ANNUAL SHOT REPORT 2013 SUMMARY

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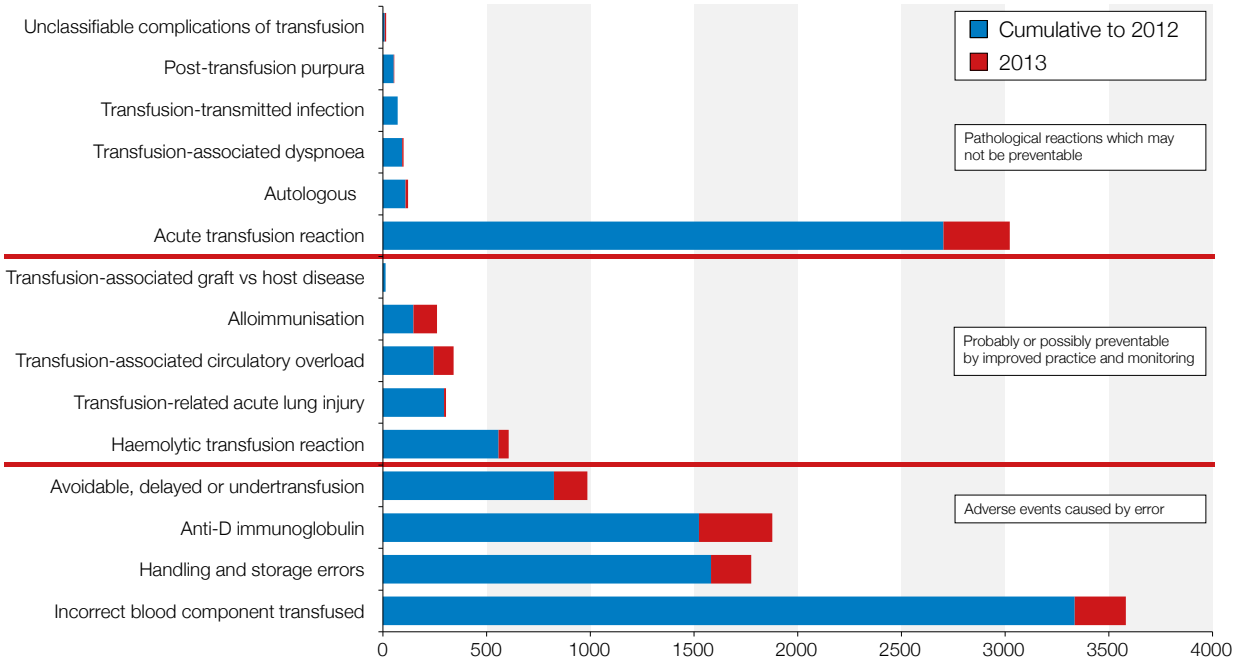
Introduction:

This 17th Annual SHOT Report summarises data received between January and December 2013 by the SHOT UK haemovigilance scheme. Participation continues to be excellent at 99.5% of NHS Trusts and Health Boards across the UK. The total number of reports submitted for 2013 was similar to 2012 at 3568, of which 2751 have been analysed for this year's report. The total includes 'near miss' (n=996) and 'right blood right patient' (n=184), events that by definition caused no harm. Most organisations make between 1 and 30 reports (84.9%) and a small number make more than 50 (7.0%).

Overall, errors, or human factors, played a part in 77.6% of reports including 9 ABO incompatible red cell transfusions which contributed to death in one patient and major morbidity in a further three.

Figure 1 shows the cumulative data for 17 years. Acute transfusion reactions remain the most common unpredictable incidents (allergic/hypotensive/severe febrile: 320 in 2013). There were no transfusion-transmitted bacterial infections reported in the past 4 years, and no new viral transmissions in 2013.

Figure 1: Cumulative data for SHOT categories 1996/7 to 2013 (n=13,141)



ABO incompatible red cell transfusions

Review of cumulative SHOT data on ABO incompatible red cell transfusions shows that 2/3 are not associated with any adverse outcome (Figure 2), but these should never occur since every one has the potential to cause death or serious harm. The risk of death is not related to the volume transfused and may occur after transfusion of less than 50mL.

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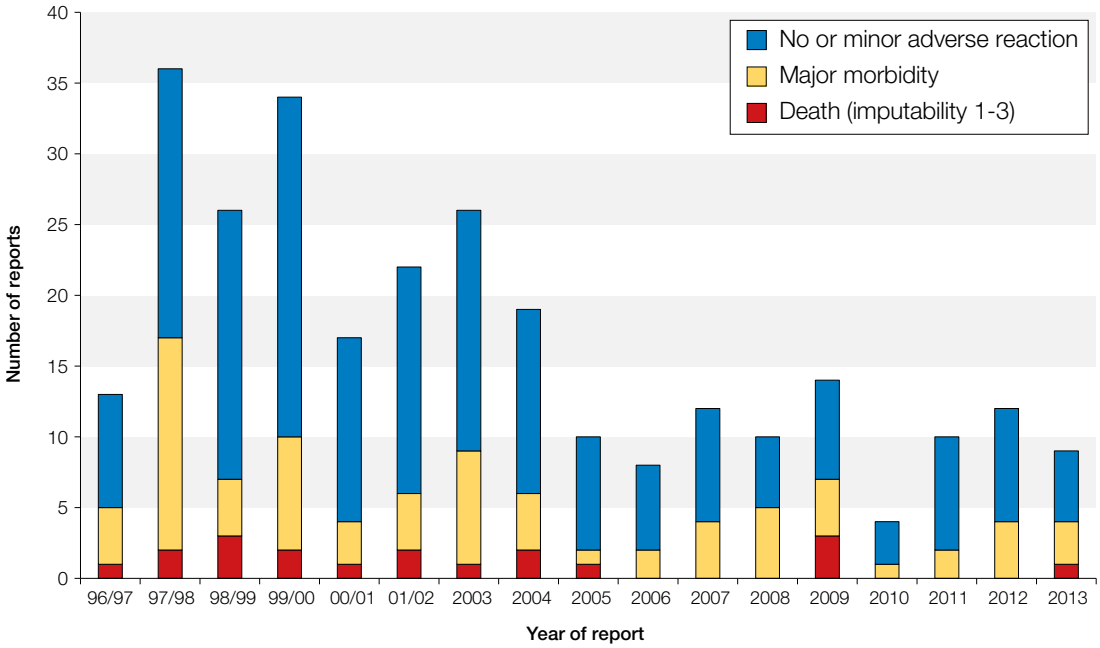
Figure 2: Outcome of ABO incompatible red cell transfusions



Near miss n=996 (980 in 2012)

The majority of these, 643 (64.6%), were 'wrong blood in tube' incidents. Near misses are indicators, or 'free lessons' as no harm is done, but at least 125 of those reported in 2013 could have resulted in ABO incompatible transfusions. Most near miss events occurred in clinical areas (n=742), 251 in the laboratory and 3 in Blood Establishments.

Human factors in hospital practice

Each year the largest group of reports relate to mistakes made in the transfusion process. In 2013, errors contributed to 77.6% of all reports (this includes 'near miss' and 'right blood right patient' reports). As the NHS Litigation Authority no longer monitor hospital transfusion against their standards, this role should be taken up by the Care Quality Commission.

Multiple errors are common

Although transfusion is generally very safe, with very good quality of blood and blood components, we need to work on the safety of the ordering and administration process. Analysis of 220 incidents where incorrect blood components were transfused (IBCT) demonstrated that errors in the multidisciplinary transfusion process were frequently multiple (median 3 errors in 117 cases, maximum 5 errors in 9). Errors were most commonly made in the request (particularly failure to request specific requirements). Many errors could and should have been detected at the final bedside check. If each person in the transfusion sequence completed their step correctly, these errors would not occur and many could be detected before transfusion, especially by the final check at the patient's side. In addition to confirmation of the patient identity (positive patient identification), the component should be checked against the prescription to ensure it is the correct one and that any patient-specific requirements are met. This could be done simply with an aide-memoire (or checklist) to include the following essentials:

- **Positive patient identification (ask the patient to state name and date of birth)**
- **Check identification of component against patient wristband**
- **Check the prescription: has this component been prescribed?**
- **Check the prescription: is this the correct component?**
- **Check for specific requirements: does the patient need irradiated components or specially selected units?**

Recommendation

- The majority of episodes resulting in an incorrect component transfusion result from multiple errors in the multidisciplinary transfusion process. All professional staff participating in transfusion must perform independent and careful checks. A simple 5-point aide memoire at the final step would remind staff to check for the correct patient identifiers, and the prescription for the correct component and confirmation of specific requirements

  Action: Hospital Transfusion Teams

Key Recommendations (1)

- **Process redesign**: Annual SHOT data consistently demonstrate errors to be the largest cause of adverse transfusion incidents. In line with human factors and ergonomics research it may be better to redesign the transfusion process by process mapping and audit at local and national level, to design out the medical errors

  Action: National Blood Transfusion Committees, working with Regional and Hospital Transfusion Committees in association with NHS England patient safety domain and equivalent organisations in the devolved countries and the National Comparative Audit Programme

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

  Action: NHS England, patient safety domain

- **Management of blood and blood component transfusion to be included as a specific standard by the Care Quality Commission.** This should include the same subset of standards as currently apply to medicines (Outcome 9)

  Action: Care Quality Commission

Serious adverse incidents associated with death and major morbidity: transfusion-associated circulatory overload and delayed transfusion

Transfusion-associated circulatory overload (TACO) is a significant cause of death and major morbidity. These reports show a steady increase with 96 cases in 2013 (82 in 2012). Half of these patients died or experienced major morbidity as a result, demonstrating that this is a serious complication. Some could be prevented by better pre and post-transfusion assessment. There is a place for single unit transfusions followed by a clinical and haemoglobin check – 'Don't give two without review' (advice inspired by a campaign devised by NHSBT's Patient Blood Management (PBM) group http://hospital.blood.co.uk).

With increasing pressure to transfuse patients as day cases there is also a risk that complications may develop after discharge as shown for both TACO and acute transfusion reactions. Several reactions (57) occurred in day case patients, and 3 developed at home. It is essential that patients are informed of the possibility of later adverse events and that they are supplied with a contact telephone number. Once again this year there were reports of inappropriate transfusions for iron deficiency, one of which resulted in circulatory overload and death.

The number of reports of delayed transfusion has increased each year. This is clearly of concern. Some of these reflect the increased burden in emergency departments. These are serious incidents: review of delays reported over the past 4 years shows that 10/69 (14.5%) patients died, with delay playing a part. These were not all related to problems with activation of the major haemorrhage protocols. None were caused by the need for a group check sample; there were many different causes. It is of particular concern that two foundation year doctors did not recognise signs of haemorrhagic shock. Other contributory factors included poor supervision of junior medical staff at nights and weekends, and confusion in clinical management when delivered by a succession of clinical teams.

Key Recommendations (2)

- **Don't give two without review**: Transfusion-associated circulatory overload is a significant hazard particularly when elderly or other patients at risk (renal impairment, cardiac disease, obstetric haemorrhage, gastrointestinal haemorrhage) receive several units of blood without review and a check on the Hb level

  Action: Trust/Health Board Chief Executive Officers and Medical Directors responsible for all clinical staff

- **Advice for patients**: Day case or outpatient transfusions: with the increased emphasis on day case and community care, patients receiving transfusions need to be given printed advice, be advised to report any symptoms or complications and provided with a 24-hour contact number

  Action: Trust/Health Board Chief Executive Officers and Medical Directors responsible for all clinical staff

Overview of the 2013 Report

Acute transfusion reactions (ATR) continue to be the major cause of unpredictable reactions, and were the leading cause of major morbidity in 2013. TACO, and avoidable, or delayed transfusions 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 2013

	Total	IBCT	ADU	ANTI-D	ATR	HTR	TRALI	TACO	TAD	UCT	PTP	Others
Death in which transfusion reaction was causal or contributory	**22**	1	5	0	0	1	1	12	0	1	1	0
Major morbidity probably or definitely attributed to transfusion reaction (imputability 2/3)	**143**	6	7	1	76	8	9	34	1	1	0	0
Minor or no morbidity as a result of transfusion reaction	**1406**	240	149	353	244	40	0	50	5	4	2	319
TOTAL	**1571**	**247**	**161**	**354**	**320**	**49**	**10**	**96**	**6**	**6**	**3**	**319**

** 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; PTP=post-transfusion purpura ; Others includes handling and storage errors, alloimmunisations and cell salvage*

Deaths n=22 (9 in 2012) 1 definitely, 7 probably and 14 possibly related

There was a substantial increase in deaths where transfusion reactions or delays played a part in 2013. One was definitely (imputability 3) related to delay: a child with sickle cell disease died from anaemia with a haemoglobin level measured at 28g/L several hours earlier. Delay contributed to four other deaths. A man died following late recognition of concealed post-operative bleeding with failure to recognise signs of haemorrhagic shock. Two patients died where delay was related to poor communication and labelling issues and in another case inadequate junior staffing and supervision contributed to failure to transfuse platelets in a timely manner.

Seven other deaths were transfusion-related with lower imputability of 2 including 5 from TACO (one transfused for iron deficiency), one HTR and one from PTP. The remaining deaths were possibly related (imputability 1) to the transfusion, a further 7 with TACO, one with TRALI, one associated with an ABO incompatible transfusion and an infant died shortly after developing necrotising enterocolitis.

Major morbidity n=143 (134 in 2012)

Acute transfusion reactions (allergic, hypotensive and severe febrile) (ATR) n=76 (68 in 2012)

These cases included 33 instances of anaphylaxis or severe allergic reactions, 22 severe febrile reactions, 5 severe hypotensive reactions and 6 severe mixed reactions. A further 10 cases were described as having severe reactions by reporters (but moderate by the SHOT experts).

Transfusion-associated circulatory overload (TACO) n=34 (29 in 2012)
This high proportion (35.4%) of major morbidity in a total of 96 reports is a reminder of the serious consequences of this complication. Fifty six patients had concomitant risk factors.

Incorrect blood component transfused (IBCT) n=6 (11 in 2012)
Three ABO incompatible red cell transfusions resulted in major morbidity and 3 women of childbearing potential were sensitised against the K antigen as a result of laboratory errors.

Haemolytic transfusion reactions (HTR) n=8 (9 in 2012)
As in previous years, patients with sickle cell disease are particularly at risk. Six of the 8 had sickle cell disease, and three of these had hyperhaemolysis.

Transfusion-related acute lung injury (TRALI) n=9 (8 in 2012)
Consistently fewer cases are recorded since the introduction of risk-reducing measures in 2003.

Anti-D errors n=1 (4 in 2012)
A woman developed anti-D after omission of anti-D immunoglobulin prophylaxis during pregnancy. There was a further group of 276 women at risk for development of anti-D whose prophylaxis was delayed or omitted.

Transfusion-transmitted infections (TTI) n=0 (3 in 2012)
No new infections were confirmed from transfusions given in 2013.

Avoidable, delayed or undertransfusion (ADU) n=7 (2 in 2012)
These 7 cases all resulted from delayed transfusions, 3 associated with cardiac arrest.

Unclassifiable complications of transfusion (UCT) n=1 (0 in 2012)
An infant developed major morbidity from necrotising enterocolitis shortly after receiving a red cell transfusion.

Transfusion-associated dyspnoea (TAD) n=1 (0 in 2012)
A middle aged man with underlying malignant disease, already very unwell, became more acutely distressed in relation to a transfusion. The reaction demonstrated features of an ATR, and occurred in the context of pre-existing pulmonary oedema and neutropenic sepsis, both of which could have been contributory to the patient's symptoms.

Reports where incidents were caused by error n=955 (1026 in 2012)
The groups of errors were: Anti-D immunoglobulin errors n=354, handling and storage errors n=193, avoidable, delayed or under transfusion n=161, incorrect blood component transfused n=247, of which the specific requirements were not met in190/247, and wrong component transfused in 57/247.

Additional lessons and recommendations from the 2013 SHOT Report

There were 284 laboratory errors: The largest group of these, 84/284 (29.6%) comprised right blood right patient incidents. A further 56/284 (19.7%) resulted in specific requirements not being met.

The reduction in manual steps associated with the use of laboratory information management systems (LIMS) adds additional safety but these systems need to be configured with correct flags that should not then be ignored or overridden. One ABO incompatible transfusion resulted from poor laboratory practice including overriding warning flags on several occasions. It is very important to take into account all the relevant patient laboratory history and to search for previous results particularly for patients with haemoglobinopathies.

Lessons for laboratory staff

- Qualified biomedical scientists who are crossmatching or issuing components must take responsibility for checking all the relevant laboratory history to ensure they issue components of the correct specification
- Electronic issue should be under the control of the laboratory information management system with no manual interventions, and logic rules and flags should be set up to support this. Warning flags should not be overridden
- Age and gender-related specific requirements are a laboratory responsibility. Laboratory IT systems should be used to their full potential to prompt staff about specific requirements either through logic rules or algorithms based on date of birth and/or gender, or by warning flags

- Duplicate patient records must be avoided to prevent essential transfusion and/or antibody history from being overlooked. There should be a policy to identify and link separate records that exist for each patient at the time of the transfusion request
- A robust service should be in place to allow fetomaternal haemorrhage testing to be completed with sufficient time to allow further testing if so required so that administration of a full dose of anti-D Ig can be completed within 72 hours of delivery, particularly where administration will take place in the community
- ABO testing must be safe and robust. BCSH guidelines for emergency testing should be followed

Additional recommendations for laboratory staff

- All blood transfusion laboratories should be familiar with and comply with the UK Transfusion Laboratory Collaborative standards. Accrediting and regulatory organisations have supported this initiative, therefore compliance with these standards is strongly recommended

  Action: Trust/Health Board Chief Executive Officers, Transfusion Laboratory Managers, Hospital Transfusion Teams

- Hospital transfusion laboratories should actively seek an antibody history when a sickle cell patient requires transfusion, using the NHS Blood & Transplant (NHSBT) Sp-ICE system where available (Specialist Services Electronic Reporting using Sunquest ICE)

  Action: Transfusion Laboratory Managers

Learning points for clinical areas

Avoidable or delayed transfusions: The number of reported delays in transfusion increases every year. These occur for many different reasons which often relate to poor communication between clinical and laboratory areas and poor continuity in clinical care. Many avoidable transfusions occur as a result of wrong blood results or inappropriate management of iron deficiency anaemia.

Transfusion-associated circulatory overload: This is a serious complication resulting in major morbidity and death. Patients at high risk may be identified pre transfusion and should be assessed after transfusion of each unit.

Lessons for clinical staff

- All clinical staff involved in blood transfusion should be aware of and receive education and training on measures to avoid TACO including identification of risk factors and the 2012 British Committee for Standards in Haematology (BCSH) addendum to the guidelines on blood administration should be followed
- Transfusion is not the most appropriate management of iron deficiency especially if the patient is asymptomatic. These patients should be discussed with a consultant haematologist before arranging transfusion

Recommendation

- **Don't give two without review**: When transfusing adult patients at increased risk of TACO, clinical review should be undertaken after transfusion of each red cell unit

  Action: Hospital Transfusion Committees, Hospital Transfusion Teams

Specific requirements not met: 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.

Lessons to reduce the risk of specific requirements not met

- It is the clinician's responsibility to identify the specific requirements for transfusion and to communicate them to the laboratory by the request form and prescription
- Prior to collection of a blood component for transfusion, the prescription should be checked by the staff who will be setting up the transfusion to ensure that the components have been prescribed for that patient and that they are of the correct specification for that individual
- The process of checking each component against the prescription and patient identity before administration is a key point when earlier errors could be detected and so prevent administration of a wrong component or one not suitable for that patient's specific requirements
- Patients with specific transfusion requirements may be treated anywhere within the health service including different departments within a hospital, different hospitals or in the community. All staff caring for a patient requiring transfusion have a responsibility for knowing what constitutes specific requirements. Staff in haematology departments in particular should be adequately trained to know when these are indicated

Acute transfusion reactions: It can be difficult to decide on the cause of reactions when the data supplied are sparse. Analysis of allergic reactions to plasma reported to SHOT 2010-2012 showed the incidence was 2 per 100,000 with SD-FFP compared to 11.5/100,000 with standard plasma ($p<0.001$). Although 'standard' SD-FFP is still available, all new stock ordered by hospitals will have been treated to eliminate prions.

Recommendations for acute transfusion reactions

- Reporters should report cases fully, including clinical data such as temperature and blood pressure prior to, and during, a reaction, especially if fever or hypotension is reported

  Action: Hospital Transfusion Teams (HTT)

- Patients who have experienced transfusion reactions should only be tested for platelet or granulocyte antibodies within guidelines such as those set out in England by the National Health Service Blood and Transplant (NHSBT) in their Histocompatibility and Immunogenetics user guide. The main indication here would be persistence of severe reactions despite the use of platelets where the plasma has been removed and replaced by suspension medium

  Action: HTTs, Histocompatibility and Immunogenetics laboratories

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 and that day case patients are given information about what to do in the event of a reaction.

Recommendation

- Outpatient departments and day case units should ensure patients have information about what to do if they experience a transfusion reaction after leaving the unit

  Action: HTTs, Day case wards

Post-transfusion purpura: This is a rare but potentially serious complication but very important to recognise and treat early. Treatment with high dose intravenous immunoglobulin should be started early as soon as PTP is suspected and without waiting for serological confirmation. Clinicians should contact the Blood Services if they suspect PTP for advice and to arrange investigations.

Paediatrics: Children continue to be at greater risk of receiving inappropriate components. There is a need to raise awareness of specific requirements for children among paediatricians, to encourage communication with haematologists for advice, and for the transfusion laboratory to be informed of any patients who might need irradiated components even if transfusion is not currently envisaged.

Two cases of neonatal necrotising enterocolitis were reported in 2013 shortly after transfusion and one infant died. SHOT encourages reporting of this association.

A 13 year old girl developed anti-D following a live donor liver transplant from an RhD positive donor indicating that policies need to be developed for RhD incompatible solid organ transplants.

Recommendation

- Guidelines should be developed that cover the procedures, particularly communication protocols, necessary for managing female transplant patients who are of childbearing potential, where RhD positive transplants have been given to RhD negative recipients. This should be a standard for all transplant centres

  Action: British Committee for Standards in Haematology Transfusion Task Force in association with the British Transplant Society

SHOT updates and developments

SHOT would like to receive reports of all cases of RhD immunisation, in both men and women. SHOT is also interested in alloimmunisation in patients who have received blood which types as RhD negative. The pilot study started in 2013 for women who are found to have a new anti-D in pregnancy will continue. Further details can be found in the full report. Cases of hyperhaemolysis should also now be reported as soon as suspected via the hospital haematologist to the local Blood Service consultant. Dr Nay Win of the NHSBT is co-ordinating the case review and will forward the anonymised data to SHOT.

Recommendations

- 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
- Reporters are asked to report any case of RhD immunisation in men and women, including where the patient has apparently received RhD negative components, as an alloimmunisation report on the SHOT database (Dendrite)

  Action: Hospital Transfusion Teams

Conclusions

The current risks from blood and blood component transfusion in the UK remains small with a risk of death at 8.0 and risk of major morbidity 51.8 per 1,000,000 components issued. New strategies are required to reduce the level of error in the transfusion process. 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. 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.