%) of the reactions the patient was female.

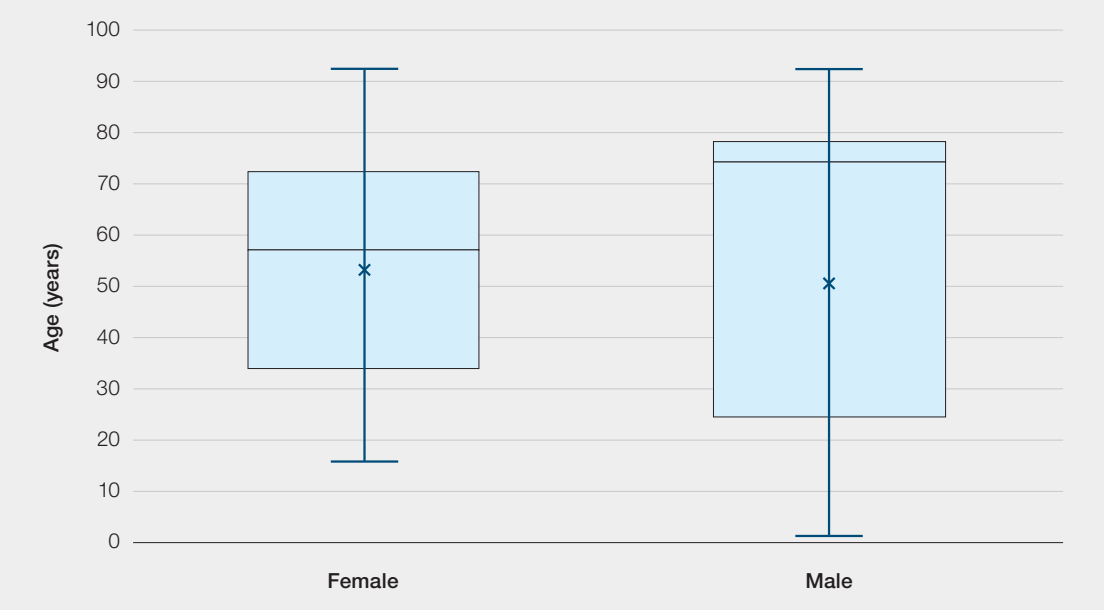


Figure 18.1: Age range in males and females experiencing an HTR

Deaths related to transfusion n=1

There was 1 death in a patient with sickle cell disease that was related to the transfusion reaction. This case is described in Chapter 23, Haemoglobin Disorders.

Major morbidity n=10

There were 10 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 4 cases of hyperhaemolysis reported with 'minor morbidity' were upgraded.

Two patients who had major morbidity following their transfusion reaction died but the death was recorded as being secondary to their underlying medical condition.

Hyperhaemolysis n=7

Five of the hyperhaemolysis cases reported occurred in patients with sickle cell disease. Hyperhaemolysis was also reported in a patient with Diamond-Blackfan anaemia and a patient with myelofibrosis post transplant.

While the majority of hyperhaemolysis is still reported in patients with sickle cell disease, a review of hyperhaemolysis reports from the last 5 years found that 5/30 (16.7%) occurred in patients with other diagnoses (Table 18.1).

Hyperhaemolysis in the last 5 years	
Sickle cell disease	25
Post transplant	2
Diamond-Blackfan anaemia	1
Myelodysplastic syndrome	1
Rosai-Dorfman syndrome	1
Total	**30**

Table 18.1: Diagnoses of patients with hyperhaemolysis reported to SHOT 2017-2021

A lower number of hyperhaemolysis cases were reported to SHOT in 2021 as compared to 2020. It is known that hyperhaemolysis is still under-reported. Staff need to be aware that all such cases should be reported to SHOT to facilitate a better understanding of this condition and identify areas for improvement. It has been reported that patients often undergo repeated episodes of hyperhaemolysis if they continue

to receive transfusions (Madu et al. 2020). Only 1 patient of the 7 cases reported to SHOT in 2021 was recorded as having had previous episodes of hyperhaemolysis.

Hyperhaemolysis can be either acute or delayed. 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). Of the 7 cases reported 2 of the reactions occurred with the first 7 days post transfusion. In contrast to other HTR, hyperhaemolysis has been reported to be accompanied by a decrease in the patient's absolute reticulocyte count and an increase in the ferritin level (Win et al. 2019).

Treatment in hyperhaemolysis

There are no published recommendations on the treatment of hyperhaemolysis. There is paucity of published randomised clinical trials in the effectiveness of the available interventions, however, eculizumab has been licensed to treat ongoing brisk haemolysis (NHS England 2020). Since 2020 SHOT has requested reporters to provide information on how these patients were managed. Generally, patients are treated with a combination of IVIg, steroids and EPO. A summary of the treatment methods reported is provided in Table 18.2, which demonstrates that huge variation exists within this field.

Table 18.2: Treatment methods used for hyperhaemolysis cases reported to SHOT in 2020 and 2021

Treatment type	2020	2021
No treatment information provided	1	2
IVIg, IV steroids and EPO	1	2
IVIg and IV steroids	3	2
IVIg only	1	1
IV steroids only	2	-
IVIg and EPO	1	-

Learning points

- Hyperhaemolysis can occur in patients with a variety of diagnoses and should not be dismissed in patients without sickle cell disease
- Hyperhaemolysis continues to be under-reported. Transfusion staff are encouraged to report all cases of hyperhaemolysis to SHOT

Clinical and laboratory signs and symptoms

Acute haemolytic transfusion reactions n=14

There were 13 cases reported where patients received red cells transfusions. Alloantibodies to red cell antibodies were identified in 9 cases. The alloantibodies implicated are shown in Figure 18.2.

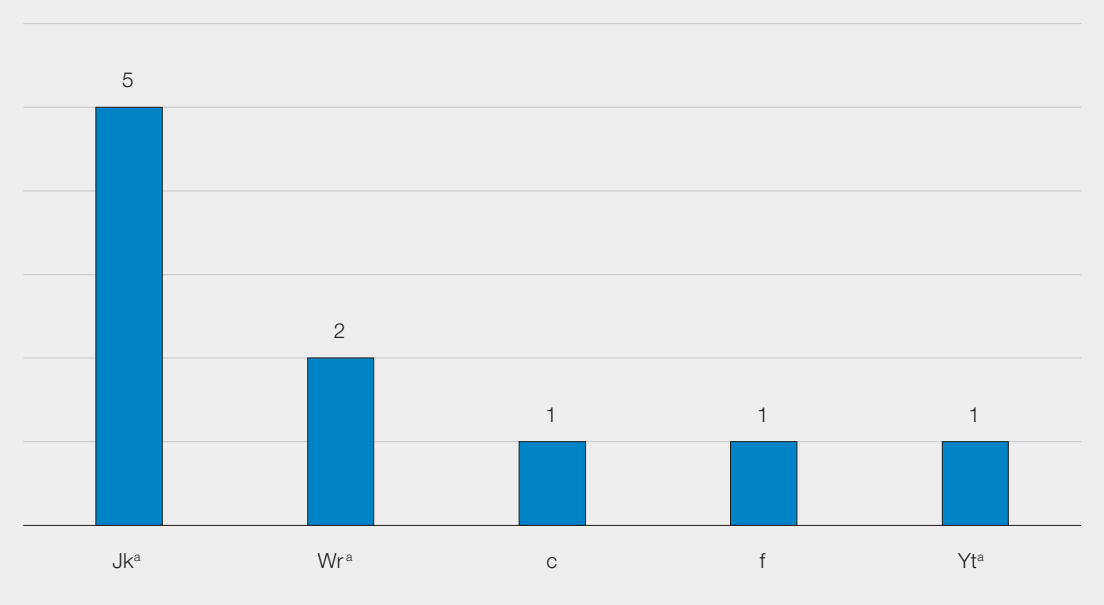


Figure 18.2: Alloantibodies reported in AHTR in 2021

There were 3 cases involving antibodies to low incidence red cell antigens: 2 due to anti-Wr^a and 1 due to anti-Kp^a. In both anti-Wr^a cases, the antibody screen had been negative, and the red cells issued by electronic issue. The post-transfusion antibody screen was also negative and the anti-Wr^a antibodies were only identified during the serological investigation following a positive repeat IAT crossmatch against the implicated unit. These cases demonstrate the importance of repeat testing against the implicated unit as part of the serological investigation of a transfusion reaction. This will allow the detection of antibodies to low incidence red cell antigens which are not expressed on the screening cells and not detectable in pre-transfusion testing or electronic crossmatching.

Reports of acute transfusion reactions emphasise the need to monitor patients closely during transfusion. This is especially important as in many cases the patients may be showing symptoms because of their underlying condition which may make the identification of a reaction more difficult.

In 2021 there was 1 AHTR due to the transfusion of non-ABO identical platelets to a patient. The last incidence of a HTR due to ABO antibodies was reported in 2016 and was also following a platelet transfusion.

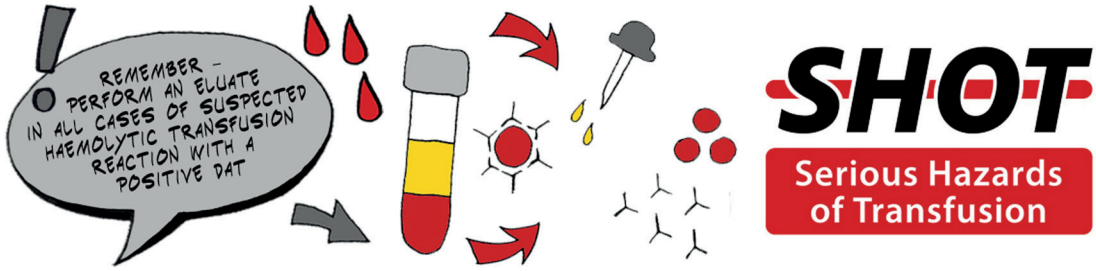
Case 18.1: Reaction due to anti-B in platelet unit

An infant with blood group AB was transfused with group A platelets. The platelets were labelled 'not for neonatal transfusion' and were not HT-negative. The patient also received a group AB red cell top up. A reaction was reported 8 hours following transfusion with an increase in the patient's bilirubin, and no Hb increment was observed following the red cell transfusion. Following investigation, it was identified that the issuing BMS in the laboratory had been focused on whether the 'not for neonatal transfusion' label was applicable to a patient >1 year of age and failed to consider the need for a HT-negative unit. Information regarding the anti-B titre in the transfused component was not available.

The risk of haemolysis due to passively transfused anti-A and anti-B is small but present and should be considered in any situation in which relatively large volumes of incompatible plasma are transfused (including platelet components). Between 2015-2021, there have been 2 cases reported to SHOT, both were due to ABO unmatched platelet transfusions in children. The case prior to the one described here was reported in 2016 where passive anti-A from a HT-negative unit of group O apheresis platelets which caused an acute reaction and haemolysis in a paediatric patient. The patient had a fall in Hb (of 22g/L) and a rise in bilirubin, with spherocytes noted on the blood film. Anti-A was confirmed in the plasma and eluate (Bolton-Maggs et al. 2017). There have been no reports in adults in the recent years. It is important to also recognise that although testing for high-titre ABO antibodies in blood donors may reduce the risk of HTR in 'out of group transfusion', it cannot be eliminated through this route. Group O platelets can cause HTR even when tested and labelled negative for high titre haemolysis. These should only be used for non-group O patients (particularly paediatric patients) as a last resort.

Learning points

- Investigation of acute transfusion reactions should include a serological crossmatch against the implicated units to facilitate the identification of antibodies directed to low incidence red cell antigens that are not routinely present in screening cells. Local processes should therefore be in place to ensure that the unit is available for a full serological investigation to take place
- The risk of haemolysis due to passively transfused anti-A and anti-B is small but present and should be considered in any situation in which relatively large volumes of incompatible plasma are transfused (including platelet components). It is important to also recognise that although testing for high-titre ABO antibodies in blood donors may reduce the risk of HTR in 'out of group transfusion', it cannot be eliminated through this route



Delayed haemolytic transfusion reactions n=23

No clinical symptoms of a transfusion reaction were reported in 9/23 DHTR cases submitted to SHOT. This remains comparable to previous years.

Antibodies were detected in 22/23 of the DHTR reported and in 20 of these cases, alloantibodies were detected in the patient's plasma post-transfusion that were not detected pre transfusion.

In every DHTR case in which the patient's bilirubin and Hb were provided, at least one of these indices was impacted and 14/23 patients diagnosed with a DHTR had exhibited both an increase in bilirubin and a drop in Hb.

The identification of a new antibody post transfusion, along with a rise in bilirubin and lack of Hb increment indicates a delayed transfusion reaction. It is important that all patients with DHTR are followed up appropriately, educated about the red cell antibodies and informed about risks with future transfusions.

Case 18.2: Investigations post transfusion identifying DHTR and prompting patient follow up

An anaemic patient was transfused two units of red cells as an outpatient. Two weeks later the patient attended for a routine check-up. DAT was positive, a new anti-Jk^a was identified and eluted from her red cells. In addition, her Hb had dropped to 64g/L from a pre-transfusion level of 78g/L with a rise in bilirubin and LDH. The transfusion laboratory recommended that the patient was monitored for a delayed transfusion reaction. A letter was sent to the patient asking her to attend the GP surgery for further blood tests at which point the patient reported that she had been feeling unwell following the transfusion and her Hb had dropped further to 49g/L.

Identification of HTR in patients

HTR is a serious complication that can occur after a blood transfusion. The identification of a reaction can be difficult as the classical symptoms often mimic symptoms of the patient's underlying diagnosis (for example, temperature increase or low Hb). It is important that all healthcare professionals involved in transfusions are aware of the signs and symptoms of transfusion reactions and take relevant actions in a timely manner. These must be investigated appropriately and reported to SHOT.

As delayed reactions typically occur after the patient has been discharged, patients need to be aware of the danger signs and know when and how to seek medical help. Appropriate post-transfusion advice must be provided to all patients.

Learning points

- All patients with laboratory evidence of haemolysis should be evaluated and followed up clinically. Procedures for investigation of transfusion reactions should be compliant with the BSH guidelines covering investigation and management of acute transfusion reactions (BSH Tinegate et al. 2012)
- Patients receiving transfusions should be educated about the signs and symptoms of transfusion reactions and know when and how to seek medical help

Antibodies implicated in HTR

Anti-Jk^{a} continues to be the most frequent antibody specificity implicated in HTR and was detected in 13/44 cases. The antibody specificities reported are shown in Figure 18.3. In 7/44 the patient had multiple red cell antibodies in the post-transfusion sample.

No serological cause for the reaction was detected in 4 of the 44 cases reported in 2021. Of these, 2/4 were in patients experiencing hyperhaemolysis. In all cases however, the patient experienced clinical symptoms of a HTR, and their laboratory results indicated haemolysis with an increased bilirubin, increased LDH and reduction in Hb, supporting this diagnosis.

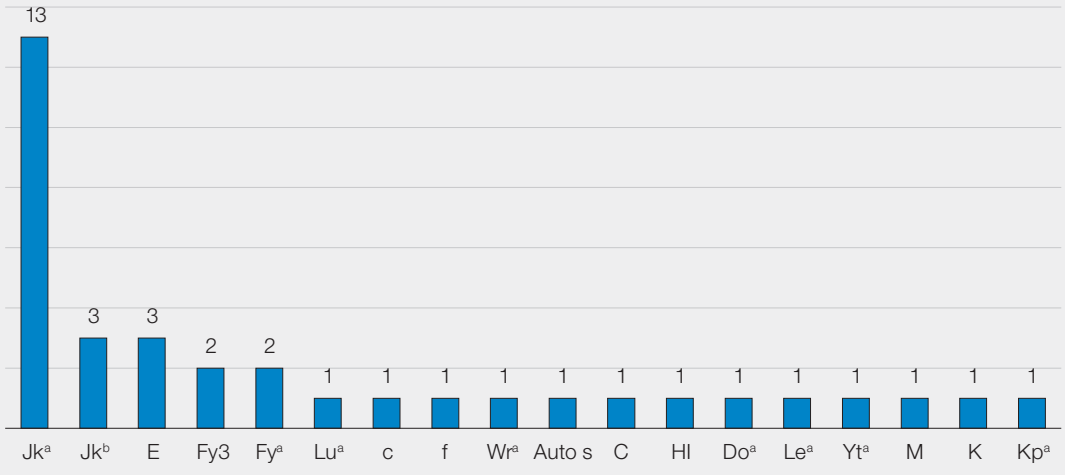


Figure 18.3: Antibody specificities implicated in HTR

Learning points

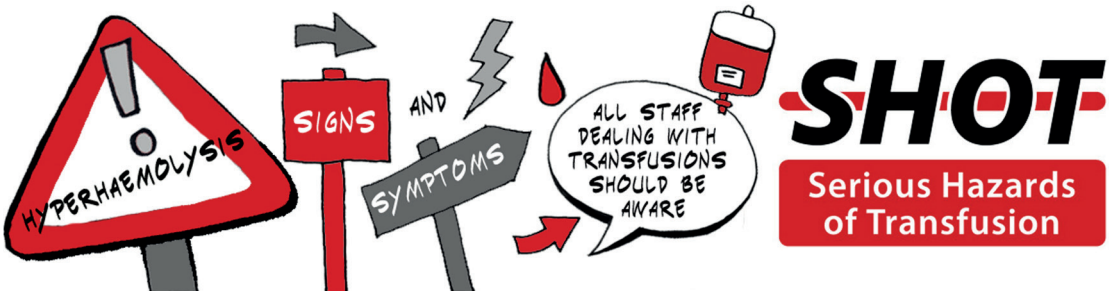
- Patients/carers should be asked if they are aware that they have any red cell antibodies as part of the pre-transfusion process. Any information obtained should be relayed by the clinical teams to the transfusion laboratory staff
- Patient databases such as Sp-ICE can provide vital antibody history for antibodies where the level has dropped below the detectable titre. Hospitals should have local polices to decide which patients to check on Sp-ICE

Conclusion

Red cell transfusions are lifesaving for patients with severe anaemia and/or bleeding and are generally safe. Haemolytic transfusion reactions most often occur when there is immunologic incompatibility between a transfusion recipient and the red blood cells from the blood donor. The main determinants of severity, site of haemolysis (intravascular or extravascular), and timing are the specific red cell antigens, and the nature and titre of alloantibodies present at the time of transfusion. HTR are recognised as an important cause of transfusion-associated reactions and may be subclinical, mild, or fatal. DHTR and hyperhaemolysis continue to pose diagnostic and therapeutic challenges. HTR are largely preventable and adherence to established protocols for prompt identification and timely management, as well as reporting them, remain the cornerstone of management of HTR. Hyperhaemolysis is one of the main causes of major morbidity and mortality reported in haemolytic transfusion reactions. Hyperhaemolysis is usually reported in patients with haemoglobinopathies, however it has also been observed in non-haemoglobinopathy patients. It is therefore important that all clinicians involved in the transfusion process have an awareness of the signs and symptoms of hyperhaemolysis and that any suspected cases are investigated and managed appropriately.

Recommended resource

SHOT Bite No. 15: Hyperhaemolysis
https://www.shotuk.org/resources/current-resources/shot-bites/



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19 Uncommon Complications of Transfusion (UCT) n=31

Author: Shruthi Narayan

Definition:

Occurrence of an adverse effect or reaction temporally related to transfusion, which cannot be classified according to an already defined transfusion event and with no other risk factor other than the transfusion, and no other explanation.

Serious reactions in this category are reportable to the European Union (EU) as 'uncategorised unintended responses'.

Abbreviations used in this chapter

BP	Blood pressure
BSH	British Standards for Haematology
CCP	COVID-19 convalescent plasma
CLL	Chronic lymphocytic leukaemia
CPR	Cardiopulmonary resuscitation
CT	Computed tomography
CVA	Cerebrovascular accident
ECG	Electrocardiogram
ED	Emergency department
Hb	Haemoglobin
ICU	Intensive care unit
IV	Intravenous
LIMS	Laboratory information management system
NEWS	National early warning score
RCI	Red cell immunohaematology
REMAP-CAP	Randomised, embedded, multi-factorial, adaptive platform trial for community-acquired pneumonia
TA-GvHD	Transfusion-associated graft-versus-host disease
TANEC	Transfusion-associated necrotising enterocolitis
UCT	Uncommon complications of transfusion

Key SHOT messages

- Reporting uncommon and unusual complications post transfusion helps to gain a better understanding of these complications, identify risk factors, and develop risk-reduction strategies
- Some complications can be avoided by making appropriate transfusion decisions including volume of the component to be transfused, rate of transfusion, specific transfusion requirements and patient monitoring
- All appropriate investigations should be carried out in case of any suspected transfusion reactions according to BSH guidelines (BSH Tinegate et al. 2012)
- Reporters must submit all relevant information including results from any investigations done when reporting the incident to SHOT to help categorise and assign imputability to reported cases
- Transfusion reactions in acutely unwell COVID-19 patients with multisystem complications continue to be a challenge and it is difficult to ascertain causality

Recommendation

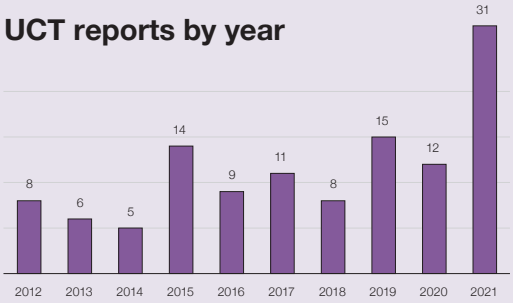
- Reporters are encouraged to continue to report cases with unusual reactions to transfusion and provide all details including clinical features and results of completed investigations when submitting the report

Action: All staff involved in transfusion

Headline data 2021

Number of reports n=31
Deaths n=7
Major morbidity n=2

UCT reports by year



Demographic data

Male n=14 | Female n=17 | Adults n=29 | Paediatric n=2

Blood component data

Red cells n=20
Platelets n=5
Plasma n=6
Multiple components n=0
Other n=0

Introduction

Cases with reactions reported in patients with temporal relation to transfusions that cannot be classified into other categories are included in this chapter. These could be due to several non-transfusion related contributory factors such as underlying diagnosis, medications, and co-morbidities. Learning from these events will improve our understanding of transfusion complications and help identify appropriate risk reduction measures. Occasionally, error reports that do not fit under other categories are included here to ensure learning is captured and shared.

The total number of incidents reported and included in this category has increased in 2021 but this may not truly reflect an increased risk from transfusions. A few cases included here may fall into other categories with some overlapping features.

Deaths related to transfusion n=7

There were 7 deaths reported in this category, all with imputability recorded as 'possible', imputability 1.

The cases are detailed below:

Stroke in acute COVID-19 patients who also received CCP n=3

Case 19.1: Stroke while sedated and on ventilation

A patient in his late 40s was admitted to the ICU with COVID-19 pneumonia. He was recruited to the REMAP-CAP trial and received one unit of CCP. He was subsequently diagnosed with a stroke approximately 3 weeks later. As the patient had been sedated for ventilation, the exact onset of the stroke could not be determined. A head CT scan confirmed a massive infarction. The patient died soon after.

Case 19.2: Stroke 3 days after receiving one unit of CCP

A patient in his 70s with hypertension, asthma (on inhalers), pre-diabetes, chronic kidney disease, bilateral total hip replacement, thalassaemia trait, thrombocytopaenia and previous cerebrovascular accident (on clopidogrel) was admitted to the ICU with a diagnosis of COVID-19. He was recruited to the REMAP-CAP trial and received one unit of CCP. He was diagnosed with a CVA 3 days later and deteriorated despite ongoing support. The main cause of death was attributed to be COVID-19 infection and stroke.

Case 19.3: Stroke diagnosed the day after receiving CCP

A patient in his 70s with high blood pressure, asthma, gastro-oesophageal reflux, and ischaemic heart disease was receiving care in ICU following a diagnosis of COVID-19. The patient had been recruited to the REMAP-CAP trial and received one unit of CCP but was diagnosed with a CVA the following day. The patient continued to deteriorate despite supportive measures and died 2 days later. The patient had been confused before intubation hence the exact onset of the stroke cannot be determined.

Commentary: Neurologic complications in patients with COVID-19 are common in hospitalised patients. More than 80% of hospitalised patients may have neurologic symptoms at some point during their disease course (Liotta et al. 2020). Stroke has been associated with COVID-19 in approximately 1 to 3% of hospitalised patients, with higher rates in those with more severe COVID-19. Several stroke subtypes may occur, including ischemic stroke, intracranial haemorrhage, and cerebral venous sinus thrombosis. In addition to traditional stroke mechanisms, potential mechanisms of ischemic stroke related to COVID-19 include hypercoagulability, inflammation, renin-angiotensin-aldosterone system dysfunction, and cardiac dysfunction (Elkind et al. 2020). Given the frequent association of stroke in COVID-19 with typical vascular risk factors and traditional stroke mechanisms, it is difficult to ascertain the degree to which the transfusion of CCP which has both anticoagulant and procoagulant plasma proteins contributed to the complication. In view of this, the imputability is recorded as 'possible' in these cases.

Other deaths reported in this category n=4

In 1 case, a premature baby died with transfusion-associated necrotising enterocolitis. This case has been described in Chapter 22, Paediatric Cases (Case 22.2).

Case 19.4: Patient death during transfusion and lack of regular observations

A patient in his 70s with type 2 diabetes mellitus, leg ulcers and hypertension was admitted to the hospital with signs of intestinal obstruction and a Hb of 73g/L. A red cell unit was requested and transfused overnight. Observations recorded for the patient an hour and 20 minutes after commencement of the transfusion had a NEWS of 3 with O2 saturations of 94%; BP 106/47 (which was drop from patient's baseline); no further observations were carried out until after 75 minutes when a cardiac arrest call was put out and CPR commenced but the patient could not be revived.

Whilst it is unclear if the death was directly related to the transfusion, the case has been included due to a temporal correlation and to highlight the importance of adequate monitoring during transfusion support and follow up investigations in case a transfusion reaction is suspected as in this case.

Case 19.5: Patient with cold agglutinins not given red cells through a warmer

A patient in his 70s was admitted to the urology ward with haematuria and received two units of red cells. The transfusion laboratory was not aware of any acute adverse reactions to the transfused units at the time as no contact had been made by the ward. The laboratory was notified by the haematology consultant 3 days later that the patient had died and queried if the blood transfusion may have been a contributory cause of death. The patient had a strong cold autoantibody and hence, samples were sent to the RCI laboratory for crossmatching red cells. The two units had been issued by RCI as 'suitable' with accompanying comments that blood should be transfused through a blood warmer. The ward was also contacted and directly relayed the same message regarding use of a blood warmer. It subsequently transpired that the first unit of red cells was not administered

via a blood warmer, and the patient became unwell. The second unit that was prescribed was administered through a warmer. Staff assessing the patient attributed the respiratory distress to COVID-19.

There were no further investigations, and it cannot be ascertained if the transfusion contributed to the patient's outcome.

Case 19.6: Acute deterioration and multiorgan dysfunction in a patient with chronic lymphocytic leukaemia

Limited details were available regarding the patient's clinical status and investigations results. A patient in his mid-80s who had chronic lymphocytic leukaemia received leucodepleted red cell transfusions as an outpatient. In view of previous treatment with purine analogue the patient needed irradiated blood components, but this was missed by the requesting medic and whilst the LIMS had a note that the patient needed irradiated components, this did not create an alert flag nor prevent issue of non-irradiated blood components. Two units of non-irradiated red cells were transfused uneventfully. The patient started feeling unwell the next day, felt tired and was pyrexial. He continued to deteriorate and developed tachypnoea with low oxygen saturations over the next 24 hours. The patient was then taken to the ED the following day (day 3 post transfusion) and was admitted with a diagnosis of suspected infection. There was a mention of multiple bilateral pulmonary emboli, acute kidney injury with worsening renal impairment and fluid overload. The patient was initially stable but deteriorated and had deranged liver functions and diarrhoea. The patient continued to deteriorate, and the decision was made after discussions with family that the patient was for end of life care. The patient needed further transfusions and two red cell units were given which were again non-irradiated. On this occasion, although it was recognised that the patient needed irradiated blood components, due to the urgency of transfusion in a deteriorating patient and potential delay in procuring irradiated components, the patient received standard blood components. The patient deteriorated and died approximately 10 days following the initial transfusion.

The initial error of elective transfusion of non-irradiated blood components was only identified during incident review after the patient's death. TA-GvHD was considered but very unlikely. No autopsy or biopsies were done.

The cause of death from the coroner was listed as 'Sepsis of unknown origin, high grade transformation of CLL, subdural haematoma, ischaemic heart disease, cerebrovascular disease and chronic kidney disease'.

Commentary: While the patient did not receive irradiated blood components following previous use of bendamustine, it is unlikely that the clinical picture of the patient was related to TA-GvHD. The clinical course was too quick for TA-GvHD as the patient was unwell from day 1 post transfusion and had other significant issues such as multiple pulmonary emboli, acute kidney injury and worsening sepsis which can explain the multiple organ dysfunction in this patient. TA-GvHD is a rare, usually fatal, complication of transfusion of cellular blood components containing lymphocytes. This is usually characterised by fever, rash, diarrhoea, hepatitis, and pancytopenia 2-30 days after transfusion. Diagnosis is confirmed by detecting persistent donor lymphocytes from a transfused component in affected tissue biopsy or peripheral blood of recipients. Diagnosis can be challenging due to competing differentials and lack of leucocytes.

The red cells received by the patient were leucodepleted and more than 14 days old which also makes TA-GvHD less likely. Components implicated in TA-GvHD have been typically whole blood and red cells and, in most cases in published literature, the implicated component was either described as fresh or as ≤10 days old. There have been no cases implicating components stored for >2 weeks (Kopolovic et al. 2015; Jawa et al. 2015 and Uchida et al. 2013). Features of TA-GvHD noted in the Kopolovic et al. review include rash (80.2%), fever (67.5%), elevated liver enzymes (66.4%), pancytopenia (65.2%), diarrhoea (43.1%), bone marrow aplasia (22.7%) or hypocellularity (17.2%) and hepatomegaly (13.5%). Relevant abnormalities occur 1-6 weeks after transfusion, with the median time from transfusion to first symptom being 11 days. Most reported cases (61.6%) occurred in men. Overall survival rate is reported to be 8.4% (Ostro et al. 2014). Irradiation remains the most effective means to reduce the risk of TA-

GvHD. Whilst leucodepletion can be protective, there is insufficient evidence to recommend leucocyte depletion alone to prevent TA-GvHD in susceptible patients (Foukaneli et al. 2020).

No investigations were undertaken in this case to help rule out TA-GvHD. The case has been included here in view of the deterioration of the patient post transfusion and there are valuable lessons to be learnt from gaps in the processes identified during the incident investigations which include: lack of staff awareness of the indications and rationale for irradiation, lack of robust processes to capture specific transfusion requirements, suboptimal LIMS which failed to create a flag despite a note indicating the need for irradiated components and allowed release of non-irradiated components.

Analysis of reports from SHOT (2010-2019), where patients failed to receive irradiated components when indicated according to BSH guidelines (BSH Tinegate et al. 2012) was carried out. There were 956 incidents of failure to receive irradiated components all due to errors. One hundred and seventy-two incidents were excluded from analysis, 125 of 172 (72.7%) because of missing essential information. No cases of TA-GvHD were reported in this cohort. The 784 patients received 2809 components (number unknown for 67 incidents). Most failures occurred in patients treated with purine analogues (365) (Elliot et al. 2021).

Major morbidity n=2

Case 19.7: Ischaemic cardiovascular event in a patient with myeloma following platelet transfusion

A woman in her 60s with refractory IgA lambda myeloma became acutely unwell 30 minutes after receiving a platelet transfusion. She reported chest tightness, developed acute respiratory distress syndrome, became hypertensive and had bilateral chest wheeze with crepitations. She continued to deteriorate despite being given chlorphenamine and IV hydrocortisone. A peri-arrest call was put out and adrenaline administered. She was assessed by the crash team, furosemide was administered, chest X-ray indicated pulmonary oedema, blood gases showed pH 7.1, PO2 10, PCO2 8, Lactate 5.3 and a decision was made to transfer to ICU for further management where the patient was intubated and ventilated. An ECG showed T wave inversion and ST depression in lateral leads. The patient improved with supportive measures in the ICU and recovered completely.

It is unclear whether the ischaemic event was coincidental, or the platelet transfusion was contributory.

Details of the 2nd case can be found in Chapter 23, Haemoglobin Disorders (Case 23.9).

Other cases n=22

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-2021/).

Conclusion

Blood components should be transfused based on guidelines and clinical assessment. Unnecessary transfusions should be avoided. While transfusions are largely safe, complications do still occur and the nature of the reaction may not be immediately apparent especially as transfusion recipients often have complex underlying clinical conditions, the symptoms of which may mimic a transfusion reaction. All team members involved in the transfusion chain play an integral role in preventing errors and in early identification of transfusion complications. Appropriate training and regular education of interdisciplinary teams consisting of transfusion laboratory staff, medical and nursing staff involved in the transfusion process is paramount to achieve safe transfusion.

SHOT
Serious Hazards of Transfusion

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20 Transfusion-Transmitted Infections (TTI) n=0

Authors: Tali Yawitch, Heli Harvala and Su Brailsford

Definition:

A report was classified as a TTI if, following investigation:

- The recipient(s) had evidence of infection post transfusion with blood components, and 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(s) was donated by a donor who had evidence of the same transmissible infection

or:

- At least one component received by the infected recipient was shown to contain the agent of infection

These may be identified as a result of infection in the patient where transfusion is the suspected source or alternatively via lookback investigations. A lookback investigation is carried out if a donation is found to be positive for infection and retrospective testing finds a previous donation to also be positive at low levels below the detection level of screening.

Note that for the purposes of the European Union (EU) 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 (MHRA) (a legal requirement). This includes all confirmed transfusion-transmitted infections.

Abbreviations used in this chapter

BSH	British Society for Haematology
DNA	Deoxyribonucleic acid
EIR	Emerging infection report
EU	European Union
FAIR	For the assessment of individualised risk
HAV	Hepatitis A virus
HBV	Hepatitis B virus
HCV	Hepatitis C virus
HEV	Hepatitis E virus
HIV	Human immunodeficiency virus
HTLV	Human T cell lymphotropic virus
JPAC	Joint UKBTS Professional Advisory Committee
LGBTQ+	Lesbian, gay, bisexual, transgender and queer
MHRA	Medicines and Healthcare products Regulatory Agency
NAT	Nucleic acid testing
NHSBT	National Health Service Blood and Transplant
NIBTS	Northern Ireland Blood Transfusion Service
OBI	Occult hepatitis B virus (HBV) infection
PTR	Post-transfusion reactions
RNA	Ribonucleic acid
SaBTO	Advisory Committee on the Safety of Blood, Tissues and Organs
SACTTI	Standing Advisory Committee on Transfusion Transmitted Infection
SAR	Serious adverse reaction
SARS-CoV-2	Severe acute respiratory syndrome coronavirus 2

SNBTS	Scottish National Blood Transfusion Service	**vCJD**	Variant Creutzfeld Jakob Disease
TTI	Transfusion-transmitted infections United	**WBS**	Welsh Blood Service
UK	Kingdom	**UKHSA**	United Kingdom Health Security Agency

Key SHOT messages

- Any suspicion of a TTI should be reported to the appropriate UK Blood Service as soon as possible for it to be fully investigated
- 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
- All lookback investigations should be reported by the UK Blood Services to the infectious disease expert sitting on the SHOT working expert group
- It is important that all healthcare professionals consenting patients for blood transfusion have up-to-date knowledge of blood donation screening and the small potential for TTI

Introduction

This chapter describes TTI incidents investigated by the UK Blood Services and reported to the NHSBT/UKHSA Epidemiology Unit's surveillance scheme in 2021.

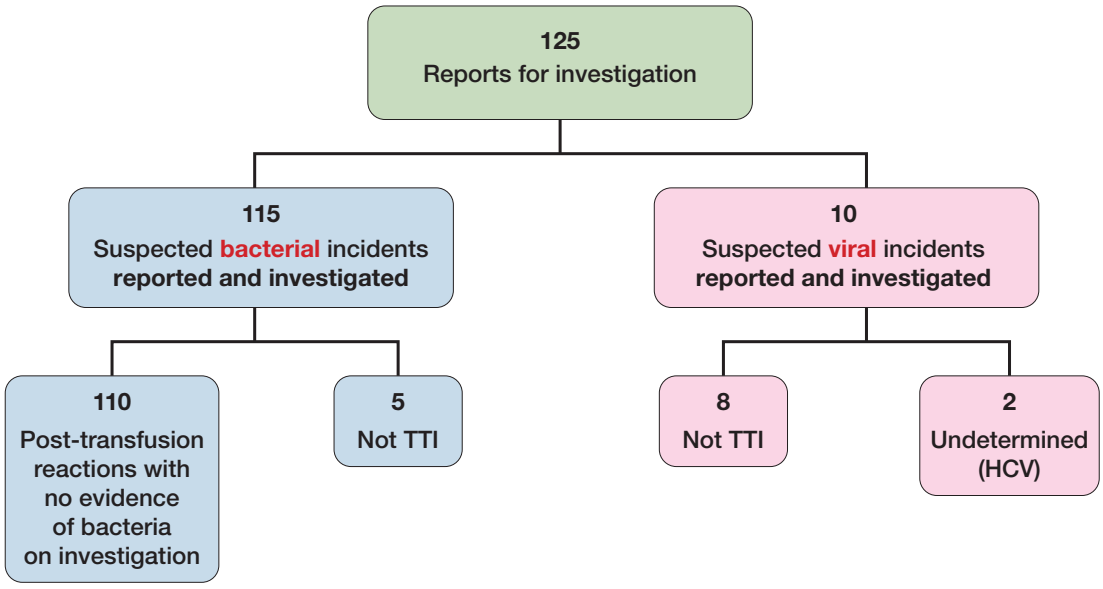
The risk of a TTI in the UK remains extremely low. During 2021, there were no reported TTI confirmed either viral or bacterial investigations.

Annual reports from the Epidemiology Unit surveillance schemes are available here: https://hospital.blood.co.uk/diagnostic-services/microbiology-services/epidemiology/

Summary of reports made to the NHSBT/UKHSA Epidemiology Unit in 2021

During 2021, UK Blood Services investigated 115 suspected bacterial incidents and 10 suspected viral incidents (Figure 20.1).

Figure 20.1 includes all investigations reported in 2021 in England, Northern Ireland, Scotland and Wales. In previous Annual SHOT Reports investigations in Northern Ireland, Scotland and Wales, concluded as bacterial PTR or not, were not included here.



TTI=transfusion-transmitted infection; HCV=hepatitis C virus

Figure 20.1: Outcome of reports of suspected TTI made to the NHSBT/UKHSA Epidemiology Unit in 2021 update

Please note:

- A **PTR** occurs when a blood transfusion recipient develops a reaction following a transfusion and bacteria were suspected. However, no bacteria were cultured in the recipient, units or donor(s); i.e. no evidence of any bacterial contamination
- A **confirmed TTI** is defined as in the above TTI definition with evidence that the virus/bacterium is indistinguishable on molecular typing between patient and donor/pack
- A **probable TTI** is classified as a TTI as in the above definition, but where molecular typing cannot be carried out to confirm this
- **Not a TTI** is defined as an investigation that concluded the infection in the recipient was NOT caused by transfusion, either as no infected donors identified (after all donors traced) or bacteria/virus identified in the recipient, but all units cleared (no bacteria/virus) in the unit and/or implicated donors
- A **near miss** is defined as either an infection was identified in the unit due to be transfused however the unit was NOT used in transfusion (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

Deaths related to transfusion n=0

No patients with confirmed TTI were reported to have died after being transfused, following investigations in 2021.

Bacterial TTI reports 2021

In 2021, no reported suspected bacterial TTI investigations were concluded to be confirmed, probable or possible. All bacterial TTI investigations were concluded to be either a PTR with no evidence of bacteria in the implicated or associated products or in the recipient, or not a TTI, with evidence of bacteria in either the products or the recipient(s) but not both. In all cases where patient blood cultures were positive, the likely source was the patient's underlying condition.

The four UK Blood Services all use the BacT/ALERT system for bacterial screening which has been successful in reducing the risk of bacterial TTI (McDonald et al. 2017). Sampling methods have recently become more consistent across the four Blood Services, but some slight variation still exist, details of which are described in Table 20.1.

Bacterial TTI 1996-2021

Screening of platelet components cannot guarantee the absence of bacterial contamination. Packs are released for issue as 'negative-to-date', which may be before bacteria have multiplied sufficiently to trigger detection on screening. There have been ten bacterial near misses, all but one in platelet components, reported to the unit between 2011 and 2021. Overall, out of a total of 44 bacterial transfusion-transmissions to individual recipients, 37 (34 incidents) have been caused by the transfusion of platelets, and 7 by red cells (Table 20.6) since reporting began in 1996.

Haemovigilance systems for bacterial TTI are passive and as such rely on clinical colleagues to suspect and report TTI. Current BSH guidance recommends that patients are advised to report any symptoms that occur within 24 hours of transfusion (BSH Tinegate et al. 2012) although our experience suggests that patients with confirmed bacterial TTI become unwell very rapidly, often during transfusion.

Table 20.1: Bacterial screening methods used by the UK Blood Services

	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	2 x 8	Pre-split	6	Day 9
SNBTS	≥36	2 x 8	Pre-split	6	Day 7
WBS	≥36	2 x 8	Post-split	12	Day 7

Viral TTI reports 2021

In 2021, no reported possible TTI were confirmed.

Viral TTI 1996-2021

The year of transfusion may be many years before the year in which the incident is investigated and reported to SHOT due to the chronic nature, and possible late recognition, of some viral infections. Since 1996, 42 confirmed transfusion-transmitted viral infections have been documented in the UK, involving 35 donors. Among these, HBV (n=12) and HEV (n=12) were the most commonly 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.

Evidence of transmission of OBI in the UK is emerging. Donors with this chronic form of HBV infection were thought to typically have a level of HBV DNA that was very unlikely to transmit, however 5 reports have been made of an HBV infection in recipients who had received components from donors with OBI in England; transmission could not be confirmed because of a lack of sequencing information.

All except two HEV transmissions were reported before the HEV RNA screening was introduced in April 2017 in the UK. The UK was one of the first Blood Services to introduce HEV screening; since implementation 2118 HEV RNA containing donations have been successfully identified by screening and removed from the blood supply (preliminary data as at 7/3/2022). 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. This gives rise to an increased chance of non-detection of HEV RNA. Furthermore, as screening is performed in pools, it is recognised that donations containing a small amount of HEV RNA can be missed and potentially transmitted via blood transfusion.

Lookback investigations

Lookback investigations are considered when the UK Blood Services identify markers of infection in a donation from a repeat donor. This may be due to seroconversion or the introduction of a new test. The archive sample of their most recent screen-negative donation is requested for retrospective re-testing and if now identified as positive, the full clinical lookback will be instigated. For NHSBT, where donors are identified with occult HBV infection, donations given during the last three years are considered in lookback investigations regardless of the screening results. This is different to the other investigations reported here that are initiated due to a potential TTI in a recipient.

For lookbacks, the associated components are traced, recipients are identified, and advice given regarding follow-up and testing. Between 2019 and 2021, NHSBT identified 5 HEV and 12 syphilis infections in retrospective testing which were below the level of detection in routine screening, these donations were included in the lookback (Table 20.2). Furthermore, 14 previous donations from 4 donors with OBI were also subjected into lookback investigations. A total 46 of 55 components were transfused, and all 46 recipients identified. Of those recipients who were alive, 22 of 30 were tested and 2 were positive for markers of hepatitis B infection and 1 HEV. These infections in recipients were concluded as a probable HBV and a confirmed HEV transmission and were reported in SHOT 2020 and 2019 reports respectively. The remaining HBV infection was classified as a possible TTI, the recipient had markers of past HBV, but this could have been due to another source.

One HEV lookback investigation was undertaken by SNBTS in 2021, following a donation positive for HEV RNA (HEV IgG and IgM negative). Their most recent donation 35 days prior to index donation was identified to contain HEV RNA in retrospective testing. Three components from positive donation were transfused, testing was not possible for one of these recipients, who was deceased, although this was unrelated to the transfusion. This individual had no clinical signs of HEV, and liver function tests remained normal. Testing of the two transfused components were found to be negative for markers of HEV infection

Table 20.2: Summary of lookback investigations in England, 2019-2021

	Number		
	Occult HBV	HEV	Syphilis
Donors with a previous donation identified as positive in retrospective testing	**4**	**5**	**12**
Donations by these donors considered here	**14**	**5**	**13**
Total components from these donations	**26**	**10**	**19**
platelets	4	10	5
cryoprecipitate	3	0	2
red cells	14	0	11
FFP	5	0	1
Components reported as transfused	**19**	**10**	**17**
Recipient identified but deceased	5	4	7
Recipient identified and alive	14	6	10
Recipients tested	**11**	**6**	**5**
Recipient tested positive	2	1	0
Recipients tested negative	9	5	5
Recipients not tested	**3**	**0**	**5**
Clinical decision made not to test	0	0	2
No response from GP or patient	2	0	0
Testing outstanding	1	0	3
	probable transmission - reported in the 2020 Annual SHOT Report, **possible transmission** - one patient with evidence of past HBV infection	**confirmed transmission** - reported in the 2019 Annual SHOT Report	

Residual risk of HBV, HCV, or HIV

The risks of a potentially infectious HBV, HCV or HIV window period donation not being detected on testing in the UK are very low at less than 1 per million donations tested (Table 20.3) (JPAC 2021). 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 sufficient to transmit. 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.

Table 20.3: The estimated residual risk (and 95% confidence interval) that a donation made in the HBV, HCV and HIV infectious window period is not detected on testing UK: 2018-2020

	HBV	HCV	HIV
Number per million donations	0.81	0.02	0.04
95% confidence interval	*(0.28-1.75)*	*(0.00-0.14)*	*(0.01-0.10)*
At 1.9 million donations per year, testing will miss a potentially infectious window period donation every:	6 months	22 years	14 years

Far fewer TTI are observed in practice than the estimated risks in Table 20.3 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 screening process

Every blood donation in the UK is screened for HBV, HCV, HEV, HIV and syphilis. HTLV is screened for in donations from new blood donors and other infections such as malaria are screened for depending on travel history of the donor. A separate bacterial screening process is also in place for platelets as the storage of platelets at 22°C encourages bacterial growth.

At the time of blood donation, separate blood samples are collected for screening purposes. For the screening of viral nucleic acids (RNA or DNA) the blood samples are pooled together in a batch of six, 16 or 24 prior to screening. If RNA/DNA is detected in that pool, then individual samples known to be in that pool are re-tested separately in order to identify a positive sample. All antibody and/or antigen testing is done using individual blood samples. If RNA/DNA is detected, or antibody result is repeatedly positive suggesting an infection then the donation is discarded, and the sample is sent to a reference laboratory for further testing to confirm the result. If a positive result is confirmed the donor will be notified, offered an opportunity to discuss these results in detail and referred to the appropriate medical care as necessary.

Testing and selection of donors

The HBV and HEV screening processes are currently under review by SaBTO (Harvala et al. 2021).

From summer 2021, the FAIR (For the Assessment of Individualised Risk) blood donation policy was implemented across the UK Blood Services. The same questions are now asked of all donors and allows anyone who has not had anal sex with new and/or multiple partners in the last 3 months to give blood if other donation safety criteria are met. Donors are no longer asked about sex between men, questions are gender neutral. As soon as these changes were implemented, routine surveillance was adapted to ensure timely monitoring of positive donors and close review of those with recently acquired infections. To date, there is no evidence that FAIR has impacted on recent viral infections, and no TTI have been reported. While syphilis in donors has continued at a higher rate in 2021, this is not thought to be because of FAIR but reflects the sustained higher level among the general population. In addition, recommendations to withdraw the questions relating to partners who have had sex in parts of the world where HIV is endemic were approved.

Parasitic TTI

There were no reported parasitic infections for investigation in 2021.

Emerging infections

The Emerging Infections Report (EIR) produced by the NHSBT/UKHSA Epidemiology Unit is distributed monthly. A range of sources are checked for relevant infection issues relating to patient safety and/or blood and tissue availability in the UK and collated into a monthly listing. Sources include outbreak alerts, various regular outbreak surveillance reports, journals, websites and online news resources, listed in more detail below.

The EIR is sent to the chair of SACTTI. The chair of SACTTI also receives early warning communications or other reports deemed urgent as they arise.

These monthly listings, alongside other sources of information are reviewed by SACTTI and may lead to further risk assessment and changes to the donor selection guidelines, or other blood safety measures, where necessary.

Currently west nile virus and usutu virus are spreading in Europe, with usutu virus presenting in birds in the UK. The current situation is being monitored carefully and all blood donors from endemic regions are screened for both viruses.

SARS-CoV-2

Any blood units obtained from donors subsequently diagnosed with SARS-CoV-2 (within 5 days for infection) are re-called and discarded. We have retrospectively investigated whether donations obtained

from these donors with SARS-CoV-2 infection with wild-type virus, Delta or Omicron variant contained SARS-CoV-2 RNA. Although a small number of donations containing SARS-CoV-2 RNA were identified, none of these units were transfused and hence did not pose a risk to a recipient. There were no known cases of transfusion-transmitted SARS-CoV-2 infections reported to the Blood Services in 2021 and there is still no evidence that SARS-CoV-2 is a TTI.

Variant Creutzfeld Jakob Disease (vCJD) 2021

There were no vCJD investigations in 2021.

vCJD 1996-2021

Three vCJD incidents (Table 20.4) 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 (SaBTO 2013).

One of these measures, the provision of imported plasma for individuals born on or after 1st January 1996, was withdrawn in September 2019. This followed a recommendation by SaBTO based on evaluation of the risk of transmission of vCJD. Other risk-reduction measures, such as leucodepletion, remain in place (SaBTO 2019).

Table 20.4: Number of confirmed TTI incidents, by year of transfusion and infection in the UK, reported to SHOT between October 1996 and December 2021 (Scotland included from October 1998)

Year of transfusion	Bacteria	HAV	HBV	HCV	HEV	HIV	HTLV	Parvovirus (B19)	Malaria	vCJD or prion	Total
Pre 1996	0	0	1	0	0	0	2	0	0	0	3
1996	0	1	1	1	0	1(3)	0	0	0	1	5 (7)
1997	3	0	1	1	0	0	0	0	1	2	8
1998	4	0	1	0	0	0	0	0	0	0	5
1999	4	0	2 (3)	0	0	0	0	0	0	0 (1)	6 (8)
2000	7	1	1	0	0	0	0	0	0	0	9
2001	5	0	0	0	0	0	0	0	0	0	5
2002	1	0	1	0	0	1	0	0	0	0	3
2003	3	0	1	0	0	0	0	0	1	0	5
2004	0	0	0	0	1	0	0	0	0	0	1
2005	2	1	1	0	0	0	0	0	0	0	4
2006	2	0	0	0	0	0	0	0	0	0	2
2007	3	0	0	0	0	0	0	0	0	0	3
2008	4 (6)	0	0	0	0	0	0	0	0	0	4 (6)
2009	2 (3)	0	0	0	0	0	0	0	0	0	2 (3)
2010	0	0	0	0	0	0	0	0	0	0	0
2011	0	0	1 (2)	0	1 (2)	0	0	0	0	0	2 (4)
2012	0	0	1	0	1	0	0	1	0	0	3
2013	0	0	0	0	0	0	0	0	0	0	0
2014	0	0	0	0	2 (3)	0	0	0	0	0	2 (3)
2015	1	0	0	0	4 (5)	0	0	0	0	0	5 (6)
2016	0	0	0	0	1	0	0	0	0	0	1
2017	0	1	0	0	0	0	0	0	0	0	1
2018	0	0	0	0	1	0	0	0	0	0	1
2019	0	0	0	0	1	0	0	0	0	0	1
2020	0	0	0	0	0	0	0	0	0	0	0
2021	0	0	0	0	0	0	0	0	0	0	0
Total number of incidents (recipients)	**41 (44)**	**4**	**12 (14)**	**2**	**12 (15)**	**2 (4)**	**2**	**1**	**2**	**3 (4)**	**81 (92)**

Year of transfusion	Red blood cells	Pooled platelets	Apheresis platelet	Fresh frozen plasma	Cryoprecipitate	Total
Pre 1996	3	0	0	0	0	**3**
1996	5	1	0	1	0	**7**
1997	6	1	1	0	0	**8**
1998	2	1	2	0	0	**5**
1999	5	3	0	0	0	**8**
2000	1	5	3	0	0	**9**
2001	0	4	1	0	0	**5**
2002	2	1	0	0	0	**3**
2003	1	1	3	0	0	**5**
2004	1	0	0	0	0	**1**
2005	1	3	0	0	0	**4**
2006	0	1	1	0	0	**2**
2007	2	1	0	0	0	**3**
2008	0	2	4	0	0	**6**
2009	1	0	2	0	0	**3**
2010	0	0	0	0	0	**0**
2011	2	0	0	2	0	**4**
2012	2	0	0	1	0	**3**
2013	0	0	0	0	0	**0**
2014	1	0	0	2	0	**3**
2015	0	3	1	1	1	**6**
2016	1	0	0	0	0	**1**
2017	0	0	1	0	0	**1**
2018	0	0	1	0	0	**1**
2019	0	0	2	0	0	**2**
2020	0	0	0	0	0	**0**
2021	0	0	0	0	0	**0**
Total number of recipients	**36**	**27**	**22**	**7**	**1**	**93**

Table 20.5: Number and type of implicated components from confirmed TTI recipients, by year of transfusion in the UK, reported to SHOT between October 1996 and December 2021 (Scotland included from October 1998)

	Bacteria	HAV	HBV	HCV	HEV	HIV	HTLV I	Parvovirus (B19)	Malaria	vCJD or prion	Total
Death due to, or contributed to, by TTI	11	0	0	0	3	0	0	0	1	3	**18**
Major morbidity	29	3	14	2	9	4	2	1	1	1	**66**
Minor morbidity	4	1	0	0	4	0	0	0	0	0	**9**
Red blood cells	7	1	11	2	4	2	2	1	2	4	**36**
Pooled platelets	21	2	1	0	2	1	0	0	0	0	**27**
Apheresis platelets	16	1	1	0	4	0	0	0	0	0	**22**
Fresh frozen plasma	0	0	1	0	5	1	0	0	0	0	**7**
Cryoprecipitate	0	0	0	0	1	0	0	0	0	0	**1**

Table 20.6: Outcome of confirmed TTI incidents and implicated components by infection in the UK, reported to SHOT between October 1996 and December 2021 (Scotland included from October 1998)

Accompanying notes for Table 20.4, 20.5 and 20.6:

- Where applicable, number of recipients are included in brackets
- No screening has been ever in place for vCJD, HAV or parvovirus B19
- HTLV screening began in 2002
- HEV screening was not in place at the time of the documented transmissions
- In both malaria transmissions, 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 figure
- The year of transfusion may be prior to year of report to SHOT due to delay in recognition of chronic infection
- The 2 HIV incidents 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

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

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SPECIAL CLINICAL GROUPS

21 Cell Salvage (CS) n=38

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

ACD	Acid-citrate-dextrose	**MHRA**	Medicines and Healthcare products Regulatory Agency
ICS	Intraoperative cell salvage	**PCS**	Postoperative cell salvage
IV	Intravenous	**UKCSAG**	United Kingdom Cell Salvage Action Group
LDF	Leucocyte depletion filter		

Key SHOT message

- Autologous red cell salvage is not without risk. Transfusion to the right patient, at the right time, in the right manner is equally important as for any blood transfusion

Recommendations

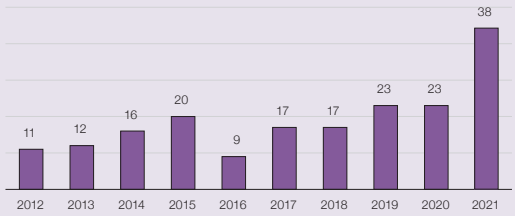
- Organisations should have defined processes in place for the safe administration of salvaged red cells
- All autologous transfusion bags must be accurately labelled with patient identifiers matching the patient's wristband to allow positive patient identification on reinfusion
- Labelling should also include an expiry time when the transfusion should be terminated
- All staff involved in the autologous cell salvage process must have adequate training to perform their role safely
- When handing a patient over to another staff member, communication relating to autologous blood transfusions must be clear and concise, including details about how to proceed

Action: Cell salvage leads, hospital transfusion teams, hospital transfusion committees

Headline data 2021

Number of reports n=38
Deaths n=0
Major morbidity n=0

CS reports by year



Demographic data

Male n=15
Female n=23
Adults n=33
Paediatric n=1
Unknown n=4

Blood component data

Red cells n=38
Platelets n=0
Plasma n=0
Multiple components n=0
Other n=0

Introduction

Thirty-nine incidents were reported; on review 1 case was withdrawn. The reports were submitted from eight different reporting centres, with one centre submitting 23 reports. This is the largest number of cell salvage reports submitted to SHOT since 2011.

Most reports came from patients undergoing obstetric or gynaecological procedures (17 combined), with orthopaedic and trauma specialities submitting 14 reports. Twenty-one incidents occurred in emergency situations, with 17 occurring in elective settings.

As with previous years, adverse events dominate, with equipment issues being the largest reporting category. This year 1 adverse reaction was reported, with hypotension in an obstetric patient receiving salvaged red cells through a LDF.

Table 21.1: Cell salvage cases by speciality

Specialty	Elective	Emergency	Total
Gynaecology	2		**2**
Obstetrics	7	8	**15**
Orthopaedic	3	1	**4**
Other		1	**1**
Trauma		10	**10**
Vascular	5	1	**6**
Grand total	**17**	**21**	**38**

Deaths related to transfusion n=0

There were no reported deaths associated with cell salvage in 2021.

Major morbidity n=0

There were no cases reported with major morbidity associated with cell salvage in 2021.

Types of cell salvage

Thirty-seven reports related to the use of ICS, with 1 case in PCS. This is the first report related to the use of a filtered PCS device since 2014.

Cell salvage adverse events n=37

Most adverse events related to machine failure (n=26). Of the remaining adverse events, 7 were preventable.

Equipment failure n=26

There were 26 reports of equipment failures, 10 in elective procedures and 16 in emergency situations. Eighteen related to device malfunction and 8 were reported as disposable manufacturing faults. All were reported to the MHRA under the yellow card scheme. For the same reporting period the MHRA received 43 user reports for autologous transfusion equipment suggesting that these are under-reported to SHOT.

Sixteen incidents related to 'long empty' cycles potentially effecting the quality of the reinfused blood. There were 9 reports of this type in the 2020 Annual SHOT Report (Narayan et al. 2021). There were 4 further reports of unidentified black particles in the reinfusion bag which were attributed to machine failure in 3 cases and reported as an adverse event in 1 case (see below). Other reported equipment issues included premature activation of the wash cycle (5), low haematocrit of the reinfusion product and a mechanical failure.

These equipment issues resulted in 2 patients receiving allogeneic blood that could have been potentially avoided.

Procedural errors n=7

In 2 cases incidents were attributed to errors made by the cell salvage operator. In the first, the operator labelled the reinfusion bag with the previous patient's details leading to a patient identification error. The error was noticed, and the red cells (100mL) were discarded. The cell salvage operator stated that they had been distracted by the presence of a student within the operating theatre. In the second incident, incorrect use of equipment resulted in a bag of unwashed red cells being handed to an anaesthetist and connected to an obstetrics patient for reinfusion. Timely intervention by theatre staff prevented infusion of a product that could have contained amniotic fluid and anticoagulant. In both of these cases the operators were trained and competency-assessed.

In a further 5 incidents, errors or inexperienced staff involved in the cell salvage process were contributory. In 2 cases, non-IV substances entered the blood collection from the operating table thereby contaminating the collection and making it unfit for purpose.

In a further 2 cases reinfusion times exceeded the 4-hour time limit. An obstetric patient was given red cells over a 9-hour period when the infusion was slow, possibly due to the position of the cannula. The patient was transferred back to the ward with the infusion running, the receiving staff member was new and unaware of cell salvage time limits. In the 2nd case, handover of a patient to recovery staff inexperienced with cell salvage had failed to highlight the expiry time written on the reinfusion bag. By the time the labelling was noticed, the reinfusion had exceeded the expiry time by 1 hour.

Case 21.1: Near miss where a patient could have potentially received another patient's blood

A woman in her 30s underwent an emergency caesarean section and ICS was facilitated. Blood loss was estimated at 900mL. At the end of the surgical procedure the patient was moved to recovery before the ICS process was completed producing 226mL of salvaged red cells (O D-positive). An anaesthetist then took the labelled reinfusion bag from theatres to the bedside of what they thought was the correct patient in recovery. The bag was hung on a drip stand and connected to a cannula in the patient's arm, but the infusion was not commenced. The doctor was initially questioned by the patient 'is that mine?' and then challenged by the midwife. Checking the patient's details on the labelled blood bag against the wristband revealed that the doctor was in the wrong bay with a different patient (B D-positive). The infusion was disconnected and removed. The doctor had failed to follow the 4-point patient identity check at the bedside before connecting the transfusion. Timely intervention by the patient and the midwife prevented the transfusion of the wrong blood into the wrong patient. The process was updated following this incident whereby a patient receiving cell salvaged blood must leave theatre with the red cell transfusion connected and running.

This incident occurred at the end of a busy night shift and fatigue played a part. Salvaged red cells are untested in relation to blood group and infectious diseases. Infusion into the wrong patient could result in an ABO-incompatible reaction or transmission of infection. The questioning by the patient and the intervention by the midwife was crucial in this case and highlights the importance of positive patient identification.

Learning points

- Accurate labelling of the cell salvage reinfusion bag with correct patient identifiers is imperative for patient safety. The label should also include the expiry time. The UKCSAG has produced a standardised label that is available from all ICS manufacturers for customer use
- The transfusion of autologous red cells should follow the same processes as for allogeneic transfusion in relation to bedside checks to confirm patient identity. This is particularly important when the reinfusion bag has not been connected within theatre

Other adverse events n=4

In 2 cases, staff trained to operate the ICS equipment were not available for surgeries where ICS was indicated. In 1 of these incidents, the patient underwent complex total hip revision surgery and lost 1700mL during surgery. This patient required a one-unit allogeneic transfusion that may have been avoided if cell salvage had been facilitated.

In a 3rd case autologous blood transfusion drains (PCS) were used in a paediatric scoliosis patient. Postoperatively, 700-800mL of the patient's blood was available for reinfusion but not given before it expired due to lack of experience and poor communication at handover.

The 4th case related to the appearance of black particles in the reinfusion bag and was reported as an adverse event as opposed to an equipment failure.

Cell salvage adverse reaction n=1

Case 21.2: Hypotension on reinfusion of salvaged red cells with a LDF

A woman in her 20s underwent an elective caesarean section and experienced an intraoperative haemorrhage post-delivery of approximately 4000mL. ICS was utilised with anticoagulation by ACD with a collection volume of approximately 800mL. Three units of allogeneic red cells were transfused prior to commencing salvaged red cells. On commencement of the autologous transfusion through a LDF the patient exhibited a sudden drop in blood pressure and became tachycardic. The salvaged red cell infusion was stopped, and the patient received vasopressors and fluids and she quickly recovered. The cell salvage transfusion of approximately 200mL was recommenced slowly without incident. Towards the end of the infusion, the remainder of the volume within the bag was drawn into a 30mL syringe via a 3-way tap downstream of the filter. Infusion of this bolus resulted in a second hypotensive event accompanied with tachycardia. The patient was resuscitated with vasopressors and fluids and made a full recovery.

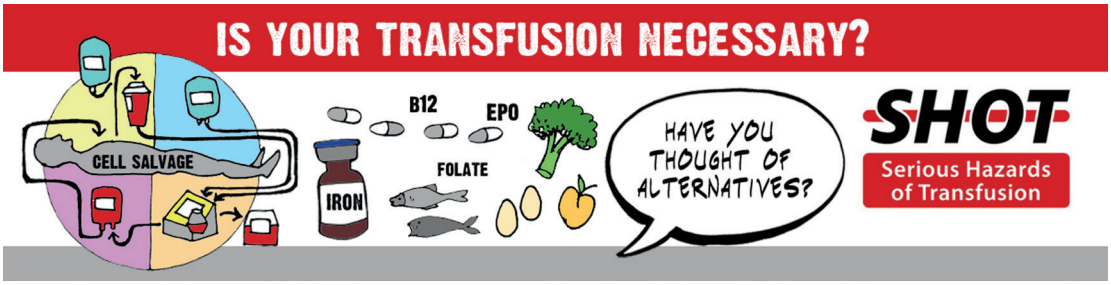
The reaction was reported as related to the reinfusion of salvaged red cells and not related to hypovolaemia following haemorrhage.

Use of a syringe to evacuate the reinfusion bag downstream of the LDF filter is outside of the manufacturer's indication of use of the LDF specifically designed for use with ICS. The effects of placing a negative pressure on the retained contents within the filter is unknown.

Hypotension on reinfusion is the most common adverse reaction reported to SHOT in relation to cell salvage. There have been 31 such reports since SHOT began collating cell salvage reports in 2010.

Conclusion

The majority of reports this year come from equipment issues and represent an increase of previous years' reporting. 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 at handover to staff unfamiliar with cell salvage infusions. The correct labelling and prescription of autologous blood, with clear instructions to those caring for patients is vital in these situations.



Recommended resources

UKCSAG:

Factsheet 5 – Administration of Salvaged Blood (version 3)
Factsheet 10 – Staff Responsibilities (version 1)
https://www.transfusionguidelines.org/transfusion-practice/uk-cell-salvage-action-group/technical-factsheets-and-frequently-asked-questions-faq

SHOT Bite No. 21: Cell Salvage
https://www.shotuk.org/resources/current-resources/shot-bites/

References

Narayan S (Ed), Poles D, et al. on behalf of the Serious Hazards of Transfusion (SHOT) Steering Group. The 2020 AnnualSHOT Report (2021). https://www.shotuk.org/shot-reports/ [accessed 06 May 2022].

Paediatric Cases n=136

22

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	**Ig**	Immunoglobulin
BSH	British Society for Haematology	**IT**	Information technology
CAS	Central alerting system	**ICU**	Intensive care unit
CS	Cell salvage	**MB**	Methylene blue-treated
CMV	Cytomegalovirus	**MHP**	Major haemorrhage protocol
DAT	Direct antiglobulin test	**NEC**	Necrotising enterocolitis
ECG	Electrocardiogram	**NM**	Near miss
ED	Emergency department	**RBRP**	Right blood right patient
FAHR	Febrile, allergic and hypotensive reactions	**SRNM**	Specific requirements not met
FFP	Fresh frozen plasma	**TACO**	Transfusion-associated circulatory overload
FY2	Foundation year 2	**TAD**	Transfusion-associated dyspnoea
Hb	Haemoglobin	**TRALI**	Transfusion-related acute lung injury
HSE	Handling and storage errors	**TTI**	Transfusion-transmitted infection
HT	High-titre	**UCT**	Uncommon complications of transfusion
HTR	Haemolytic transfusion reactions	**WCT**	Wrong component transfused
IBCT	Incorrect blood component transfused		

Key SHOT messages

- Clinical staff must be trained and be aware of the specific transfusion requirements for patients with haemoglobin disorders. These requirements should be communicated to the transfusion laboratory staff in a timely manner
- All staff must be aware of the paediatric major haemorrhage protocol in their hospitals
- Hospitals should ensure the correct use of the paediatric red cell transfusion formula, with the Hb units in g/L (BSH New et al. 2016)
- There remains uncertainty over the precise definitions of paediatric pulmonary complications, particularly for neonates. Clinicians should be alert to the possibility of the diagnosis in these patients
- Hyperkalaemia is a recognised complication of large volume transfusion in neonates and infants, and 'fresh' red cells are recommended for this situation to reduce risk

Recommendations

- Paediatric medical and nursing education must include specific transfusion requirements for patients with haemoglobinopathies and processes must be in place to ensure these are communicated effectively to the hospital transfusion laboratories to ensure safe transfusions
- Protocols must be in place for the management of massive haemorrhage in infants and children. These should include guidance on the appropriate component volumes to be used in resuscitation. Staff involved in paediatric transfusions must be trained and aware of the content of this protocol

Action: Hospital transfusion teams, hospital transfusion laboratories, Royal College of Paediatrics and Child Health, clinical leads, medical and nursing educators

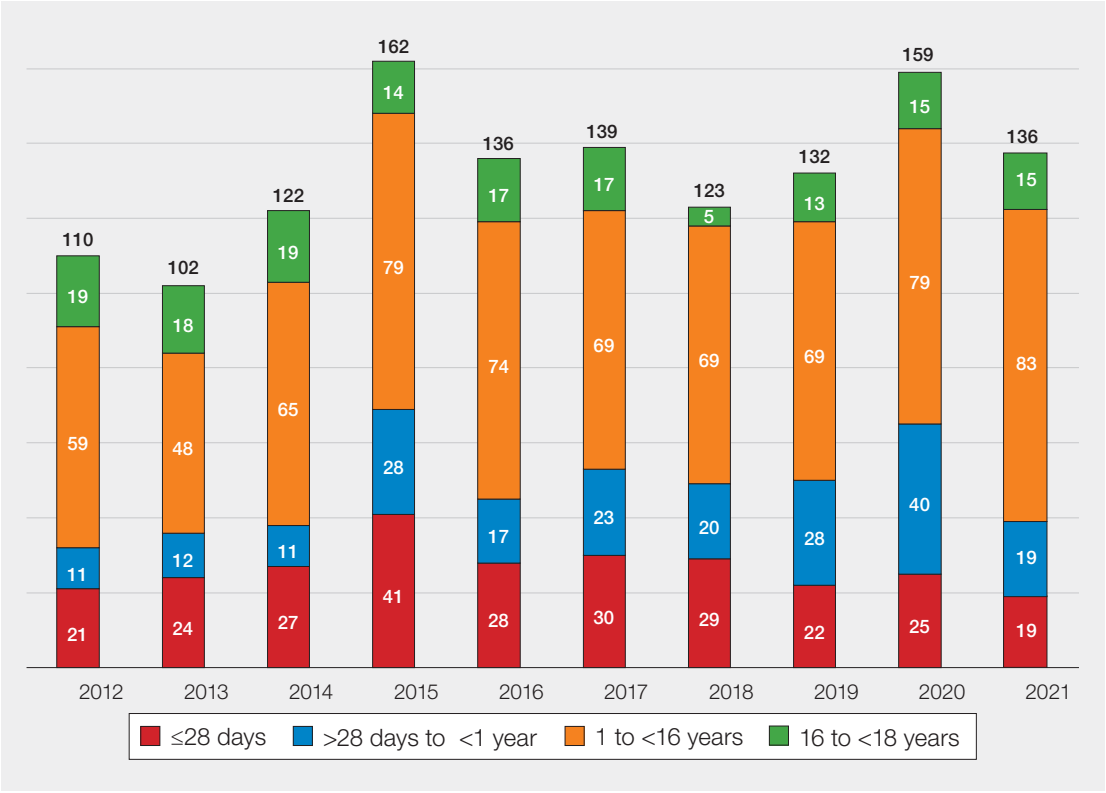
Introduction

There were fewer paediatric cases overall in 2021 compared to 2020 (136 vs 159), with reporting levels this year similar to 2019. Paediatric cases were 7.6% (136/1790) of total cases analysed excluding NM and RBRP and 7.7% (244/3161) if NM and RBRP are included.

Paediatric cases continue to be over-represented in FAHR, ADU (particularly overtransfusion) and IBCT. This year there is also a relative increase in paediatric HTR reports. However, the large increase seen last year in the FAHR reports following platelet transfusion has not been sustained.

This year 53/83 (63.9%) of paediatric error reports were considered clinical errors and only 30/83 (36.1%) laboratory errors. This constitutes both an increase in the number of clinical errors and decrease in the number of laboratory errors. There has been a drop in total laboratory reports overall, discussed in Chapter 14, Laboratory Errors; it is not clear whether this is due to improvement in practice or a reduction in reporting. The paediatric categories with high percentages of clinical errors in 2021 were ADU (28/33, 84.8%), HSE (14/15, 93.3%) and all the reports in cell salvage (n=1) and anti-D Ig categories (n=3).

Figure 22.1: Trends in paediatric reports 2012-2021



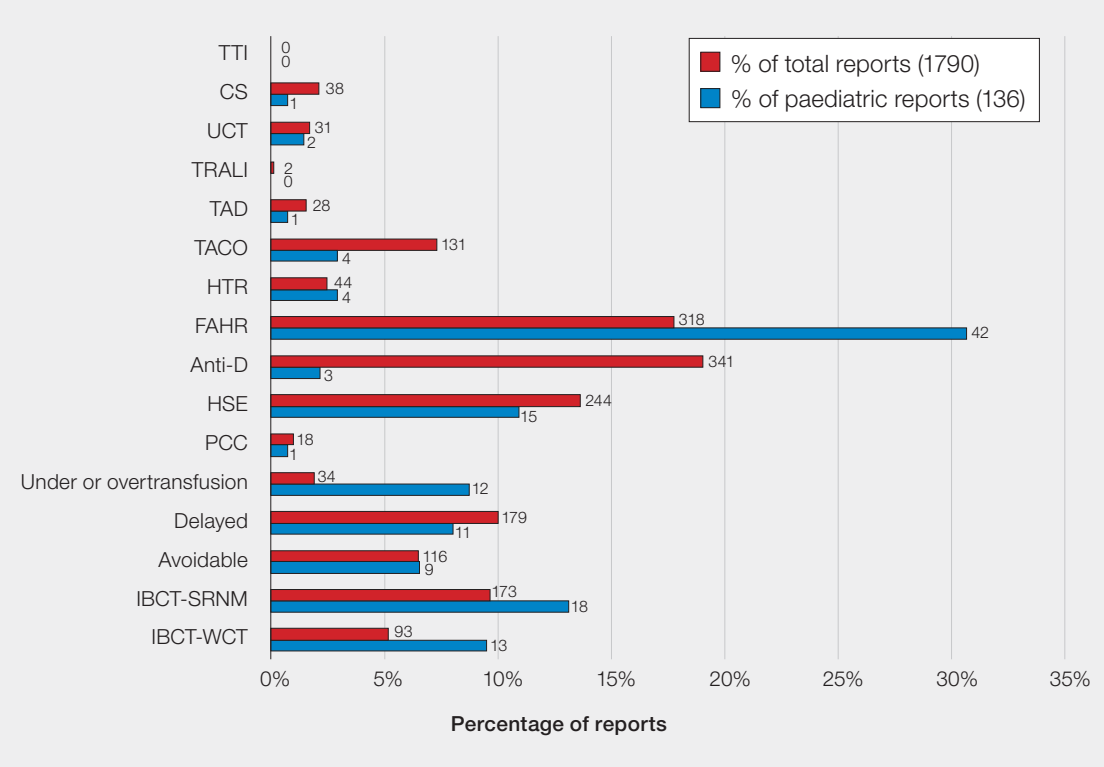


Figure 22.2: Percentages of paediatric and total reports in each category

TTI=transfusion-transmitted infection; CS=cell salvage; UCT=uncommon complications of transfusion; TRALI=transfusion-related acute lung injury; TAD=transfusion-associated dyspnoea; TACO=transfusion-associated circulatory overload; HTR=haemolytic transfusion reactions; FAHR=febrile, allergic and hypotensive reactions; HSE=handling and storage errors; PCC=prothrombin complex concentrate; IBCT-SRNM=incorrect blood component transfused-specific requirements not met; IBCT-WCT=IBCT-wrong component transfused

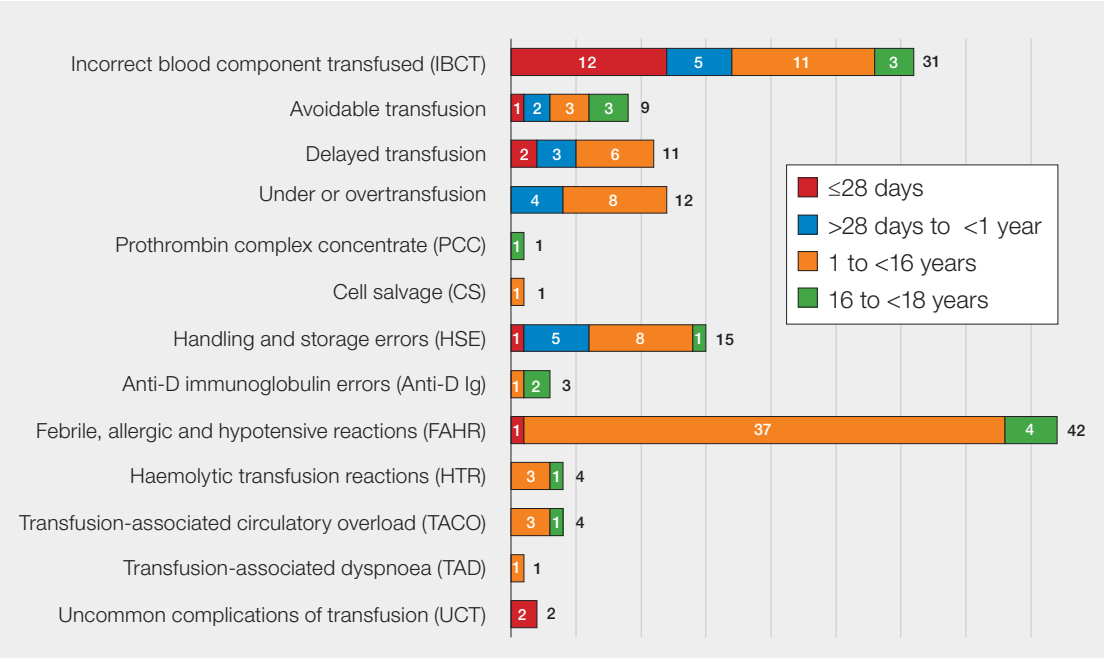


Figure 22.3: Summary of paediatric cases by category and age 2021

Deaths related to transfusion n=2

There were 2 paediatric deaths felt to be possibly related to transfusion. One of these deaths was in the ADU category and was a delay in transfusion. The other was in the UCT category and was a case of transfusion-associated necrotising enterocolitis.

The delay in transfusion is discussed below and was in the emergency provision of red cells. This highlights the importance of robust communication pathways in an emergency.

Case 22.1: Communication failure resulting in delay in provision of red cells

A preterm baby was born in a poor condition and required resuscitation. The Hb on a blood gas was 50g/L. Due to a communication error, the call for emergency blood was not received by the transfusion laboratory and no red cell units were provided before attempts at resuscitation were abandoned.

Case 22.2: Case of necrotising enterocolitis following transfusion

An extremely preterm baby with respiratory distress, sepsis (site unspecified) and hypoglycaemia developed falling oxygen saturation and became pale with distended, tense abdomen 7 hours following a red cell transfusion for severe anaemia. The baby continued to deteriorate despite resuscitation and abdominal X-ray showed a perforation. Death was felt to be possibly related to transfusion. This was a suspected case of transfusion-associated necrotising enterocolitis.

Major morbidity n=20

There were similar numbers of cases this year which were judged to have resulted in major morbidity, with the largest category being FAHR.

There were 14 in the FAHR category, 1 of which is illustrated below. It is a reminder that significant hypotension can occur in association with transfusion reactions including in very tiny babies (Bolton-Maggs et al. 2016). FAHR should be considered if there is unexpected hypotension following transfusion, although this can be difficult to distinguish from complex underlying diagnoses.

Case 22.3: Hypotension during MB-FFP infusion in child with pre-existing cardiac condition

A preterm baby developed significant hypotension and drop in oxygen saturation 5 minutes into an infusion of MB-FFP. The baby responded to resuscitation. Of note the baby had pre-existing fetal arrhythmia and reduced ventricular function so it is difficult to know the contribution of the pre-existing condition to the episode of hypotension.

There were 3 cases in TACO, 1 of which was an episode of TACO in a young child following FFP infusion, which resulted in ICU admission.

Two cases were in the HTR category with 1 being a complex case involving both an allo anti-Jk^{b} and autoantibodies (auto anti-c and anti-E) with positive DAT in a child following a multi-visceral transplant. The other was a teenager with sickle cell disease and hyperhaemolysis with anti-S and anti-Fy^{a}.

The final case was in the ADU category and was a delayed transfusion due to lack of awareness of a paediatric MHP (discussed in the ADU section of this chapter).

Error related reports n=83

Apart from a set of IBCT reports in 2020 from a single centre due to a look back exercise, the number of paediatric error reports is broadly similar over the last 3 years.

Incorrect blood component transfused (IBCT) n=31

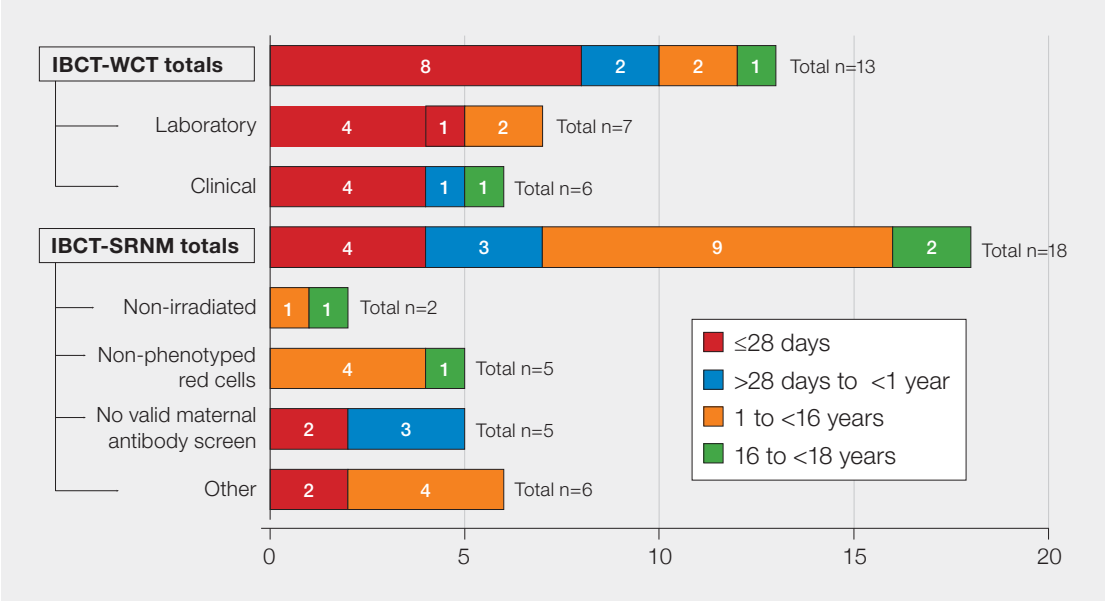


Figure 22.4: Breakdown of incorrect blood component transfused reports

Other includes incomplete testing (n=3), invalid time-expired sample (n=1), failure to provide CMV-negative (n=1) and inappropriate D-positive component (n=1)

IBCT-WCT=incorrect blood component transfused-wrong component transfused; IBCT-SRNM=IBCT-specific requirements not met; CMV=cytomegalovirus

IBCT wrong component transfused (WCT) n=13

IBCT-WCT clinical errors n=6

Adult O D-negative red cells to a neonate n=5

There remain a significant number of reports of adult specification O D-negative red cells being administered to children under 1 year of age. Of these, 3 were neonatal resuscitation, and suitable neonatal specification units were available. The other 2 incidents were emergency situations involving infants where adult specification units were used but neonatal units could have been provided.

Incorrect blood component to haemopoietic stem cell transplant recipient n=1

A child post haemopoietic stem cell transplant (patient's blood group was A D-positive and stem cell donor was O D-positive) received incorrect but compatible blood components due to a lack of communication from the clinical team to the transfusion laboratory about the transplant status.

IBCT-WCT laboratory errors n=7

Issues with grouping n=3

All cases involved neonates. One case involved issue against another patient's sample, 1 involved lack of two historical groups and the other resulted in incorrect provision of FFP based on an inconclusive blood group.

Adult specification component to a neonate or infant n=2

One of these was FFP and 1 red cells.

Wrong ABO/D blood components provided to a haemopoietic stem cell transplant recipient n=2

Two cases involved issues around communication resulting in provision of components of the wrong ABO (although compatible) or D-type to a haemopoietic stem cell transplant recipient.

IBCT-specific requirements not met (SRNM) n=18

IBCT-SRNM clinical errors n=1

A child with sickle cell disease was admitted to ICU following transfer from another hospital and received non-phenotyped red cells which were also not sickle negative due to poor communication. This highlights the importance of communication of specific requirements between clinicians and laboratory.

IBCT-SRNM laboratory errors n=17

Most paediatric SRNM reports were primarily due to errors in the laboratory.

In 5 cases (all infants aged 1 month old and younger), there was a failure to perform an antibody screen on a maternal sample. In 3 cases testing was incomplete. Of these, 1 child only had a single group and save sample, 1 child the DAT was not complete prior to issue, and in the 3rd, 1 infant had platelets issued when their blood group was not known. There were 4 children (3 with sickle cell and 1 with thalassaemia) that received non-phenotyped non-HbS negative blood.

Case 22.4: Alloimmunisation in a patient with thalassaemia resulting from failure to provide phenotype matched red cells

A teenager with thalassaemia had previously had red cell phenotyping performed. There was no alert on the laboratory system indicating that this patient required phenotyped red cells and they were transfused with E-positive red cells. The patient developed an anti-E.

Two patients (1 child and 1 teenager) with Hodgkin's disease were given non-irradiated blood components. There was 1 case reported where the maternal sample was invalid and had expired.

Another patient received D-positive blood components inappropriately due to a selection error (patient was group A D-variant and should have been transfused D-negative red cells), and in the final case a CMV-negative teenager received two units of CMV untested granulocytes against local policy.

Learning points

- Provision of appropriate blood components with the correct specification for chronically transfused patients is vital
- Transfusion errors where specific requirements for paediatric haemoglobinopathy patients have not been met continue to be reported to SHOT. BSH guidelines (BSH New et al. 2016) recommend that children with haemoglobinopathies should have extended red cell phenotyping or genotyping. It is considered good practice for these same recommendations to apply to children on chronic transfusion programmes, such as bone marrow failure syndromes
- The All-Party Parliamentary Group 'No One's Listening' report (Sickle Cell Society 2021) into poor care for patients with sickle cell anaemia has made several recommendations to improve standards of care provided for these patients and enhance patient safety

SHOT
Serious Hazards of Transfusion

Avoidable, delayed, under or overtransfusion (ADU) n=33

Avoidable transfusions n=9

In 4 cases erroneous results were acted upon. These included looking the result of wrong baby (n=1), acting on previous results (n=2) and acting on a dilute sample when a repeat showing a much higher Hb was available (n=1).

For 3 children, O D-negative components were used when in all cases crossmatched blood was appropriate and available.

One case involved lack of knowledge of recommended transfusion thresholds and was exacerbated by poor handover between clinical staff. In the final case an additional platelet unit was given in error to a child with aplastic anaemia as the IT system did not allow a unit to be ordered but merely be on 'stand-by' in case needed.

Delayed transfusions n=11

Five errors directly involved communication issues, including the case of the neonate who died (Case 22.1). In 1 case there was a delay in clinical decision making and in another a calculation error was noted and had to be corrected before the child received the blood component. Three errors involved laboratory processes: not thawing FFP in a timely manner, incorrect rejection of a sample that was not a duplicate, and not reserving red cells for a blood prime for an apheresis procedure. In the final case, management of a major haemorrhage was delayed due to lack of awareness of the paediatric MHP.

Prothrombin complex concentrate (PCC) n=1

There was a delay in the management of the coagulopathy in a teenage patient with acute promyelocytic leukaemia due to confusion around the optimal recommended components and/or blood products (PCC had been prescribed).

Case 22.5: Lack of awareness of paediatric MHP

The paediatric MHP was activated in the ED. The laboratory scientist was not aware that there was a separate protocol for children and advised the ED to contact the on-call consultant paediatric haematologist instead of preparing packs, resulting in a 20-minute delay in provision of the blood components.

SHOT
Serious Hazards of Transfusion

Learning points

- The importance of MHP was highlighted in the 2022 CAS Alert (SHOT 2022) and was also discussed in the 2020 Annual SHOT Report paediatric chapter (Narayan et al. 2021). The recently published 2018 paediatric National Comparative Audit found that only 21% of reporting sites had an MHP for children (as distinct from adults) and that the MHP was only activated in 55% of cases of paediatric major haemorrhage (NCA 2021)
- All staff, clinical and laboratory, involved in paediatric and neonatal transfusions must be familiar with the paediatric MHP protocol

Overtransfusions n=12

Most (9/12) paediatric overtransfusion events were related to incorrect prescribing. All were transfusions of red cells except 1 infant who received an excess of platelets. Prescribing errors included whole adult units given to children, correct volume prescribed but whole unit given in error, and a mis-transcription of a child's weight (see Case 22.11 in the supplementary information on the SHOT website (https://www.shotuk.org/shot-reports/report-summary-and-supplement-2021/).

In 2 cases illustrated below, erroneous use of the formula to calculate the red cell transfusion volume required (using Hb in g/dL rather than g/L) resulted in a 10-fold volume error. Hb has been measured in g/L rather than g/dL for several years and guidance on using the calculation formula is given in the paediatric transfusion guidelines, including a reminder to use Hb in g/L, to double-check that the final volume calculated is not excessive, and that the final volume should not exceed the maximum normally transfused to an adult in a similar situation (BSH New et al. 2016).

In 7/12 cases, overtransfusions were prescribed by paediatric staff, 2 by paediatric haematologists and 1 by a gynaecologist (2 were not specified). Where specified these clinicians were speciality registrars in 6, consultants in 2 and a FY2 in 1 case.

Case 22.6: Calculation error that illustrates the pitfalls but also safety mechanisms that worked

An infant received an overtransfusion due to a calculation error. The Hb was 68g/L and there was an error in calculating the required dose (mL) of red cells. The registrar used g/L (68) to calculate the volume rather than g/dL still in use in this department (6.8). The intended amount therefore was a tenfold error (432mL rather than 43.2mL). A safety net on the formula states a maximum transfusion volume of 20mL/kg (170mL) therefore this is how much was prescribed. The nurses checking prescription both stated they did not check the formula themselves. After handover a different nurse realised patient had received 110mL (12mL/kg) and paused the pump as it is unusual to give more than 10mL/kg to a patient with liver disease. Repeat testing showed Hb was 96g/L.

The outcome of this episode was to revise the formula for blood transfusion to reflect g/L and no longer use g/dL.

Two further cases in this category are described in the supplementary information on the SHOT website (https://www.shotuk.org/shot-reports/report-summary-and-supplement-2021/).

Learning points

- Prescribing errors for blood components in children are common. Hospitals should review their paediatric transfusion guidelines and ensure they contain updated units and calculations. The Hb values used for that the calculations should be in g/L and not g/dL
- When a calculation (BSH New et al. 2016) is performed to determine the volume of red cells required, it is vital to 'sense check' that the volume prescribed is <20mL/kg, other than for specific large volume transfusions, and if not recheck the calculation
- The patient's weight (child or neonate) should be recorded accurately as this is the basis for all calculations including transfusion support
- Electronic prescribing systems can assist in prevention of paediatric prescribing errors by limiting the total volume of blood component that can be authorised. However, the design of such systems can be complex as they must allow for large volumes transfusions either in emergency or for exchange transfusion

Cell salvage (CS) n=1

Relatively few CS reports are seen in the paediatric age group probably reflecting the proportion of paediatric patients receiving this form of transfusion. It is even more critical that all members of staff involved understand the process when a procedure is performed less frequently for a patient group.

Case 22.7: Communication issues resulted in confusion about whether to utilise salvaged blood

Autologous re-transfusion was not performed for a teenager following scoliosis surgery despite the Hb being below the local postoperative transfusion threshold. On review there had been uncertainty as to whether to give the transfusion of the salvaged blood to this patient and the blood expired before it could be transfused.

Handling and storage errors (HSE) n=15

Most of the HSE were primarily clinical rather than laboratory (14 out of 15).

There were 7 technical administration errors. Of these, 4 were errors in transfusion rate, 2 involved incorrect prescription and 2 incorrect pump programming. One error involved running red cells alongside an incompatible fluid and the other 2 were problems with the giving set.

In 3 cases, duration of transfusions were greater than 5 hours for 2 red cell transfusions and nearly 2 hours for a platelet transfusion, although in the latter case the patient had a sudden deterioration in the middle of the transfusion (felt to be unrelated to the transfusion) and this was the reason given for the long duration.

The remaining cases included 4 reports where time-expired or wasted units were transfused, and in 1 case there was an error in the cold chain.

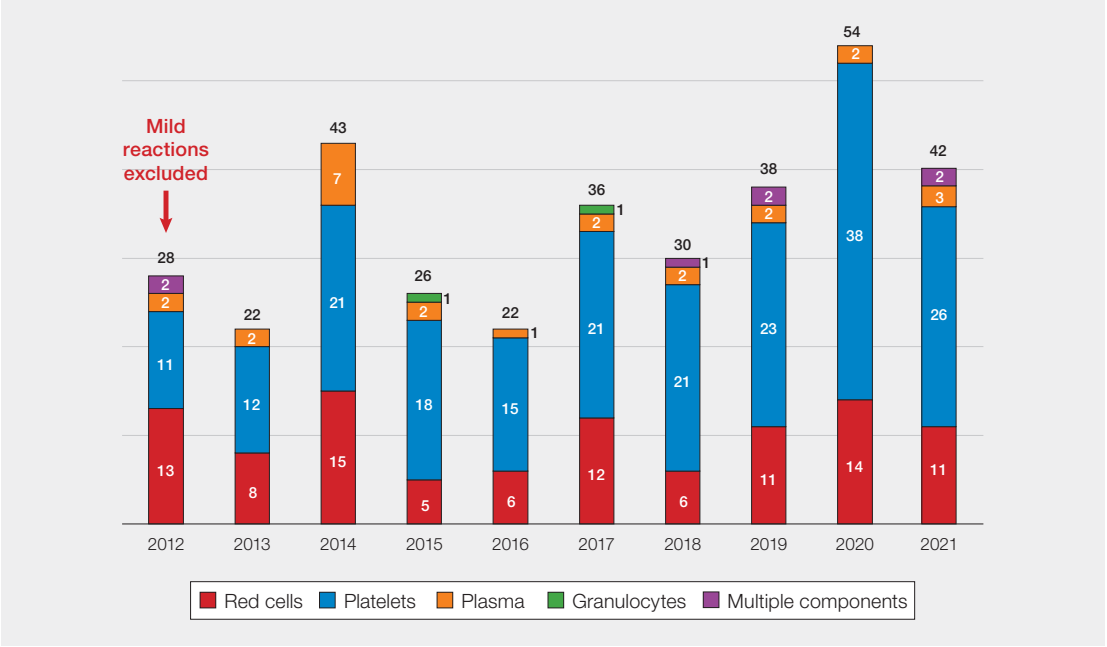
Anti-D immunoglobulin (Ig) n=3

One case involved failure to give anti-D Ig to a D-negative teenager who received D-positive platelets. The other 2 cases were failure to give anti-D Ig prophylaxis to D-negative teenage mothers.

Transfusion reactions n=54

Febrile, allergic and hypotensive reactions (FAHR) n=42

Figure 22.5 Summary of FAHR reports by component type from 2012 to 2021

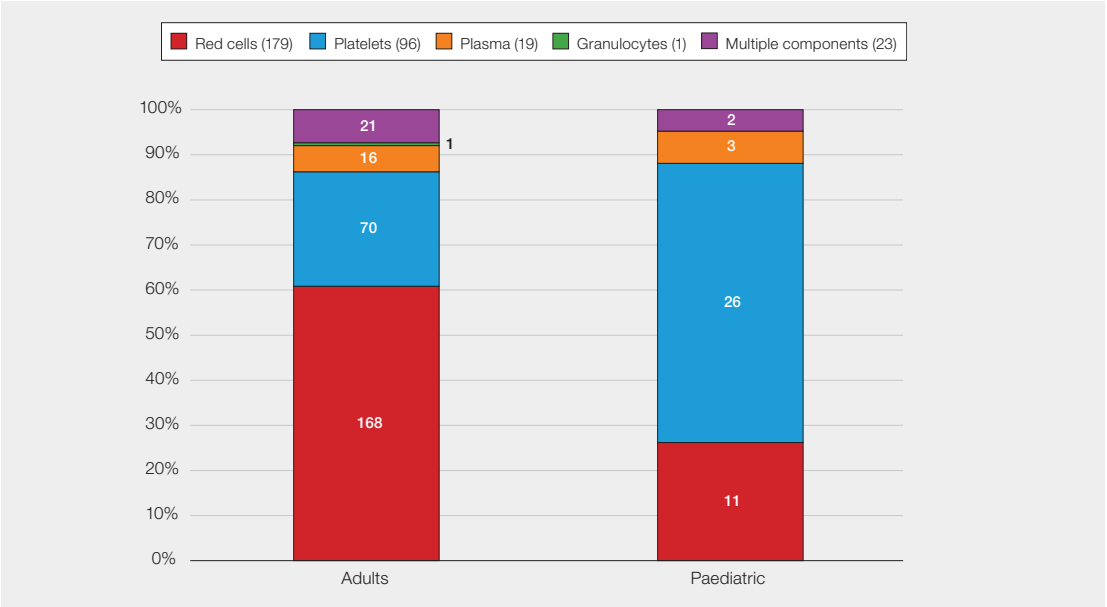


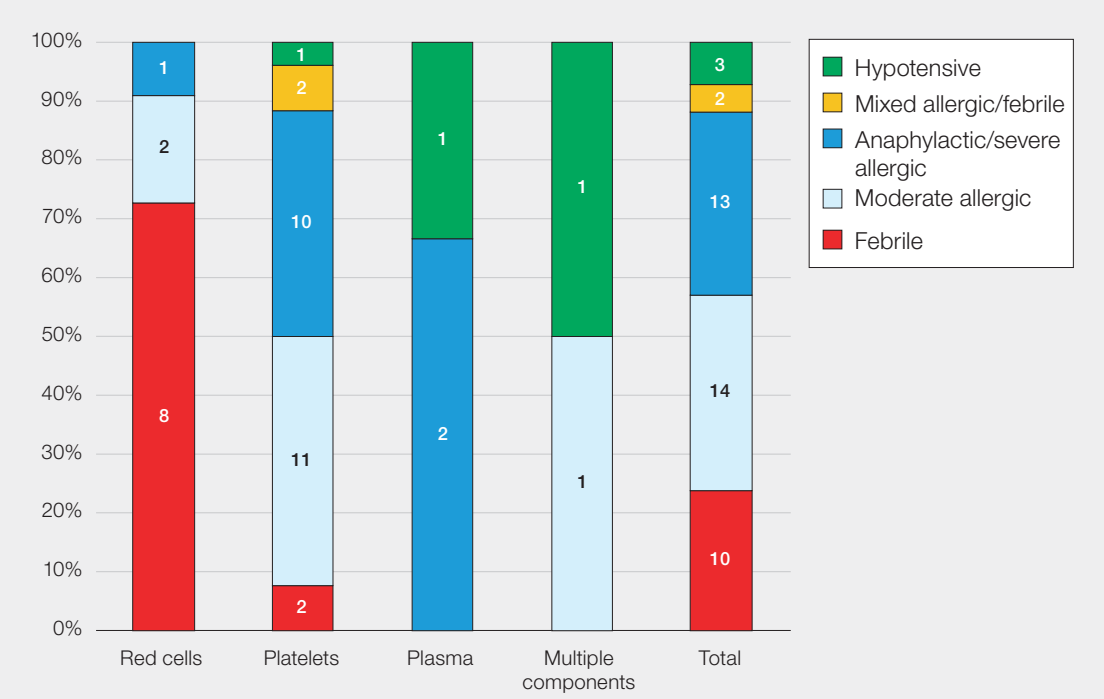
The total number of reports have reduced from a peak of 54 in 2020 (Figure 22.5). Platelet reactions continue to account for a higher proportion of paediatric FAHR as compared to adults, 26/42 (61.9%) (Figure 22.5), although these were fewer than the previous year. It is unknown whether paediatric platelet transfusion demand has changed in this period.

The relative frequency, and often severity, of paediatric FAHR to platelets is a reminder that prophylactic platelet transfusions should only be given according to guidelines. For neonates, this message is accentuated by the findings of the PlaNeT-2 trial showing evidence of harm of prophylactic platelet transfusions given above a threshold of $25x10^9$/L (Curley et al. 2019).

There was 1 possible reaction in a preterm neonate with pre-existing cardiac condition, discussed in the major morbidity section (Case 22.3). This case is a reminder that reactions can occur in this age group, sometimes hypotensive, and may be difficult to identify or distinguish from other complex co-morbidities.

Figure 22.6: Paediatric FAHR reports a. Comparison of proportions of adult and paediatric FAHR related to different components





b. Percentages of reaction types of each component for paediatric reports

Haemolytic transfusion reaction (HTR) n=4

There were 4 cases reported. Two of these cases resulted in major morbidity and are described in the relevant section above (a case of auto/alloantibodies in a multi-visceral transplant patient and the other a case of hyperhaemolysis in a patient with sickle cell disease).

A young child developed a bilirubin rise following a group A platelet transfusion of non-HT negative group A platelets to a group AB child. This case is a reminder that for ABO minor-mismatched platelet transfusions to children, platelets should be tested and negative for high-titre antibodies (anti-A and anti-B; New et al. 2016). The other case was of a delayed HTR following a red cell exchange, and an eluate showed an auto anti-C and anti-E. See Chapter 18, Haemolytic Transfusion Reactions (HTR) for further details of both cases.

Pulmonary complications of transfusion in neonates and children

Identification of pulmonary complications of transfusion in children remains challenging without age-specific definitions, and reports in this age category are few and intermittent. There has been no pattern in reporting of pulmonary complications evident over the last 10 years.

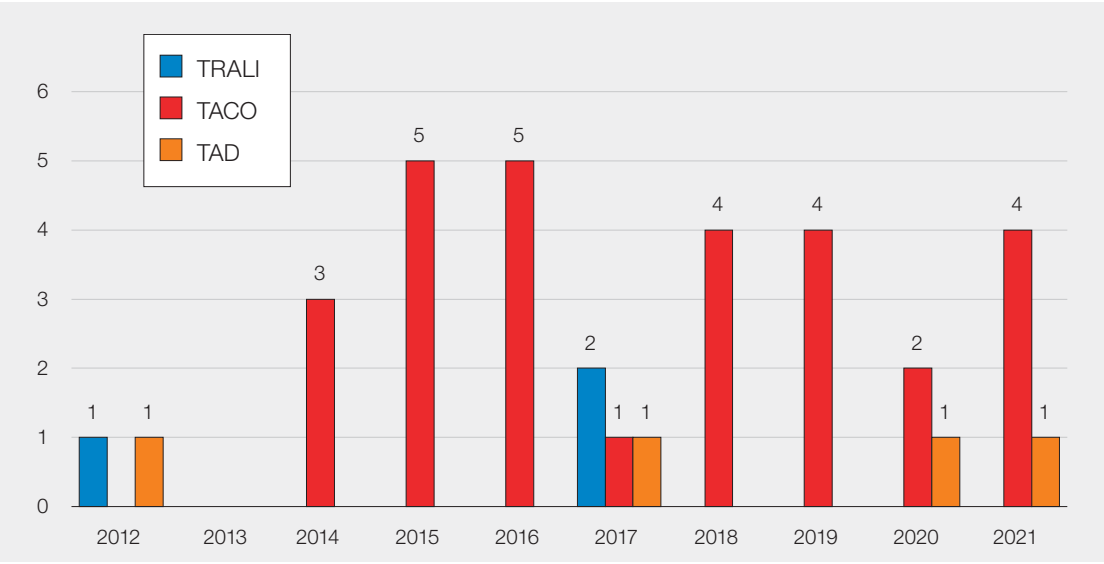
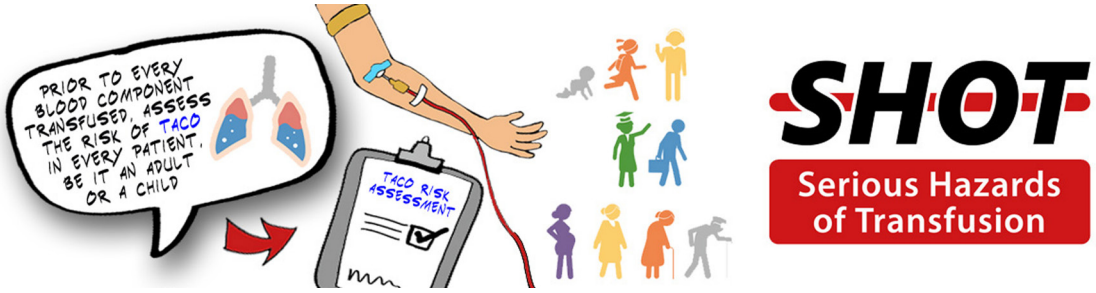


Figure 22.7: Pulmonary complications in children and neonates 2012-2021

Transfusion-associated circulatory overload (TACO) n=4

There were 4 cases of TACO in 2021. One of these followed red cell transfusion alone, 1 apheresis platelets. Two followed transfusions of multiple components. The range of age of presentation was 2 to 16 years. Of note there is an established SHOT checklist for TACO in adult patients and although not validated in children several of the main points in the checklist are relevant.



Non-TACO pulmonary case n=1

One case was classified as TAD but also involved an overtransfusion.

Case 22.8: Overtransfusion of a young child resulted in TAD

A child with leukaemia had been correctly prescribed 10mL/kg of red cells over 1 hour. However due to an error in the pump programming 40mL/kg was administered over 4 hours. This resulted in tachycardia and increased respiratory rate. This settled without any specific treatment and no chest X-ray was performed and thus did not meet the criteria for TACO. Both the nurses checking the transfusion were inexperienced in checking transfusions and one had not performed this role at the hospital before.

There were no cases of TRALI in 2021.

Learning points

- Pulmonary complications of transfusion can be difficult to identify in young children, particularly in neonates who may have multiple causes that could result in respiratory deterioration
- It is vital that those caring for children and infants are aware of TACO/TAD/TRALI as a potential cause of respiratory deterioration following transfusion

Transfusion-transmitted infection (TTI) n=0

There were no cases of paediatric TTI in 2021.

Uncommon complications of transfusion (UCT) n=2

There were 2 uncommon complications of transfusion in children in 2021. One was a case of NEC (Case 22.2) which resulted in the neonatal death. Causality of red cell transfusion in relation to NEC is still unclear. The other was a case of hyperkalaemia following rapid transfusion of red cells irradiated several days previously.

Case 22.9: Iatrogenic hyperkalaemia secondary to transfusion of large volume of irradiated red cells

An infant with Di-George syndrome with lymphopenia was taken to theatre for washout of infected cardiothoracic surgical wound. The infant had a surgical complication and required urgent large volume, rapid red cell transfusion due to significant bleeding. The red cell unit had been irradiated approximately 7 days previously. The child developed abnormal ECG secondary to hyperkalaemia from the transfused blood with an arterial blood gas showing a potassium of 8.5. This was managed appropriately and the infant recovered and survived.

Learning points

- Hyperkalaemia following transfusion is recognised. Significant clinical sequelae including cardiac arrest are rare, but risk factors include hypovolaemia, and large volume transfusions in particular to neonates and infants (Vraets et al. 2011, Burke et al. 2021)
- In order to reduce the risk of hyperkalaemia following transfusion, the use of red cells within 5 days of donation, and if irradiated, within 24 hours of irradiation, is recommended for large volume neonatal and infant transfusions, including for cardiac surgery (BSH New et al. 2016)
- Use of irradiated red cells in an emergency to treat major haemorrhage can increase the risk of hyperkalaemia following transfusion so it is probably safer to avoid unless irradiated blood is otherwise indicated (BSH Foukaneli et al. 2020)

Recommended resources

SHOT Video: Paediatric SHOT
SHOT Video: Delayed Transfusions in Major Haemorrhage
https://www.shotuk.org/resources/current-resources/videos/

SHOT Bite No. 4: Paediatrics
SHOT Bite No. 8: Massive Haemorrhage Delays
https://www.shotuk.org/resources/current-resources/shot-bites/

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23 Haemoglobin Disorders n=46

Author: Joseph Sharif

Abbreviations used in this chapter

ADU	Avoidable, delayed and under/overtransfusion
AHTR	Acute haemolytic transfusion reaction
APPG	All-party parliamentary group
BSH	British Society for Haematology
CMV	Cytomegalovirus
CT	Computerised tomography
DAT	Direct antiglobulin test
DHTR	Delayed haemolytic transfusion reaction
Hb	Haemoglobin
HCC	Haemoglobinopathy Coordinating Centre
HPLC	High-performance liquid chromatography
HTR	Haemolytic transfusion reactions
LIMS	Laboratory information management system
NHS	National Health Service
NHSBT	NHS Blood & Transplant
SCD	Sickle cell disease
Sp-ICE	Specialist Services electronic reporting using Sunquest's Integrated Clinical Environment
SRNM	Specific requirements not met

Key SHOT messages

- Alloimmunisation is a significant problem in SCD and therefore each transfusion decision must take into consideration the intended benefits and potential risks
- Transfusion in SCD should have a clear indication in line with national guidance (BSH Davis et al. 2017)
- Robust processes must be in place to ensure haemoglobinopathy patients are highlighted on transfusion requests

Recommendations

- Haematology teams must be informed when sickle cell patients are admitted to secondary care
- All haemoglobinopathy patients should have an extended phenotype and receive extended Rh- and K-matched units
- Transfusion history should be sought including history of previous alloimmunisation and transfusion reactions. Antigen-negative blood should be given for any corresponding historic clinically significant alloantibodies
- Red cell genotyping can provide more accurate information and confirm any discrepancies identified on serological testing (NHSBT n.d.)

Action: All clinical staff involved in transfusion

Introduction

Patients with haemoglobinopathies are at increased risk of red cell alloimmunisation and therefore require extended Rh- and K-matched blood. Patients with SCD are at increased risk of HTR which can be severe and associated with significant morbidity. Transfusion decisions should be made with input from a specialist haemoglobinopathy team. NHS England has now commissioned the providers of specialised haemoglobinopathy services to support the provision of both specialist and non-specialist haemoglobinopathy services, expert opinion and management of complex patients (NHS England 2019).

Deaths related to transfusion n=2

There were 2 deaths reported. The first report was of a thalassaemia intermedia patient in her 70s with a history of previous transfusion reactions. The patient attended the haematology unit for a transfusion and received antigen-positive blood. During the transfusion the patient developed bronchospasm and had acute loss of consciousness requiring intubation and ventilation. A CT brain scan demonstrated extensive ischaemia secondary to carotid artery dissection. Acute haemolytic transfusion reaction was listed on the death certificate as a significant condition contributing to death.

A young male with SCD underwent an endoscopic procedure and was readmitted the following day with biliary sepsis. During the admission he developed an acute vaso-occlusive crisis and was transferred to critical care where he was transfused. He continued to deteriorate and developed multi-organ failure and died. The coroner report suggested earlier transfusion should have been considered. This case has been discussed in further detail in Chapter 11a. Delayed Transfusions (Case 11a.3).

Major morbidity n=10

There were 7 reports associated with major morbidity occurring in patients with SCD, and 3 in patients with thalassaemia, 3 of which required critical care admission. These included 6 cases of HTR, 3 cases of FAHR and 1 case in UCT.

Haemolytic transfusion reactions n=13

There were 13 cases of haemolytic transfusion reactions reported, 12 cases were in patients with SCD and 1 case in a thalassaemia patient. The reports included 1 case of AHTR, 7 DHTR and 5 with hyperhaemolysis. Further details can be found in Chapter 18, Haemolytic Transfusion Reactions (HTR).

Figure 23.1: HTR in haemoglobinopathy patients in 2021 (n=13)

HTR=haemolytic transfusion reactions

Case 23.1: Hyperhaemolysis in a patient with SCD

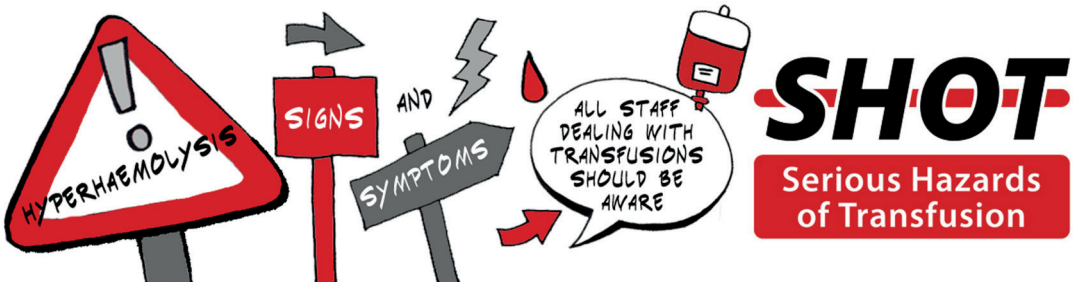
A young female with SCD received a two-unit top up transfusion. There was a history of alloimmunisation with anti-S and therefore she received S-negative units. The patient presented 5 days later with a Hb of 30g/L. Urine HPLC was reported as consistent with hyperhaemolysis. A new anti-Fy^a antibody was identified, and a decision was made to transfuse further red cells. The patient developed additional complications with transient encephalopathy and hypertensive crisis. She was treated with corticosteroids, intravenous immunoglobulin, eculizumab and rituximab.

Case 23.2: Delayed haemolysis in a patient with SCD

A young female with SCD and a history of alloimmunisation received a red cell exchange transfusion. She presented 8 days later with generalised body pains and fever. She was known to have anti-Fy^a and anti-Jk^b but had now developed an anti-Fy3.

Learning point

- Anti-Fy3 develops in individuals with a null Fy(^{a}-negative,^{b}-negative) phenotype and reacts strongly with Fy^a-positive and Fy^b-positive cells. This phenotype is rare in most of the UK population (<1%) but common in individuals from black African/Caribbean backgrounds and therefore this restricts the individual to predominantly black African/Caribbean blood donors for future transfusion (Daniels 2002)



Febrile, allergic and hypotensive reactions (FAHR) n=10

There were 5 febrile reactions and 5 allergic reactions. Most were following red cell transfusion with 1 anaphylactic reaction following platelets in a SCD patient post haemopoietic stem cell transplant.

Avoidable, delayed and under or overtransfusion (ADU) n=9

There were 3 reports of avoidable transfusion in SCD where transfusion was not indicated or intended. There were 3 reports of delayed transfusion, 1 of which resulted in death described in the section above. There were a further 3 transfusions reported as overtransfusion where an incorrect volume of red cells was administered however none of these resulted in adverse outcome.

Case 23.3: Unnecessary transfusion due to assumption by staff resulting in incorrect handover

A young male with SCD was admitted and a group and crossmatch was requested to have red cells on standby in case of clinical deterioration. The day nursing staff assumed that a transfusion was required and handed this over to the night nursing staff who then asked the junior night doctor to prescribe the blood which was then administered.

The treatment plan should be clearly communicated to all involved in the care of the patient and documented in the patient's notes. Handover must be accurate and all staff authorising transfusions must have sound understanding of the indication instead of just doing this based on a nursing handover. Shared decision-making involving patients is recommended.

Case 23.4: 20-hour delay in transfusion for a patient with acute chest syndrome

A female in her 20s with SCD was admitted with a vaso-occlusive pain crisis, increasing oxygen requirement and chest signs in keeping with acute chest syndrome. The haematologist requested for the patient to be transferred to the haematology ward and to receive an urgent two-unit top-up transfusion. Due to delays with bed availability the patient was not transferred until later that night, and the transfusion was not administered until 20 hours after the decision to transfuse. There had been a clinical deterioration in the patient which the haematologist thought was due to delay in transfusion and subsequently the patient required a further two-unit blood transfusion.

Specific requirements not met (SRNM) n=12

There were 8 SCD and 4 thalassaemia patients who did not receive blood components meeting their specific requirements. In 10 of these cases, extended Rh and K-matched units were not provided. There was 1 report where antigen-negative red cells were not provided for the corresponding antigen and 1 case where CMV-negative red cells were not provided in pregnancy.

Case 23.5: Alloimmunisation after not receiving extended Rh-matched red cells in thalassaemia

A young patient with thalassaemia attended for routine transfusion but was not provided with extended Rh and K-matched red cells and subsequently developed an anti-E antibody. The reason for the error noted was that no specific system flag was in place at the laboratory to provide extended phenotype-matched red cells.

Case 23.6: Ambiguous antibody investigation report on national database (Sp-ICE)

A SCD patient in his 40s received eight units of red cells during a red cell exchange procedure. The laboratory checked the Sp-ICE record which stated there was a previous positive DAT but insufficient sample for antibody investigation. It was reported that there were no further instructions on what blood to crossmatch. It was later confirmed after contacting the previous hospital the patient had visited that he had developed an alloantibody, but this had not been updated on Sp-ICE.

Sp-ICE is an important reference point for confirming a patient's antibody status particularly if the patient has attended more than one hospital. It is vital that this record is updated in real time to ensure the information is accurate.

Case 23.7: D-positive red cells transfused to female child with SCD

Transfusion was requested for a young female with SCD with a known D-variant who should have received D-negative red cells. The Blood Service supplied D-positive units following the 'over the telephone' request. The LIMS flagged up that there was a mismatch in relation to the specific transfusion requirement. The laboratory staff overrode the system and issued the units. Explanation provided by the laboratory staff for the error included low staffing levels and increased workload.

Case 23.8: Laboratory not informed of a diagnosis of SCD when requesting red cells

A male child with SCD was admitted to critical care and required a four-unit red cell transfusion. The transfusion was requested by a junior doctor who did not state on the request that the patient had SCD, and the transfusion laboratory staff were not aware of the diagnosis or need to provide extended Rh and K-matched and HbS-negative red cells.

Uncommon complications of transfusion n=1

Case 23.9: Seizures during transfusion

A pregnant patient in her 30s underwent an elective 10-unit red cell exchange for sickle cell disease. This was the patient's seventh red cell exchange in the last 18 months and all previous procedures had been well tolerated. The patient suffered a prolonged grand mal seizure during the 10th red cell exchange unit. There was no change in blood pressure or other observations. The patient received a calcium infusion, IV diazepam, but had recurrence of seizures after 10-15 minutes. The patient was intubated, ventilated and transferred for escalation of care. A head CT scan was normal and CT

venogram showed no abnormality either. The patient made a full recovery and was discharged 48 hours after admission. There was no evidence of a serological or haemolytic transfusion reaction. No biochemical abnormality was found. It was later discovered that the patient did have a history of seizures which had not previously been recorded. The seizure threshold could have been lowered due to pregnancy and other medication (cyclizine, opiates, venlafaxine) worsened by possible citrate with transient hypocalcaemia relating to the exchange transfusion.

Near miss n=1

Case 23.10: Surgical team arranging transfusion in SCD

A patient with SCD in his 50s was admitted for a renal transplant. Three units of red cells were requested however the transfusion laboratory was not informed of the diagnosis of SCD. Due to a grouping anomaly the laboratory contacted the patient's usual hospital and discovered the patient was known to have SCD. The haematology team were only informed following transfusion that the patient was admitted. The learning point highlighted by the reporter was that sickle cell patients requiring transfusion should be discussed with the haematology team.

'No One's Listening' APPG report

An APPG inquiry report 'No One's Listening: An inquiry into the avoidable deaths and failures of care for sickle cell patients in secondary care' was published in November 2021 (Sickle Cell Society 2021).

This report highlighted multiple failures in sickle cell care and has made 31 recommendations including the following which must be put in place to enhance patient safety and promote safe transfusion practice.

Improving joined-up sickle cell care:

All NHS Trusts/Health Boards to require that haematology teams are informed when sickle cell patients are admitted to hospital.

Improving education and training for healthcare professionals about sickle cell care:

Undergraduate training in sickle cell as part of curriculums for training healthcare professionals.

Health Education England to provide additional funding for sickle cell training programmes including for training in the delivery of blood transfusion for non-specialist doctors.

National Haemoglobinopathy Registry (NHR)

Contributed by Dr Nandini Sadasivam, Consultant Haematologist at Manchester University Hospitals Foundation Trust and Dr Farrukh Shah, Consultant Haematologist at Whittington Hospital, London, Chair of NHR and Transfusion Medical director at NHSBT.

The NHR is a register of people in the UK with all types of inherited red cell disorders. The register is held by NHS England and is intended to support direct clinical care, and for commissioning services within England.

The current system to find up-to-date transfusion records about the red cell antibody status of a patient requires hospital transfusion laboratories to opt-in to the NHSBT Sp-ICE system, and for patients to carry antibody cards if they have been transfused elsewhere.

As part of a national initiative to improve access to antibody results and enhance patient safety, a NHR-NHSBT linkage is being developed. This will allow NHSBT to upload antibody test results and eventually genotype and phenotype results from the Hematos system within NHSBT to the NHR based on NHS number and diagnosis. Transfusion laboratories will be able to upload antibody test results onto the NHR.

These changes will allow clinical teams to have an up-to-date record of antibody status on the NHR which will be a step further in improving patient safety, reduce risk of DHTR and development of alloimmunisation.

For further information please visit https://nhr.mdsas.com

Conclusion

HTR are a significant risk for haemoglobinopathy patients, in particular those with SCD. To minimise this risk, it is important that each transfusion decision is carefully considered, taking into account individual risk factors and potential benefits.

A detailed history should be obtained for all haemoglobinopathy patients requiring transfusion including any prior alloimmunisation or transfusion reactions. Clear communication between clinical and laboratory staff is essential to ensure specific transfusion requirements are provided. All hospitals should have protocols for the management of acute complications of SCD. Specialist haemoglobinopathy teams should be involved in the management of all these patients.

The APPG report has highlighted the inadequacies in healthcare for sickle cell patients. SHOT supports the recommendations set out in the report. Education and training for all healthcare professionals is essential to ensure safe transfusion practice, reducing the risk of morbidity and mortality.

To support safe transfusion in haemoglobinopathy patients, several new online resources have been developed by NHSBT and SHOT (listed below). These resources are intended for use within HCC and specialist hospital teams to support the development of training programmes for their haemoglobinopathy networks.

Recommended resources

SHOT Bite No. 14: 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/

Patient Blood Management England Video: Setting up and Performing a Manual Exchange Red Cell Exchange in Sickle Cell Disease (Under 40kg)
https://youtu.be/e2itKcfXQAE

Patient Blood Management England Video: Setting up and Performing a Manual Exchange Red Cell Exchange in Sickle Cell Disease (Over 40kg)
https://youtu.be/5QFiLziDxbc

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Transfusion Errors in Transplant Cases n=56

24

Author: Shruthi Narayan and Jennifer Davies

Abbreviations used in this chapter

CMV	Cytomegalovirus	**LIMS**	Laboratory information management system
HLA	Human leukocyte antigen	**NM**	Near miss
HSCT	Haemopoietic stem cell transplant	**SRNM**	Specific requirements not met
IBCT	Incorrect blood component transfused	**WCT**	Wrong component transfused

HSCT and solid organ transplant introduce complexities into the transfusion process, both in the clinical and laboratory setting. In 2021, 56 cases have been analysed, 45 involving HSCT and 11 involving solid organ transplant. IBCT-WCT accounted for 26/56 (46.4%) of cases, with 16/56 (28.6%) NM events and 14/56 (25.0%) IBCT-SRNM (Figure 24.1).

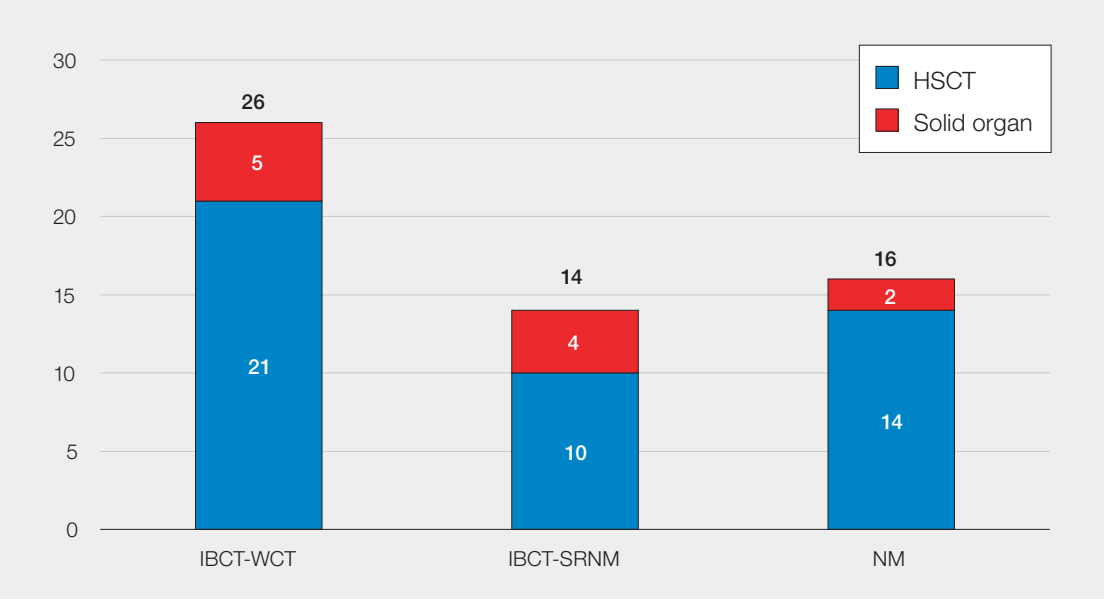

Figure 24.1: Transplant cases by reporting category and type of transplant in 2021 (n=56)

HSCT=haemopoietic stem cell transplant; IBCT-WCT=incorrect blood component transfused-wrong component transfused; IBCT-SRNM=IBCT-specific requirements not met; NM=near miss

The success of an HSCT is dependent on HLA-match between donor and recipient rather than ABO blood group compatibility. Hence 40-50% of HSCT are ABO-mismatched (Worel 2016), with D-mismatches also being commonplace. ABO-mismatches with solid organ transplantation is also possible and may be performed where limited number of donor organs are available (Alhamad 2019). When transfusing a transplant patient, it is important that red cells and plasma components are compatible with both the donor and the recipient ABO/D type, and this may not align with standard blood grouping compatibility. Provision of components of the appropriate ABO/D-type is reliant on effective communication of the donor and recipient blood groups to the transfusion laboratory, and effective measures within the laboratory processes for component selection.

Errors within the laboratory including failures to add or heed flags, and unclear flags, within the LIMS accounted for 32/56 (57.1%) cases. Failures in communication accounted for 20/56 (35.7%) cases.

Within the IBCT-WCT cases, 21/26 (80.8%) were related to HSCT and 5/26 (19.2%) for solid organ transplant. Of these, 21/26 (80.8%) involved selection of components with the wrong ABO/D group.

Failure to transfuse components meeting the patient specific requirements (IBCT-SRNM) was noted in 14 cases, 10 HSCT and 4 solid organ transplants. Failure to provide irradiated components accounted for 7/14 cases, failure to provide CMV-negative components occurred in 3/14 cases, inappropriate electronic issue of red cells occurred in 2 cases and failure to provide HLA-matched platelets in 2 cases. Failure to communicate the specific requirements to the laboratory accounted for 8/14 errors, failure to add or heed the flag in the LIMS accounted for 2 cases, in 2 cases the LIMS had no algorithm to control appropriate component selection and in 1 case incorrect advice was given by the Blood Service.

Near miss events (n=16) mainly occurred in HSCT patients (14/16). IBCT-SRNM was implicated in 10/16 events and IBCT-WCT in 6/16 cases. NM events occurred mainly in the laboratory area (14/16), with failures in the LIMS accounting for 12/14 cases.

Errors in the clinical setting accounted for 16 cases, 13/16 due to failures in communication to the laboratory, 1/16 resulting from order of the wrong component, 1/16 where the component was administered to the wrong patient and 1/16 failure to prescribe a CMV-negative component. Laboratory errors occurred in 40 cases, 21/40 failures to heed alert in LIMS or request form, 8/40 failures to add flag to LIMS, 1/40 unclear flag in LIMS, 3/40 no algorithms in LIMS to support good practice.

HSCT reports n=45

Reports of errors involving HSCT patients accounted for 45/56 cases, with IBCT-WCT seen in 21/45 cases, NM events in 14/45 cases and IBCT-SRNM in 10/45 cases (Figure 24.1). Most IBCT-WCT cases involved transfusion of an inappropriate ABO group components (14/21), inappropriate D-type components were transfused in 6/21 cases and in 1 case the component was transfused to the wrong patient. Most IBCT-SRNM cases involved failure to transfuse irradiated components (6/10), failures in provision of CMV-negative components accounted for 2/10 cases, failure to transfuse HLA-matched platelets accounted for 1 case and inappropriate electronic issue was implicated in 1 case. NM cases included failures in provision of irradiated components (7/14), inappropriate ABO groups (5/14), failure to select high-titre negative platelets (1/14), and inappropriate use of electronic issue (1/14).

Case 24.1: Communication failure and flag fatigue leads to D-mismatch platelet transfusion

A HSCT patient transferred from another hospital was transfused with B D-positive platelets when they should have received D-negative platelets. No communication was given to the laboratory that the patient was a post-HSCT patient. No shared-care document from the transplanting hospital was received. The transfusion sample showed anomalous results, the laboratory staff contacted the ward and obtained patient history that the patient had received an HSCT (donor O D-positive, recipient B D-negative). This was recorded in the LIMS notepad, but the specific requirement flags were not updated on the LIMS. A platelet component of the incorrect D-type was issued to the patient The BMS overrode the warning flags, as the LIMS functionality was limited on management of blood component requirements of HSCT patients, and showed many alerts, leading to alert fatigue.

Case 24.2: Inadequate remote issue algorithm resulted in transfusion of non-irradiated red cells

The transfusion laboratory informed the ward that the patient's red cells were ready for collection in the 'smart' blood refrigerator. A nurse used remote issue to release a unit of red cells for the patient. Early on in the transfusion the nurse realised blood issued should have been irradiated. Red cells for patients who require irradiated components cannot be remotely issued by the smart refrigerator as algorithms are not configured to select irradiated blood. There was a sign on the smart refrigerator to advise staff to contact the transfusion laboratory if the patient required irradiated red cells. In this incident the ward contacted the transfusion laboratory who advised in error that the patient was suitable for remote issue.

Solid organ transplant reports n=11

Errors involving patients with solid organ transplants accounted for 11/56 cases, IBCT-WCT (5/11), IBCT-SRNM (4/11) and NM (2/11) (Figure 24.1). IBCT-WCT events all involved transfusion of inappropriate ABO groups, 4/5 were red cells and 1/5 related to plasma components. Failure to provide CMV-negative components accounted for 1 IBCT-SRNM case and 1 NM case, other IBCT-SRNM cases included failure to transfuse HLA-matched platelets, inappropriate use of electronic issue and failure to transfuse irradiated components. Failures in provision of antigen-negative red cells was implicated in 1 NM case.

Conclusion

Patients receiving HSCT or solid organ transplants are often under the shared care of multiple hospitals. Transfusions may not be performed in the transplant centre and so it is imperative that all relevant organisations are made aware of the transplant and, in particular the ABO/D group and specific requirements of components for transfusion. Transplant centres and referring organisations should ensure that robust processes are in place for transfer of information across sites, including to the transfusion laboratories. Communication of transplant information to the laboratory could include email communication to a generic email account that is regularly monitored. Transplant protocols must include clear information relating to the appropriate ABO/D group of components for transfusion post transplantation.

Processes must be in place in laboratories to ensure that flags are added to the LIMS in a timely fashion. The LIMS should support good practice within the laboratory setting, flags and alerts should be relevant and appropriate to reduce risk of alert fatigue. Flag overrides should include a requirement for justification that can be audited. LIMS should include algorithms that support component release that is appropriate for ABO/D mis-matched transplant patients rather than relying on comments or notes attached to the patient record. Where smart refrigerators are employed for remote issue of red cells the algorithms supporting this process must include controls for component and patient specific requirements.

Recommended resources

SHOT Bite No. 18: Transplant Patients
SHOT Bite No. 20: IBCT-SRNM
https://www.shotuk.org/resources/current-resources/shot-bites/

SHOT Video: Transfusion errors in haemopoietic stem cell transplant recipients
https://www.shotuk.org/resources/current-resources/videos/

Safe Transfusion Checklist
https://www.shotuk.org/resources/current-resources/

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25 Immune Anti-D in Pregnancy n=56

Author: 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
BMI	Body mass index
BSH	British Society for Haematology
CffDNA	Cell-free fetal deoxyribonucleic acid
FMH	Fetomaternal haemorrhage
HDFN	Haemolytic disease of the fetus and newborn
Ig	Immunoglobulin
IT	Information technology
IUD	Intrauterine death
NHS	National Health Service
NHSBT	NHS Blood and Transplant
NICE	National Institute for Health and Care Excellence
NIPT	Non-invasive prenatal testing
NPP	No previous pregnancies
PP	Previous pregnancies
PPP	Postpartum prophylaxis
PSE	Potentially sensitising event
RAADP	Routine antenatal anti-D Ig prophylaxis
UK	United Kingdom

Key SHOT messages

- Cases of alloimmune anti-D found for the first time in pregnancy should be reported to SHOT, aiming to provide a complete data set after delivery
- Cases of immunisation are still occurring even where current best practice is being followed
- Obesity and delivery beyond 40 weeks remain potential risk factors for sensitisation in cases which are otherwise ideally managed
- There are missed opportunities where pregnancy management is not ideal
- Interoperability of IT systems to improve the pathway and outcome for D-negative women in pregnancy and postpartum remains a challenge

Recommendations

- All UK hospitals should check that they have signed up to share results access in Sp-ICE
- Electronic health record providers and hospitals who plan to implement or continue to develop an electronic health record should map the pathway for D-negative women in pregnancy and post-partum and jointly develop intelligent pathways that support decision making
- All blood transfusion IT solutions must ensure appropriate IT interfaces between the laboratory information management system and electronic health record to remove the requirement of healthcare professionals to manually enter a blood group or D-type to reduce the risk of a transcription error that may prevent appropriate management

Actions: Transfusion laboratory management, maternity services, hospital IT departments

Introduction

SHOT has been reviewing cases where immune anti-D has been detected for the first time in the current (index) pregnancy since 2012 to improve understanding of the causes of continuing anti-D immunisations. Reporters are requested to provide data on booking weight, 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).

Results

In 2021 a total of 56 cases were reported, 11 cases occurred in women with NPP, and 45 in women with PP. While there is a steady increase in the number of cases reported, available data suggests that anti-D immunisation 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 116 women with NPP and 317 women with PP.

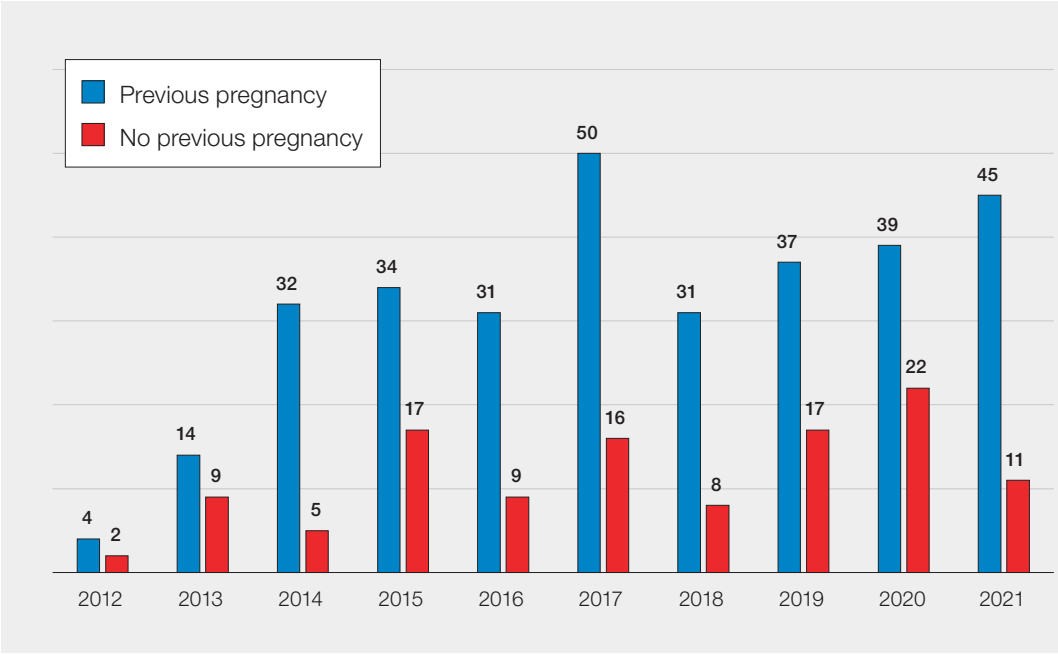
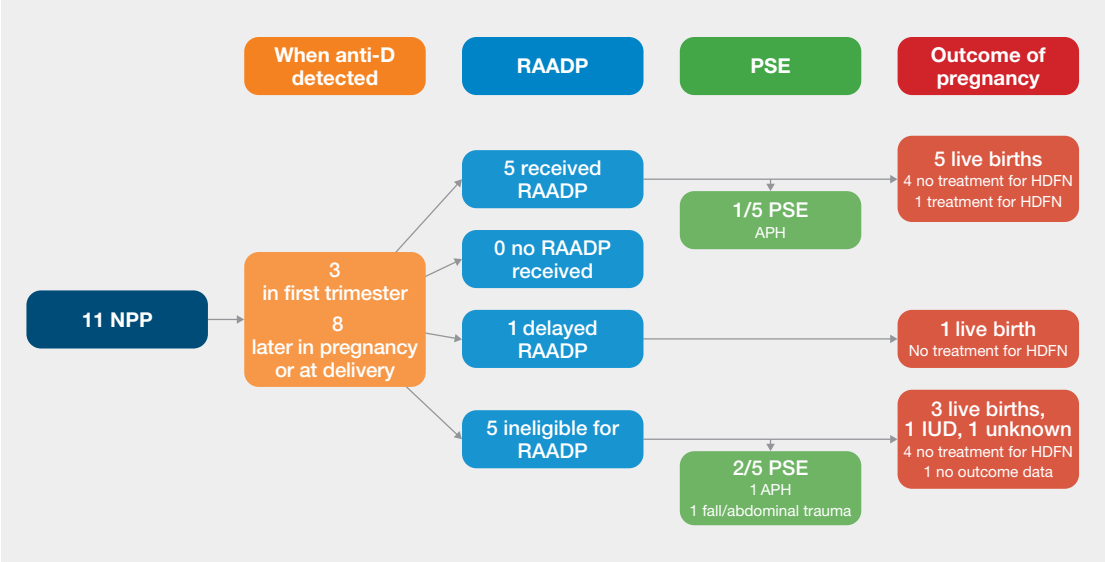


Figure 25.1: Number of reports of anti-D immunisation in pregnancy by year, 2012-2021

No previous pregnancy (NPP) n=11

For a detailed discussion of the NPP cases, and tables containing similar details to those published in previous Annual SHOT Reports, see the supplementary information on the SHOT website (https://www.shotuk.org/shot-reports/report-summary-and-supplement-2021/).

Figure 25.2: Summary of 2021 NPP data (n=11)



NPP=no previous pregnancy; RAADP=routine antenatal anti-D Ig prophylaxis; PSE=potentially sensitising event; APH=antepartum haemorrhage; IUD=intrauterine death; HDFN=haemolytic disease of the fetus and newborn

Illustrative cases

Case 25.1: Missed PSE

A primiparous woman in her 30s booked at 8 weeks, no alloantibodies were detected. The woman had a fall at 9 weeks but no medical attention was sought at the time. Maternal blood sampling for cffDNA predicted a D-positive fetus at 17 weeks. At 28^{+3} the woman attended for a scan following concern regarding reduced movements which identified an IUD. Anti-D was detected however there was no quantification. No postmortem was performed according to communications with the SHOT team.

In the absence of a postmortem it is not possible to conclude the cause of the IUD.

The PSE occurred the week after the booking and it is not known whether the maternal D-type and risk of sensitisation had been conveyed to the woman at booking. Where systems enable patient portal access to the electronic health record, this provides the advantage of real-time access for patients to blood results prior to the next appointment. Such a system could have triggered the provision of relevant information regarding the risk of sensitisation, when and how to seek medical advice to the patient.

Case 25.2: Detection of anti-D in early pregnancy

A primiparous woman in her 30s, BMI 46 booked at 8 weeks. Alloimmune anti-D was detected at booking, quantification 13.38IU/mL, highest quantification 15.5IU/mL. The woman delivered a D-negative infant at 37^{+3}.

There were no details provided with this case to determine whether there were definitively no prior sensitising events including transfusion or biochemical pregnancies. It is not clear if a maternal blood sample was sent for fetal genotyping following detection of alloimmune anti-D, potentially a missed opportunity to provide parental reassurance and limit repeat blood sampling and appointments for quantification during pregnancy.

Case 25.3: Sensitisation despite ideal management

A primiparous woman in her early 20s booked at 8 weeks, group and antibody screen detected the mother to be D-negative, no alloantibodies detected. She presented with abdominal pain at 12 weeks, no associated bleeding, scan did not detect any abnormality, she was reassured and discharged. Maternal sample for cffDNA at 13 weeks predicted the fetus to be D-positive. The maternal blood sample at 28 weeks prior to RAADP detected alloimmune anti-D, quantification 0.7IU/mL, the highest recorded quantification at 36 weeks was 3IU/mL. The pregnancy resulted in a live birth at 38/40, the baby showed no signs of jaundice, no treatment required.

In this case, there were no prior unidentified sensitisation events reported. This highlights the potential risk that some pregnant women may still be sensitised with a risk of HDFN, despite the recommended mitigating measures being implemented.

Case 25.4: Ideal management, gestation 41^{+5}

A primiparous woman, D-negative, 66kg in her late 30s, received ideal management throughout pregnancy receiving RAADP, no PSE. Following delivery at 41^{+5} a maternal blood sample detected anti-D, quantification 2.7IU/mL.

This is an example of sensitisation despite ideal management with the only risk factor identified to be a gestation beyond 40 weeks.

Previous pregnancies (PP) n=45

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-2021/).

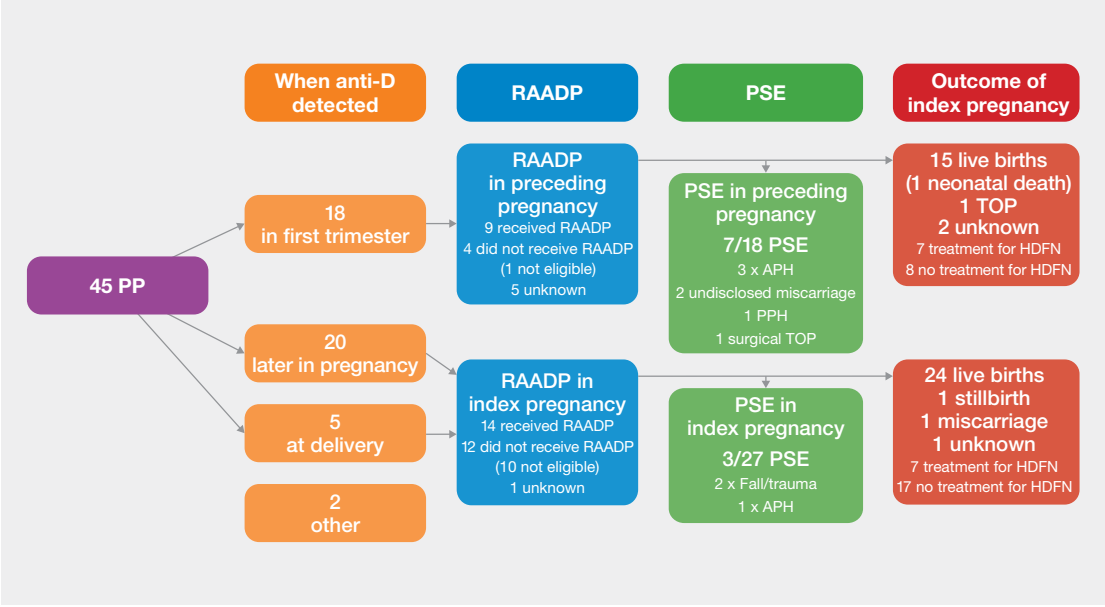


Figure 25.3: Summary of 2021 PP data (n=45)

PP=previous pregnancy; RAADP=routine antenatal anti-D immunoglobulin prophylaxis; PSE=potentially sensitising event; APH=antepartum haemorrhage; PPH=postpartum haemorrhage; TOP=termination of pregnancy; HDFN=haemolytic disease of the fetus and newborn

Illustrative cases

Case 25.5: HDFN treatment

A D-negative woman in her 20s who weighed 87kg, gravida 2 para 1 was booked at 11 weeks. The previous pregnancy was managed at a different healthcare provider and details of the prior pregnancy were limited. In the previous pregnancy this woman received four doses of anti-D Ig, timing and dose not provided and she delivered a D-positive baby. She suffered a postpartum haemorrhage. In the index pregnancy, alloimmune anti-D was detected at booking. The highest quantification of anti-D was 330IU/mL at 36 weeks. The mother delivered a D-positive baby at 37^{+1}, the baby required phototherapy and due to increasing bilirubin levels was transferred to the neonatal unit and received immunoglobulin and an exchange blood transfusion.

It is not possible to determine if the woman received ideal management in the previous pregnancy. These cases are much less common since implementation of RAADP reduced the risk of HDFN. This case demonstrates the intense management that neonates with HDFN can require and the importance of prevention wherever possible.

Case 25.6: Baby D-positive, cffDNA predicted D-negative fetus

A D-negative female in her 20s, gravida 3 para 2, weight 77kg, booking bloods did not detect alloimmune anti-D and cffDNA in the index pregnancy at 13 weeks predicted a D-negative fetus. The woman as such did not receive RAADP. Maternal transfusion sample at delivery 37^{+1} detected alloimmune anti-D and anti-E, anti-D quantification 14.2IU/mL. Following delivery, the baby was identified to be jaundiced, D-positive and DAT 3+, phototherapy was required. The preceding pregnancy management was appropriate.

When the baby D-type is disconcordant with the cffDNA fetal D-screening test, it is important to notify the laboratory as further samples are required to enable further investigation. Whilst the test is highly accurate and can be performed from 11^{+2} weeks' gestation owing to the sensitivity of the test, there is a small chance (0.1%) that a fetus predicted to be D-negative will be D-positive at birth.

Case 25.7 Maternal blood group transcription error

A D-negative woman gravida 2 para 1 presented in her second pregnancy. In her first pregnancy due to the method of the test request the maternal blood group was not automatically transmitted to the maternity IT system. The maternal blood group was incorrectly transcribed A D-positive. In the subsequent pregnancy the error was detected when the woman's booking bloods were resulted and identified her to be A D-negative with alloimmune anti-D, quantification 0.1IU/mL. In the prior pregnancy no RAADP nor treatment for a PSE was provided. The pregnancy resulted in a live birth, baby was A D-negative.

The maternal D-type transcription error resulted in the failure to provide appropriate RAADP and treatment of a PSE. Appropriate IT interfaces between laboratory information management systems and the electronic health record must remove the requirement for healthcare professionals to manually enter a blood group or D-type as they may be referenced regarding future management.

Conclusions

The data this year (detailed in the supplementary information on the SHOT website) demonstrate residual issues around ideal management of D-negative women during pregnancy to prevent immunisation. The 2021 data continue to illustrate missed opportunities where pregnancy management is not ideal. This is demonstrated in the NPP RAADP and PSE data by delay in treatment and in the PP data by failure to provide RAADP and PSE anti-D Ig due to an electronic health record transcription error regarding documentation of maternal D-type. Cumulative data includes a total of 82 PSE in the preceding pregnancies of which 53 (64.6%) were managed correctly. It is encouraging to see the antepartum haemorrhages reported have been managed appropriately, however, the need for a focused approach to ensure the correct pathway and decision making for D-negative women in pregnancy is necessary.

The maternal D-type transcription error results in failure to provide appropriate RAADP and treatment of a PSE. Appropriate IT interfaces between LIMS and the electronic health record must remove the requirement for healthcare professionals to manually enter a blood group or D-type as they may be referenced regarding future management.

The emerging questions on ideal management from the cumulative data including the increased risk in obesity and particularly the increased risk of gestation beyond 40 weeks remain supported by the additional 2021 data. However, the differential between the 18 PP preceding pregnancy obesity rate of 25% and 27 PP cases of immune anti-D Ig detected beyond the first trimester index pregnancy obesity rate of 23.4% versus the national data (NHS Digital 2019) report 22% incidence of obesity in pregnant women in England is narrowing. The cumulative data with regards to gestation beyond 40 weeks is perhaps more convincing demonstrating 48 pregnancies where alloimmune anti-D was first detected at delivery in the index pregnancy, 17 cases (35.4%) were delivered after 40 weeks gestation. NHS maternity statistics 2019-2020 indicate 15.9% pregnancies extended beyond 40 weeks (NHS Digital 2020). All cases reported should endeavor to provide gestation in weeks and days and provide booking weight and BMI to enable direct comparison to national data sets.

The data collection on cffDNA highlights ongoing barriers to implementation. IBGRL are currently testing >4,000 samples per month. These samples come from NHS Trusts, private service providers (a minority) and 3 Republic of Ireland Trusts. The Trusts, which were on hold during the COVID-19 pandemic, were invited to implement the fetal D-screening test from September 2021. Although 60% of maternity hospitals in England send samples for fetal D-screening, staff shortages in obstetrics and pathology departments have slowed progress, not only for the Trusts which were on hold but also for Trusts who have not implemented this test. (personal communication International Blood Grouping Reference Laboratory).

The 2021 data suggest:

- Ideal management does not equal no sensitisation
- Delivery beyond 40 weeks may be a risk factor for sensitisation even when managed appropriately
- Women who are obese may not be adequately 'protected' by standard doses of anti-D Ig, however the cumulative data is less convincing
- There are missed opportunities where pregnancy management is not ideal

Further work needed

A review of the cumulative data with regards to obesity, delivery beyond 40 weeks and FMH >4mL should be undertaken to see if the data provide enough evidence to modify current guidelines.

A focused approach to ensure treatment decisions are right for D-negative women is necessary to prevent sensitisation.

Appropriate IT interfaces between laboratory information management systems and the electronic health record must remove the requirement for healthcare professionals to manually enter a blood group or D-type as they may be referenced regarding future management.

A review of the material available and the possibility of an electronic application to support decision making should be considered. Electronic health record providers and hospitals who plan to implement or continue to develop an electronic health record should map the pathway for D-negative women in pregnancy and post-partum developing intelligent pathways that support pathway management and decision making.

SHOT
Serious Hazards of Transfusion

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NHS Digital. Maternity Services Monthly Statistics. England, March 2019, Experimental Statistics (2019). https://digital.nhs.uk/data-and-information/publications/statistical/maternity-services-monthly-statistics [accessed 06 May 2022].

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All collaborators who have contributed to this Annual SHOT Report.

MHRA Report on Blood Safety and Quality Regulations (BSQR) in 2021

26

Authors: Chris Robbie, Mike Dawe and Shirley Stagg

Abbreviations used in this chapter

BCR	Blood compliance report
BE	Blood Establishment
BSQR	Blood Safety and Quality Regulations 2005 (as amended)
BMS	Biomedical Scientist
CAPA	Corrective and preventative 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
EI	Electronic issue
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
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

- Hospital transfusion teams must review their own incidents alongside the findings in this chapter to identify their most frequently occurring SAE and RC
- Attention should be made to the SAE and RC highlighted in this chapter to ensure these are being reported consistently and that QMS are reviewed for robustness and effectiveness

Summary

It was another difficult year for everyone coping with the effects of the COVID-19 pandemic. As last year, changes to clinical focus and practice, process affecting the quality and safety of blood and blood component, workloads, staffing levels, skill-mix and education and training mean that comparison of data from 2021 to previous years is difficult. The number of events received increased, presumably due to increased blood usage as hospitals struggled to get back to normal. Although the spread of the categories of reports was largely consistent to previous years, there was a marked increase in some individual reporting categories.

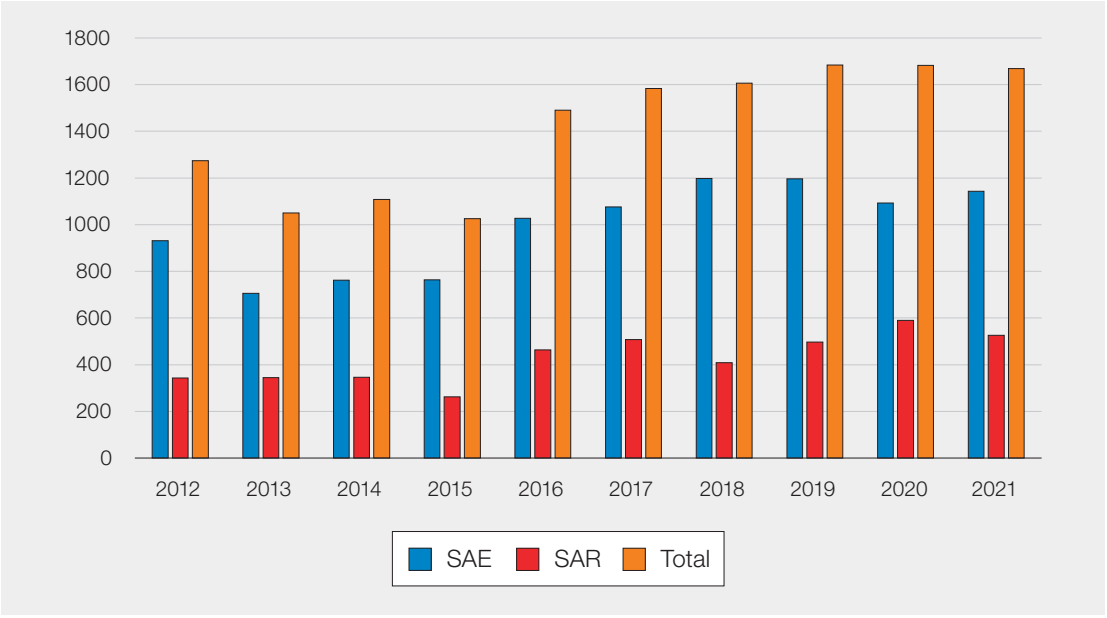
SABRE report data

Table 26.1 and Figure 26.1 show the total numbers of reports and the numbers of reports submitted as SAE and SAR for the previous 10 years. Although the figures remain broadly similar to previous years, the data show a slight decrease in the total number of reports overall with a decrease in SAR reports received and an increase in SAE reports. The reasons for the increase in SAE reports will be explored later in the chapter.

Table 26.1: Submitted confirmation reports 2012–2021

	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021
SAE	931	705	762	764	1027	1076	1198	1197	1093	1143
SAR	343	345	346	262	464	508	408	497	590	526
Total	1274	1050	1108	1026	1491	1584	1606	1684	1683	1669

Figure 26.1: Submitted confirmation reports 2012-2021



SAE=serious adverse event; SAR=serious adverse reaction

Serious adverse events n=1143 (+50)

Definition:

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 (BSQR 2005).

Storage data n=293 (+19)

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 Senior Haemovigilance Specialist has broken this category down further to try and identify specific storage error sub-types, Table 26.2. For a description of the subcategories used, see Appendix 1.

Table 26.2: SAE storage error sub-classifications

Storage sub-classification	2021 (+/- 2020)	2020 position
Incorrect storage of component	137 (+25)	1
Component expiry	50 (-5)	2
Sample expiry	40 (+10)	3
Return to stock error	17 (-4)	4
Security	16 (+4)	5
Storage temperature deviation	13 (NC)	7
Failure to action alarm	13 (-3)	5
Miscellaneous	6 (+2)	9
30 or 60 minute rule	1 (-5)	8
Total	**293 (+19)**	**x**

Unofficial data from BE suggest a slight increase in blood usage in 2021 during the continuing COVID-19 pandemic. It would not therefore be considered unusual then for the number of storage errors to increase by approximately 7%. Similar to last year, there has been an increase in the number of incorrect storage of components and again this increase has largely been seen due to a number of factors relating to changes in staffing and practice during the pandemic.

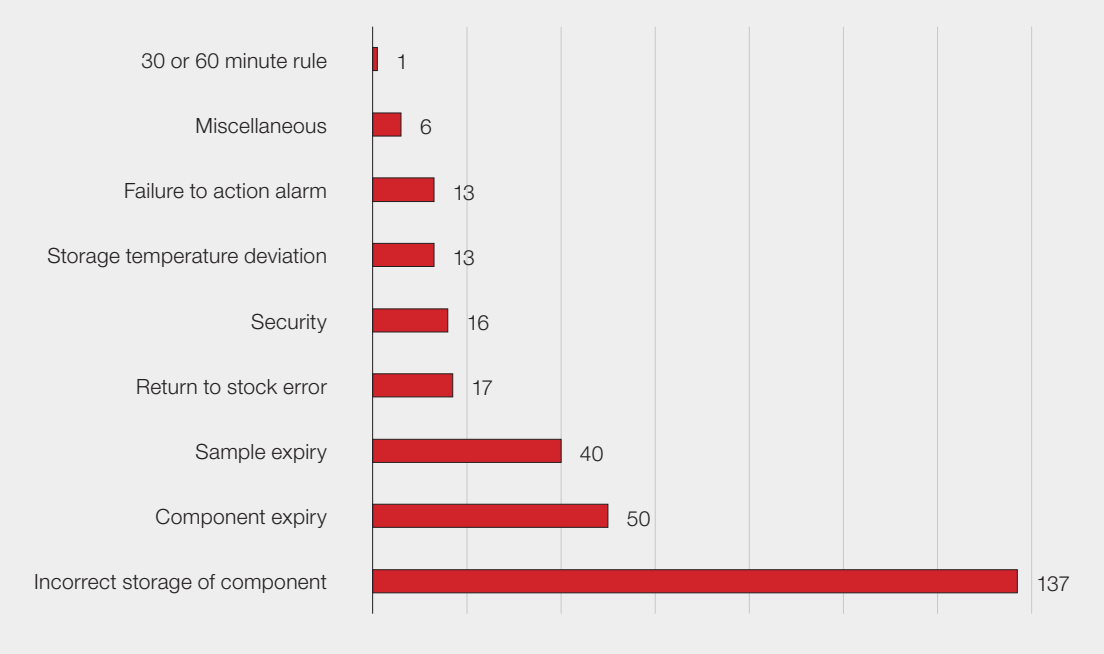


Figure 26.2: Incorrect storage of component by specification 2021 (n=293)

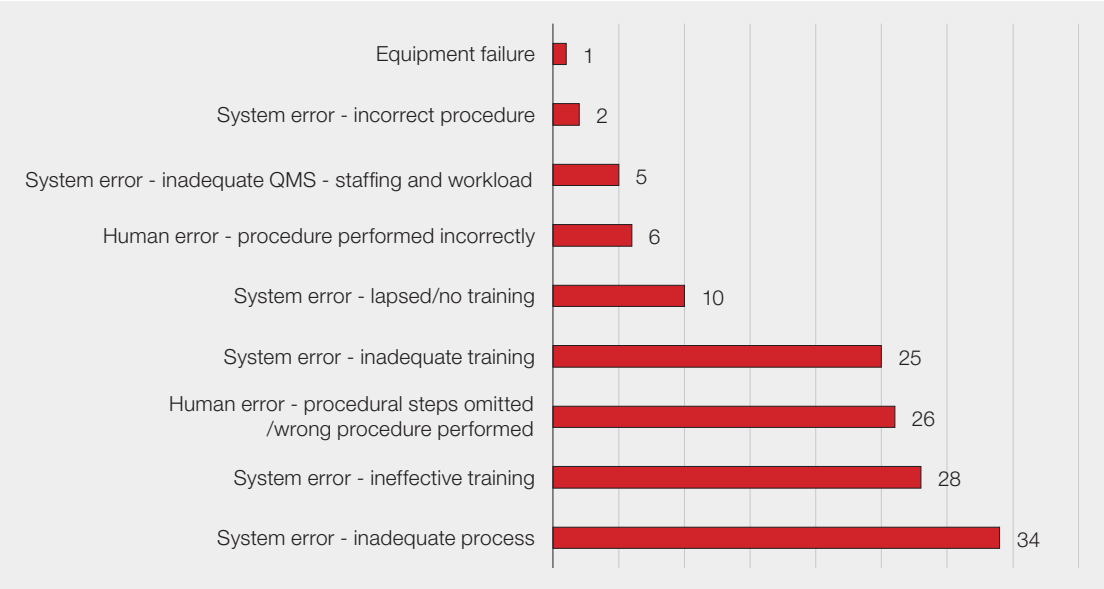


Figure 26.3: Root causes of the incorrect storage of components subcategory in 2021 (n=137)

QMS=quality management system

As last year, the majority of root causes of these types of error are system errors, especially relating to inadequate process design and the inadequate design, delivery and understanding of the training in the storage of components. In fact, only 23% of the errors are assessed as 'human error' with the remaining 77% a result of 'system errors'.

From last year's chapter it was stated that;

'As hospitals adapted processes to cope with the effects of the pandemic, storage locations were either moved or became inaccessible as areas of the hospital were adapted into 'hot' or 'cold' areas. Staff were also redeployed to unfamiliar areas. Therefore, errors in the Incorrect storage of components were

likely to be the result of poor business continuity planning, resulting in inadequately planned changes to storage processes, with a lack of thought to how the changes made might affect how components might be correctly stored. Further factors highlighted within the narrative of the reports received demonstrated poor communication of these changes to staff, failure to provide adequate training and ensuring shifts were covered by staff with the correct access to storage locations. It is accepted that coping with the pandemic presented hospital staff with many challenging circumstances and staff should not be criticised for the increase in Incorrect storage errors, but it does demonstrate how errors can be prevented using robust change management controls.'

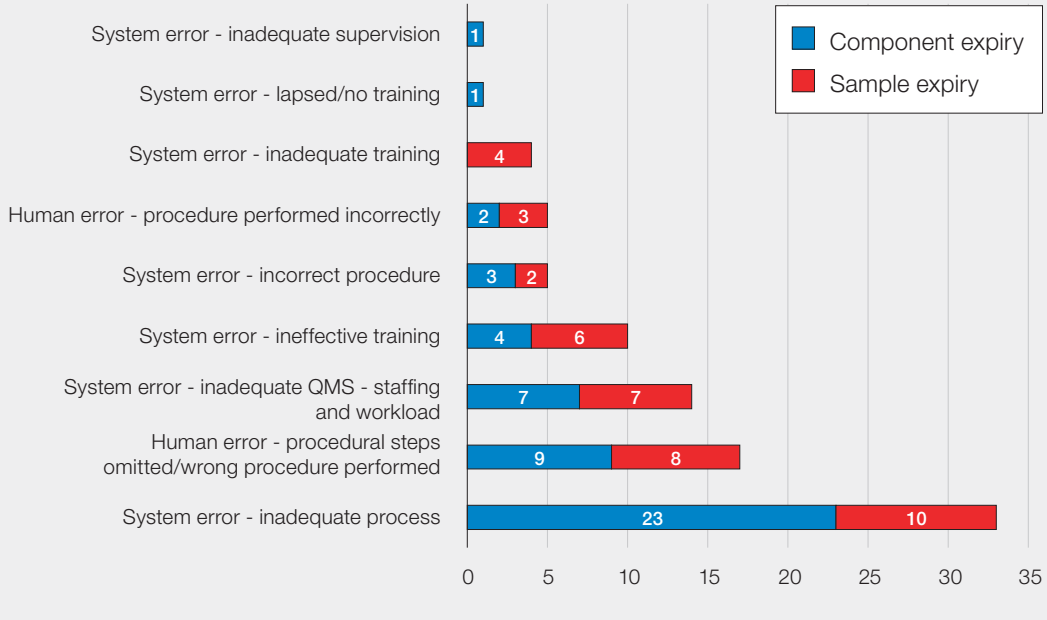
It would appear that last year's recommendation, repeated below, was not taken up by all HTT.

Recommendation

- Review business continuity plans to ensure all changes to storage processes are adequately managed, ensuring the new processes are robust, covered with updated SOP and that re-training of staff is adequately planned and delivered

Action: Hospital transfusion teams

Figure 26.4: Root causes of the combined component and sample expiry subcategories



QMS=quality management system

The cause of error in these categories demonstrate a split of 78% system errors compared to 22% human errors, with the largest proportion relating to inadequate process design.

Recommendation

- Review processes that involve the removal of expired components from storage locations and their re-stocking or disposal to ensure they are thoroughly robust

Action: Transfusion laboratories

Other n=743 (+18)

Other subcategory	2021 (+/- 2020)	2020 position
Incorrect blood component issued (IBCI)	172 (+15)	1
Component collection error (CCE)	152 (+33)	3
Sample processing error (SPE)	132 (+23)	5
Component labelling error (CLE)	100 (-14)	4
Pre-transfusion testing error (PTTE)	84 (-43)	2
Data entry error (DEE)	60 (NC)	6
Failed recall (FR)	20 (+8)	7
Unspecified (UNSPEC)	10 (+4)	9
Component available for transfusion past de- reservation (CATPD)	4 (-7)	8
Incorrect blood component ordered (IBCO)	3 (-1)	11
Handling damage (HD)	3 (+1)	13
Expired component available for transfusion (ECAT)	2 (-3)	10
Incorrect blood component accepted (IBCA)	1 (-2)	12
Total	**743 (+18)**	**X**

Table 26.3: 'Other'

Table 26.3 shows the number of reports in the 'other' category of SAE. There has been a slight increase (2.5%) in events that fall into the 'other' category. This is most likely due to the increase in blood usage as the health service recovered from the initial effects of the pandemic. Although the number of reports increased in most categories, there was a marked reduction in the number of reports of pre-transfusion testing errors (34%) and the number of component labelling errors (12%). With the increase in blood usage, such a reduction is welcome, but unusual. With no apparent explanation for the reduction, other than improved practices, it would be interesting to see if this reduction is maintained next year. Please see Appendix 2 for a description of the subcategories.

Human and system error categories and human factors

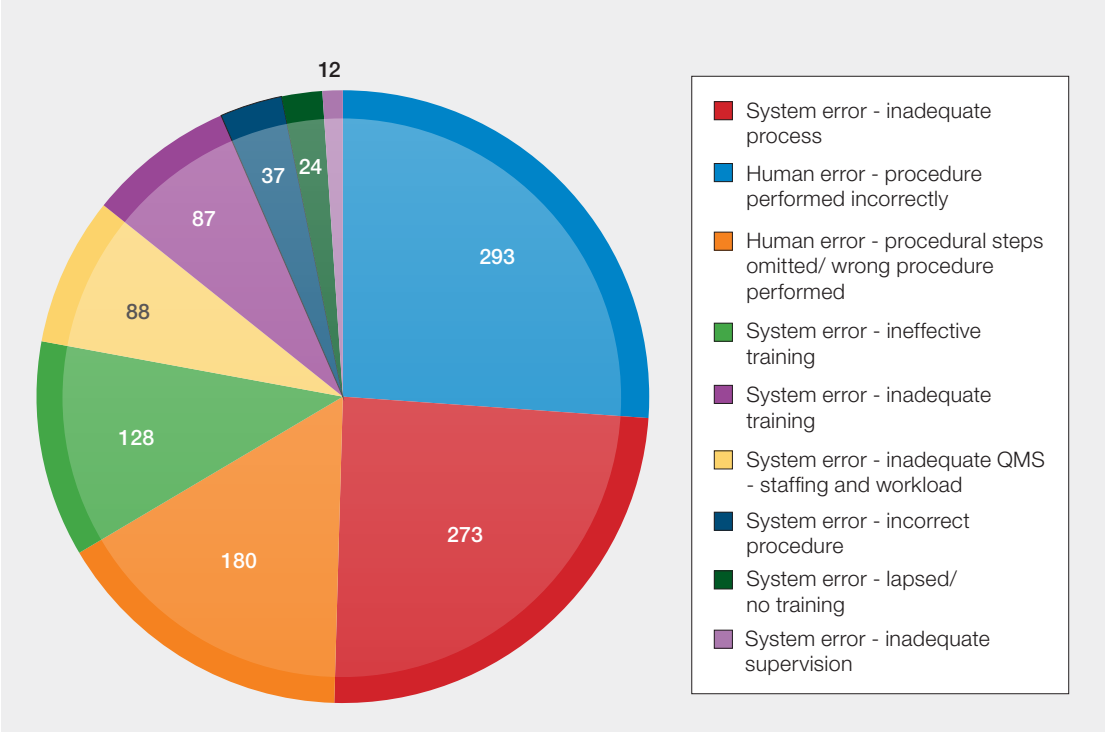
In line with the requirements of EU reporting, the category of system error has formally been adopted, based on the MHRA subcategorisation of human error reports. The MHRA assign a category on review of an SAE report to reflect the most prominent causative factor. Assessment of these reports can distinguish between events caused by system errors (human factors) and human errors (slips/lapses/omissions). For a description of the categories used, see Appendix 3.

Table 26.4 shows the breakdown of reports in the human/system error subcategories.

Human error subcategory	Total 2021 (+/- 2020)	2020 position
Human error/procedure performed incorrectly	293 (+49)	2
System error/inadequate process	273 (+5)	1
Human error/procedural steps omitted/wrong procedure performed	180 (+1)	3
System error/ineffective training	128 (-14)	4
System error/inadequate QMS – staffing and workload	88 (-2)	5
System error/inadequate training	87 (+5)	6
System error/incorrect procedure	37 (-9)	7
System error/lapsed/no training	24 (NC)	8
System error/inadequate supervision	12 (-2)	9
Total	**1122 (+33)**	**x**

Table 26.4: Human/system error subcategories in 2021

Figure 26.5: Human/system error subcategories in 2021 (n=1122)



NOTE: These numbers should be used as guidance only. The quality of this data is limited by a number of factors
QMS=quality management system

- The RC of incidents are usually the result of many contributory factors. The subcategory 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 subcategory rather than choosing a category that best fits the main SAE reported
- The subcategory 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 subcategorised appropriately

An increase in the number of SAE due to the increase in blood usage was to be expected. The split of root causes mirrors previous years with 42% being identified as human error and 58% as system error.

Investigations and reporting on SABRE

While the MHRA recognise that time pressure and lack of resource affect a transfusion team's ability to investigate events, it is a vital part of the quality system. The EU Good Practice Guidelines for Blood Establishments (GPG 2018) apply to HBB as well as BE. They apply to all SAE reportable under the BSQR including SAE that have occurred in a clinical area. One of the requirements relates to the investigation of root cause:

- 9.4.6. An appropriate level of root cause analysis work should be applied during the investigation of deviations. In cases where the true root cause(s) cannot be determined, consideration should be given to identifying the most likely root cause(s) and to addressing those. 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

Most SAE reports to SABRE initially lack depth and attribute the root cause to human error without first addressing system errors and human factors. This same finding is frequently raised during inspection. SABRE reports that lack depth will require additional contact from the SABRE Haemovigilance Team and will either require further investigation or further detail in the SABRE report. Therefore, the same recommendation from last year is repeated below.

Recommendations

- All reporters must continue to thoroughly investigate all SAE, even those with no actual harm to patients. It is through thorough investigation 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
- Ensure that training regimes adequately cover the process or task being trained
- Ensure that any changes to processes are adequately planned, including the planning and delivery of training programmes
- 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 recurrence

Action: Hospital transfusion teams

Top 5 SAE

SAE deviation subcategory	System error subcategory
Incorrect blood component issued (IBCI)	Inadequate process
Component collection error (CCE)	Inadequate process
Incorrect storage of component	Inadequate process
Component collection error (CCE)	Ineffective training
Incorrect storage of component	Ineffective training

Table 26.5: Top 5 SAE with system error subcategory

Incorrect blood component issued – inadequate process (n=59)

SAE that fall into this category will typically involve blood being issued that does not meet a patient's specific requirements.

RCs will often be due to:

- Processes that do not require a BMS to access Sp-ICE
- Information from a clinical area not acted upon in a timely or consistent manner
- Poorly kept patient history on the LIMS that is easily overlooked or misunderstood

Although functionality within a LIMS should be used to provide warnings and barriers to issuing the incorrect component, the overall process should focus on the selection of the correct component in the first place, rather than a reliance on systems to detect errors already made.

Component collection error – inadequate process (n=37)

SAE that fall into this category will often involve porters, but can also involve doctors, nurses, healthcare assistants as well as laboratory staff if the collection process directly involves them helping or handing over components. Errors can involve electronic tracking systems as well as manual processes.

Many of these reports have been assessed as a combination of multiple root causes rather than simply being a result of a poorly designed collection process. Therefore, it is essential that then designing processes that involve collection of components the whole process is considered, including but not limited to ensuring:

- The correct information is provided to the collector
- The process includes checks of all the vital patient identifiers
- All equipment used in the process works
- A written procedure is produced that describes the process

- Training material is produced that covers all aspects of the process, including what to do if something does not occur as it should
- Training is delivered, understood and assessed
- Enough staff have been identified to perform the process when necessary
- Enough trained staff are available on each shift

Storage/incorrect storage of component – inadequate process (n=34)

SAE in this category can involve both portering, clinical and laboratory staff. Many of these SAE are a direct result of the effects of coping with the COVID-19 pandemic. Changes that were necessary that affected hospital locations and environments, staffing levels, skill-mix as well as staff sickness and isolation resulted in changes to storage locations, processes and the availability of trained staff. Changes were often made without thorough planning using change control procedures and considering all the possible factors. As well as poor planning as a whole, often the RC involved multiple factors, including:

- No consideration made to changing storage arrangements
- Inadequate process design
- No or insufficient SOP
- No or inadequate training
- No review of capacity plans to ensure adequate staffing or skill-mix

Component collection error – ineffective training (n=33)

Component collection errors have been mentioned above. However, they appear a second time in the top five specifically relating to ineffective training. Where staff have been redeployed, or storage locations moved, or staff off work for sickness, this often meant new staff were identified for training in collection of components at short notice. Report narratives suggest that although training was delivered it may not have been understood at the time and staff continued to attempt to collect components when not being entirely sure what to do.

Storage/incorrect storage of component – ineffective training (n=28)

SAE in this category primarily involve clinical staff but may also involve other staff categories. These SAE typically involve staff have been trained, but have still performed the task incorrectly. This is often stated that the staff involved have either forgotten the training or had not understood it when it came to storing a component. RC often involve:

- Staff not performing storage tasks frequently enough to re-enforce their training
- Staff thinking they are doing the right thing without checking
- Being unfamiliar with less frequently used component types
- Not understanding the difference between unmonitored ward refrigerators and blood refrigerators

Recommendations

- Review QMS to ensure the processes involved in the most frequently occurring SAE are robust. Ensure that:
- The process is thoroughly defined
- Procedures are written giving full and clear instructions how to perform the task
- Training is planned, adequate, delivered and understood

Action: Hospital transfusion teams

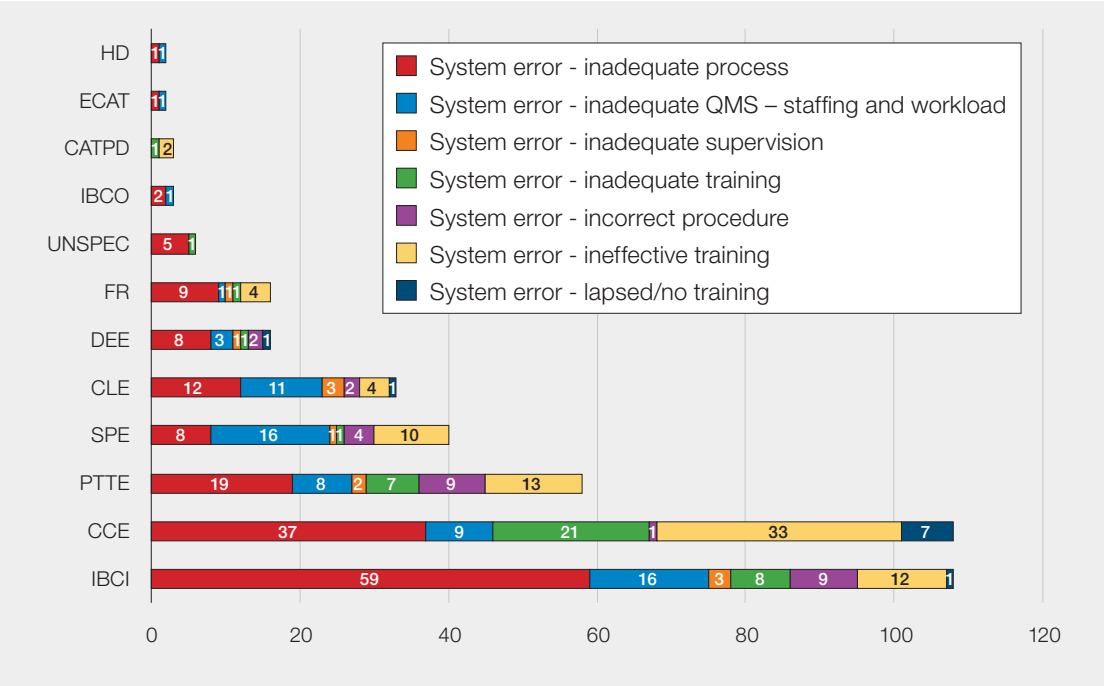


Figure 26.6
Other subcategory and system error

See Appendix 2 for key to category abbreviations. QMS=quality management system

Figure 26.6 demonstrates all the most frequently occurring SAE that fall into the other category and their root causes where the QMS was deemed to have been insufficient.

From Jan 1st 2021 the MHRA have been assigning human and system error subcategories directly on individual reports once they have been reviewed and closed.

Notification

Date of event:	15 Mar 2021
Event involving:	Other
If other, please state here:	PTTE - Pre-transfusion testing error
Specification:	System error / Inadequate process
If other, please state here:	
Implicated Component:	Red blood cells
Blood component transfused:	No

Recommendations

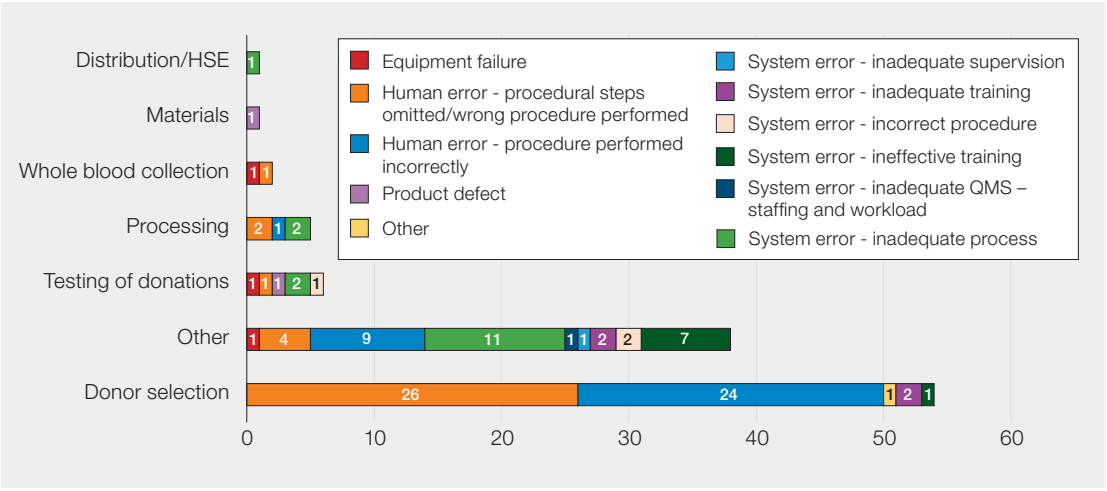
- Review SAE closed by MHRA and take note of the RC subcategory and event subcategory to trend and identify a site's own most commonly occurring SAE and RC

Action: Hospital transfusion teams

Blood establishment reporting n=107 (=+12)

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 26.7 displays the reported BE SAE in 2021.

Figure 26.7: Blood establishment SAE event category by specification

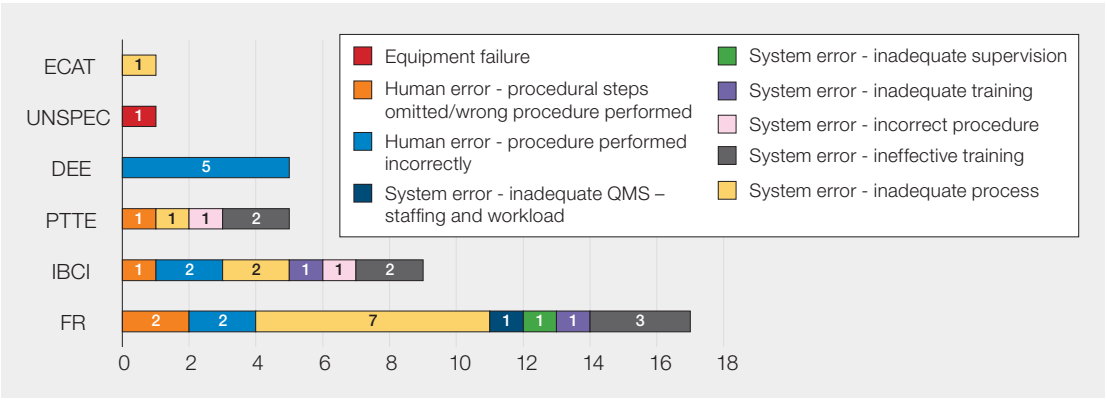


QMS=quality management system; HSE=handling and storage error

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 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 26.8 shows a breakdown of the 38 reports which fall into the 'other' category.

Figure 26.8 BE reports in 'other' category



QMS=quality management system. See Appendix 2 for key to category abbreviations

Comment from Julie Staves, Chair of the NBTC Laboratory Managers' Working Group

I am pleased to see that hospital transfusion laboratories continue to engage well with haemovigilance reporting despite all the ongoing challenges we are all facing. It is important that we all continue to report these incidents so we continue to learn, not only from our own reports, but from the overall national picture.

The thorough investigation of all incidents remains important, even those which have not caused harm. This will allow us to identify potential risks to our patients and ensure we are providing safe and timely service to reduce these risks.

The 7% increase in the number of reports related to incorrect storage of components is a concern, as is the information that 77% of these errors are the result of a system error. I'd urge everyone to review their systems in light of these figures and consider what changes may be needed to prevent such incidents.

Serious adverse reactions (SAR)

Definition:

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
(BSQR 2005)

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 26.9.

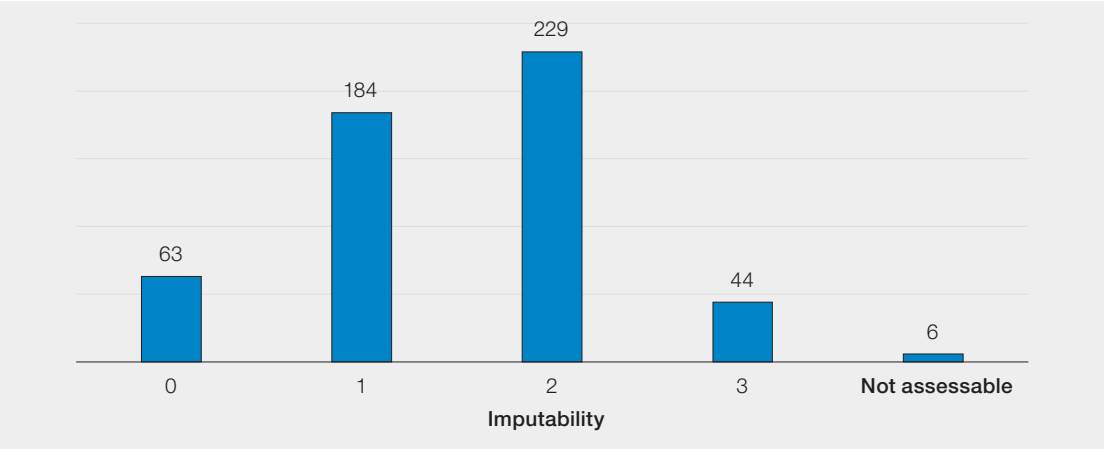


Figure 26.9: SAR reports, by imputability, reported to SABRE in 2021

MHRA inspection activity on hospital blood banks

Authors: Shirley Stagg and Mike Dawe

The Haemovigilance Team Manager is now conducting blood inspections and as such the Haemovigilance Team Manager's update will be incorporated in the inspectorate report. Blood education days are continuing and can be requested from the Senior Haemovigilance Specialist.

The MHRA inspectorate have continued to verify blood compliance reports and have conducted 23 inspections since August 2021. Although different sites have been inspected, the issues found are much the same as previous years. In lieu of a separate inspector's report, you are urged to take note of last year's section.

References

BSQR. The Blood Safety and Quality Regulations ISBN 0110990412 (2005). http://www.legislation.gov.uk/uksi/2005/50/contents/made [accessed 04 May 2022].

GPG (2018). Good Practice Guidelines for Blood Establishment Required to Comply with Directive 2005/62/EC, 15/02/2018 https://www.edqm.eu/en/good-practice-guidelines-for-blood-establishments [accessed 03 April 2022].

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

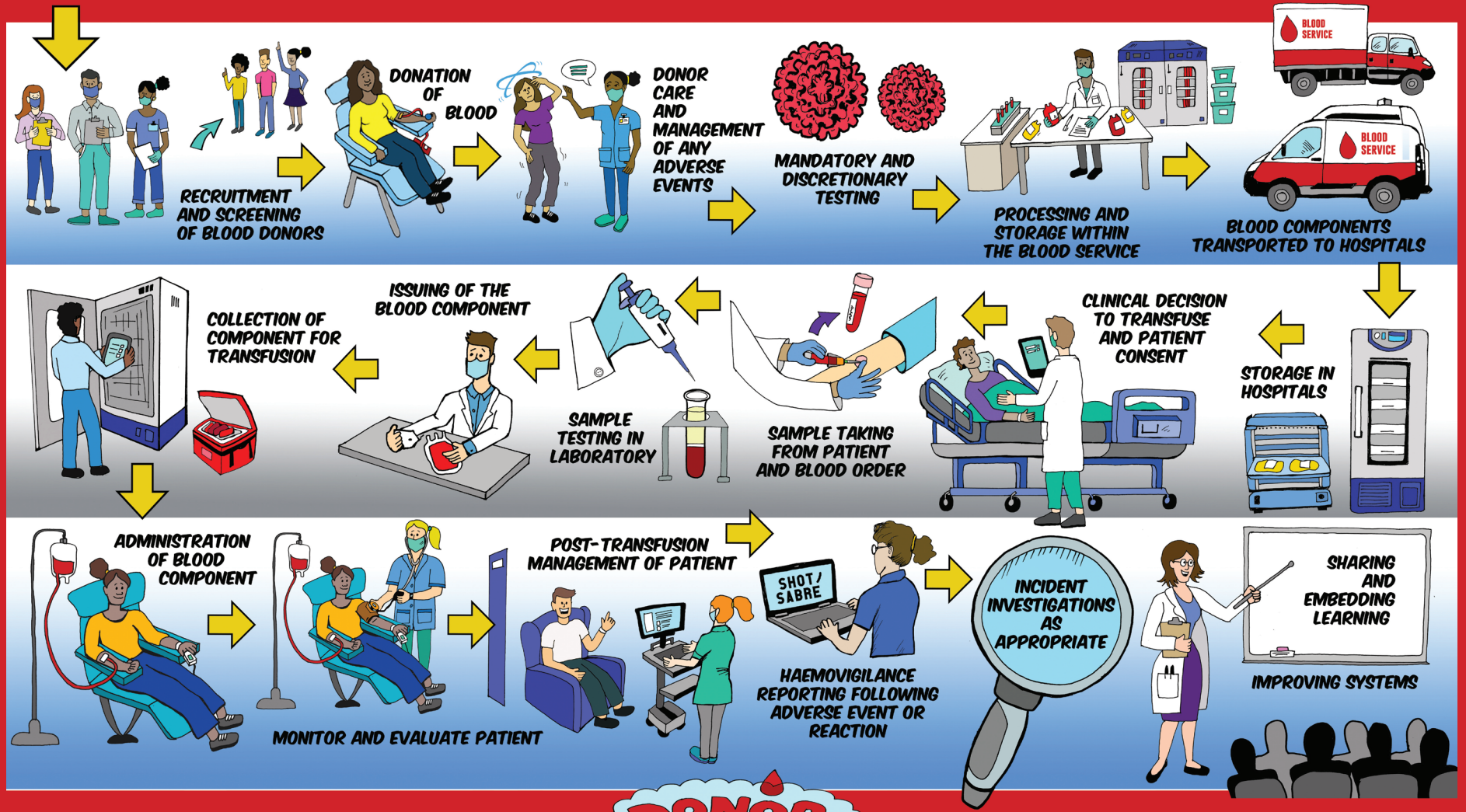
Appendix 3: Human error subcategories

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

HAEMOVIGILANCE: VEIN TO VEIN

SHOT
Serious Hazards of Transfusion

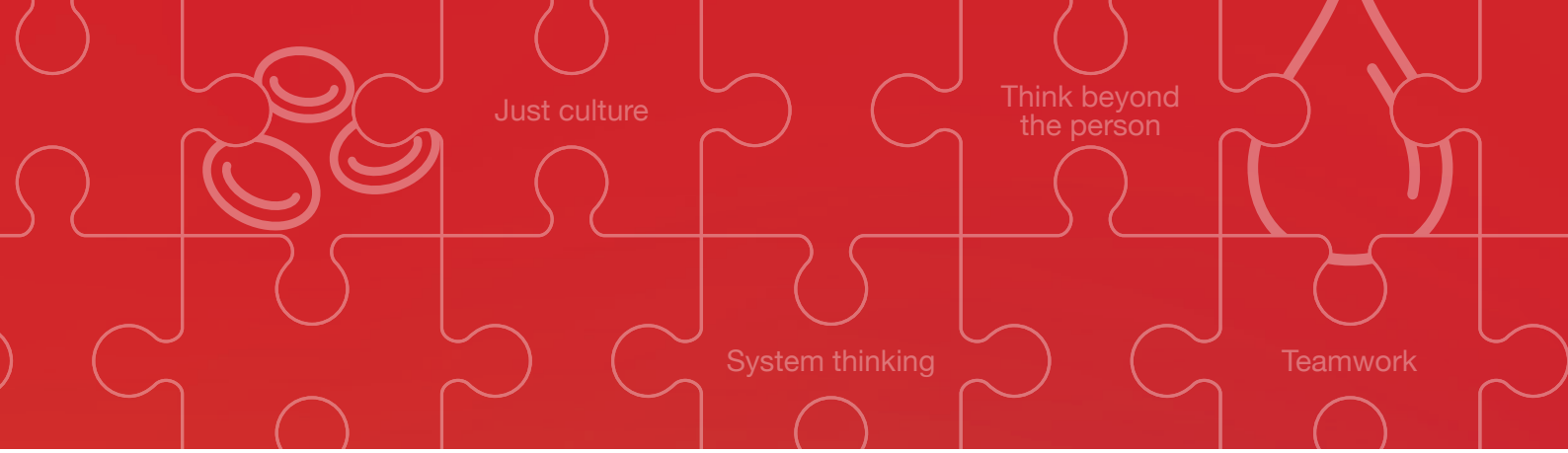
HAEMOVIGILANCE COVERS THE ENTIRE VEIN TO VEIN TRANSFUSION CHAIN AND IMPROVES PATIENT SAFETY



TRACEABILITY AND COLD CHAIN COMPLIANCE

DONOR TO RECIPIENT

ILLUSTRATION: JENNY LEONARD ART



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

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