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Annual Report 2010 SUMMARY

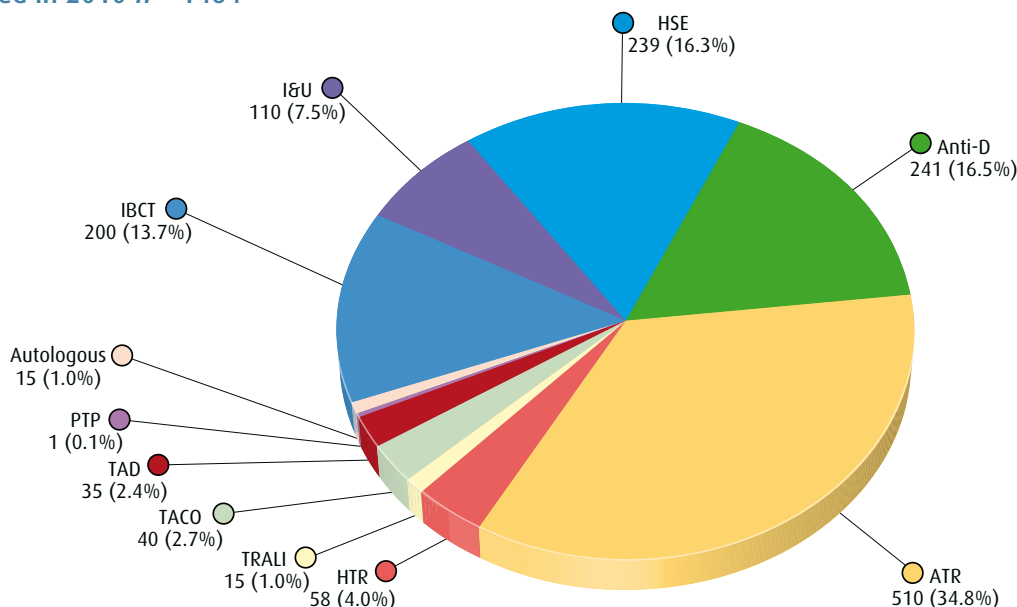
Introduction

This 2010 report is the 14th annual report of data collected and recommendations made by the Serious Hazards of Transfusion (SHOT) UK Haemovigilance Scheme. In 2010, reports were submitted by 94.7% of NHS hospitals or Trusts, and 91.4% of organisations reported incidents in all three broad categories (adverse events, near misses and physiological reactions). In total, 1464 cases were analysed (in addition to 863 instances of near miss and 137 right blood right patient incidents), which represents a 14.5% increase from 2009.

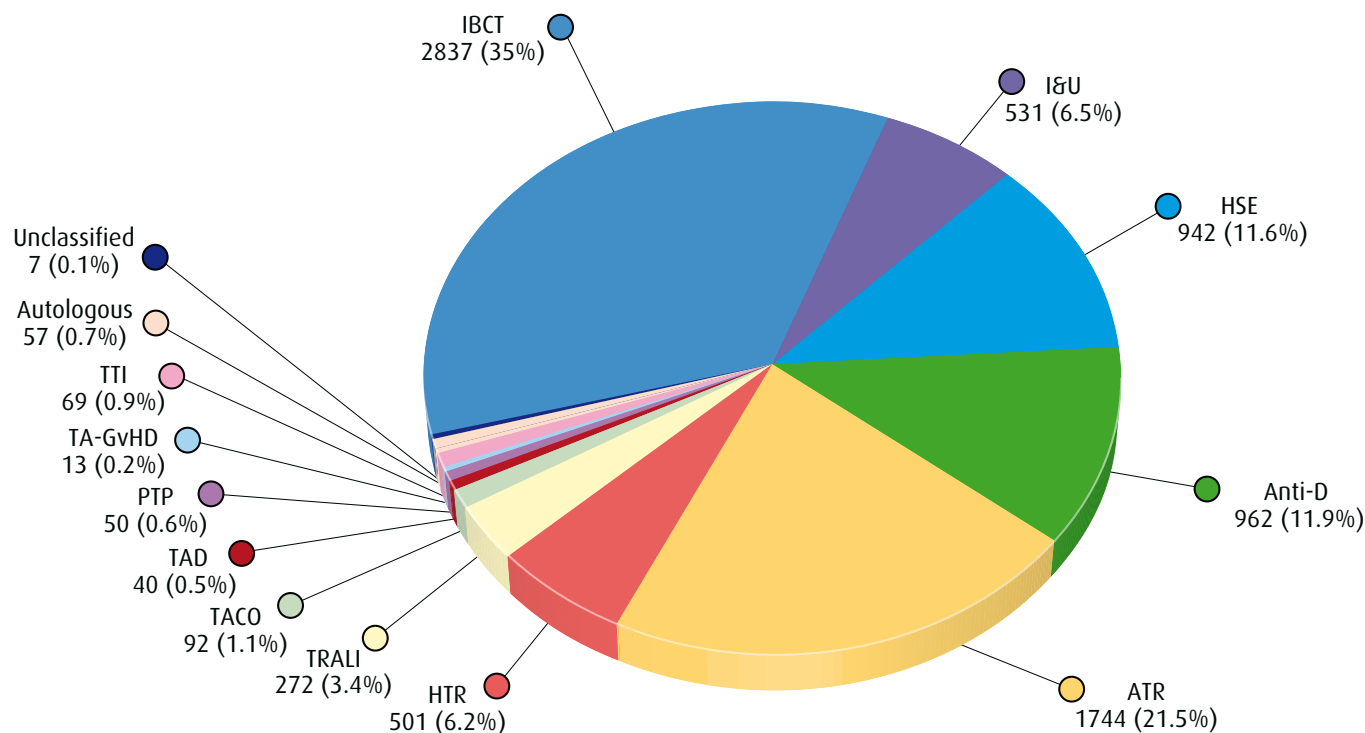
Notably, this is the first year in which there has been no confirmed case of transfusion-transmitted infection (TTI). Furthermore there has been a 29% reduction overall in the number of incorrect blood component transfused (IBCT) reports: 57% less in the clinical area and 28% less in the laboratory. These figures indicate that efforts to train and competency assess clinical staff in transfusion, such as the National Patient Safety Agency (NPSA) Safer Practice Notice (SPN) 14, are having an effect in the clinical area. In the laboratory, the improvement is likely to be due to a combination of the requirements of meeting the Blood Safety and Quality Regulations (BSQR) 2005 and the recommendations of the UK Transfusion Laboratory Collaborative (UKTLC). However, transfusion-associated circulatory overload (TACO) and inappropriate and unnecessary transfusions (I&U) are becoming major issues and have been responsible for the majority of cases of mortality with imputability ≥ 2 . (*Imputability is a measure of the likelihood that the reaction was linked to the blood component and is not related to the severity of the reaction: 0, excluded/unlikely to be related; 1, possibly related; 2, probably or likely to be related; 3, certainly related to the reaction*).

Transfusion contributed to a varying extent to 13 deaths. There were also 101 reports of major morbidity, with acute transfusion reactions (ATR) being the single highest cause, resulting in a serious outcome for 7.8% of those cases reported. These cases are summarised below but further details and additional learning points can be found in the relevant chapters of the full SHOT Annual Report 2010.

Cases reviewed in 2010 $n = 1464$



Cumulative numbers of cases reviewed 1996–2010 *n* = 8117



* IBCT, incorrect blood component transfused; I&U, inappropriate, unnecessary and under/delayed transfusions; HSE, handling and storage errors; ATR, acute transfusion reactions; HTR, haemolytic transfusion reactions; TRALI, transfusion-related acute lung injury; TACO, transfusion-associated circulatory overload; TAD, transfusion-associated dyspnoea; PTP, post-transfusion purpura; TA-GvHD, transfusion-associated graft versus host disease; TTI, transfusion-transmitted infection.

Mortality/morbidity data 2010

	Total	IBCT	I&U	HSE	Anti-D*	ATR	HTR	TRALI	TACO	TAD	PTP	TA-GvHD	TTI	Autologous
Death in which transfusion reaction was causal or contributory (imputability 1/2/3)	13	0	2	0	0	3	1	1	6	0	0	0	0	0
Major morbidity probably or definitely attributed to transfusion reaction (imputability 2/3)	101	2	4	0	1	57	2	13	15	6	0	0	0	1
Minor or no morbidity as a result of transfusion reaction	1357	198	104	239	240	450	55	1	19	29	1	0	0	14
Total	1464	200	110	239	241	510	58	15	40	35	1	0	0	15

* Cases with potential for major morbidity are excluded from this table.

Deaths $n = 13$

Deaths definitely due to transfusion

Three deaths were of imputability 3 (definitely due to the transfusion). There was 1 case of sudden unexpected death during a red cell transfusion. Although there were no diagnostic changes on post mortem examination, the death was attributed to an anaphylactic reaction on the basis of mast cell tryptase levels on a post-mortem blood specimen. The second death was due to TACO, again confirmed on a coroner's post-mortem, and the final death occurred in a child with sickle cell disease who suffered from hyperhaemolysis exacerbated by further transfusion.

TACO

TACO was the most common reaction implicated in death, contributing to the demise of 6 further patients: 3 where the death was assessed as highly likely or probably due to the transfusion (imputability 2) and 3 where the possibility that TACO had contributed to death could not be excluded (imputability 1). One of the deaths from TACO (imputability 1) was due to over-transfusion and is included in the inappropriate and unnecessary (I&U) chapter of the full SHOT report.

Under-transfusion

Under-transfusion of a patient with massive gastrointestinal blood loss who was given 10.5 litres of colloid but only 4 units of red cells over a period of 1½ half hours in A&E was thought to have possibly contributed to death (imputability 1).

ATR

The possibility that severe ATRs had contributed to death could not be excluded in 2 patients (imputability 1).

- A septic neonate suffered a cardiac arrest during the transfusion of apheresis platelets and died 2 hours later.
- An adult patient with a cerebral tumour developed hypertension and rigors during the transfusion of apheresis platelets and died several hours later following a bleed into the tumour.

Transfusion-related acute lung injury (TRALI)

A patient with upper gastrointestinal bleeding received a massive transfusion and died later the same day of cardio-respiratory failure. A patient sample was unavailable for complete investigations to confirm whether or not the patient had died from TRALI (imputability 1).

Major morbidity $n = 101$

ATR

ATR was most common contributor to major morbidity. There were 57 reports in which the symptoms and signs of the transfusion reaction were sufficiently severe to imply that delay in treatment could be life-threatening. These included 34 cases of anaphylactic and 1 angioedema reaction, 11 allergic reactions with bronchospasm and 10 severe hypotensive reactions (including 2 cases associated with the onset of dysrhythmias) and 1 supraventricular tachycardia with a fever.

Pulmonary complications of transfusion (TACO, TRALI and TAD)

Of 15 patients with TACO who suffered major morbidity, 13 required intensive therapy unit (ITU) admission and/or ventilation and the remaining 2, who were already on ITU, required increased ventilatory support. A further 19 patients required ITU admission as a result of pulmonary complications of transfusion: 13 with TRALI and a further 6 because of transfusion-associated dyspnoea (TAD).

I&U

Four patients who were over-transfused suffered major morbidity: 2 developed TACO (one of whom was venesected), a third sustained a cerebral infarct and the final patient, a neonate, had a post-transfusion haemoglobin (Hb) of 20.0 g/dL.

IBCT

'Wrong blood' (IBCT) incidents contributed to 2 cases of major morbidity. One patient was given an ABO-incompatible transfusion as a result of a collection and administration error and required admission to ITU because of intravascular haemolysis and renal failure. A second female patient of childbearing potential was transfused with K+ red cells and became alloimmunised.

HTR

Two patients with delayed haemolytic transfusion reactions (HTR) suffered major morbidity. One required admission to ITU and a second developed renal impairment.

Failure to give anti-D immunoglobulin

In one case an RhD negative female patient aged 18 years developed anti-D after receiving RhD positive platelets during transfusion for traumatic haemorrhage, for which no anti-D Ig prophylaxis was administered.

Autologous

One patient who had an emergency Caesarean section developed a severe coagulopathy following the reinfusion of 1110 mL of salvaged blood. She required further blood component therapy and was also given rVIIa.

Lessons and recommendations from the 2010 SHOT report

The medical assessment and management of patients receiving blood transfusions

Numerous reports this year in the TACO and I&U chapters have shown that there is often inadequate medical assessment of patients before the prescription of blood components followed by suboptimal monitoring of transfusion episodes. Salient findings include the following:

- Lack of attention to fluid balance, particularly in patients over 70 years of age and those with concomitant medical conditions that predispose to TACO, such as cardiac failure, renal impairment, hypoalbuminaemia and fluid overload.
- Lack of appreciation that the rate of transfusion is another risk factor in the development of TACO.
- Over-transfusion when prescribing red cells for smaller patients. The evidence base for weight-related prescription of red cells in older children and adults is poor and the rule that 1 unit of red cells gives an increment of approximately 1 g/dL Hb can at best only be applied to a 70–80 kg patient. For patients of lower body weight the prescription should be reduced.
- Over-transfusion in patients with minor but ongoing blood loss, owing to the lack of regular monitoring of the Hb after every 2 or 3 units of red cells.

Learning points

- In those patients predisposed to TACO, careful assessment must be made of their pre-transfusion fluid balance status and the tolerable rate of transfusion, followed by very careful monitoring during transfusion.
- In the absence of massive haemorrhage, the patient's Hb should be checked after every 2 or 3 units of red cells.

Recommendations

- The existing British Committee for Standards in Haematology (BCSH) guidelines for the Administration of Blood Components should be supplemented by an amendment dealing with measures to avoid the development of TACO and over-transfusion, particularly in vulnerable patients, including pre-transfusion clinical assessment, rate of transfusion, fluid balance, regular monitoring of Hb and prescription of diuretics.

Action: BCSH Transfusion Taskforce

- There should be a systematic review of the application of weight-related empirical formulae or algorithms in prescribing for low body weight adults.

Action: NHS Blood and Transplant

Recognition and management of ATR

Anaphylactic transfusion reactions present a challenge since although they occur most frequently during the first 15 minutes of a transfusion (mean time to onset 26 minutes in the cases reported in 2010), there is a risk throughout the transfusion episode. The symptoms and signs of other ATRs are frequently not unique and may be mistakenly attributed to the patient's underlying condition or therapy. Any significant change in symptoms, signs or physiological monitoring during transfusion should lead to prompt clinical assessment and intervention.

Learning point

- Transfusion should only take place if there are sufficient competent staff available to monitor the patient and the patient can be readily observed throughout the transfusion episode.

Recommendation

- Transfusions should only be performed where there are facilities to recognise and treat anaphylaxis, according to the UK Resuscitation Council guidelines. In supplying to community hospitals or for home transfusions, providers must ensure that staff caring for patients have the competency and facilities to deal with this adverse reaction.

Action: Hospital transfusion committees (HTCs)

Clinical knowledge and handover information related to transfusion

There is evidence in this year's report that whilst some prescribing errors leading to I&U transfusions are undoubtedly due to a lack of knowledge of transfusion medicine by the (usually junior) doctor, there are many instances where it is clear that the doctor has insufficient information about the patient to prescribe safely. Examples include overlooking previous test results or decisions documented in the notes concerning the need for transfusion, and prescriptions produced for the wrong patient or the wrong component.

With respect to medical staff training, requests from the Royal Colleges/Specialist Societies subgroup of the National Blood Transfusion Committee to the Postgraduate Medical Education and Training Board and the General Medical Council for the inclusion of blood transfusion in undergraduate teaching and Foundation Year competencies have been unsuccessful. However, to limit avoidable patient morbidity and mortality arising from blood transfusion SHOT is firmly of the opinion that knowledge of prescribing blood components must be recognised as a core requirement of medical training.

Furthermore, clinical handover templates should include the decisions taken for future management of the patient, including planned transfusion support.

Recommendations

- Transfusion medicine must be part of the core curriculum for doctors in training.

Action: Education working groups of national transfusion committees

- To avoid I&U transfusions due to lack of adequate clinical handover, decisions made concerning the need for transfusion support should be documented in the clinical handover templates.

Action: Trusts/hospitals

DH 'never events' list 2011/12

This revised list now includes 'Death or serious harm as a result of the inadvertent transfusion of ABO-incompatible blood components'. This emphasises the need for all organisations that undertake blood transfusion to take all reasonable measures to prevent 'wrong blood' incidents.

It is encouraging that there have been fewer clinical and laboratory errors in the 2010 SHOT report leading to ABO-incompatible transfusions, with only 1 case of major morbidity and no deaths. This is likely to be due to the impact of efforts to improve training and competency assessment (for example NPSA SPN 14) in the clinical area and a combination of the requirements of meeting the BSQR 2005 and the recommendations of the UKTLC in the laboratory. However, in the current difficult healthcare financial climate, there are concerns that the resources to maintain these improvements may be, or are being, eroded.

With respect to the clinical area, a recent survey on the implementation of the Health Service Circular 2007/001 in England and North Wales has shown that only 77% of Trusts have provided competency-based training and assessment for blood administration for 50–91% of staff. Furthermore, the 2010 National Transfusion Practitioner Survey of England and North Wales emphasised that transfusion practitioners typically spend the majority of their time ensuring compliance with NPSA SPN 14 and BSQR 2005, to the detriment of involvement in transfusion safety initiatives or reducing inappropriate blood component use. This is a critical factor in 25% of transfusion practitioners being dissatisfied with their role. Furthermore, one-third of respondents commented that they receive little support from managers and the Trust in general.

As in previous reports, SHOT emphasises the recommendations of the UKTLC with regard to hospital transfusion laboratory staffing, technology, training and competencies. A number of the reports sent to SHOT this year commented that low staffing levels, stress and absence or unavailability of senior staff members contributed to human error in the transfusion laboratory. These incidents, and those analysed in previous SHOT reports, add weight to the UKTLC recommendations for training programmes and annual competency assessment for *all* staff who work at any time in the transfusion laboratory. SHOT also supports the recommendations on routine use of 'walk away' automation, used 24/7 to eliminate manual errors, and the use of electronic issue of red cells, where national guidelines are met. Six out of seven grouping errors reported this year and all grouping errors in the near miss chapter of the full SHOT Annual Report were made using manual procedures.

Recommendations

- There should be a review of the practical aspects of the implementation of NPSA SPN 14 and other national transfusion competency initiatives with a view to new guidance being issued. All hospitals and Trusts should ensure that individual transfusion practitioners are fully supported and resourced to perform their key roles, and that training and competency assessment in transfusion is delegated to 'link' staff and clinical educators with allocated time, where appropriate.

Action: National transfusion committees, Trust/hospital chief executive officers

- Organisations with transfusion laboratories should implement the recommendations of the UKTLC.

Action: Trusts/hospitals

- Work should continue with suppliers of laboratory information management systems to improve the capability of IT systems to generate warning flags and implement component selection algorithms based on data incorporated in the component label. These improvements should be in line with the recommendations of the BCSH guidelines on laboratory IT systems currently in preparation.

Action: Manufacturers of laboratory IT systems

Rapid Response Report NPSA/2010/017: The transfusion of blood and blood components in an emergency

SHOT has requested reports of under or delayed transfusion and although only 2 reports have been submitted (and it is recognised that there is substantial under-reporting), both show a lack of understanding of the requirement to make blood components rapidly available for patients with massive haemorrhage in line with the recommendations of the NPSA Rapid Response Report 2010/017.

SHOT fully supports the content of this publication, which requires all organisations to have robust protocols that emphasise the importance of clearly understood communication channels between the clinical area and the laboratory, and outlines the actions and responsibilities of both parties in this emergency situation.

SHOT encourages the continued reporting of such events but recognises that the current Dendrite database requires enhancement to fully capture all salient details.

Recommendations

- All under and delayed transfusions that have an impact on patient outcomes should be reported to SHOT.

Action: HTTs

- The Dendrite database should be enhanced to fully capture the salient clinical features and details of the timeliness of blood component support.

Action: SHOT team

Haemolytic transfusion reactions in sickle cell disease

Patients with sickle cell disease were again the subject of acute and delayed HTR. In addition to the 1 patient who died following an episode of post-transfusion hyperhaemolysis, another probably had a delayed HTR that was overlooked because all of the symptoms were attributed to sickle crisis and further transfusion of antigen-positive red cells could have been avoided. A third patient could have avoided a delayed HTR if a transfusion history had been known or if the patient had been carrying an antibody card. Distinguishing between a sickle crisis and immune haemolysis can be difficult but is aided by serial measurements of Hb, reticulocyte counts, HbS/A% and urinary high-performance liquid chromatography (HPLC).

Learning points

- A hyperhaemolytic transfusion reaction (in which both autologous and transfused red cells are destroyed) should be suspected if the patient rapidly develops a more marked anaemia than was present pre-transfusion. Further transfusion should be avoided if possible, since this may exacerbate the haemolysis and lead to a protracted course or even death. Expert advice should be sought from a specialist sickle cell disease unit or a Blood Service transfusion medicine specialist.
- A delayed HTR should be considered in the differential diagnosis of patients with sickle cell disease presenting with an apparent haemolytic crisis up to 14 days post transfusion.

CONCLUSION

SHOT was first established in 1996 as an independent, professionally-led UK haemovigilance scheme, initially on a voluntary basis. Since the first year, when 141 reports were submitted, participation has increased year on year until in 2010, 94.7% of NHS organisations reported 1464 cases. Whilst total reports have increased, transfusion-related deaths and major morbidity have fallen in the UK from 34% of total reports in 1996/1997 to 7.8% in 2010. In particular, ABO-incompatible transfusions have decreased from a peak of 34 of 156 IBCT reports in 1999/2000 to 4 of 200 in 2010, and IBCT events now comprise 13.6% of total reports as opposed to 39.6% in 1996–2009. These improvements have been achieved as a result of the increased awareness of blood safety issues and the initiatives arising from the SHOT data and recommendations.

SHOT data have also provided the evidence basis for strategies to improve the safety of the blood supply, such as the preferential use of male plasma donors by the Blood Services in 2003 to reduce the risk of TRALI and measures to reduce the risk of bacterial contamination of blood components. There has been a significant fall in bacterial TTI by platelets in response to measures such as enhanced donor arm cleansing and diversion pouches and SHOT will continue to monitor the impact of newer initiatives such as routine automated bacterial screening of platelets.

In this year's report the emphasis has changed. Reports of mortality and morbidity from TACO and over-transfusion have increased. Although this partly represents improved awareness and reporting, it is clear that insufficient attention is often given to the medical assessment of patients prior to the transfusion together with errors in prescribing and inadequate monitoring of their response to transfusion. Cases reported to SHOT continue to highlight gaps in doctors' knowledge of transfusion medicine and the special requirements of their patients, problems of communication, especially around clinical handover, and misinterpretation of laboratory results.

The number of ATRs being reported continues to rise, again largely due to increased awareness and better reporting processes in hospitals. Recognising that initial classification of the type of ATR or its distinction from a change in the patient's underlying condition can be difficult, it is essential that all potentially serious adverse clinical events occurring during a transfusion episode are assessed and treated promptly (this will be addressed by a forthcoming BCSH guideline). Patients should only be transfused in locations that have the facilities and competent staff to treat potentially fatal anaphylactic reactions.

SHOT is indebted to all reporters who have provided the case material for this Annual Report and to the members of the Working Expert Group, who have provided invaluable expertise.

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