CHAPTER 11

Clinical Activities: Medical Decision-making, Sampling, Ordering Components, Administration, and Patient Monitoring

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Introduction

The safety of blood transfusion concerns the entire process of delivering transfusion-related care to patients. Originally, hemovigilance started as a way of recording numbers of cases and data trends for recognized and defined adverse physiological reactions in patients receiving blood and blood components. In the UK the blood safety initiatives that arose during the first five years in which Serious Hazards of Transfusion (SHOT) collected data focused mainly on reduction of viral and bacterial transmissions by blood components, precautions against vCJD transmission, irradiation, and donor selection to reduce Transfusion Related Acute Lung Injury (TRALI).[1]

Over the years a great deal of resource has been invested in the safety of the blood component itself, with the involvement of regulators and the setting of standards by both external agencies and internal governance in blood establishments and hospitals. The result has been a measurable and significant reduction in the risks of transfusion transmitted infection, such that blood components are safer than they have ever been, and vastly safer than many licensed pharmaceutical agents.[2] The rate of virus transmission in the developed world is probably lower than it has ever been.[3] In addition measures in the UK, now also being put in place in other countries, have reduced the incidence of TRALI.[4] However, there is a paradox in spending vast sums on reducing the already extremely low risk of a therapy or medication when it is frequently used unnecessarily or inappropriately.[5]

More recently overall transfusion safety has been addressed, in particular the noninfectious hazards and the impact of human error. The decision to transfuse is poorly taught and documented, and there are few data from controlled trials to aid standardization of this part of the process. Several studies have documented that wrongly labeled samples are frequent, and more worryingly, "wrong blood in tube" samples continue to occur. The bedside administration of blood components is another frequent focus of errors that puts patients at high risk.

Education and training of medical staff, nurses, and other staff groups involved in the transfusion process is of paramount importance. Blood components are intrinsically extremely safe, but they must be used properly. In all hemovigilance

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systems, human error is a major cause of adverse events.[6]

Reporting of error-based adverse incidents to hemovigilance systems

The category for "incorrect blood component transfused" (IBCT) has been used by SHOT to categorize incidents relating to blood that was transfused in error, intended for a different patient, or of the incorrect group due to laboratory error. This original core material collected by hemovigilance systems has gradually evolved and the scope has broadened. In particular the IBCT category has expanded to include errors of clinical decision-making, inappropriate or unnecessary transfusions, and knowledge-related mistakes, even though initially these were not actively requested by SHOT.[7] Also, handling and storage errors (breaches in the cold chain in clinical or laboratory areas) were gathered in this category by the UK's SHOT scheme.

In 2008 the SHOT report separated out inappropriate and unnecessary transfusion (I&U) and handling and storage errors (HSE) into completely separate categories. Incorrect transfusions due to errors in phlebotomy, laboratory testing, and issue or ward based errors remained as true IBCT events.

This widening of scope brings hemovigilance into the arena of good medical practice, medical education and training, as well as competency, and levels of knowledge and skills. Communication breakdown, between individual members of staff and different professional groups, is a recurrent theme of events in these categories. Although some errors and mistakes may be prevented by proper knowledge of and adherence to guidelines and protocols, clinical practice is complex and the exercising of informed clinical judgement of individual cases is not always readily addressed by such documents. Barcode readers and other IT systems may help to prevent some forms of human error, but are not a panacea.

This chapter highlights the different types of errors that occur in the clinical area and are reported to hemovigilance systems; cases and trends from SHOT are used in each section.

Figure 11.1 shows the incidence of error-related reports: IBCT, I&U, and HSE, and

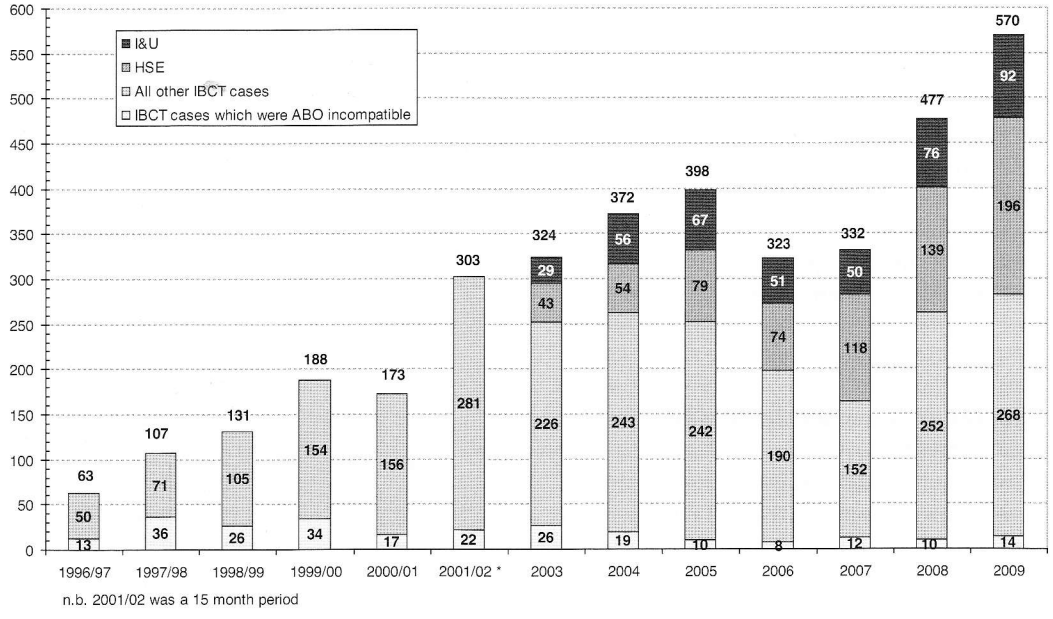

Figure 11.1 Error-related reports to SHOT from 1996 to 2009.

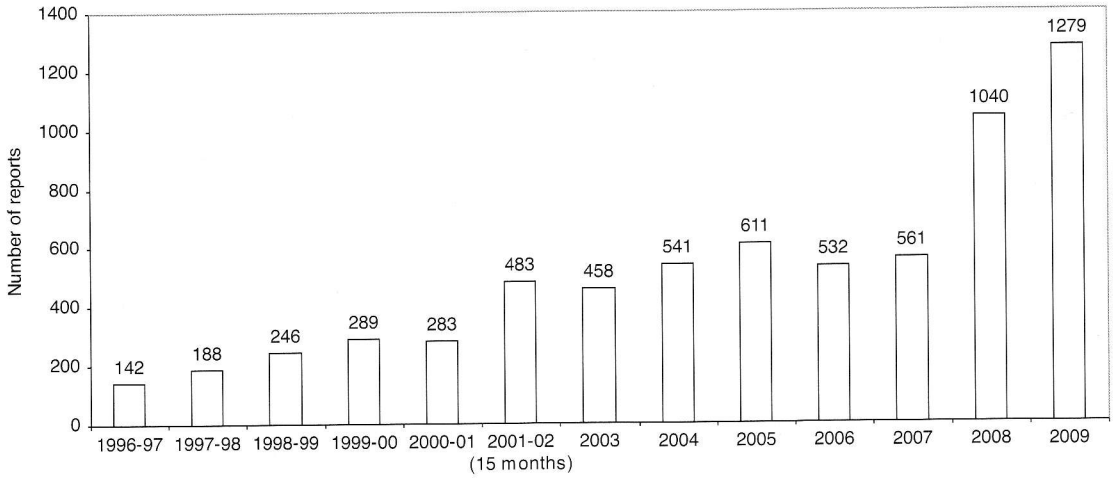

Figure 11.2 Total SHOT reports 1996 to 2009.

ABO-incompatible transfusions, in 13 years of SHOT reporting from 1996 until 2009. HAS and I&U were not collected as separate categories until 2008, but the figures for 2003 onwards were extracted retrospectively. Prior to that, the separation of data for those categories was not possible, hence the contour of the histogram. The dip in reporting in 2006 and 2007 follows the introduction of the EU Directive,[8] implemented as the Blood Safety and Quality Regulations (BSQR) 2005 in the UK.[9] Since 2007 reporting in these error-related categories has returned to join the previous curve and to increase at the predicted rate.

Overall SHOT reporting has increased very substantially because SHOT has commenced a campaign to increase awareness of transfusion errors, and striven to make reporting easy, accessible, and user-friendly, with an increase in constructive feedback to reporters (see Figure 11.2).

Categories of errors relating to clinical activities

Errors can occur in any of the stages of the clinical transfusion process as listed in Box 11.1. The three focal points for errors are the decision to transfuse, the collection of blood samples for pre-transfusion testing, and the bedside administration of components. These areas need to be recognized as critical in delivering safe transfusion care to patients, and must be embraced by the professions involved as key tasks.

Box 11.1 The clinical transfusion process

- The decision to transfuse:
  - clinical evaluation of the patient;
  - evaluation of laboratory results;
  - knowledge and experience.
- Informing the patient and documentation:
  - informing the patient about benefits and potential risk of transfusion;
  - discussion of possible alternative strategies (with colleagues and patient);
  - documentation of reason for transfusion in patient notes.
- Obtaining the patient sample for pre-transfusion testing
  - patient wristband *in situ* bearing at least three unique identifiers;
  - positive verbal identification of the patient;
  - labeling of sample tube at the bedside with three unique identifiers, plus signature;
  - use of electronic barcode reader to match wristband and print label if available.
- Ordering the component(s):
  - written (request form) or verbal request to laboratory must include at least three unique patient identifiers;
  - details of special component requirements, e.g., irradiated or CMV negative cells;

- urgent or emergency requests must be telephoned to the laboratory, invoking hemorrhage protocols if required;
- details of indication for request, transfusion history, obstetric history, recent blood results, known hematological conditions.

- Collecting the component:
  - check the patient's identification details on the documentation against the patient compatibility label on the blood component;
  - documentation of removal of the component by paper or electronic system.
- Checks before commencing transfusion:
  - check that the component has been prescribed by a physician, including dose and rate of administration;
  - check for any special requirements in the notes or on the prescription;
  - check the expiry data and time of the component, and visually check the unit for discoloration etc.;
  - check the donation number on the component and the compatibility label;
  - **check the patient identification using three unique identifiers on the patient's wristband and the patient compatibility label on the component;**
  - ensure these checks are fully documented with staff names and signatures in the notes, on the prescription chart, and on the traceability tag.
- Monitoring during transfusion:
  - record baseline measurements of temperature, pulse, and blood pressure;
  - repeat the observations 15 minutes into the transfusion;
  - repeat according to patients condition and/or local guidance;
  - record time of completion and observations at finish of transfusion.

In this arena, hemovigilance extends far beyond an audit function (i.e., evaluation of compliance with an agreed set of standards) because it identifies problems, errors, and deviations during parts of the process that are not easily protocol-driven.

Decision to transfuse

In the SHOT Annual Report 2009, there were 92 cases in the category of I&U transfusion[10] (see Table 11.1). This has been a new category since 2008, because previously such cases were reported sporadically under the IBCT heading. The cases

Table 11.1 Categories of 92 cases of inappropriate or unnecessary transfusion reported to SHOT in 2009.

Category of I&U transfusion	Number of cases reported to SHOT in 2009	
Transfusions based on wrong results	**53**	
Clinical causes of falsely low Hb value		36
Laboratory causes of falsely low Hb value		6
Unknown cause of erroneous count		3
Falsely low platelet count		8
Transfusion given based on poor knowledge, incorrect decision-making, or poor prescribing	**37**	
Excessive rate or volume transfused to a child		8
Red cell transfusion to Hb above normal range		7
Inappropriate transfusion for hematinic anemia		6
Transfusion of incorrect components due to lack of knowledge		10
Other		6
Undertransfusion	**2**	
TOTAL	**92**	

reported are undoubtedly only a fraction of the errors and mistakes in clinical practice that occur, but tend to be those in which there was a degree of patient harm rather than purely a breach of good medical practice. In a review in 2006 of ten years of SHOT reporting, it was stated that these cases were not encompassed by SHOT at the time, though the role of wrong clinical decision-making was acknowledged together with erroneous, misdocumented, and misinterpreted results.[11]

Most cases of inappropriate and unnecessary transfusion were the result of errors of judgment, lack of knowledge, or lack of procedural awareness among medical staff (56 cases across all categories). These errors were made predominantly by junior doctors, but included those made by more senior doctors and consultants. A further 18 cases were of "clinical" origin, although exactly which staff group was primarily involved is unclear (doctor, nurse, possibly phlebotomist). Ten of these were

phlebotomy-related problems (diluted or drip arm samples), but it is not known who took the samples. There were also cases illustrating problems of confusion between types of component, and clinical requirement for components. In five cases there were communication failures between the laboratory and the clinical teams regarding the need to repeat inadequate (short, clotted, clumped) samples. There were two cases of undertransfusion owing to multifactorial clinical errors, including communication and knowledge (see below).

In ten cases there was clear responsibility for the error in a member of the nursing staff; four of these cases involved transfusion of blood to an infant or small child at a volume and/or rate which was much greater than that prescribed. There was one case of an excessive rate of transfusion of red cells to an adult. A fatal case was multifactorial, involving a mislabeled Hb sample that had been taken by a member of the nursing staff. Four further cases involved incorrect verbal relay of Hb results and misinterpretation of instructions in notes.

Hospital hematology laboratories were responsible for eight cases of inappropriate or unnecessary transfusion by issuing incorrect results to clinicians before checking for clots, platelet clumping, or short sample errors.

In many medical schools, certainly in the UK, there is very little, or even no, curriculum time available for education about clinical indications for blood transfusion, as well as little formal training about the specific use of different blood components. There appears to be a tendency for clinical evaluation of individual patients to be obscured by uncritical appraisal of laboratory results, with transfusion therapy based upon these alone. These problems are compounded by the lack of good quality clinical trials about indications for the proper use of blood components.

As stated above, the cases reported to SHOT are generally at the extreme end of a spectrum of possible scenarios for this type of error.

There were two deaths in which the transfusion of red cells possibly or probably contributed to the death. The cases often include more than one error as in Case 1 below in which there is a mislabeled full blood count sample, and a clinical failure of initial evaluation of the patient and review. There is a clear overlap between inappropriate transfusion and the occurrence of Transfusion Associated Circulatory Overload (TACO), which should be a condition that is possible to predict and avoid in many patients.

Case 1

A patient was admitted and a sample for FBC was taken by a member of nursing staff. The hospital policy for positive ID of the patient was not followed and the sample tube was labeled with a different patient's details. (The report does not state whether a transfusion sample was mislabeled at the same time, only that both patients were group O D positive.) The patient's true Hb was 10.9 g/dL and there was no indication of bleeding or hemolysis. The incorrect patient's Hb was 6.0 g/dL and based on this, a 3-unit transfusion was prescribed without querying the surprisingly low result. The patient suffered acute pulmonary complications with a drop in pO_2, and the transfusion was stopped. A CXR post-transfusion may have indicated TACO or TRALI. The patient deteriorated rapidly and died. The report stated that the death was considered to be possibly related to transfusion.

The second fatality below illustrates the consequences of communication failure, in which the person relaying the message perhaps did not have sufficient knowledge or understanding to know its importance. At the same time the doctors on the ward round did not, from a clinical perspective, assess the results to be inaccurate. No clinical assessment seems to have been made, nor basic observations. In any patient it is very rarely appropriate to transfuse 4 units of red cells back to back without review and repeat sampling—perhaps only in cases of massive active hemorrhage. It is possible that the outcome might have been different had venesection been carried out once the very high Hb was discovered.

Case 2

Following abdominal surgery a patient fell in the ward and fractured her femur. Her most recent previous Hb was 15.9 g/dL. On testing a new FBC sample, the biomedical scientist called the ward, gave an Hb of 6.1 g/dL, and

requested another sample because he thought the result was incorrect. However, the result was passed to the medical team on the ward round by a nurse who did not mention the need to repeat the test. On the basis of the erroneous result, even though clinically there was not extensive bleeding, a 4 unit red cell transfusion was ordered by the consultant, and all 4 units were given without further review. The patient's Hb was 20.2 g/dL before surgery on the following day, and the anesthetist was aware of this. The patient developed cardiac failure and died. This was thought to be probably related to the excessive transfusion.

The next five cases are some typical examples in which the excessive volumes transfused posed a potential or actual risk to the patient, rather than being inappropriate purely on the basis of compliance with national guidelines or protocols.

Case 3

An elderly patient had coffee-ground hematemesis and melena, and a crossmatch request for 4 units of red cells was made. The Hb dropped but was at no time lower than 10.7 g/dL and the patient remained cardiovascularly stable throughout. All 4 units of red cells were transfused resulting in a post-transfusion Hb of 16.2 g/dL.

The junior doctor who prescribed the blood was perhaps inexperienced in assessing bleeding patients and worried by the visible blood loss. Hospitals should use the National Guidelines, for example those available from the Scottish Intercollegiate Guidelines Network[12] and local protocols and training should reflect this aspect.

Case 4

A 79-year-old female patient with CMV colitis weighing 91.5 lbs (41.5 kg) had a Hb of 6.7 g/dL. She was given a 4 unit red cell transfusion resulting in a post-transfusion Hb of 18.1 g/dL.

Case 5

A 2-year-old girl was admitted with peritonism, (possibly ruptured appendix, later found to be a ruptured tumor). Hb was 6.7 g/dL and the surgical team decided to transfuse, writing a dose of 15 ml/kg in the notes. The junior doctor wrote up 2 units and she was given 2 adult bags over 6 hours. Hb was 18.6 g/dL post-transfusion.

Junior doctors require knowledge of the appropriate dose of red cells to correct Hb to safe levels in adults, taking account of the size of the patient, whether there is active ongoing blood loss, and co-morbidities. Poor clinical assessment of the patient and the degree of blood loss continues to be a cause of overtransfusion.

Case 6

A patient was admitted for a liver biopsy and became hypotensive 2 hours after the procedure. The Hb was 7.7 g/dL (pre-procedure Hb not given) and the patient was transfused 2 units on three separate occasions over the next three days. In total 6 units of red cells were administered. No monitoring of the patient's laboratory parameters took place. A subsequent Hb was 17.1 g/dL. The patient died and no further clinical details or test results are available.

A recurrent problem is the unnecessary transfusion of patients with chronic nutritional or hematinic deficiency anemias, who should be managed without transfusion unless they are severly symptomatic.

Case 7

A GP detected an Hb of 6.6 g/dL in a young woman with chronic menorrhagia and referred the patient to the Emergency Department. The junior doctor there asked advice of the locum specialist trainee doctor who said to go ahead and transfuse, but the case was not discussed with a hematologist.

Undertransfusion

There have been very few cases of patient harm from undertransfusion reported to SHOT to date, but these cases have been actively requested only in the 2010 reporting year. It is probable that this is a more common occurrence but that it is not well documented. Data on something that does not happen can be difficult to collect. In 2010 in the UK a new Rapid Response Report (RRR) on transfusion of blood components in an emergency

was produced from the NPSA[13] following reports of 11 deaths and 83 incidents between 2006 and 2010 where the patient suffered harm as a result of delays in the provision of blood. The cases were evaluated together with the SHOT team, and the causes of the problems were identified as process failures, communication failures, and logistic difficulties.

A similar problem was identified in France in a retrospective study of anesthetic-related deaths that took place in 1999.[14] Most frequent were deaths associated with intraoperative hypotension and anemia, and once again these were found to be related to deviation from standard practice and organizational failure.

It may be that there are a significant number of suboptimal outcomes in bleeding patients, whether intra-operative or emergency, because of delays in transfusion of approprate blood components. Hemovigilance systems should develop mechanisms for collecting this important data, which may be causing more excess deaths than all other adverse incidents combined.

Sample collection

Errors at this stage, in particular collection of the sample from the incorrect patient, can result in ABO-incompatible transfusion with the potential for a fatal outcome. An estimate from the USA suggested that 15% of ABO-incompatible transfusions arose from phlebotomy errors.[15]

In 2002 the ISBT Working Party for Safer Transfusion carried out a large international audit of nearly 700,000 samples from ten countries including data from 62 hospitals.[16] It was found that 1 in every 165 samples was mislabeled and 1 in every 1986 was miscollected resulting in WBIT. The rates of error were similar in all the countries submitting data.

A study from the National Haemovigilance Office (NHO) in Ireland[17] analyzed 759 near-miss events from ten hospitals, reporting that sample collection was the most high-risk step in the transfusion process and was the first site of error in 62% of events. Of these, 13% involved samples taken from the incorrect patient, with medical staff frequently being implicated.

This finding was echoed in the "Near Miss" pilot study performed by SHOT in 2008,[18] which was carried out because previous near-miss SHOT data pointed to sampling as a focus point of errors.

In phase 1, data were analyzed on 8535 rejected samples out of 224,829 samples received in 121 hospital laboratories in the UK during April 2008. The key findings were as follows:

- The average rate of rejection of samples across the UK was 3.8% with 76% of those samples being rejected due to missing or incorrect information.
- Overall 40% of hospitals in the UK allow relabeling of incorrectly labeled samples.
- 32% of rejected samples were taken by medical staff, 25% by nurses or midwives.
- 27% of rejected samples arrived outside of core hours (generally 0800–2000 hours).
- 19% of rejected samples were received from the Emergency Department, 19% from Obstetrics & Gynaecology, and 30% from general wards.

Many hospitals have adopted the concept of "zero tolerance" toward sample errors, and insist that an erroneous sample is re-taken, but it is clear that nearly 40% of hospitals across the UK, and 50% in Wales and Scotland, still allow amendments to be made prior to testing. Of particular concern are the 271 cases (3.2% of all rejected samples) where samples have been relabeled despite not knowing who had performed the original venipuncture and labeling.

The bulk of incorrect samples where it is recorded who performed the venipuncture are taken by medical staff (31%), followed by midwives (15%) and nurses (10%). In 38% of mislabeled samples it was not documented who took the sample. Although at present there is a lack of denominator data regarding the overall breakdown of who bleeds patients for transfusion samples, it is felt that the proportion of medical staff involved in these errors is high.

In phase 2 the focus was on sample errors detected by the laboratory quality management system (QMS) after acceptance for testing. Of 214 samples included in the six-month study, 123 were samples from the correct patient but with incorrect

details, while 90 were completely mislabeled "wrong blood in tube" samples with potential for ABO-incompatible transfusion and fatal outcome. The majority (74) were detected because of historical data held in the laboratory, and those remaining by various serendipitous routes. As before, the sample errors detected after acceptance for testing originated predominantly with medical staff (45%), with fewer from midwives (15%), nurses (14%), and phlebotomists (10%). The percentage of sample errors attributed to medical staff seems disproportionately high, and it would be necessary to obtain denominator data as to what proportion of all samples are taken by which groups of staff.

Wrong Blood in Tube (WBIT)

WBIT means the taking of a sample for transfusion from a different patient than the one whose details are then written on the tube label.

The causal errors and problems identified in WBIT cases reported to SHOT include:

- not checking patient ID verbally or by wristband;
- labeling the filled tube away from the bedside;
- using a computer-generated sticky ID label on a (pre-labeled) tube;
- deployment of staff not trained or familiar with standard procedures;
- reliance on bedside technology without full understanding.

Case 1

An elderly patient was bled and grouped as B D positive and transfused with 2 units of B D positive cells because of anemia (cause not given). This patient had been bled by a doctor during normal working hours. A subsequent sample grouped as A D positive, which was rechecked and proved to be the correct group. The wrong patient had been bled when the original sample was required. Fortunately the patient did not suffer any ill effects from 2 units of ABO-incompatible blood.

Case 2

A patient with anemia due to malignancy was receiving a red cell transfusion as an outpatient. After <50 ml had been transfused, he developed fever, rigors, and bronchospasm followed by a respiratory arrest 20 minutes after commencement. The transfusion was stopped and he was admitted to the ward and stabilized successfully. Upon investigation it has been discovered that the original group and screen sample had been mislabeled by a trained phlebotomist using a bedside computer-generated label, and it belonged to another patient who was group A D positive. The recipient was group O D positive. This was the patient's first transfusion and so there was no previous transfusion history.

Root causes of sampling errors include both organizational failure and human error. All WBIT errors are preventable if the person taking the sample follows national guidelines and local policy for taking transfusion samples, for instance the British Committee on Standards in Haematology (BCSH) guidelines in the UK.[19] Training must be successfully delivered to all involved staff, and systems must be in place to ensure access to training and to prevent untrained staff carrying out phlebotomy. Despite staff completing their blood transfusion training and competency assessments, work pressures can lead to staff "cutting corners" and losing sight of the reasons for completing a comprehensive ID check.

Ordering components

Once a decision to transfuse has been made, and a sample taken, blood components need to be ordered. The order may be written on a form accompanying the sample, or there may be arrangements in place for telephone or intranet ordering. The order must include as a minimum the three unique patient identifiers, the component(s) being requested, the date and time the components are required, and degree of urgency, and any special requirements. Other information as agreed by local policy will include history and indication, obstetric and transfusion history, recent blood test results, and other details.

There are several types of adverse incident arising from blood ordering errors:

- ordering for the wrong patient or with the incorrect details;

- ordering the wrong type of component due to lack of knowledge and/or communication problems;
- omitting the special requirements for the patient, from lack of knowledge or awareness;
- communication failure regarding the degree of urgency of the order, for bleeding patients.

Special requirements not met (SRNM)

In the 2009 there were 87 SRNM cases reported to SHOT due to clinical errors and omissions (and 67 cases due to laboratory causes).[10] As in previous years the majority of cases related to requests for patients who required irradiated components, but this requirement was not made clear to the laboratory by the clinical staff at the time of requesting the component.

Case 1

A baby who had been the recipient of intrauterine red cell transfusions (IUTs) was given 4 nonirradiated pedipaks of red cells on two separate occasions. The request form did state that the mother had antibodies and that there had been 3 IUTs, but the special requirements were not specified. The prescription form did not specify irradiated blood.

A smaller number of cases related to the non-communication of a requirement for CMV negative components or requiring both specifications. Generally, it appears from the information supplied to SHOT that the doctor ordering the components either did not know of the criteria for irradiated or CMV negative products or was not familiar enough with the patient to realize that this was necessary. Other clinical omissions to make a request for special requirements probably also related to a lack of transfusion medicine knowledge in non-specialized staff admitting patients through the emergency department.

Case 2

A 22-weeks-pregnant patient was admitted via the Emergency Department with status epilepticus and transferred to ITU. The Hb was 6.7g/dL and 2 units of red cells were requested. No diagnosis was given on the request form despite boxes being available to tick (i.e., pregnant yes/no/unsure). The following day it was discovered by transfusion laboratory staff that the patient was pregnant and the units were investigated. One had been, by chance, CMV negative, the other had not.

In 15 of the 87 cases linked with the clinical omission to provide special requirements, a root cause of the problem related to the fact that the patient was undergoing shared care between two hospital sites.

Case 3

A patient known to the hospital had FFP requested which was issued according to the historical blood group—O. However, the patient had received a BMT (for CLL) at another hospital and the blood group had changed from group O to group B. None of the request forms indicated that the patient had had a recent BMT.

Doctors not usually working in hematology or oncology may be required to request blood components for patients despite unfamiliarity with special requirements—this problem arises from shift working and extensive cross covering. This issue has become more significant since implementation of the EU working time directive.[20]

Doctors working in non-hematology specialties, including in the Emergency Department, must be educated sufficiently in transfusion medicine to know that certain patient groups, such as pregnant women and sickle cell patients, have important special requirements for safe transfusion.

Shared care inevitably results in a situation where communication of essential information is required, and there is a risk of communication breakdown. Again this appears frequently to be the result of lack of knowledge of the part of the referring clinicians regarding the transfusion implications arising from the diagnosis or treatment of the shared patient. Detailed information changes hands, but transfusion details may be omitted or the transfusion staff left out of the communication loop.

Administration

The bedside patient identification check is the final barrier to error in many cases of potential mistransfusion, even when the error has originated at an earlier stage in the transfusion process. Staff carrying out this task must understand that, although routine, this is an absolutely critical step. SHOT reporting has found that relatively high proportions of cases of administration error occur out of hours or in emergency situations.[10]

Case 1

An elderly patient was admitted as an emergency during the night with chest pain, ECG changes, chest infection, and iron deficiency anemia, and was deteriorating. A decision was taken to transfuse her but the incorrect unit was collected from the issue fridge of the blood-transfusion laboratory. The patients shared a first name, had a similar surname and date of birth, and were on the same ward. The recipient, who was group A D positive, had recently become unconscious at the time of transfusion and did not have a wristband. She received approximately 150 ml of group AB D positive red cells. She continued to deteriorate and died a few hours later. The report stated that it was not thought that the transfusion contributed to her death.

The single most frequent stage at which an error is introduced is when the component pack is collected from the issue fridge or transfusion laboratory. The beside check, which could prevent transfusion of this incorrect unit, then also fails and a patient receives blood intended for another patient.

Case 2

An elderly man with a lower GI hemorrhage was undergoing angiography and required emergency transfusion. A nurse took the correct documentation with her to collect the blood but did not check it formally and collected a unit for another patient with the same last name. This incorrect unit was handed to the nurse in theater who checked the unit only against the accompanying compatibility form, not against the patient's wristband. The patient, who was group B D negative, received 150 ml of group A D positive blood but did not suffer any adverse reaction. He proceeded to surgery the same day with no problems.

Although professional responsibility must be taken at every stage by the personnel involved, the final barrier to wrong blood administration is at the bedside, and this cannot be overemphasized. Patient identification is at the root of a large number of errors in hospitals—not only in transfusion practice, but also in drug administration, investigations, operative procedures, and so on. It is essential that formal bedside patient identification becomes second nature to all healthcare personnel whenever they are involved with delivery of individualized patient care.

Box 11.2 Component administration errors

- Errors in following process for collection of components:
  - poor knowledge and recognition of different component types;
  - failure to act appropriately on discovering an "unlabelled" component;
  - deployment of unqualified staff to collect components;
  - use of inappropriate documentation, or no documentation, to collect component.
- Failures of bedside checking procedure:
  - no checking done at bedside;
  - misunderstanding that ID "checking" can be performed remotely from patient's side;
  - checking against paper documents being substituted for cross check with patients ID wristband;
  - failure to check for special requirements, e.g., irradiation or CMV negative;
  - failure to observe prescribed dose and rate of transfusion;
  - failure to check expiry date and time;
  - omission of visual check of components.
- Non-recognition of a transfusion reaction:
  - lack of understanding of the imperative to monitor patients receiving blood components;
  - failure to recognize a transfusion reaction, due to insufficient knowledge or experience;
  - not responding appropriately when a patient suffers a reaction, due to lack of appreciation of the potential seriousness.

The bedside check has a role not only in correct patient identification, but also in prevention of other errors and omissions, such as ensuring that

special requirements are met (see page 134), the unit is within its expiry date and time, and the visual appearance of the component is normal.

Patient monitoring

Observation and monitoring of the patient receiving the transfusion is a crucial part of the process and a key contributor to overall transfusion safety for patients. Even the most severe reactions may not be life-threatening if they are detected immediately, the transfusion stopped, and appropriate action taken. Although morbidity and mortality from transfusion in developed countries is low, this could be reduced still further by rigorous monitoring of patients at this crucial time. UK guidelines from the BCSH on blood component administration, updated in 2009,[19] state the following:

> Our recommendations for *minimum* patient observations during transfusion episodes now include baseline measurement of respiratory rate. The importance of an early (15-minute) check on pulse rate, blood pressure and temperature with each component administered, repeated not more than 60 minutes after the transfusion is completed, and regular visual observation throughout the transfusion is re-emphasized. It is now recognized that adverse reactions may manifest many hours after the transfusion is completed. We recommend that patients, such as day cases, discharged within 24 hours of transfusion are issued with a *contact card* giving 24-hour access to clinical advice (as commonly used for outpatient chemotherapy).

This statement followed exactly the recommendations from SHOT in 2008[21] based on data on acute transfusion reactions (ATR). In 2008 the time between commencement of the implicated transfusion and the start of the reaction was noted in 274 cases, with an average of 66 minutes, with a range of <1 minute to 440 minutes (7 hours and 20 minutes). Crucially 199 reactions (72.6%) occurred more than 15 minutes after commencing the transfusion, which highlights the need for proper regular monitoring of the patient and the requirement for transfusions to be carried out where there are sufficient trained staff to observe the patient. In 2009 there were 400 ATR cases reported, 366 of which gave the time of onset of the reaction. The median time was 45 minutes after commencement of the transfusion, with a median for anaphylactic reactions of 15 minutes, and 60 minutes for febrile reactions. This emphasises the need for close observation of patients throughout the period of transfusion.

National Comparative Audits of blood transfusion, UK

In the UK, the Royal College of Physicians and the blood services have joined together to perform a number of National Comparative Audits of blood transfusion practice.[22] The audit of bedside transfusion practice including blood administration and monitoring has been carried out several times over a number of years, the most recent being in 2008. This audit of 6943 transfusion episodes from 180 hospitals found that 10% (891) of patients were put at risk of an undetected transfusion reaction or a delay in detecting a reaction, because baseline observations were not recorded prior to starting the transfusion. Observations during blood transfusion were not done for 12% (1118) of patients, placing them at risk of an undetected transfusion reaction, even if they had baseline observations recorded. Over one-third of patients did not have their observations checked at the end of the transfusion. These results suggest that there is not widespread implementation of the BCSH guidelines on blood administration and raises the question of what is an optimal way to monitor a transfused patient.

In addition, in the opinion of the auditors, only 64% of patients could readily be observed. In certain hospitals patients are in side wards and cannot be observed at all times, and since the last BCSH guidelines were published the design of hospitals has changed and many more are being built with single rooms. This increases the risk to patients of suffering a transfusion reaction undetected, or detected late, and may be a particularly worrying issue at night when staff numbers are lower.

Since the series of audits commenced in 1995 the number of patients having observations within

30 minutes during transfusion has increased from 59% to 73%, but the number of patients having no observations recorded at all is unchanged at about 12%.

Under-reporting

This is a problem in any vigilance system, and reporting rates in hemovigilance are no exception. Variability in reporting rates is found between different countries and reporting systems, and within regions and institutions within a country.[3] Under-reporting may be attributed to various reasons. For an adverse event or reaction to be reported it first has to be recognized as a complication, and be related to the transfusion. Where monitoring is not rigorous, and where staffing levels are low, or education and training adequate, reactions such as fever and hypotension due to bacterial contamination can be wrongly attributed, or missed completely, or worse still a patient death can be thought to be due to underlying disease rather than transfusion.

Inevitably, even assiduous patient monitoring does not improve outcomes for patients unless the data collected is interpreted correctly and acted on appropriately—by stopping the transfusion—and treatment and investigations are carried out in accordance with the clinical picture. Education and knowledge is also therefore a prerequisite in staff carrying out the patient monitoring.

Initiatives to improve clinical transfusion activities

Two themes have emerged regularly from clinical hemovigilance data over the last decade or more. The first is the continued reports of failures of bedside-checking procedures that would have prevented the wrong blood administration; a properly carried out bedside check can prevent a large number of ABO-incompatible transfusions. The second is the prominence of knowledge gaps and lack of training and education in junior doctors; this has been instrumental in the large number of cases of inappropriate or unnecessary transfusion.

Transfusion education and training initiatives in the UK

Transfusion medicine education

In the UK there has been a multi-stranded approach to improving availability and quality of transfusion education for doctors and nurses. Much of this has been driven by the Chief Medical Officer's National Blood Transfusion Committee (NBTC),[23] a subgroup of which is working closely with the Royal Colleges and Specialist Societies to ensure that adequate transfusion medicine education and experience is a requirement across all hospital specialities. A unified curriculum is necessary for junior medical staff in training grades and completion of the module should be mandatory before a certificate of completion of specialist training (CCST) can be achieved. For junior doctors in the foundation years (first and second year after qualification) an e-Learning package has been developed and made available across the UK and is being made mandatory for accreditation and appraisal before entering specialist training grades.[24] The professional qualification and licensing bodies for nurses, midwives, and biomedical scientists need to incorporate transfusion education into the curriculum as a requirement before registration can take place.

Increasing transfusion awareness at managerial and executive level

The Department of Health has spearheaded a Better Blood Transfusion campaign in partnership with the UK blood services and the NBTC, which started in 1998, with further health service circulars directed at Hospital Chief Executive Officers and transfusion professionals in 2002 and 2007.[25]

Blood administration and component training and competency

The National Patient Safety Agency (NPSA) issued a Safer Practice Notice in 2006 (SPN 14)[26] setting out standards for training and competency assessment of all staff of all grades and professional groups that are involved in the administration of blood components. It states that all staff, medical or non-medical, qualified or unqualified, from consultants

to medical laboratory assistants (MLAs), operating department assistants (ODAs), and portering staff must be trained and competency assessed before they are permitted to perform a role in the blood transfusion pathway. This includes: obtaining a venous blood sample; organizing the receipt of blood/blood products for transfusion; collecting blood/blood components for transfusion; preparing to administer a transfusion of blood components to patients; and administering a transfusion of blood components. Deadlines for achieving all staff training and competency assessments have been set, and training must be renewed every three years.

National guidelines and protocols

The UK has national guidance for the use of blood components, drawn up by the British Committee for Standards in Haematology and other professional bodies and Royal Colleges.[27] These are evidence-based documents and are used nationwide to underpin local and regional guidance.

Formal clinical handover

A significant number of cases, in several SHOT reporting categories, have occurred out of hours, at times when staffing was reduced for various reasons, or when shift working meant that junior doctors were caring for large numbers of patients with whom they were not familiar.

The European Working Time Directive (EWTD)[20] has been implemented by law across the EU but in many hospitals, certainly in the UK, there have been few practical arrangements put in place to deal with the inevitable problems for patient care that this poses. Proactive new systems are required, and need to be implemented by high-level management to ensure effective handover between shifts and teams, and continuity of patient care. This will not only enhance patient safety and satisfaction, but also reduce unnecessary prolongation of stay due to communication failures.

Despite the reduced hours, hospital doctors are increasingly stressed by being spread thinly over many patients without proper information about the clinical progress and plans for those patients. Sick leave among junior doctors has increased hugely since implementation of the EWTD, and job satisfaction has reduced.[28] A new initiative in the UK spearheaded by the Royal College of Physicians, has developed a cross-disciplinary patient handover tool that allows a rolling update of current care and problems of patients. This is then used as the basis for a formal handover session at times of changing shift or on-call team.

IT solutions

If finances are available, it may at times be worthwhile to invest in a lockable/barcode-protected issue fridge, and satellite fridges that only allow trained and accredited personnel access. This automatically releases only the correct unit of blood on presentation of the patient's details and the details of the member of staff collecting. Although reducing the risk of error, this does not reduce the burden of training and competency assessment, because involved staff must be trained in this process. Computerized refrigerator systems have been particularly effective in reducing errors in hospitals with large numbers of satellite fridges where monitoring of the audit trail, especially with regard to traceability and the cold chain, can be particularly difficult. These systems may extend to barcode readers for increased accuracy of bedside checking, together with ordering, label printing, and entry of monitoring observations.[29] These systems are expensive in terms of capital expenditure and implementation and training time. Such expenditure needs to be fully evaluated in terms of cost effectiveness for blood safety, as well as prioritized against other patient safety interventions in hospitals.

There were 61 reported incidents of IBCT errors relating to IT systems reported to SHOT in 2009, compared with 44 in 2008 and 25 in 2007. As electronic "blood tracking" systems enter more general use, SHOT is starting to receive reports of their misuse leading to IBCT.[10]

IT solutions for patient identification and for documentation of the audit trail for blood components have become more common in recent years. A variety of systems are on the market currently, with more in development. There is an enormous drive toward use of these systems from those who have implemented them successfully, from national advisory groups, and naturally from the manufacturers and retailers of the equipment.

Care must be taken to avoid the inherent problems of this approach, while maximizing the benefit to patient safety. IT-based interventions cannot eradicate error, and indeed do not directly address the problem of human error.

Undoubtedly the occurrence of certain errors can be reduced by appropriate implementation of IT-based checking systems, but new possibilities of error may also be introduced. Over-reliance on IT and believing that it circumvents human error can result in a decrease in understanding of, and engagement with, the transfusion process among the staff involved.

Box 11.3 What IT systems can and cannot do

IT can:

- Match barcodes scanned from different source material.
- Transfer data between parts of the system, parts of the same record, or between records.
- Recall data attached to specific patient ID accurately and completely.
- Print, without transcription error, labels or results on requested patient.
- Be set to produce alarms and warning messages if non-matching data is scanned.
- Display warning alarms and messages according to preset algorithms (e.g., date of birth).
- Allow specific data and high visibility warning flags to be added manually to patient records.

IT cannot:

- Ensure that the correct barcoded item is scanned.
- Ensure that data is transferred between correct records (e.g., merging incorrect patients).
- Ensure that all the patient-specific information recorded is accessed, read, and understood.
- Ensure that labels or results are requested on the correct patient.
- Ensure that alarms, warning messages, and flags are read and heeded.
- Enhance patient safety unless it is used appropriately.

IT systems have a major contribution to make in adding electronic checking at vulnerable steps in the transfusion chain, and can provide accurate and complete data at the relevant stage in the process for consideration by the users; but they cannot prevent human error. Adequate knowledge and skills are no less essential in the presence of a vein-to-vein electronic-tracking system, and education and training must be comprehensive and appropriate to the staff groups involved at each stage. All staff must be familiar with the process, able to carry it out safely (with or without an electronic aid), able to detect deviations from normal situations, and make safe, appropriate decisions as each circumstance arises. In addition, training specific to the use of electronic systems is required.

Professional responsibility

It is of concern that, by concentrating on the many issues surrounding the training and competency assessment of unqualified staff in the transfusion chain, the ultimate and overriding importance of the professional staff groups may be overlooked. Only professionally qualified staff can be held accountable and responsible for the work they carry out. It is also a professional responsibility for individual staff to ensure that they have adequate knowledge, skills, and understanding to perform the tasks that are required of them. It is through the knowledge and vigilance of professional staff that errors in transfusion can be prevented, whether at the time of the decision to transfuse and the prescription of components, in the laboratory, or at the time of blood administration at the bedside. Unqualified staff (i.e., not medical, nursing, or scientific staff) cannot be held responsible for ensuring that the correct component is transfused to a patient.

If properly conducted, the bedside check of patient identification against the intended component would prevent the vast majority of wrong blood episodes. Staff performing bedside checks must take full responsibility for correctly identifying the patient and for ensuring that the unit that they transfuse is the correct unit bearing the correct details of the patient, and that the specification of the unit and the manner of its transfusion are all in accordance with the prescription and clinical indication as documented by the medical staff.

Medical staff must possess sufficient knowledge, skills, and understanding to assess the patient fully and to make a competent decision regarding the necessity to transfuse, the correct component, and the rate of transfusion required. Only junior doctors who have sufficient knowledge to prescribe

blood appropriately, effectively, and safely should be permitted to do so. Doctors must satisfy themselves that any laboratory results they use to inform the transfusion decision relate to the correct patient, and have been correctly documented.

It is also a medical responsibility to document the details of the transfusion in the notes together with the clinical indications of transfusion and intended outcome. The transfusion rate and any specific caveats relating to the patient must also be documented, together with any follow-up actions required from other staff. Effective handover is essential when going off duty.

The prescribing of the component on the prescription sheet is only the endpoint in a complex decision-making process in which a large number of variables need to have been taken into account. Who finally prescribes the blood component is therefore a much less important issue than the level of knowledge and skills of the personnel involved in the decision-making process.

Nursing staff are also professionals and fully and individually accountable for their role in transfusion safety. If nurse-prescribing of blood components is practiced, responsibility lies fully with the prescriber, who must have sufficient knowledge and skills for this task. If medical staff members are taking professional responsibility for a patient group directive, an individual prescription, or the treatment plan for a patient, the carrying out of the instruction lies with the medical or nursing staff who complete the action. Unqualified, or student nurses, or staff with no professional accountability, must not be involved in critical steps of the transfusion process.

Future hemovigilance

The inclusion of clinical practice in hemovigilance data is an important step forward in improving the safety of transfusion rather than only safety of blood components. In many developed countries components are now extremely safe, and more than half of the patient harm arising from transfusion arises from human error, in particular knowledge gaps, communication failures, and administrative mistakes.[2] Hemovigilance must continue to monitor clinical transfusion medicine, to gain an insight into areas where improvements can be made. Appropriate or optimal use of blood components is already high on the patient safety agenda, along with education and training. Alternatives to transfusion, however, are also in increasing use, such as cell salvage techniques and pharmaceutical adjuncts to reduce blood loss. Hemovigilance systems need to further expand their scope to collect adverse events data on the use of these alternative strategies.

Analysis of these data will allow standards and performance indicators to be agreed, against which blood component use can be assessed. Protocols for documentation and communication are also essential, because many adverse incidents leading to patient harm from transfusion include one or more administrative failure. Weak links in the process need to be identified and protocols should be tested in practice scenarios in hospitals to ensure that all personnel are aware of their role, of the communication pathways, and to identify any flaws in the agreed system.

Box 11.4 SHOT UK general recommendations for transfusion safety

- Mandatory participation in hemovigilance reporting schemes by all blood establishments and all hospitals where blood is transfused.
- A culture of adverse-event reporting with no fear of disciplinary action, for the improved safety of patients and the education of transfusion professionals.
- Adequate education and training of all staff involved in blood transfusion, linked to career progression where appropriate.
- Continuous review of the whole transfusion process in the light of hemovigilance data to identify areas for improvement of systems or practice.
- Broadening of the scope of hemovigilance to include patient harm from under- or overtransfusion, and to gather data on the use of some alternative strategies, e.g., cell salvage.
- To gather and learn from data from other hemovigilance systems worldwide, through the activities of the International Haemovigilance Network, the EU Commission, and the WHO.

Conclusions

Data from SHOT and from other hemovigilance schemes has demonstrated that human error is responsible for approximately 50% of transfusion-related adverse incidents reports. Although individual error may contribute to this figure, a majority of cases are related to multiple errors due to systems failure and organizational failure. The number of reports that are received by hemovigilance systems is probably still very low compared with the true number of such incidents taking place in clinical areas. It may be that some staff are still wary of reporting adverse incidents of this nature because they feel it may have implications, because of their professional accountability. It is important that a culture of incident reporting is nurtured in clinical areas. The characteristics of the ideal medical event reporting system were defined in a seminal paper by Leape in 2002:[30] nonpunitive, confidential, independent, expertly analyzed, with timely reports and a system oriented approach.

A culture shift in the clinical arena is required so that when a doctor feels unable to handle a clinical scenario, requesting and obtaining appropriate help is easy and negative judgement avoided. Doctors, nurses, midwives, biomedical scientists, and other staff should be encouraged to ask for help and clarification when they recognize that their own knowledge and skills are inadequate for a situation in which they find themselves. Failure to do so could be deemed negligent if an incident occurred. A culture of supportive, friendly surveillance and teamwork needs to be encouraged and nurtured in all clinical and laboratory areas, and any lessons learnt must be shared with the relevant Governance and Risk Management groups and users.

In fact, blood transfusion is one of the safest interventions that a patient may undergo in hospital and the actual rate of severe outcomes, that is, major morbidity or mortality, is very low. A higher incidence of adverse events is reported with pharmaceutical therapies and surgical interventions. In the SHOT report in 2009 there were 73 cases of major morbidity and 12 deaths in which the transfusion may have contributed out of a total of 1279 reports, hence in total 6.7% of patients with serious outcomes. The overall rate of adverse events reported to SHOT is 4.4 per 10,000 components transfused, or 0.04% of components that are implicated in an adverse event or reaction. A report published 2007 from the Netherlands found that 5.7% of patients out of the 1.3 million hospital admissions in 2004 suffered unintentional harm or an adverse event.[31] Worldwide this percentage ranges from 2.9% to 16.6%, according to the US Institute of Medicine's 1999 report "To Err is Human."[32] The rate of ABO-incompatible transfusion in the UK as reported to SHOT has fallen in the years since 1996 when reporting began. This may represent the impact of the collaboration between SHOT, the NPSA, and the National Blood Transfusion Committee, aimed at raising awareness and implementing a raft of strategies to improve bedside transfusion safety.

Hemovigilance systems have been proven to be an excellent tool for identifying areas for improvement of practice in transfusion medicine. Many of the problems identified that relate to human error are in no way specific to the practice of transfusion medicine but are generic problems. The most obvious of these is the perennial problem of patient identification, which is common to all areas of healthcare delivery including investigations, invasive procedures, surgery, and perhaps most importantly the prescribing of pharmaceutical agents.

Hemovigilance has set standards of data collection for patient safety purposes, and other specialties and subspecialties within medicine and surgery would do well to follow suit by developing similar systems.

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