

ANNUAL SHOT REPORT 2012

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SUMMARY

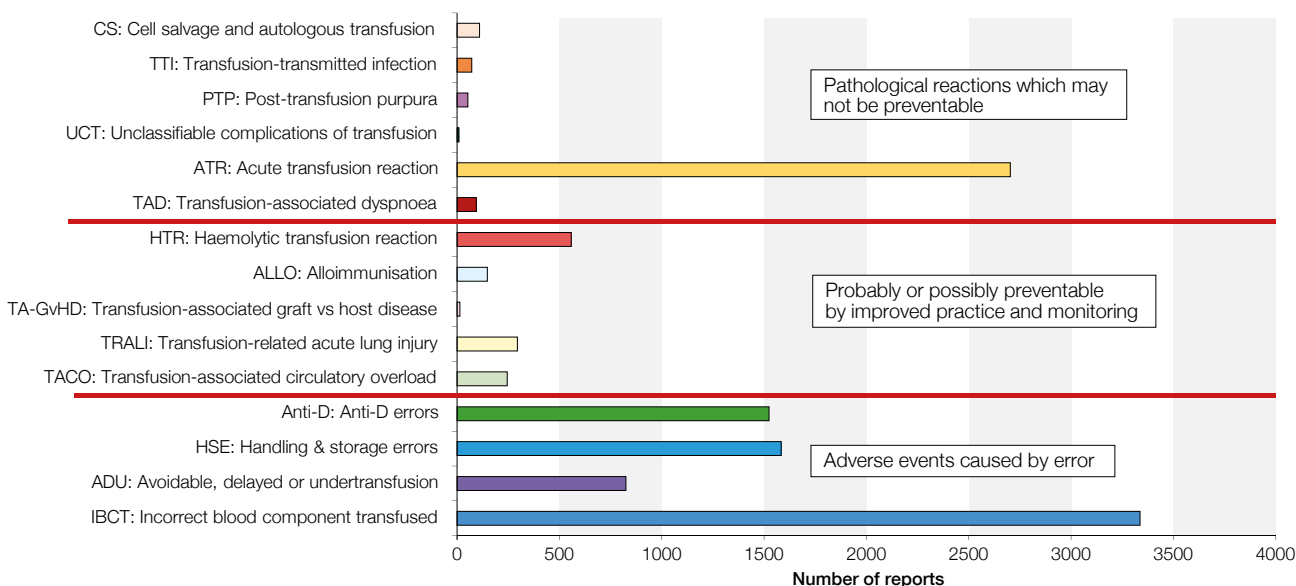
Introduction

The 16th Annual SHOT Report is compiled from reports submitted, and subsequently completed between January and December 2012, to the SHOT UK haemovigilance scheme. We now have 99.5% of National Health Service Trusts and Health Boards across the UK registered to report to SHOT. The number of reports submitted for 2012 was 3545 (a 3.2% increase compared with 2011) of which 2466 have been analysed in this year's report (the majority of the remainder, including mild acute transfusion reactions which are not required to be reported, were withdrawn). In addition, 172 reports are carried over from 2011 as they were not completed in time for last year's report. This brings the total reports analysed to 2638 relating to 2767 incidents (145 multiple incidents in 16 single reports). The total includes 'near miss' (n=980) and 'right blood right patient' (n=142) events that by definition caused no harm.

New incidents this year included transfusion-transmitted viral infections (parvovirus, hepatitis B and hepatitis E infections) and a death in infancy from transfusion-associated graft versus host disease following an emergency intrauterine transfusion of maternal blood (for anaemia caused by parvovirus). This has resulted in a national review of procedures in fetal medicine units and recommendations for safer practice, detailed below.

Disappointingly, more than half of the cases reported to SHOT, 1026/1645 (62.4%) this year, are due to preventable mistakes (this excludes the 'near miss' and 'right blood right patient' reports where no harm was done but, which, if included bring the errors to 2148/2767 (77.6%)), with the remaining 619/1645 (37.6%) due to pathological reactions. This is a higher percentage of errors than in 2011 (53.4%). Figure 1 shows cumulative numbers in all categories over 16 years. The leading category of pathological (and unpredictable) incident is acute transfusion reactions. However, the leading error remains incorrect blood component transfused. Figure 2 shows the distribution of cases for 2012. There were 10 reports of ABO incompatible red cell transfusions reported, all resulting from clinical errors; 4 resulted in major morbidity from haemolysis (Department of Health 'Never Events' 2012), fortunately there were no deaths.

Figure 1: Cumulative data for SHOT categories 1996/7–2012 (n=11,570)



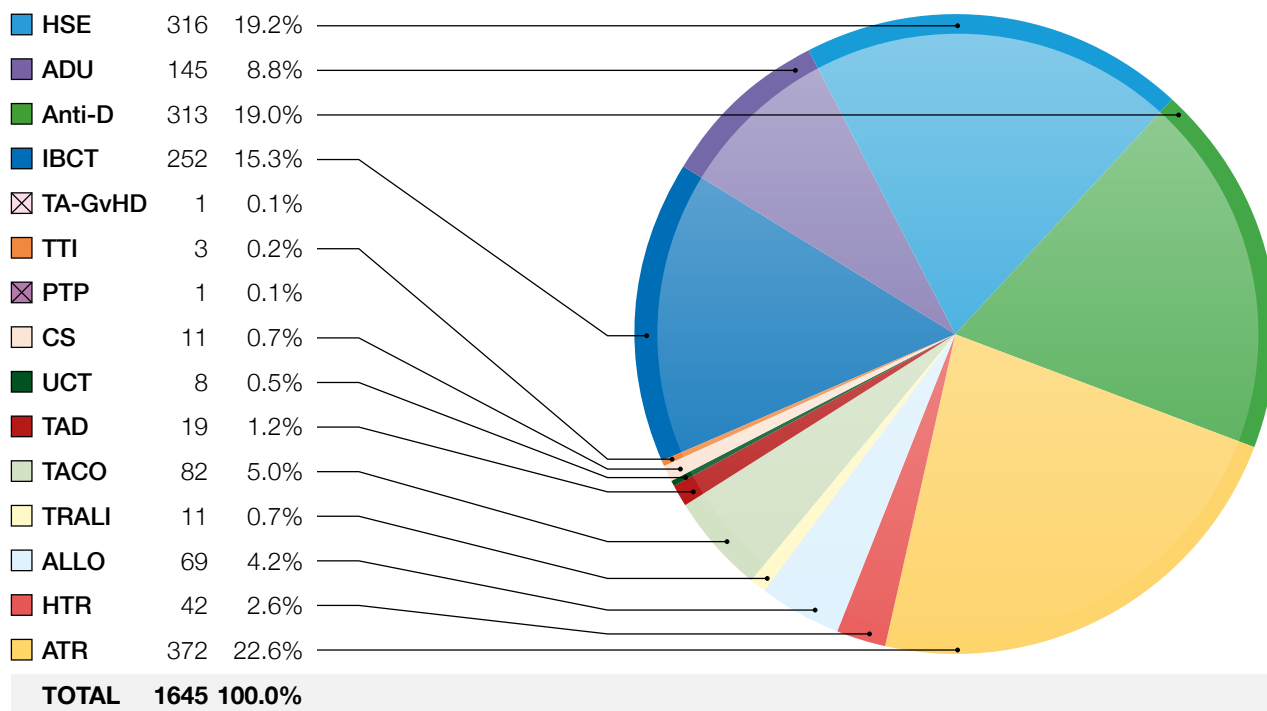
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SERIOUS HAZARDS OF TRANSFUSION

SHOT

Figure 2: Cases reviewed in 2012



☒ = The number of cases for TA-GvHD and PTP are too small to be represented on this Figure 2.

Patient identification and improved communication

The key lessons from 2012 are those emphasised every year: it is essential to confirm **the patient identity at every step of the transfusion process**. This focus on ‘back to basics’ needs to continue. It is clear from the SHOT 2012 data that mistakes frequently arise due to poor communication between clinical areas and the laboratory, and between different hospitals, departments within hospitals and between shifts. The increased fragmentation of medical care probably contributes to this. Multiple errors have been highlighted before (Annual SHOT Report 2004), and errors occur which could have been identified at the final check at the patient’s side, had this been done properly. As recommended last year, a **checklist for the transfusion process**, from patient through laboratory testing and back to the patient would likely reduce and possibly eliminate errors (see www.shotuk.org/resources/current-resources/).

Receiving a transfusion of a blood component should be treated in the same way as having a surgical procedure; the patient should be correctly and positively identified, the transfusion should be done in the right place (not across various wards) with appropriate resuscitation facilities, on the correct patient, at the right time (i.e. not overnight unless urgent or emergency), by the right person (i.e. staff who are trained in pre-transfusion clinical review and to recognise and treat immediate complications), under the care of a single named consultant, and with appropriate review and follow up. These measures are likely to reduce the risk of transfusion-associated circulatory overload.

Analysis of the ‘near miss’ data for the past three 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. Review of these events (980 in 2012) provides important learning opportunities. The majority originate in clinical areas, 694/980 (70.8%), and most of these (534/694) are sample errors due to ‘wrong blood in tube’, 505/534 (94.6%). These occur mainly because either the patient is initially not properly identified or the sample is not labelled at the patient’s side (together making up 79.6% of ‘wrong blood in tube’ errors). Doctors are the largest group responsible for ‘wrong blood in tube’ in 223/505 (44.2%) with nurses and midwives making up 186/505 (36.8%). Most of the serious adverse events reported to the MHRA are also attributable to human error. More work needs to be done to understand the ‘human factors’ which contribute to these as similar errors are reported in all areas of medicine, particularly in the prescription and administration of medication.

The number of laboratory errors has increased from 217 last year to 247 in 2012. Addition of cases of handling and storage errors, and anti-D immunoglobulin issues where multiple patients were affected, together with instances of ‘right blood right patient’, brings the total errors to 430/1168, accounting for 36.8% of all error-related events. As in 2011, where information is collected about competency assessment, the majority of personnel involved (71.4%) have passed their assessments (this information is collected for anti-D immunoglobulin errors, laboratory errors where the specific requirements are not met, and where an incorrect blood component was transfused).

Key Recommendations – Identification and Communication

- **Patient identification:** Correct and positive patient identification at every step remains absolutely essential, and is the responsibility of every member of staff. Hospitals/Trusts/Health Boards should review their identification procedures to ensure that patients are safely identified throughout their hospital journey. All UK patient safety programmes should take the identification agenda forward as part of person-centred care

Action: Patient safety programmes – for England the NHS Commissioning Board Special Health Authority; and equivalent bodies in Scotland, Wales and Northern Ireland. Hospital, Trust and Health Board Chief Executive Officers, Risk Managers, Pathology Laboratory Managers and all staff involved in blood transfusion

- **A zero tolerance policy** is recommended for the identification of all pathology specimens. In other words, samples should not be accepted by the laboratory for analysis without the standard 4 identifiers used for transfusion samples, first name, surname, date of birth and an identity number, ideally the National Health Service (NHS) number or equivalent. All pathology samples should be taken only after positive confirmation of identity, and be labelled at the patient's side

Action: Hospital Trust and Health Board Pathology Managers, supported by Chief Executive Officers

- **Communication and handover:** Hospital and primary care staff should work at building relationships to improve communication and handover. Communication failures within hospitals, between hospitals and between hospital and primary care are all responsible for adverse incidents. Good communication is required between laboratories and clinical staff and vice versa to ensure specific requirements are met, and correct results communicated to clinical areas

Action: All clinical and laboratory staff in Hospitals, Trusts and Health Boards, General Practice and Community Hospitals

ADDITIONAL RECOMMENDATIONS

- **Transfusion reactions:** All staff responsible for blood transfusion must know how to recognise anaphylaxis and other acute transfusion reactions. Transfusions should only take place where there are facilities to recognise and treat anaphylaxis and other adverse incidents, and local policies must ensure that procedures are in place to manage any adverse event or incident, including transfusions in the community

Action: Hospital Transfusion Teams, all clinicians involved in transfusion

- **Learn from adverse incidents:** Incident reviews and root cause analyses should be completed and the findings reported back to the participants and the patients to ensure that lessons are learned which may reduce future errors

Action: Hospital Risk Managers; Hospital Transfusion Teams; all clinicians

- **Near miss reporting:** Hospital staff should report near miss as well as actual incidents in keeping with good medical practice as defined by the General Medical Council (GMC). Reporting is mandatory, not voluntary, to ensure that the focus is improved patient safety

Action: Hospital Transfusion Teams

Overview of the 2012 Report

Acute transfusion reactions (ATR) continue to be the major cause of pathological and unpredictable reactions, and were the leading cause of major morbidity in 2012. Transfusion-associated circulatory overload (TACO), and avoidable, delayed or undertransfusion (ADU, formerly I&U) remain important causes of potentially avoidable major morbidity and death. Haemolytic transfusion reactions are a significant cause of major morbidity, particularly in patients with sickle cell disease.

Mortality/morbidity data 2012

	Total	IBCT	ADU	ANTI-D	ATR	HTR	TRALI	TACO	TAD	UCT	TA-GvHD	TTI	Others
Death in which transfusion reaction was causal or contributory	9	0	0	0	0	1	0	6	0	1	1	0	0
Major morbidity probably or definitely attributed to transfusion reaction (imputability 2/3)	134	11	2	4	68	9	8	29	0	0	0	3	0
Minor or no morbidity as a result of transfusion reaction	1502	241	143	309	304	32	3	47	19	7	0	0	397
TOTAL	1645	252	145	313	372	42	11	82	19	8	1	3	397

* Cases with potential for major morbidity are included in minor or no morbidity. IBCT=incorrect blood component transfused; ADU=avoidable, delayed or undertransfusion; Anti-D=errors with anti-D immunoglobulin administration; ATR=acute transfusion reactions; HTR=haemolytic transfusion reactions; TRALI=transfusion-related acute lung injury; TACO=transfusion-associated circulatory overload; TAD=transfusion-associated dyspnoea; UCT=unclassifiable complications of transfusion; TA-GvHD=transfusion-associated graft versus host disease; TTI=transfusion-transmitted infection; Others includes handling and storage errors, alloimmunisations, cell salvage and post-transfusion purpura

Deaths n=9

Transfusion-associated graft versus host disease (TA-GvHD) There was one death definitely related to transfusion (imputability 3, i.e. conclusive evidence of association). This was an infant who died from TA-GvHD, following an intrauterine transfusion (IUT) with maternal blood (non-leucodepleted, non-irradiated and related). The cause of the fetal anaemia was maternal parvovirus infection. Non-irradiated maternal blood should not be used for IUT. A survey of fetal medicine units established that this is rare. Irradiated, or even non-irradiated paedipacks may be used if there is not time to obtain a specific IUT unit; requests for IUT should involve early direct discussion between the hospital clinician and Blood Service consultant, and all fetal medicine units should develop a protocol detailing the available options.

The other 8 deaths were possibly or likely associated with transfusion. Three of imputability 2 (probably/likely related to transfusion) included 2 deaths from **haemolysis**, 1 after intravenous immunoglobulin treatment (with additional renal failure), and 1 due to a delayed haemolytic transfusion reaction from anti-Jk^a in an elderly unwell patient with myelodysplastic syndrome. The third death was due to **transfusion-associated circulatory overload (TACO)**. There were 5 other deaths from TACO, of imputability 1 (possibly related to transfusion).

Major morbidity n=134

Acute transfusion reactions – allergic, hypotensive and severe febrile (ATR) n=68: These were 50 individuals with severe or life-threatening reactions who required urgent treatment and 18 others who required admission to intensive or high-dependency care, or had renal dysfunction. There were 29 cases with anaphylaxis.

Pulmonary complications of transfusion (transfusion-associated circulatory overload (TACO) n=29, and transfusion-related acute lung injury (TRALI) n=8): TACO continues to be the largest group of pulmonary reactions. Together, death and major morbidity was reported in 35/82 (42.7%) cases of TACO, demonstrating the serious nature of this complication.

Haemolytic transfusion reactions (HTR) n=9: Five of the 9 cases of major morbidity occurred in patients with sickle cell disease (SCD). Over three years of reporting (2010–2012) there have been 16 cases of HTR in patients with SCD, with 11 (68.8%) instances of major morbidity or death. Some of these reactions were potentially preventable, occurring 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=17 (Incorrect blood component transfused (IBCT) n=11, anti-D errors n=4, avoidable, delayed or undertransfusion (ADU) n=2): Major morbidity occurring as a result of mistakes in the transfusion process continues to be disappointing. **IBCT** – 4 patients experienced serious reactions after ABO incompatible transfusions, 5 women developed anti-K following inappropriate transfusion of K positive units, and 2 patients were transfused with antigen positive units where their alloantibodies had been missed in the antibody screening panel. **Anti-D** immunoglobulin (Ig) – 4 mothers developed immune anti-D following delay or omission of

prophylaxis during the current or previous pregnancy. **ADU** – Two patients experienced major morbidity: one was a child massively overtransfused to a Hb of 270g/L because of inappropriate prescribing, and the other was a person of low body weight repeatedly transfused without reference to blood results, causing polycythaemia and renal impairment.

Transfusion-transmitted infections were reported this year in 3 instances (4 infections). A child with sickle cell disease developed proven transfusion-transmitted parvovirus infection. There was a case of hepatitis E transmission (not reported to SHOT in 2012) and 2 patients were infected with hepatitis B from a single donor.

Additional lessons and recommendations from the 2012 SHOT Report

Laboratory errors were increased in 2012 overall to 430 (including RBPR and multiple reports – see page 1) compared with 217 in 2011. The majority of these, 182/430 (42.3%) were handling and storage errors (mostly failures of cold chain monitoring). In 70 cases, specific requirements such as irradiation or phenotype selection were not met. In a third of incidents (10/31) where a wrong component was transfused, these were to haemopoietic stem cell transplant patients, one resulting in major morbidity from haemolysis.

The reduction in manual steps associated with the use of laboratory information management systems (LIMS) adds additional safety but these systems need 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

- SHOT reports have consistently demonstrated that the majority of ABO/RhD grouping errors result from manual testing or interventions. The ABO and RhD group must wherever possible be verified against previous results and the validated grouping method in use in the laboratory
- Correct patient identification is imperative and must always be ensured at each critical point of the laboratory process starting with entering patient demographics onto the laboratory information management system (LIMS)
- Maintaining an accurate patient database is a critical safety measure in the treatment of patients and transfusion laboratories must have a robust search protocol in place to identify historic patient records
- Failure to provide appropriate units for patients with sickle cell disease can have serious consequences with alloimmunisation and delayed haemolytic transfusion reactions
- The information technology (IT) system should be configured to flag a discrepancy between the component type requested and the component selected for issue and this should be fully validated. If this is not possible locally then these development requirements must be raised with the laboratory information management system (LIMS) suppliers
- Training and competency-based assessment must include appropriate actions on receipt of alerts/warnings on the laboratory information management system (LIMS) or an analyser
- The qualified biomedical scientist (BMS) who performs crossmatching of red cells or issuing components must take responsibility for checking all available patient information to ensure that components issued are of the correct specification
- Staff should not short cut established procedures. Transfusion laboratories should have a standard operating procedure for abbreviated pre-transfusion testing for the provision of blood in emergencies
- Note that the updated British Committee for Standards in Haematology (BCSH) Guidelines for pre-transfusion compatibility procedures, including standards for emergency grouping, are now available at www.bcshguidelines.com

Recommendations for laboratory staff

- Regular practice and competency assessment of manual techniques is important. Where possible this should include checks of the critical steps by a second person when manual methods are employed

- Competency assessment in laboratories must be linked to process. Biomedical scientist (BMS) staff must be competent performing the test but must also have a thorough understanding of the context in which the test is being performed, i.e. the test in relation to a specific patient and the clinical information. Basing competency assessment on National Occupational Standards (NOS) will enable this, as NOS have both 'Performance' criteria and 'Knowledge and Understanding' criteria

Action: Transfusion Laboratory Managers

- Hospital Transfusion Teams should perform a local risk assessment on the way in which the transfusion laboratory is informed by clinicians of either specific requirements, or previous history provided by patients direct to clinicians. For example, having a robust process to inform the laboratory when treatment on purine analogues starts, rather than when blood is requested, has merit

Action: Transfusion Laboratory Managers, Pathology IT Managers, Laboratory Information Management Systems (LIMS) providers, Hospital Transfusion Teams

Laboratory information management systems improve safety by removing manual steps, but must be set up carefully (80 cases related to IT systems are included in the 2012 report – this number increases year on year)

- Warning flags in the LIMS must be clear and appear on all relevant screens in the transfusion process and if overridden, should include a positive response from the user with rationale behind the decision

Action: Transfusion Laboratory Managers, Pathology IT Managers, LIMS providers, Hospital Transfusion Teams

- Hospital transfusion laboratories should be encouraged to participate in the national electronic access scheme for blood group and antibody information which is being developed by National Health Service Blood & Transplant (NHSBT) (called Sp-ICE), and equivalent systems in Wales, Scotland and Northern Ireland for patients with complex transfusion requirements, and as recommended by National Patient Safety Agency (NPSA) safer practice notice, to use the NHS or equivalent number

Action: Hospital Transfusion Laboratory Managers; Pathology Managers

Lessons for clinical areas

- **Responsibility and communication:** A named consultant should take responsibility for each patient receiving a transfusion. Having more than one team involved with a patient may result in confusion over 'ownership' i.e. whose responsibility it was to review results, but no transfusion should be prescribed or given without proper assessment of the patient including review of the latest haemoglobin results
- **Wrong results:** The use of point of care haemoglobin machines or blood gas analysers may lead to wrong results. It is essential that any point of care machines are properly quality assured for Hb results and that they are used only by staff who have received appropriate training. A UK National External Quality Assurance Scheme (UKNEQAS) is now available for haemoglobin analysis on blood gas analysers – contact haem@ukneqas.org.uk for further information
- **Intravenous immunoglobulin (IVIg):** IVIg has been associated with a death from haemolysis this year, an instance of major morbidity from haemolysis in 2011, and also with suspected TRALI in 2012. Patients should be observed for evidence of haemolysis or other adverse transfusion-related reactions and cases reported. Clinicians should be aware that IVIg contains passive antibodies which may be mistaken for infection (e.g. hepatitis B)

Identify and communicate any specific requirements to the laboratory and to colleagues (including haemopoietic stem cell transplant timetables)

Specific requirements not met: This continues to be a major problem. Clinicians fail to inform laboratories of important diagnoses, particularly sickle cell diseases, and other specific requirements, such as the need for irradiated components. 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. A particular issue emerged this year in relation to failures in communication between transplant units and their hospital transfusion laboratories (in the transplant centre and/or at the referring centre). These 37 incidents are described in a stand alone chapter. There were 18 ABO/RhD errors and 19 additional failures related to provision of irradiated/CMV negative components.

Recommendations for clinical staff

- To minimise transfusion errors, a written transplant programme detailing key dates and blood group information, should be developed for each transplant recipient. This should be sent, with written confirmation of receipt, to the transfusion laboratory in the hospital where the transplant is being undertaken, the shared care centre and its transfusion laboratory

Action: Clinical Transplant Teams; Transfusion Laboratory Managers, Hospital Transfusion Teams

- Guidelines should be developed that cover the procedures, particularly communication protocols, necessary for managing transplant patients, especially where ABO/RhD mismatched transplants have been given. This should be a standard for all transplant centres

Action: The BCSH Transfusion Task Force; the British Society of Blood and Marrow Transplantation (BSBMT)

Avoidable, delayed or undertransfusion (145 in 2012, 149 in 2011): Many avoidable transfusions occur as a result of wrong blood results (46 cases), with 9 instances resulting from wrong samples. The same standard of identification and labelling should apply to all pathology samples. This is identified in the main recommendations – a policy of zero tolerance for labelling, and reminder that samples must be labelled at the patient's side. Delayed transfusion in an interventional radiology setting identified a lack of training for this group of doctors in emergency haemorrhage procedures.

Recommendation to ensure training in all appropriate specialties

- Hospital transfusion committees should review their transfusion protocols and training to ensure that all relevant departments in their hospitals, including radiology and any others where invasive procedures are performed, have appropriate measures in place

Action: Hospital Transfusion Committees; Hospital Transfusion Teams

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. SHOT no longer requires reporting of mild reactions (i.e. fever $\geq 38^{\circ}\text{C}$ and a rise of 1 or 2°C from pre-transfusion values, but no other symptoms; or transient flushing, urticaria or rash). With the potential increase in transfusion in community hospitals or other locations out of hospitals it is important that there are trained staff and facilities for emergency treatment of anaphylaxis and other acute transfusion reactions.

Recommendations for acute transfusion reactions

- Transfusions should only be performed where there are facilities to recognise and treat anaphylaxis, according to UK Resuscitation Council (UKRC) guidelines. This recommendation is also relevant for other transfusion-related emergencies such as respiratory distress caused by transfusion-associated circulatory overload (TACO) or transfusion-related acute lung injury (TRALI). 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 adverse incidents. This is particularly relevant in the light of the proposed increase in treatment of patients outside the secondary care setting

Action: Hospital Transfusion Teams, General Practitioners

- Retain suspected bacterially contaminated packs, even if near empty, for return to the Blood Service as the residue can be washed out and cultured. It is important to contact the Blood Service to allow recall of any associated packs for testing. If sampling packs locally for bacterial testing, use ports rather than breaching the pack to minimise environmental contamination of the pack

Action: Clinicians, Transfusion and Microbiology Laboratory Managers

Safe transfusion practice

The new BCSH guideline advice (Guidelines for pre-transfusion compatibility procedures in blood transfusion laboratories, see www.bcsghguidelines.com) for patients, whenever possible, to have a second sample prior to transfusion has been made partly based on the evidence from previous SHOT reports (incorrect blood component transfused and 'near miss' data). There should be strict adherence to this guidance. It is important to realise that it is in emergency situations that patients may be at higher risk of being misidentified. Particular care must be taken with blood sampling in this setting, especially where it may not be possible to obtain a group check sample due to the need for urgent transfusion. Improved communication is needed between laboratories and clinical areas to ensure that the request for a second, group check sample is fully understood as a safety check to confirm that the patient has been correctly identified. Positive identity techniques must be used and identity bands generated only at the point of admission, and if essential, replacement must follow National Patient Safety Agency guidance.

SHOT updates and developments

Definitions for the SHOT categories have been reviewed and updated; they can be viewed and downloaded from the website: www.shotuk.org/wp-content/uploads/2010/03/SHOT-definitions-Nov012-final.pdf. We have decided not to collect reports of transfusions outside the 4-hour rule for duration unless the transfusion of a unit has lasted more than 5 hours. A review of all the prolonged transfusion data demonstrated that there have been no clinical events associated with prolonged transfusion.

SHOT and MHRA continue to work collaboratively towards an integrated haemovigilance reporting system. The first step has been the introduction of improved links between the SABRE and SHOT online data collection systems and this has been welcomed by reporters.

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 delivery. From 2013 SHOT plans to collect information about women who are found to have immune anti-D for the first time at booking, during pregnancy or at delivery.

Recommendation

- Reporters should inform the SHOT office when they find a case of a woman who has developed a new immune anti-D that is detected during pregnancy, at delivery, or in a subsequent pregnancy, and a questionnaire will be provided

Action: Hospital Transfusion Teams, SHOT office

General updates

In 2013, the General Medical Council published an updated version of 'Good Medical Practice' which includes a new 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 the MHRA as appropriate.

Conclusions

The current risks from blood and blood component transfusion in the UK remains small with a risk of death at 3.1 and risk of major morbidity 46.5 per 1,000,000 components issued. New strategies are required to reduce the level of error in the transfusion process. Transfusion education is under review by a subgroup of the CMO's National Blood Transfusion Committee and new methods of training and competency assessment are also under development. Checklists are very useful to ensure all the steps of a process have been completed and should be introduced for transfusion as recommended in 2011 (<http://www.shotuk.org/resources/current-resources/>). Any unexpected transfusion reactions must be promptly recognised and treated and continue to be reported to ensure patient safety. Appropriate local review of incidents including root cause analysis where indicated will help to identify systems problems which can be remedied.

All staff involved in transfusion are reminded that they have a duty of care to report adverse events which potentially or actually affect patient safety.