

ANNUAL SHOT REPORT 2014

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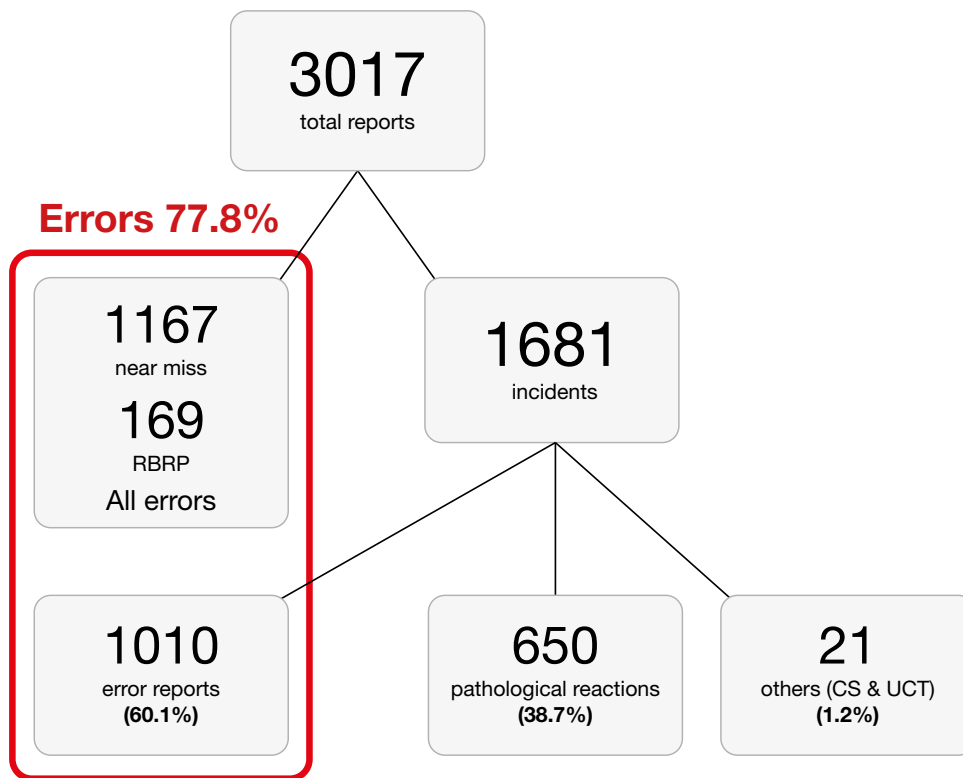
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SUMMARY

Introduction:

Blood and blood component transfusion in the UK is very safe with a small number of adverse incidents in relation to the number of components issued and transfused. In 2014 (January to December) the total number of reports made to SHOT was 3668 and 3017 were analysed for this Annual Report (others were incomplete or withdrawn). The total number of reports made to the Medicines and Healthcare products Regulatory Agency (MHRA) was 1110 of which 764 were serious adverse events (errors in 97.8%) and 346 were serious adverse reactions. The proportion of SHOT reports where errors were the underlying cause was similar to 2013, 77.8% (2346 reports). Acute transfusion reactions (allergic/febrile) were the most common pathological reactions. The cumulative data (18 years) can be viewed on the website, www.shotuk.org.

Figure 1: Categorisation of SHOT reports analysed in 2014



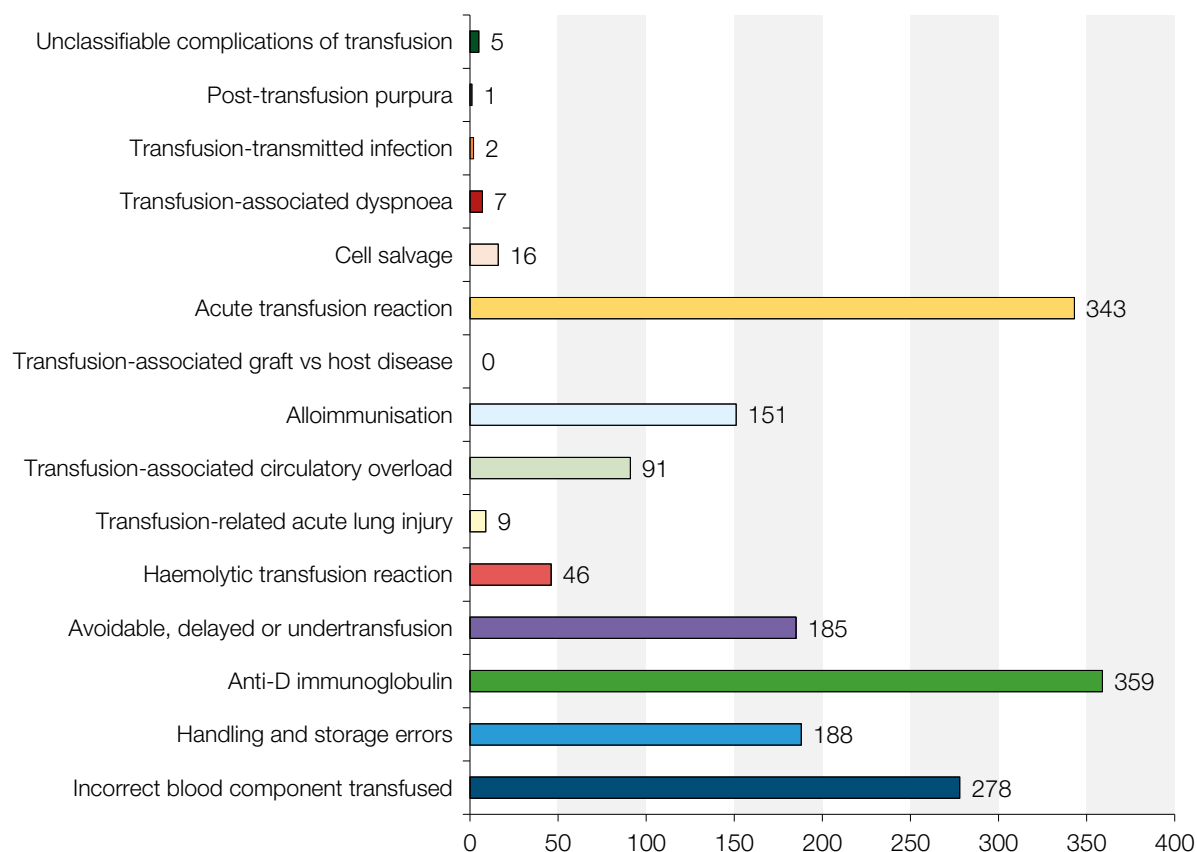
*CS=cell salvage; UCT=unclassifiable complications of transfusion

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SERIOUS HAZARDS OF TRANSFUSION

SHOT

Figure 2: SHOT cases reviewed in 2014 (excluding near miss and right blood right patient) for the cumulative data chart please see website www.shotuk.org



There were **10 ABO-incompatible red cell transfusions** all due to clinical errors resulting in one patient requiring renal dialysis, but no deaths.

Overview of deaths and major morbidity:

Table 1: Mortality and morbidity data by reporting category

	Death definitely related	Death probably/likely related	Death possibly related	Major morbidity	Potential for major morbidity
Avoidable, delayed or undertransfusion (ADU)	-	-	3	4	-
Anti-D immunoglobulin (Ig)	-	-	-	4	270
Acute transfusion reactions (ATR)	-	-	-	104	-
Haemolytic transfusion reactions (HTR)	1	-	-	5	-
Incorrect blood component transfused (IBCT)	-	-	-	4	7
New or unclassifiable complication of transfusion (UCT)	-	-	-	2	-
Transfusion-associated circulatory overload (TACO)	1	3	2	36	-
Transfusion-associated dyspnoea (TAD)	-	1	2	2	-
Transfusion-related acute lung injury (TRALI)	-	1	1	7	-
Transfusion-transmitted infection (TTI)	-	-	-	1	-
Total	2	5	8	169	277

(Potential for major morbidity=potential risk of D or K sensitisation in a woman of childbearing potential)

Deaths n=15 (22 in 2013). Only 2 deaths were definitely related to transfusion, one haemolytic transfusion reaction, and one case of transfusion-associated circulatory overload. Delayed transfusion contributed to 3 deaths. Two of these were related to confusion and poor communication during activation of major haemorrhage protocols, and the third was a patient admitted from an anticoagulant clinic with gastrointestinal haemorrhage whose overall care was poor. The risk of death (imputability 1-3) is calculated at 5.6 per million components issued.

Major morbidity n=169 (143 in 2013). Most of these cases were acute transfusion reactions (ATR) (allergic/febrile). The risk of major morbidity is 63.5 per million components issued. The overall data are shown in Table 1.

Transfusion-associated circulatory overload (TACO) is a dangerous complication and was associated with 36 cases of major morbidity and contributed to 6 deaths, together 42/91 (46.2%) of all cases of TACO.

Key SHOT messages:

The majority of reports both to SHOT and the MHRA relate to errors in the transfusion process. **It is important that incident investigation is appropriate** for the actual or potential severity of the incident. Investigations can consume significant time. Root cause analysis should be completed and identify factors to prompt corrective and preventative actions.

Recommendations are not rules and should be interpreted according to the individual patient needs. The recommendation concerning transfusion at night has been updated. Some patients have been denied transfusion at night when it was essential, and there are some patient groups where regular transfusion is required and this can be scheduled to minimise time lost from education and employment.

Transfusion at night: Revised recommendation:

- Transfusions should be given with the same attention to patient observations whatever the time of day or night
- Transfusions at night must proceed where there is a clear clinical indication, and may be given as long as the staffing is sufficient to permit transfusion according to the standards defined in the British Committee for Standards in Haematology (BCSH) guideline on administration of blood components 2009 (BCSH Harris et al. 2009). These standards include adequate pre-transfusion assessment, observations at 15 minutes after the start of each component and regular visual observation throughout the transfusion
- Decisions to transfuse should not be made simply on the basis of the haemoglobin result, but taking into account the full medical history, the patient's current medical condition and the wishes of the patient. Junior medical staff should review the patient, consult the case notes and take advice from senior medical staff before deciding to transfuse at night, particularly when the team concerned are not familiar with the patient's case and are not responsible for the overall management plan

Action: Trust/Health Board Chief Executive Officers, Hospital Transfusion Teams, Medical Directors responsible for all clinical staff

Serious adverse reactions (SAR) must be reported to the European Union via the competent authority, MHRA: It is a requirement under EU legislation.

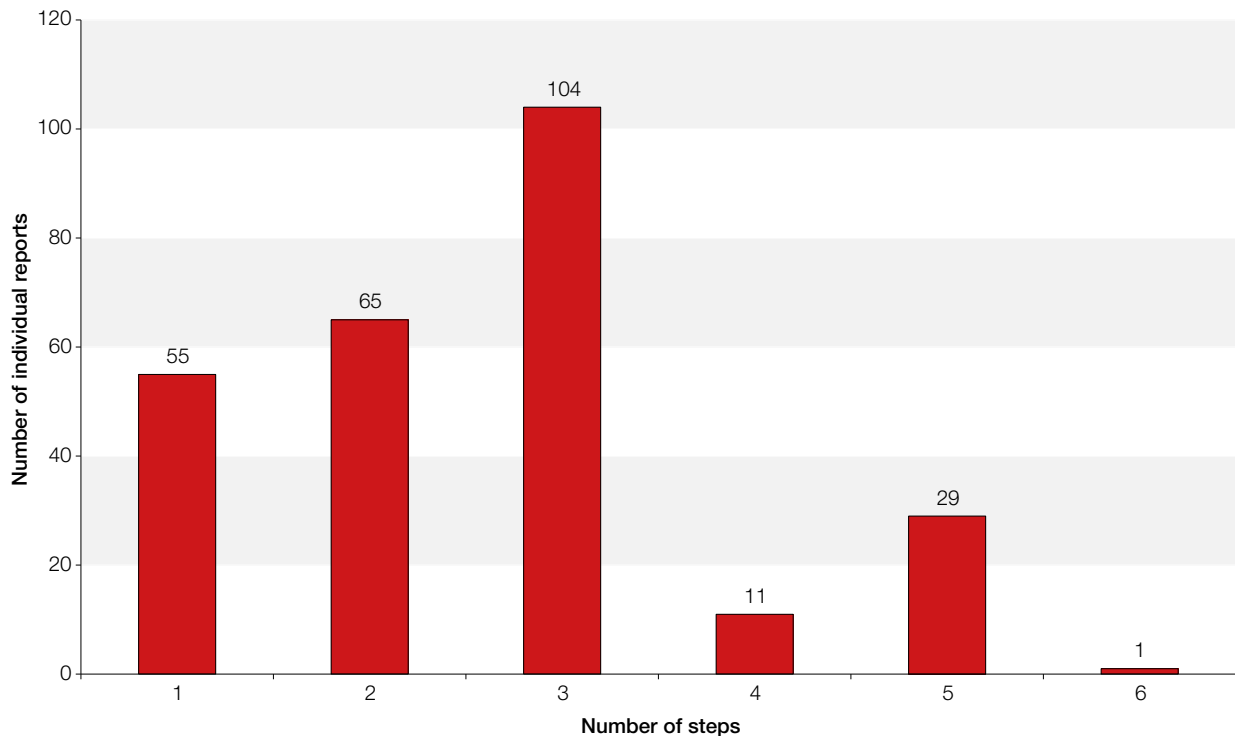
Following a detailed reconciliation of 2013 report data between the two organisations, it became apparent that there was some underreporting of SARs to the MHRA. This analysis identified 192 reaction reports made to SHOT that were not reported as SARs to the MHRA. Based on the initial brief description of the report to SHOT 98/192 (51.0%) should definitely have been reported to the MHRA as well, while another 30/192 (15.6%) were probably reportable but would require further information from the reporter. A similar analysis has been done for reports made in 2014.

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 prolong hospitalisation or morbidity.'** These must be reported to the MHRA (a legal requirement).

Update on human factors: In addition to instances of failures in patient identification, communication and documentation, many reports demonstrate poor clinical decision-making or confusion as a result of too many clinical opinions with poor handover.

Incorrect blood component transfused and multiple errors: Reports of errors within the transfusion process leading to incorrect blood component transfused (n=265/278) were analysed to see how many errors occurred at critical points in single transfusion episodes. The findings are similar to 2013 with a median of 3 errors (104 cases) and a maximum of 6. Many of these incorrect transfusions could have been avoided if the request and prescription were correct in all details. The pre-administration bedside check is a fundamental step as it is the final opportunity to detect errors made earlier in the process and prevent a wrong transfusion. In 2014 162/265 (61.1%) of cases the errors made earlier in the process could have been detected at this point. A 5-point bedside checklist was recommended by SHOT in the 2013 Annual Report.

Figure 3: Number of steps with errors in each transfusion: 265 reports

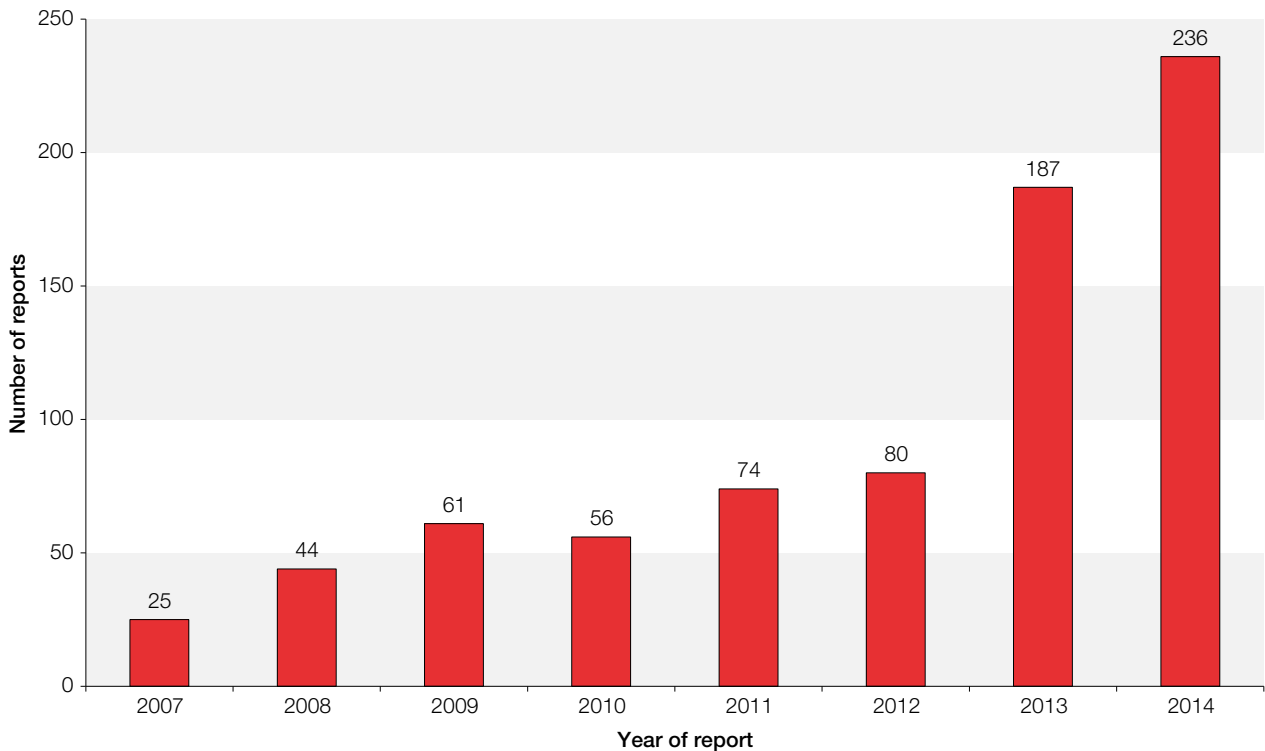


Delayed (n=50) and avoidable (n=129) transfusions: It is disappointing to see reports of delayed transfusion increasing; these included several problems with major haemorrhage protocols not being followed or not understood.

Key SHOT messages

- The recommendations made in the National Patient Safety Agency (NPSA) Rapid Response Report (2010) remain relevant and should be followed, notably that 'local protocols should enable release of blood and blood components without the initial approval of a haematologist' and that the major haemorrhage protocol is 'supported by training and regular drills'
- Avoidable and delayed transfusions continue to occur, many associated with poor communication or inappropriate clinical decisions contributing to serious outcomes including death

Information technology (IT) and computing problems: IT can improve transfusion safety when set up and used properly. An increasing number of cases are reported each year where the use or misuse of IT systems played a part (Figure 4). These are more often caused by human factors, such as inappropriate set up and work-arounds. An example of this was transfusion of 273 units (by 105 different members of staff) where the set up of the IT system permitted use of the emergency button for routine transfusions thus bypassing the bedside check (these are counted as a single case in Figure 4). In other cases, errors occurred because laboratory staff ignored warning flags or had not set them up in the first place. Cases of IT malfunction are, by contrast, very rare. However it is essential that users work closely with developers of any IT system to remove design faults before these translate into system faults and incidents of potential or actual harm.

Figure 4: IT cases 2007-2014

Laboratory errors: These have increased to 334 in 2014 compared with 284 in 2013. Testing errors increased from 51 to 88, and 61.4% of these were due to incomplete testing.

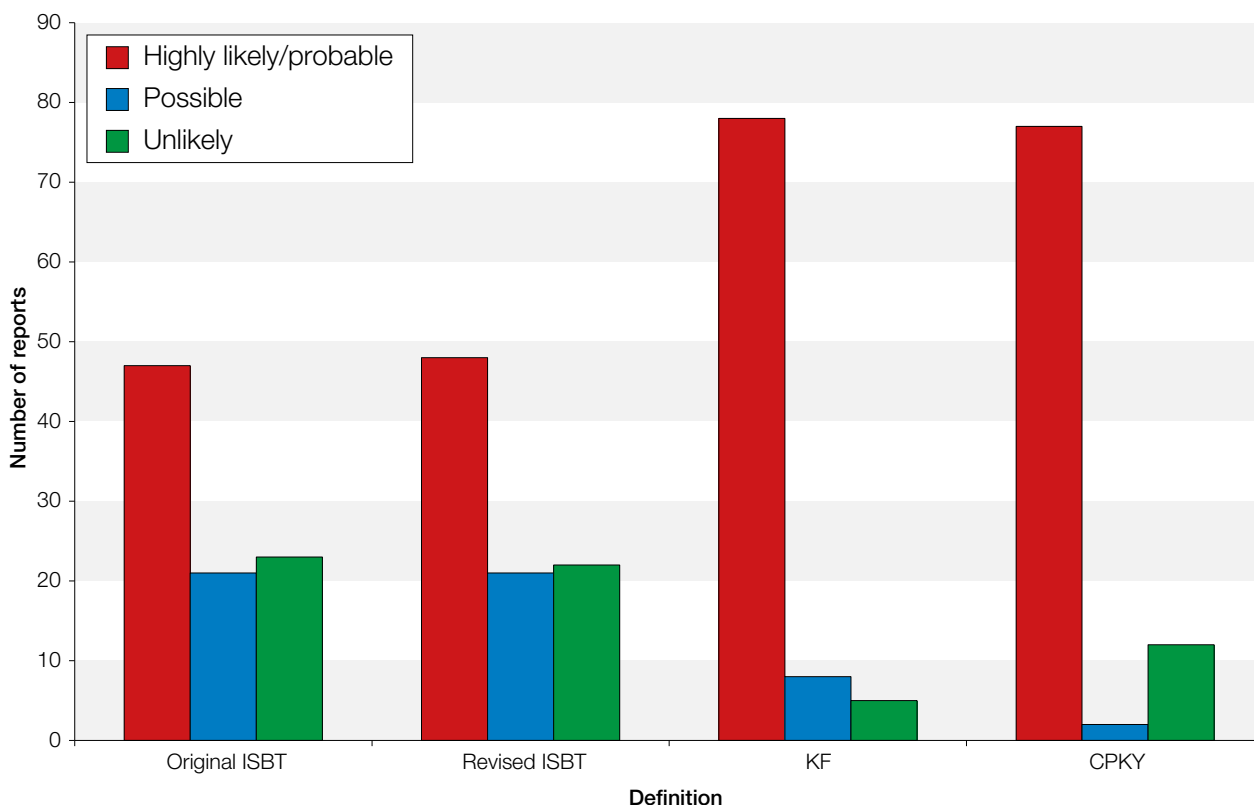
Laboratory success: Good quality management resulted in detection of 684 wrong blood in tube samples, the majority (77.3%) during testing. In 2014 there were no instances where a wrong blood in tube transfusion sample resulted in a wrong transfusion.

Key SHOT messages

- Errors with sample receipt and registration, and testing all highlight key areas for improvement, particularly lack of effective communication together with poor serological knowledge and understanding in laboratory staff. During the 'booking in' process it is essential to take into account any historic patient laboratory information and to ensure that all previous results and any specific requirements have been taken into consideration
- The BCSH guidelines on IT in blood transfusion (BCSH Jones et al. 2015) and the UK Transfusion Laboratory Collaborative standards (Chaffe et al. 2014) have both been published recently, and laboratory staff are strongly encouraged to perform a gap analysis and ensure their laboratories comply with them

Transfusion-associated circulatory overload: The current definition (International Society of Blood Transfusion, ISBT) is unsatisfactory and the data for 2014 were analysed using 4 different definitions (Figure 5). These result in different proportions of cases classified as 'highly likely' or 'probable' TACO; 52% using ISBT original and draft revised definitions, but 85% using two definitions with clinical interpretation. The ISBT working party will continue to work on revision of the definition. TACO can occur at any age, and a death was reported in a patient aged 22 years.

Figure 5: Probability of TACO by 4 different definitions



KF=key features (SHOT 2013); CPKY=clinical prioritisation of key features (SHOT 2014)

Transfusion-related acute lung injury: Nine cases of suspected TRALI were reported, and in one of these, cryoprecipitate was implicated. The patient had received a pool in which three female donors had concordant HLA classes 1 and 2 antibodies.

Recommendation:

- UK Blood Services should avoid the use of female donor plasma in the production of cryoprecipitate whenever possible
- All UK Blood Services are encouraged to refer cases of suspected transfusion-related acute lung injury (TRALI) to the independent TRALI intensive care experts for assessment before laboratory investigations are initiated

Action: UK Blood Services

Transfusion-transmitted infections: No bacterial transmissions have occurred since 2009, but there were two near miss events in 2014 where *Staphylococcus aureus* was isolated from platelet packs. These were detected initially by visual inspection and are a reminder of the importance of this and rapid reporting to the Blood Service so that associated packs can be withdrawn. One hepatitis E transmission to two recipients was reported. This is not currently screened for by the Blood Services.

Anti-D immunoglobulin: The number of errors continues to increase and was 359 in 2014, and 279 of these related to omission or late administration. In one case immune anti-D was assumed to be prophylactic so the pregnancy continued unmonitored resulting in severe haemolytic disease of the newborn.

Anti-D sensitisation study: A total of 66 cases have been reported (2012-2014), 16 in women with no previous pregnancy (NPP) and 50 in women with previous pregnancies (PP). Although in many cases deficiencies in care were apparent, in 5/16 NPP no risk factors were identified, and 8/50 PP women were sensitised despite apparent appropriate and good care. These data suggest that the use of prophylactic anti-D Ig does not prevent immunisation in every case.

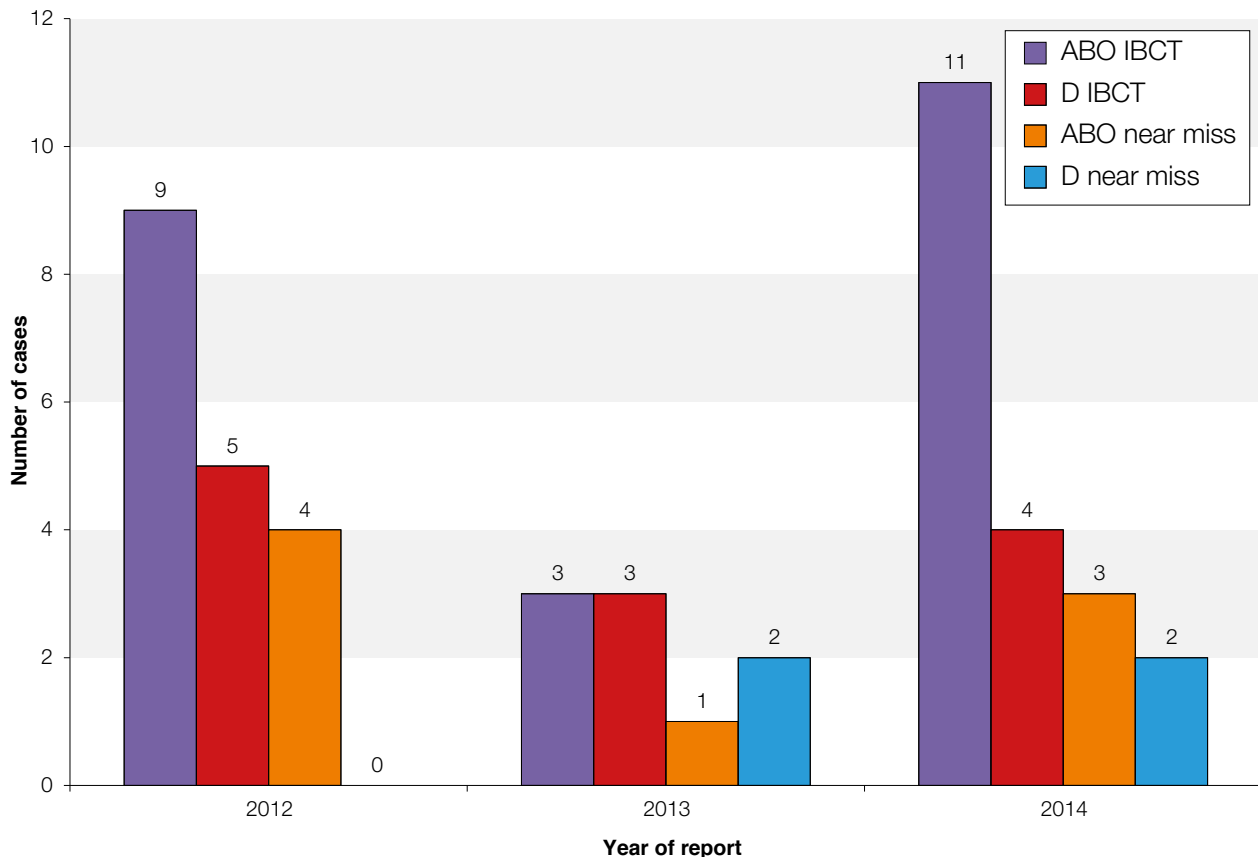
Paediatric cases: There were 122 reports in patients <18 years of age (38 <1 year of age) with findings similar to previous years apart from an increase in ATR, particularly severe allergic reactions (ATR comprised 35% of all paediatric reports compared to 20% of all cases).

Key SHOT messages

- Blood components should be prescribed in volumes for children related to their weight, but not more than the standard accepted dose for an adult
- Patients with suspected DiGeorge syndrome should receive irradiated cellular components until immunodeficiency is excluded, and this should be communicated to the laboratory. There should be local guidelines for the timely investigation of suspected immunodeficiency in order to reduce unnecessary provision of irradiated components
- There has been an increase in the number of severe allergic reactions across all component types reported following paediatric transfusions, although not in the neonatal/infant group

Transplant cases: This is the third year in which SHOT has summarised errors related to transplants, both of haemopoietic stem cells and solid organs. There were 20 ABO/D errors and 22 instances where specific requirements were not met (19 failures to transfuse irradiated components). Some of these data are shown in Figure 6. These are mostly caused by poor communication or lack of knowledge and indicate that guidelines are needed, particularly to cover transfusion requirements for recipients of ABO-incompatible solid organ transplants.

Figure 6: Haemopoietic stem cell transplant ABO and D errors



IBCT=incorrect blood component transfused

Update on recommendations made from 2013 report:

All ABO-incompatible red cell transfusions to be included as 'never events': ABO-incompatible red cell transfusions may be fatal and are absolutely preventable. The two thirds that do not result in harm should be included as reportable 'never events' (England).

The new 'never events' (England) list published March 2015 includes all ABO-incompatible transfusions (all components), and not only those which result in death or serious harm.

Management of blood and blood component transfusion to be included as a specific standard by the Care Quality Commission: Discussions have taken place between CQC (England) and SHOT as to how SHOT data could be used by CQC to help understand transfusion practices. Reported benchmarking data will be shared with CQC to examine how this information can support inspections. CQC fully understand that rates of reporting vary considerably and for different reasons but guidance will be provided by SHOT to ensure these data are interpreted correctly and used appropriately during inspection to discover how Trusts manage risks and learn from errors. These questions are already in place for other areas of clinical practice.

Reporting reminders:

Hyperhaemolysis (HH) is a condition of excessive red cell destruction where both transfused and autologous cells are haemolysed, most commonly reported in sickle cell disease. An advisory panel may be consulted via National Health Service Blood and Transplant (NHSBT). Clinicians should contact their red cell immunohaematology (RCI) consultant in normal hours, or the Blood Service consultant on call as soon as possible after HH is suspected. Details will be recorded on a proforma but clinicians should also make their own report to SHOT. The devolved countries are invited to participate in this study.

Transfusion-associated necrotising enterocolitis (TANEC) occurs in premature neonates. Necrotising enterocolitis is a serious disorder which in some cases appears to be triggered by red cell transfusion. Two cases were reported to SHOT in 2011. No cases have been reported since then despite published data suggesting that 27-38% of NEC cases are transfusion-related (Gephart 2012). These are defined as those occurring within 48 hours of red cell transfusion.

Joint haemovigilance reporting: We are working towards a closer alignment with the MHRA and reporting to the European Union (EU) following recognition that many SARs reported to SHOT only should also have been reported to the MHRA. During 2015 the SHOT Working Expert Group (WEG) will take over analysis of all the adverse reactions and will forward to the MHRA those that require inclusion in the returns to the EU.

Conclusion: An increased interest in 'human factors' is evident across all areas of medicine and further research is needed to understand how the working environment can be made more safety-orientated. SHOT's multiple errors data demonstrates a need for all participants in the transfusion pathway to understand their individual responsibility for patient safety.

SHOT is grateful to hospitals for reporting and for the Working Expert Group, acknowledging in particular the great contribution over several years of those who are stepping down: Hannah Cohen, Hazel Tinegate, Catherine Chapman and Alexandra Gray.

References:

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