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SERIOUS HAZARDS OF TRANSFUSION SHOT

ANNUAL SHOT REPORT 2011 SUMMARY

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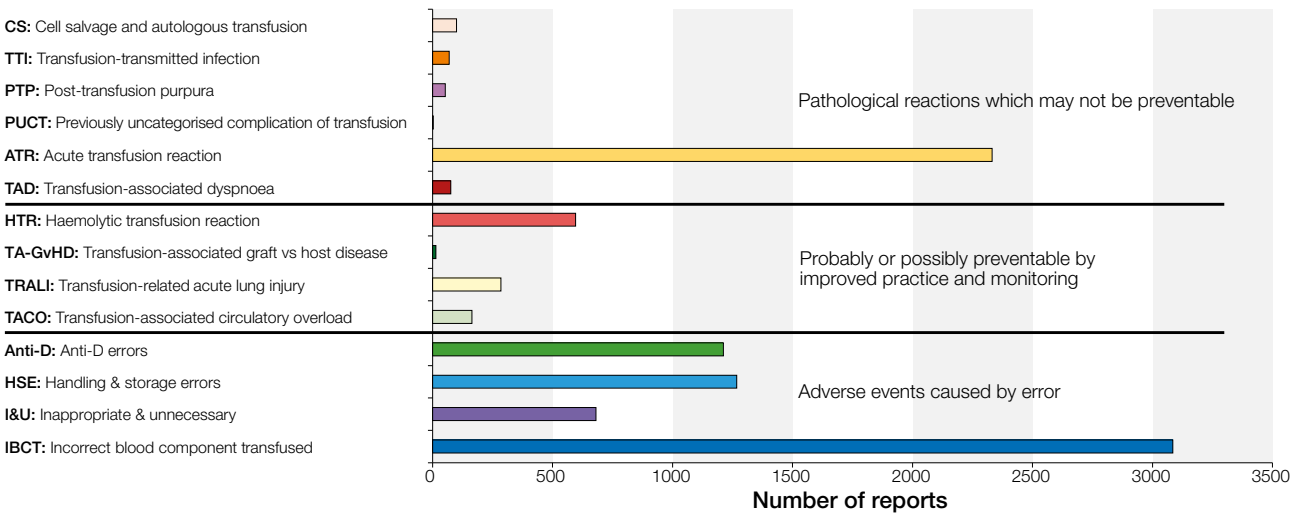
Introduction

The 15th Annual SHOT Report is compiled from data received between January and December 2011 by the SHOT UK national haemovigilance scheme. We are approaching universal participation with 98.4% of National Health Service (NHS) Hospitals, Trusts and Health Boards across the UK now registered to report to SHOT and registrations for independent organisations have also increased. The number of reports has increased to a total of 3038 in 2011 (this total includes 'near miss' n=1080 and 'right blood right patient' n=159 events which by definition caused no harm). This is an increase in analysed reports of 23.3% (3038 vs 2464) compared to the 2010 Annual Report. For the second consecutive year there were no transfusion-transmitted infections.

It is disappointing that half of all the events reported to SHOT in 2011 relate to errors in the basic transfusion process. The key lesson from 2011 is therefore '**back to basics**'.

Figure 1 shows that many incidents are potentially preventable; particularly all adverse events due to errors, and also pathological reactions caused by TA-GvHD, TRALI and TACO. In addition, some cases of haemolytic transfusion reactions (HTR) could be prevented if the diagnosis (e.g. sickle cell disease) and previous transfusion history (or presence of alloantibodies in the past) were more carefully obtained.

Figure 1: Cumulative numbers of cases reviewed 1996-2011 n=9925



Back to basics

'Back to basics', the key lesson from 2011, is an emphasis again on the importance of the essential steps of the transfusion process: taking the blood sample from the correct patient, correct laboratory procedures, issuing of the correct component and finally, identification of the right patient at the bedside at the time of transfusion. It is clear from the SHOT 2011 data that identification of the correct patient remains a key issue and that this must become a core clinical skill. The observation that mistakes are still made by individuals despite competency assessment has underlined the need to review education (to ensure a sound knowledge base) and competency, and communication failures arising between shifts or from shared care must be addressed by improved handover.

About half of the cases reported to SHOT are due to preventable mistakes. Analysis of the 'near miss' data for the past two years indicates that for every 'wrong blood in tube' error that results in a wrong blood incident, there are about 100 'near miss' sample mistakes. Similarly, most of the serious adverse events reported to the Medicines and Healthcare products Regulatory Agency (MHRA) are also attributable to human error (788/811). For the first time this year the SHOT report includes a chapter from the MHRA Serious Adverse Blood Reactions and Events (SABRE) reporting system (1556 reports) and work has begun to see to what extent our two systems for haemovigilance can be harmonised.

KEY RECOMMENDATIONS – BACK TO BASICS

- **CORRECT PATIENT IDENTIFICATION** should be a core clinical skill. Errors of identification impact on every area of medicine. The use of a transfusion checklist across the complete transfusion process is recommended to ensure correct completion of each step. A model template can be found on the SHOT website at www.shotuk.org/resources/current-resources/

  Action: Trust/hospital/Health Board Chief Executive Officers (CEOs); for formal consideration by the General Medical Council (GMC) and the Nursing and Midwifery Council (NMC)

- **EDUCATION AND COMPETENCY** in blood transfusion safety remains a key issue in patient safety. Competency assessment must be underpinned by an adequate and assessable knowledge base for both laboratory and clinical staff at every level.

  Action: UK Transfusion Laboratory Collective, UK NEQAS (Blood Transfusion Laboratory Practice), Education subgroup of the National Blood Transfusion Committee

- **KNOWLEDGE OF TRANSFUSION MEDICINE AND OF PRESCRIBING/AUTHORISING** of blood components are essential core requirements for any practitioner (medical and nursing) who prescribes or authorises blood components.

  Action: For formal consideration by the GMC, NMC

- **CLINICAL AND TRANSFUSION LABORATORY HANDOVER** templates should be improved to include information about diagnosis (particularly haemoglobinopathies), irregular antibodies and special requirements. Patients are vulnerable with the increase in shared care between hospitals, within a hospital particularly between shifts, and between hospital and community. (A handover toolkit for acute care is available at http://www.rcplondon.ac.uk/resources/acute-care-toolkit-1-handover)

  Action: Trust/hospital/Health Board CEOs, General Practitioners

Overview of the 2011 Report

Acute transfusion reactions (ATR) provide the largest category of pathological and unforeseen reactions, and were the leading cause of major morbidity in 2011. Transfusion-related circulatory overload (TACO), and inappropriate, unnecessary or under/delayed (I&U) transfusions remain important causes of potentially avoidable major morbidity and death.

Figure 2: Cases reviewed in 2011: Overall n=3038 reports (3054 cases); but the data in this graph represents n=1815 analysed cases, because it excludes 'near miss' and 'right blood right patient' cases.

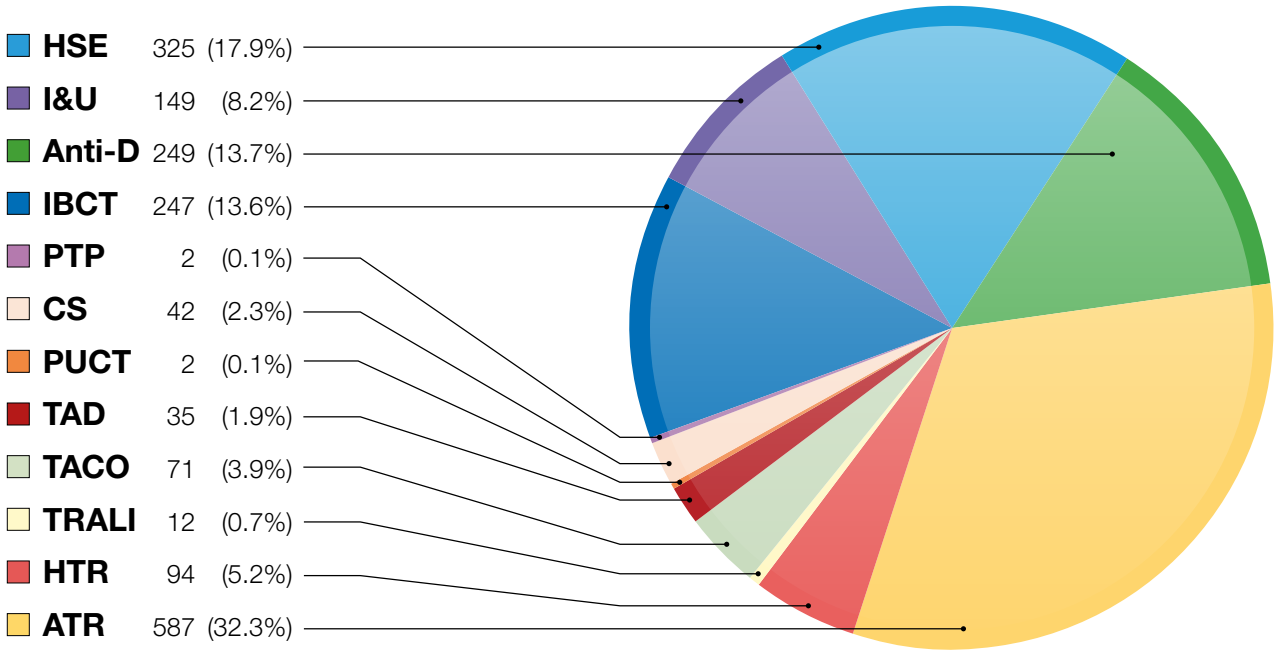


Figure 2 shows that other pathological reactions remain infrequent following measures taken by the UK Blood Services (e.g. use of male plasma to reduce the risk of transfusion-related acute lung injury (TRALI), and strategies to reduce the bacterial contamination of blood components).

Deaths n=8

There were two deaths definitely related to transfusion (imputability 3). One occurred in an elderly woman who received an excessive transfusion in relation to her low body weight resulting in death from TACO, and the other related to delayed and inadequate transfusion in a woman after childbirth.

The other six deaths were of lower imputability (1) including 2 deaths after acute transfusion reactions, 1 in relation to TRALI, 2 in relation to TACO and 1 death occurred in a premature infant who developed necrotizing enterocolitis following transfusion (relationship uncertain in this case which is categorised under PUCT).

Major morbidity n=117

Acute transfusion reactions (ATR n=53): As in 2010, the largest number of episodes that were complicated by major morbidity was due to ATR. These were individuals with severe or life-threatening reactions who required urgent treatment.

Pulmonary complications of transfusion (Transfusion-associated circulatory overload (TACO) n=24, Transfusion-associated dyspnoea (TAD) n=3 and TRALI n=8): TACO continues to be the largest group of pulmonary reactions with 23/24 requiring intensive or high-dependency care, and one required emergency dialysis. The median age of patients with TACO was 72 years, and the median duration of a red cell unit transfusion was short, 2.5 hours, suggesting that some susceptible elderly patients are being transfused too rapidly.

Haemolytic transfusion reactions (HTR n=11) Nine instances of major morbidity occurred after delayed HTR and 5 of these had sickle cell disease. People with haemoglobinopathies (particularly sickle cell disease – 5 cases in 2011) are at high risk of haemolytic complications. Some of these reactions occurred due to failure to inform the laboratory about known sickle cell disease (so that appropriately typed red cells were not provided) and others relate to failure in the laboratory to discover or heed previously documented alloantibodies.

Errors in the transfusion process (n=16: incorrect blood component transfused (IBCT) n=2, anti-D n=9, inappropriate, unnecessary or delayed transfusions (I&U) n=5): Major morbidity occurring as a result of mistakes in the transfusion process continues to be disappointing. **IBCT** - Two patients experienced serious reactions after ABO incompatible transfusions. **Anti-D** immunoglobulin (Ig) - Mistakes in the interpretation or administration of Anti-D Ig this year resulted in 2 mothers developing new immune anti-D. In addition 7 mothers developed immune anti-D during pregnancy which was not recognised, and 6 babies suffered varying degrees of RhD haemolytic disease, 3 requiring transfusion. **I&U** - Three patients experienced major morbidity associated with delayed transfusion.

The other two cases with major morbidity were 1=PTP and 1=PUCT (a child who developed necrotising enterocolitis after a transfusion -relationship not proven).

Table 1: Mortality/morbidity data 2011

	Total	IBCT	I&U	HSE	ANTI-D	ATR	HTR	TRALI	TACO	TAD	PTP	PUCT	TA-GvHD	TTI	CS
Death in which transfusion reaction was causal or contributory	8	0	2	0	0	2	0	1	2	0	0	1	0	0	0
Major morbidity probably or definitely attributed to transfusion reaction (imputability 2/3)	117	2	5	0	9	53	11	8	24	3	1	1	0	0	0
Minor or no morbidity as a result of transfusion reaction	1690	245	142	325	240*	532	83	3	45	32	1	0	0	0	42
TOTAL	**1815**	**247**	**149**	**325**	**249**	**587**	**94**	**12**	**71**	**35**	**2**	**2**	**0**	**0**	**42**

** Cases with potential for major morbidity are included in minor or no morbidity. CS=cell salvage autologous transfusion*

Additional lessons and recommendations from the 2011 SHOT Report

Laboratory errors increased slightly in 2011 to 217 compared with 205 in 2010. There were 7 ABO grouping errors, 4 of which occurred in emergency situations when staff may have been rushed and tempted to take short cuts. The presence of anti-D in pregnant women must be carefully interpreted; in 7 women anti-D was assumed to be due to prophylaxis when it was in fact immune anti-D. The misinterpretation meant that these pregnancies were not followed as closely as they should have been, resulting in the 6 cases of RhD haemolytic disease of the newborn detailed above.

The reduction in manual steps associated with the use of laboratory information management systems (LIMS) adds additional safety but needs to be set up with correct flags that should not then be ignored or overridden. It is very important to take into account all the relevant patient history and to search for previous results particularly for patients with haemoglobinopathies.

Lessons for laboratory staff

Standards for emergency grouping (see BCSH guidelines for compatibility testing 2004 www.bcshguidelines.com and an update is in progress 2012):

Learning points

- The ABO and RhD group must, wherever possible, be verified against previous results for the patient.
- Emergency groups performed in these circumstances MUST include a test against anti-A, anti-B and anti-D with appropriate controls or a reverse group.
- If there is insufficient time to complete this level of testing, group O red cells MUST be issued. Short cuts lead to errors. Standard procedures must be followed. Transfusion laboratories should have a procedure for abbreviated pre-transfusion testing for provision of blood in emergencies.

Standards for interpretation of Rh and other irregular antibodies

Learning point

- It is essential that staff performing antenatal screening for blood group serology understand the importance of obtaining all the relevant history before interpreting whether the presence of anti-D antibodies may be as a result of prophylaxis or immune anti-D.

Laboratory recommendations

Laboratory information management systems improve safety by removing manual steps, but must be set up carefully (74 cases related to IT systems are included in the 2011 report Chapter 8 and additional recommendations are detailed there)

- Where possible all critical processes in the transfusion laboratory should be under the control of the Laboratory Information Management System.

  Action: Transfusion Laboratory Managers, Pathology IT managers, LIMS Providers

- When new IT systems are implemented, and existing systems upgraded, they should be validated using a wide range of scenarios to ensure they are working as intended.

  Action: Transfusion Laboratory Managers, Pathology IT managers, LIMS Providers

Lessons and recommendations for clinical areas

Identify and communicate any special requirements to the laboratory and to colleagues

Special requirements not met: Problems arise when clinicians fail to inform laboratories of important diagnoses, particularly sickle cell disease, and other special requirements, such as the need for irradiated components.

Learning point

Communication failures are particularly likely to occur where patients are under shared care in more than one hospital, or between the hospital and community care.

Recommendation

- Patients with special requirements must be identified to the laboratory – patients can be provided with cards (obtainable from the UK Blood Services) indicating their need for irradiated products, and cards are also appropriate for patients with haemoglobinopathies, and those with irregular red cell antibodies (provided by UK Blood Service reference laboratories). Such information should be explained carefully to the patient at a face-to-face meeting.

  Action: Trusts/Health Boards/Hospitals, Hospital Transfusion Teams (HTTs), Education subgroup of the CMO's National Blood Transfusion Committee (NBTC) with patient support groups

Do not subject the patient to transfusion unless it is clearly indicated

Inappropriate transfusions (35.5% increase, 149 in 2011 compared to 110 in 2010) continue to occur in many cases due to wrong blood results (53 cases of wrong Hb, 8 wrong platelet results).

Learning point

Patients should be carefully assessed with regard to transfusion appropriateness, and blood tests repeated if results are unexpected. As recommended in 2010, laboratory staff should be empowered to challenge requests for components when a repeat test has been requested but not received, and should not issue results which they suspect to be incorrect.

Inappropriate treatment of iron deficiency anaemia was noted in 5 cases of TACO and in 5 cases of I&U.

Recommendation

- Blood transfusion is not an appropriate treatment for iron deficiency and puts patients, particularly the elderly, at risk of TACO. Iron deficiency should be diagnosed and appropriately corrected with iron supplements, and the underlying cause established and treated.

  Action: All clinical staff

  Understand the major haemorrhage protocol and practice it

- Emergency transfusion in acute haemorrhage: Practice drills for activation of major haemorrhage protocols should be regularly performed to ensure that all staff know what to do in an emergency.

  Action: Transfusion Laboratory Managers, Clinical Risk Managers, Medical Directors

Acute transfusion reactions: There are many causes for acute transfusion reactions which may be difficult to distinguish. These include anaphylaxis but also bacterial infection and pulmonary complications. Reporters are encouraged to report in as much detail as possible, and will be triggered to fill in the new pulmonary questionnaire if there is dyspnoea. Reactions to FFP occur and may be serious. There is current concern about methylene blue-treated FFP in some countries where it may be associated with an increased incidence of serious reactions. SHOT has not observed any increase in the UK to date.

Learning point:

Patients with serious ATR need further investigation and forward planning for transfusion management in the future.

Be careful not to miss bacterial infections

Recommendations for acute transfusion reactions

- If there is reason to suspect bacterial contamination, it is important to contact the Blood Service, even if the hospital is performing their own cultures of the unit, in order that the need for a recall of associated components can be considered promptly.

  Allergic reactions must be reported and plans made for safe future transfusions

- Any reactions to FFP (all types) should be reported to SHOT and investigated in detail.
- Patients who have experienced an anaphylactic transfusion reaction should be discussed with an immunologist regarding further investigation and management.

  Action: Hospital Transfusion Committees (HTCs), Haematologists

Pulmonary complications of transfusion

It can be difficult to decide on the cause of respiratory symptoms associated with transfusion. This results in cases being moved between categories (20 cases moved to TACO in 2011 from other categories and 19 moved to TAD).

Analyse carefully the causes of dyspnoea associated with transfusion

Recommendation:

- Reporters are encouraged to obtain as much information as possible for all types of reports to SHOT, and to update their reports if more information becomes available. Reporters will be directed to a common pulmonary questionnaire when reporting dyspnoea in ATR, as well as when reporting known pulmonary complications (TRALI, TACO and TAD). This will enable more accurate classification of pulmonary complications of transfusion, because cases can be transferred more easily between categories and particularly will allow better recognition of TAD and its appropriate investigation and management.

  Action: Hospital transfusion teams

- TACO is a particular risk for elderly patients and may be preventable with improved pre-transfusion assessment to identify additional risk factors, to assess the need for a reduced rate of transfusion and diuretic cover and to consider if transfusion can be avoided. Fluid balance should be monitored carefully and recorded.

  Action: Transfusion practitioners, Hospital Transfusion Teams, Hospital Transfusion Committees

Safe transfusion practice

The deaths and major morbidities reported in 2011 demonstrate the importance of appropriate assessment of all patients prior to transfusion, to ensure that a transfusion is appropriate, that the rate and amount are correct for that patient and that the transfusion is completed with appropriate monitoring as recommended by BCSH guidelines 2010 (www.bcshguidelines.com/documents/Admin_blood_components_bcsh_05012010.pdf). Patients should be educated to report adverse events occurring in the several days after transfusion.

SHOT updates and developments

From January 2012 the TAD, TACO and TRALI questionnaires have been replaced by a new common pulmonary questionnaire and ATR reports listing dyspnoea as the main symptom will trigger the same questionnaire. The reporter will need to decide which category to report to, but once a report is made in any of these categories it can be transferred between them if necessary without the need for a new questionnaire to be completed. Please see some minor changes to some definitions which are listed on the SHOT website.

SHOT and MHRA are working in collaboration towards a more integrated haemovigilance reporting system. For the first time, in the 2011 report a chapter is included from the MHRA. SHOT and MHRA staff are meeting regularly to reconcile case-reporting data.

Discussion with several specialist groups has identified interest in summarising SHOT data by specialty in addition to by event. Work is progressing on this and a chapter on haemoglobinopathies is included in the 2011 report.

New reporting categories:

Anti-D immunisation: There are continued failures to administer anti-D Ig in a timely manner to RhD negative women at risk. A checklist for anti-D administration is available on the SHOT website to assist practitioners to get this right (www.shotuk.org/resources/current-resources/). In addition, the presence of immune anti-D antibodies during pregnancy has been erroneously interpreted to represent the result of prophylactic doses given earlier. There are also concerns that current prophylaxis regimens may not result in an adequate level of anti-D at birth. From 2013 SHOT plans to collect information about women who are found to have immune anti-D at booking, during pregnancy or at delivery.

Haemosiderosis as a result of transfusion may have serious consequences and is included in the international haemovigilance definitions. SHOT does not collect information about people with haemoglobin disorders who are on regular transfusion regimens, but is interested to receive reports of other cases of iron overload, such as people transfused for haematological disorders whose overall transfusion burden may be overlooked.

General updates:

Guidance has been issued by the Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO) about consent for blood transfusion recommending verbal consent documented in the case notes. Patients need adequate information, and those receiving transfusions who were unable to give consent at the time of transfusion should be informed and consented in retrospect.

In March 2012 SaBTO published a position statement on cytomegalovirus (CMV) tested blood components. The recommendations are that CMV seronegative components should continue to be provided for intrauterine transfusions and for neonates, and for elective transfusions during pregnancy (but are not essential for emergency transfusions during pregnancy). A search for evidence led SaBTO to conclude that there is no support for using CMV seronegative components for immunodeficient patients and that CMV seronegative components are therefore not necessary following haematopoietic stem cell transplantation (HSCT). SaBTO also advises that CMV PCR monitoring should be considered for all patients to allow early detection of any possible CMV infection (whether transfusion-transmitted or not).

Cases of suspected transfusion-transmitted CMV infection are, and always have been, reportable to SHOT. The changes in the recommendations will mean that the issue of non-CMV screened components to immunodeficient or HSCT recipients will no longer be regarded as 'special requirements not met' even if there are local policies in place which still require CMV seronegative components. Where errors are made according to local policies, they should be reported and investigated locally.

CMV is the most frequent infection following solid organ transplant but there is no evidence that this is related to transfusion transmission, and therefore organ transplant recipients do not need CMV seronegative blood.

Both of these recommendations can be viewed in full on the SaBTO website (www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_132965)

Recommendation:

- With the change in recommendations for CMV-screened products from SaBTO, hospitals are reminded that suspected transfusion-transmitted CMV infection should continue to be reported to SHOT, the Health Protection Agency (HPA) and MHRA.

  Action: General practitioners, hospital doctors, HTTs

In 2012, the General Medical Council published an updated version of 'Good Medical Practice' which includes a new section on safety and quality. The recommendations include the instruction to doctors that they 'must help to reduce risk to patients by providing information for confidential inquiries and significant event recognition and reporting, to help reduce risk to patients'. This means reporting adverse events related to transfusion to SHOT and/or MHRA as appropriate.

Conclusions

Transfusion of blood components in the UK remains remarkably safe, with the risk of death 0.0027 and risk of major morbidity 0.0396 per 1000 components issued respectively. However, the level of error in the transfusion process is a cause for concern, indicating the need for continued education, which should underpin competency assessment, and vigilance. Checklists are very useful to ensure all the steps of a process have been completed; information on these is given above. Any unexpected transfusion reactions must be promptly recognised and treated and continue to be reported to ensure patient safety, particularly with the advent of new products and changing policies in relation to CMV screening. All staff involved in transfusion should remain aware that they have a duty of care to report adverse events which potentially or actually affect patient safety.