Incorrect Blood Components Transfused (IBCT) n=331

10

Laboratory errors n=170

Clinical errors n=161

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Definitions:

Wrong component transfused (WCT)

Where a patient was transfused with a blood component of an incorrect blood group, or which was intended for another patient and was incompatible with the recipient, which was intended for another recipient but happened to be compatible with the recipient, or which was other than that prescribed e.g. platelets instead of red cells.

Specific requirements not met (SRNM)

Where a patient was transfused with a blood component that did not meet their specific requirements, for example irradiated components, human leucocyte antigen (HLA)-matched platelets when indicated, antigen-negative red cell units for a patient with known antibodies, red cells of extended phenotype for a patient with a specific clinical condition (e.g. haemoglobinopathy), or a component with a neonatal specification where indicated. (This does not include cases where a clinical decision was taken to knowingly transfuse components not meeting the specification in view of clinical urgency).

Key SHOT messages

- Obtaining a second sample confirms the ABO group of a first time patient prior to transfusion and prevents wrong blood in tube (WBIT) incidents and ABO-incompatible blood components being transfused (BSH Milkins et al. 2013)
- Collecting more than one unit at a time or units for more than one patient can split the focus of the person collecting and leads to errors – collect one unit for one patient at a time where possible (BSH Harris et al. 2017)
- Good communication and teamwork is essential to aid patient safety and transfusion safety – all staff involved in the transfusion process should be encouraged to work cohesively as one team
- There has been a striking increase in laboratory errors over time resulting in specific requirements not met

Figure 10.1a: Overview of reports where an incorrect blood component was transfused in 2016

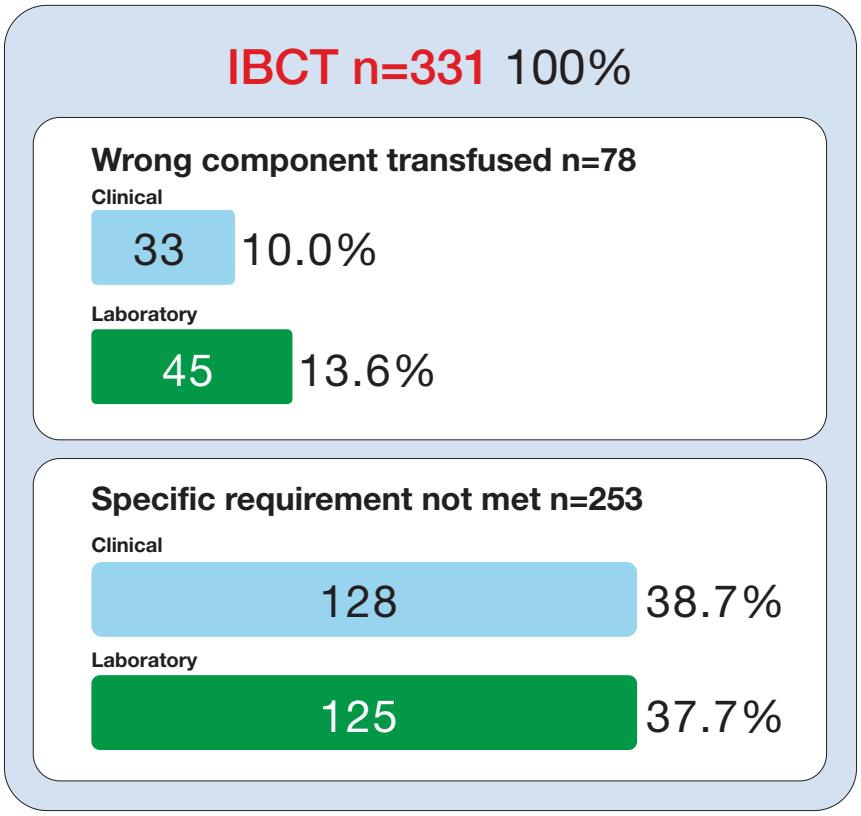
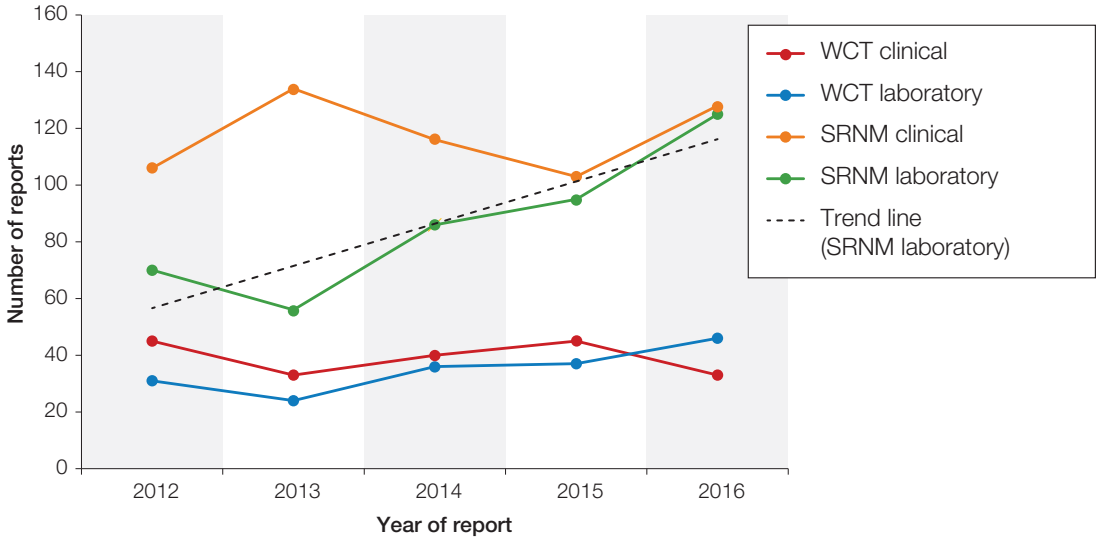


Figure 10.1b: Incorrect blood component transfused 2012 to 2016



The striking feature noted in Figure 10.1b is the increase over time of reports where specific requirements were not met. Review of data in Chapter 7, Laboratory Errors, shows that the most common cause of these in 2016 was failure to notice information on the request form, or failure to check available historical records (Figure 7.4a). There is also an upward trend in laboratory wrong component transfused reports whereas there is little change in the clinical reports.

Deaths n=0

There were 22 deaths reported in the IBCT category. None of these were related to the transfusion (imputability 0: excluded or unlikely).

Major morbidity n=8 (2 clinical, 6 laboratory)

Clinical n=2

Two patients experienced serious harm as a result of transfusion of ABO-incompatible red cells. One incident was due to a sample error (WBIT) and the other due to collection and subsequent administration of the incorrect component. For further details, see Cases 10.3 and 10.5 in the ABO-incompatible red cell section below.

Laboratory n=6

Two patients experienced haemolytic transfusion reactions, one a 4-day-old baby due to a component selection error, and the other resulted from a testing error, Cases 10.1 and 10.2 below.

Four women of childbearing potential developed anti-K or anti-D when transfused with K-positive/D-positive components:

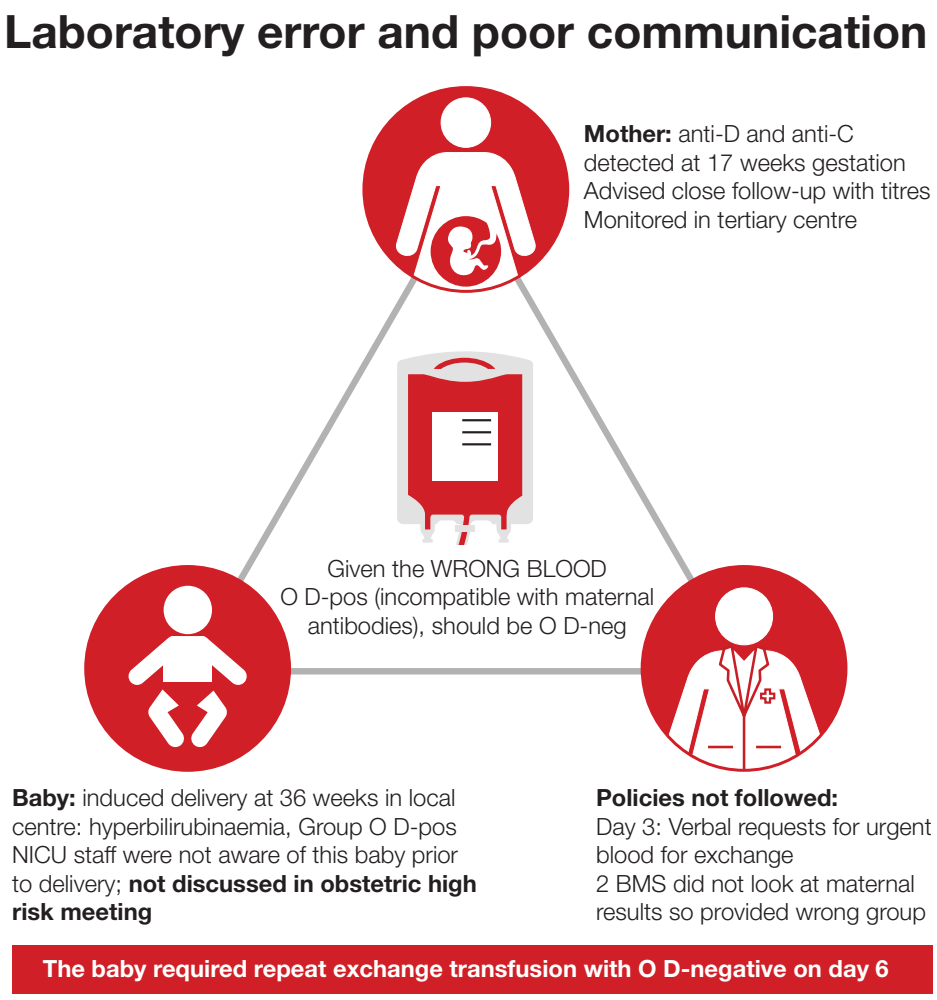
- Two resulted from component selection errors where the biomedical scientist (BMS) ignored warning flags stating that the unit was not K-negative
- The Blood Service issued D-positive platelets for a D-negative woman without informing the laboratory; the laboratory staff did not check the group and therefore did not provide anti-D immunoglobulin for the patient
- A transcription error was made in D grouping when a BMS was working alone out-of-hours

Case 10.1: Selection error results in a 4-day-old baby with haemolytic disease of the fetus and newborn (HDFN) due to anti-D receiving incompatible red cells (O D-positive) and requiring further exchange (Figure 10.2)

A maternal antenatal sample (the second) taken at 16/40 was found to contain anti-D+C. The mother was monitored at a specialist fetomaternal centre throughout pregnancy. The baby was induced and born (at the local hospital) at 36^{+3}/40 with hyperbilirubinaemia but levels were below the threshold for exchange transfusion, so the baby was treated with phototherapy and intravenous immunoglobulin. By the third day the serum bilirubin had risen so the clinician alerted the transfusion laboratory (verbally) that an exchange would be needed; the BMS stated he had O D-positive (the baby's group) neonatal red cells in stock. On the fourth day a request for two red cell units for exchange transfusion was made verbally. The BMS issued two units of O D-positive red cells without checking maternal group and antibody details, and without crossmatch against maternal plasma. Two registered nurses checked the units during the final bedside check. Three days after the exchange the baby's bilirubin continued to rise and a further two units were requested. A clinician reviewing the case realised that the wrong group red cells had been administered and requested a further exchange transfusion with two units of O D-negative red cells. The baby's bilirubin reduced and the baby was discharged 5 days later.

In addition, a Kleihauer test was wrongly requested on the mother, and she had inappropriate anti-D Ig administered.

Figure 10.2: Combination of errors resulting in D-incompatible exchange transfusion



Root cause investigation

- On the 3rd day when the clinician alerted the transfusion laboratory, the BMS did not review the maternal details and issued O D-positive cells, the baby's group but incompatible with the antibody
- All requests were made by telephone, and the handover in the laboratory was not effective, although no follow up request form was received in the laboratory (several BMS were involved over the subsequent days)
- On several occasions (4th and 7th days) the BMS did not check the mother's blood group and antibody results and issued two O D-positive red cells units without crossmatching against the mother's sample. There were additional human factors during the initial transfusion episode: in the daytime there was a sole BMS dealing with haematology/coagulation/transfusion and an engineer on site. Subsequent transfusion episodes were dealt with at night by a lone worker

The Kleihauer test was inappropriate due to the mother's antibody status and the laboratory staff should not have issued the anti-D Ig. The nurses should have sufficient transfusion knowledge to question the group of the red cell units in this context. There need to be clear procedures in place and regular competency-assessment of all staff involved in the transfusion process. It is imperative that good communication links and updates are in place, especially during shared care.

Lone-working also appeared to be a factor in this event. The laboratory may need to produce or review their capacity plan to ensure that staffing levels are adequate for workload. Contingency plans must be written and implemented to cover periods when staffing levels are below minimum or workload is unacceptably high.

Learning points

- Laboratories should always have sufficient staffing, correct staffing can support staff that require training (Chaffe et al. 2014)
- Telephoned requests should always be followed up with a request completed as described in British Society for Haematology (BSH) guidelines (BSH Milkins et al. 2013)

MHRA regulatory reflection: Standard operating procedures (SOP) should cover all tasks that staff might need to undertake, and they must be detailed enough to instruct the staff exactly what to do, even in rare or infrequent situations. Infrequently-performed tasks might require staff to be re-trained more frequently than daily tasks which are more familiar. Staff must recognise for themselves when they are unsure of the correct procedure and consult that SOP to ensure accuracy rather than asking other staff or improvising.

Case 10.2: Elderly male patient given incorrect phenotype due to transcription error

An 81-year-old male patient with myelodysplastic syndrome undergoing routine transfusion for anaemia required two units of red cells. The patient had a laboratory record of anti-S, a pan-reactive enzyme antibody and was direct antiglobulin test (DAT)-positive. Transfusion of the first unit was uneventful, however during the second unit the patient experienced a rise in temperature (35.5°C to 37.6°C) with rigors, hypotension (140/70 to 100/60mmHg) and tachycardia (70 to 104 beats per minute (bpm)), there was no change in respiratory rate. Haemoglobinuria was detected. Following the reaction the pre- and post-transfusion samples were sent to the Blood Centre and the second unit was found to be incompatible (S-positive). The symptoms were treated and the patient was discharged the same day.

Root cause investigation

- The second unit was S-positive and retrospective testing showed the unit was incompatible. The testing also confirmed haemolysis
- Further investigation identified that the laboratory staff:
  - Failed to select an antigen-negative component (the BMS mistook HbS-negative for S-negative)
  - Were unsure of the order of the units on the worksheet leading to a transcription error and failing to identify the incompatible unit
  - Failed to detect the unit was not S-negative during the second check

Care is required when selecting and checking components for patients with a specific requirement. Procedures must be robust, prescriptive and clear so as to avoid any confusion when using worklists.

MHRA regulatory reflection: The most significant error appears to surround the difference between HbS-negative and S-negative. It is vital that laboratory staff are aware of blood component labelling formats and where to find and how to use the information on labels and dispatch notes. Where possible, this information should be available on the laboratory information management system (LIMS) and used to prevent the issue of unsuitable components. Training in these procedures could be used to verify the laboratory staff's understanding of the component labelling information. This incident demonstrates that nothing should be taken for granted, even someone's understanding of component labelling.

One of the aspects of the corrective and preventive action (CAPA) relates to reinforcing the thoroughness of second checks. Checking work is vital to any quality management system (QMS) and laboratory managers need to ensure the benefit of additional checking steps and that they add value to the process. A second check may identify an error if performed correctly, but does not prevent the initial error from having occurred. Reliance on second checks alone as CAPA is to overlook the root causes of the error. Second checks may actually provide a false sense of security leading to inaccurate working practices, and even add distractions and increase workload for those expected to perform them.

ABO-incompatible blood component transfusions n=6 (3 clinical, and 3 laboratory)

Unintentional transfusion of ABO-incompatible blood components is a National Health Service (NHS) 'Never Event' (NHS England 2015). In Scotland these would be reported as 'red incidents' through the Scottish National Blood Transfusion Service clinical governance system and/or those of the Health Board.

These cases do not include a further 15 cases (12 laboratory errors, 3 clinical) where patients received incorrect ABO or D red cell transfusions related to haemopoietic stem cell transplants (HSCT) of which 6 could be classified as ABO never events (Table 23.4 in Chapter 23, Summary of Incidents Related to Transplant Cases).

ABO-incompatible red cell transfusions n=3 clinical (2 resulting in major morbidity)

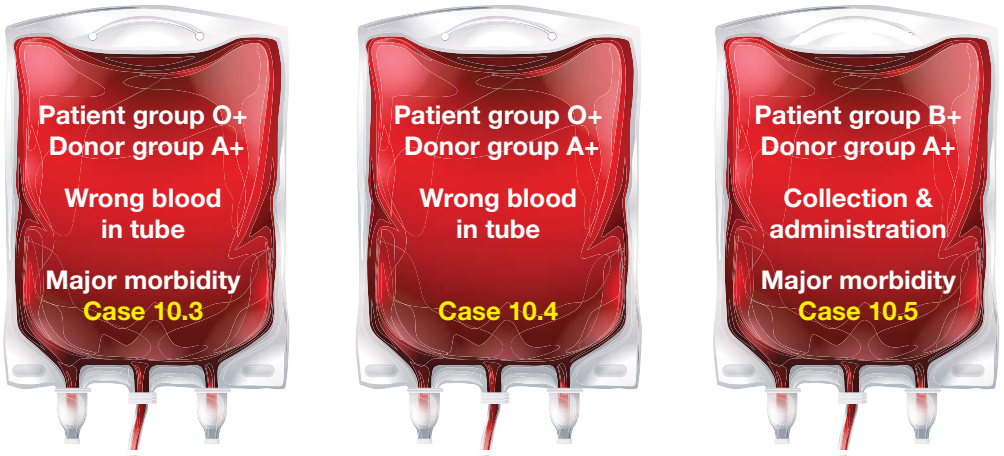


Figure 10.3: ABO-incompatible red cell transfusions

Case 10.3: Wrong blood in tube leads to ABO-incompatible transfusion and major morbidity

A 61-year-old male (Patient 1) was admitted for coronary artery bypass graft. He received four units of group A D-positive red cells, had an uneventful stay in hospital and was discharged home. Fourteen days later he was admitted to critical care via the emergency department (ED) with renal impairment and a falling haemoglobin. On this second admission Patient 1 was grouped as O D-positive. The sample used for the crossmatch 14 days previous had been taken from the wrong patient (Patient 2) and labelled with Patient 1's details. A second sample was not obtained to confirm the ABO group although it was the hospital policy.

The haemolysis in this case must have been slow, probably because the anti-A was low titre and non-lytic. Red cell destruction in this setting usually starts much sooner, perhaps even immediately, but if the patient had no clinical symptoms, it would have gone unnoticed.

The investigation revealed that the trolley containing all patient request forms and labels was taken to the bedside. While the sample was being taken a colleague placed another set of labels on top of the current sets. The member of staff then labelled the sample using the incorrect labels and did not fully identify the patient. Positive identification of the patient and obtaining a second sample to confirm the ABO group at this critical step in the transfusion process could result in detection of the error and prevent serious harm.

Case 10.4: Wrong blood in tube leads to ABO-incompatible transfusion

A sample was taken from a 66-year-old male with symptomatic iron deficiency anaemia and grouped as A D-positive. One unit of A D-positive blood was issued, a group-check (or second sample) was not obtained despite the hospital having a 2-sample policy in place. Three days later a further sample was sent to the laboratory which grouped as O D-positive; an additional check sample was sent on this occasion which confirmed the group as O D-positive. The patient experienced mild loin pain and mild 'haematuria' lasting 24 hours but made a full recovery.

Learning points

- Both clinical and biomedical scientist (BMS) staff should adhere to a 2-sample policy/standard operating procedure (SOP) if this is the local arrangement. This process confirms the ABO group of a first time patient prior to transfusion (BSH Milkins et al. 2013)
- ABO-incompatibility does not necessarily cause immediate intravascular red cell destruction, but still potentially causes major morbidity

Importance of a group-check policy, also known as the two-sample rule

The concept of a group-check policy was recommended in the 2013 BSH guidelines for pre-transfusion compatibility procedures in blood transfusion laboratories (BSH Milkins et al. 2013). Prior to a first transfusion, in the absence of a secure bedside electronic patient identification system, patients must have a blood sample grouped on two separate occasions where this does not impede the delivery of urgent red cells or other components. In practice, if the laboratory does not have a historical record for a patient, a second sample should be requested for all routine first time transfusions and components issued only if the results match. The importance of a group-check is also illustrated by Case 12.3, a near miss IT error where the LIMS auto-validation system assigned the wrong ABO group to a patient.

The second sample is a group check to confirm the sample was taken from the same intended patient on both occasions. The two sampling episodes must be separated and it is recommended that the samples are taken by different people. The time difference between episodes is not prescriptive in the guidelines but full and careful patient identification procedures must be followed on each occasion.

The 2012 Annual SHOT Report recommended strict adherence to the requirements for a group-check sample on patients without a historical group (Bolton-Maggs et al. 2013). It has been estimated that 1/2000 samples is from the wrong patient (Dzik 2003; Murphy 2004) i.e. wrong blood in tube (WBIT).

The practice of taking two samples from the patient at the same time is flawed. If the wrong patient is bled or the sample labelled with someone else's details, both samples will group identically but incorrectly. The patient could receive an ABO-incompatible blood transfusion. Analysis of SHOT data shows that about 33% of ABO-incompatible transfusions result in death or major morbidity (Bolton-Maggs et al. 2014).

Case 10.5: Collection of the wrong component and subsequent failure of bedside check leads to ABO-incompatible transfusion and major morbidity

A 69-year-old male was admitted for an aortic valve replacement and coronary artery bypass surgery. A healthcare support worker (HCSW) was asked to collect two units of blood for this patient and one unit of blood for another. Both patients had the same forename. The two nurses who requested the collection were each unaware that the HCSW had been asked by the other nurse, however, it was not against hospital policy to collect more than one unit at a time. Communication between the HCSW and the laboratory staff was unclear but it seems this had an impact on failure to complete identification checks correctly when collecting the three units of blood. The three units were delivered to the correct clinical area. The registered nurse looking after the patient who required two units of blood failed to complete the identification checks for the first unit and consequently did not realise the wrong component was administered. When she commenced the second unit, there was a failure of checks again. Another nurse noted the error and the transfusion of the second unit was stopped. The patient suffered an acute transfusion reaction with haemolysis and respiratory distress. The patient was already on the intensive therapy unit (ITU) but required re-ventilation.

Learning points

- Collection of more than one unit at a time splits the focus of the person collecting and can contribute to the wrong component being collected
- If more than one blood component is required then patients should be prioritised and one unit collected at a time

The root cause investigation also revealed that the nurse was interrupted by a telephone call from a relative and at the same time distracted by the deteriorating condition of the patient requiring the transfusion. *This case is a mirror image of the case reported in 2015 where the patient died.*

Learning point

- If staff are interrupted and/or distracted during the final bedside administration check, they should re-start the process from the beginning (BSH Harris et al. 2017)

ABO-mismatched or incompatible fresh frozen plasma (FFP) transfusions n=3 laboratory (these are also 'never events')

In 2 cases the wrong component was selected. In one case the BMS followed the SOP for issuing platelets rather than FFP and there was no warning flag in the LIMS to alert the BMS to the selection of the ABO-incompatible plasma components. Case 10.6 describes the second selection error. In the third case the BMS failed to heed the patient history where the group of the 1-month-old baby was recorded.

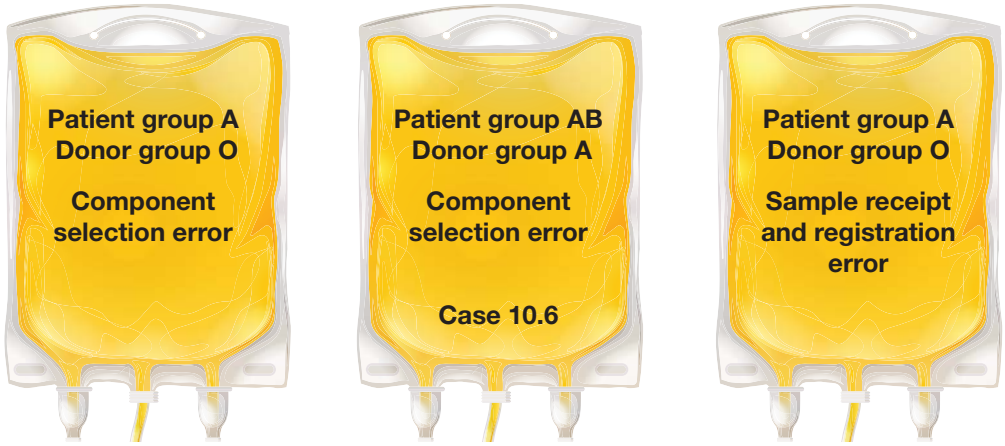


Figure 10.4: Incompatible FFP transfusions n=2 (O to A) and mismatched n=1

Case 10.6: Failure to heed warning flag results in group A FFP being given to a group AB patient despite group AB FFP being available

An 81-year-old male grouped as AB D-positive with anti-E and anti-K. The sample was also DAT-positive and further testing identified the patient phenotype to be C-E-c+e+ (Ro) and K-negative. Two units of red cells were requested and the consultant haematologist authorised group AB D-negative CDE-negative K-negative. A major haemorrhage pack (four units of red cells and four units of FFP) was later requested uncrossmatched. Only two group AB D-negative K-negative units were available so the consultant authorised and issued two group A D-negative (CDE-negative) K-negative units. A second BMS came to assist the first BMS and proceeded to thaw four group A FFP although group AB units were available. This BMS overrode the LIMS warning flag alerting them of the incompatibility. The second BMS was experienced in transfusion and had read the SOP and had been observed issuing components on several occasions, but had not been signed off as competent as there was an outstanding question surrounding lone working. This incident happened out-of-hours and was not detected until checking the work the following morning. It is thought the BMS may have been confused by the consultant authorising group A red cells and went on to issue group A FFP as well. The patient suffered no adverse reaction.

Group A FFP may be given to AB recipients as long as it is high-titre negative. If not high-titre tested, group A FFP should only be used in an emergency.

Learning points

- Laboratory and clinical staff should not undertake any procedure that they have not been fully trained and assessed to perform. It is the responsibility of both managers and staff to ensure this happens
- Warning flags on the laboratory information management system (LIMS) are there to alert and warn the user and require appropriate consideration before being overridden
- Always recheck the patient record on the LIMS before issuing any components

MHRA regulatory reflection: In this situation, the laboratory could have activated other contingency plans, or the BMS could have performed other activities they had been fully trained in to alleviate the pressures in the laboratory.

Incompatible red cell unit transfused n=1

There was one laboratory labelling error, where the patient was transfused a serologically crossmatched but incompatible unit (not ABO-incompatible).

Case 10.7: Failure to check donation number against the compatibility label results in a serologically crossmatched but incompatible unit transfused to the patient

A 21-year-old male in sickle cell crisis with anti-E, anti-Le^a, a pan-reacting autoantibody and a positive DAT required transfusion. Two units that were CDE-negative, K-negative and HbS-negative were crossmatched and issued. A unit of compatible red cells was later identified as transfused but found in the stock refrigerator. A further unit associated with this crossmatch should have been returned to stock but could not be accounted for. Unfortunately a unit of blood deemed incompatible on the basis of a reaction with the patient's existing autoantibodies was selected in error and labelled with a compatibility label and transfused instead of being returned to stock.

The compatibility label must always be cross-checked with the donor unit and preferably signed for an audit check. Any red cells identified as incompatible must be removed from temporary reservation and placed back into stock immediately. Electronic blood-tracking solutions can help identify any units incorrectly issued to a patient.

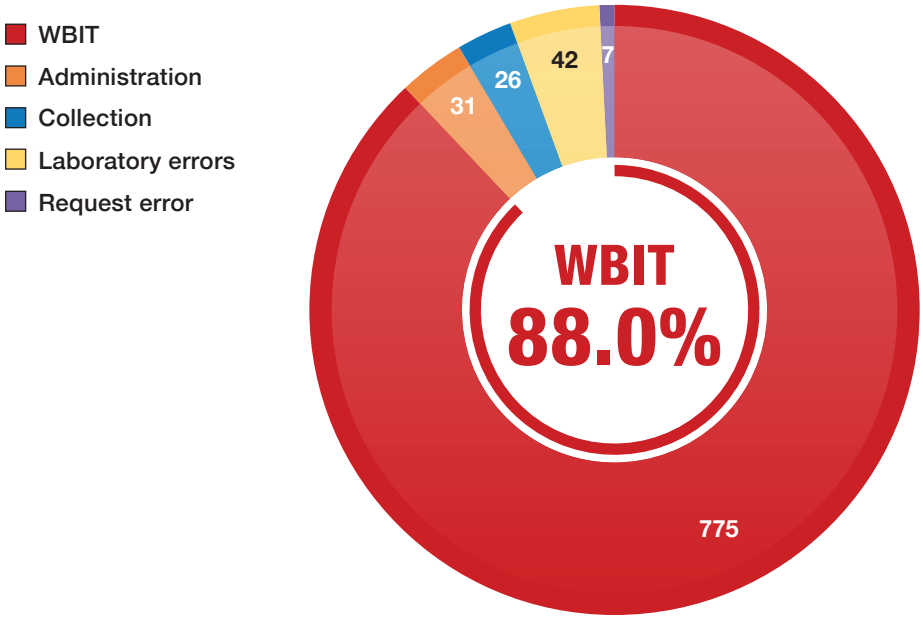
Learning point

- Staff completing the final bedside checking process must check the compatibility label with the component donation number and document the donation number of the component pack and not the compatibility label into the patient notes

MHRA regulatory reflection: The investigation report identified a number of contributory factors. One of these was an increased workload at the time of the error as a result of a build-up of work which should have been completed overnight. Although staffing levels were adequate at the time of the error, the additional workload, due to the failure to complete the antenatal work from the previous night, is thought to have added additional pressures to the staff at the time. The lone-working BMS from the previous night was used to working in a different hospital and had not been trained in antenatal data entry procedures. It is essential that any member of staff working in the laboratory is fully trained to perform all of the duties expected of them.

Near miss IBCT-WCT cases n=881

Figure 10.5: Most near misses were WBIT

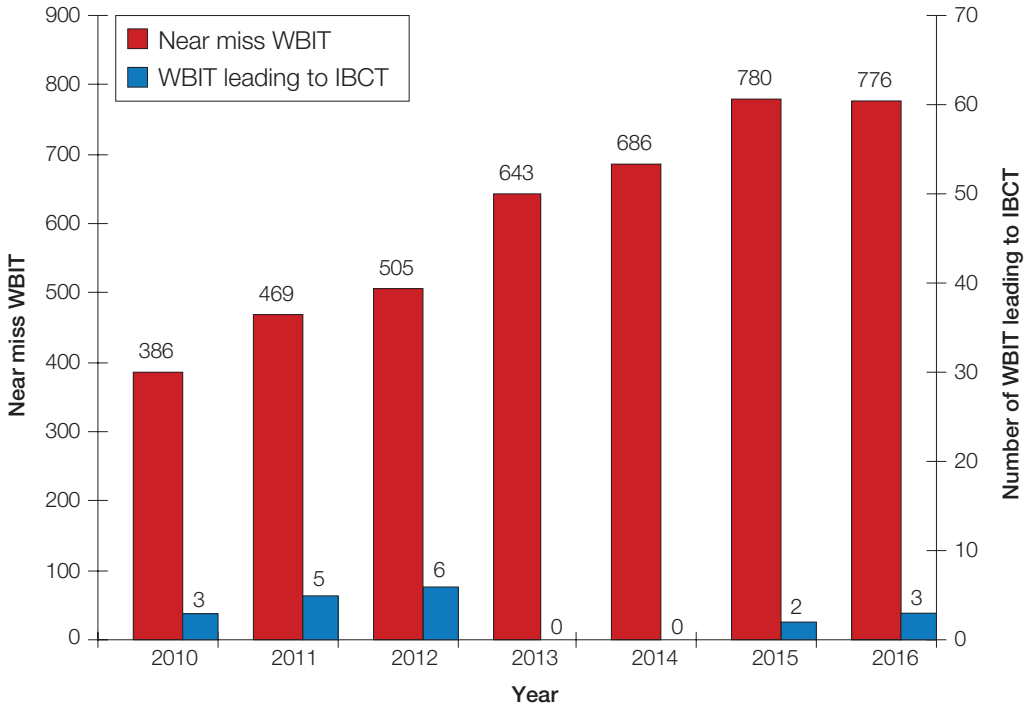


WBIT potentially leading to IBCT n=775 (+1 avoidable n=776 WBIT in total)

Definition of WBIT incidents:

- **Blood is taken from the wrong patient and is labelled with the intended patient's details**
- **Blood is taken from the intended patient, but labelled with another patient's details**

Figure 10.6: Cumulative comparison of near miss WBIT and those leading to IBCT



Detection of WBIT incidents

Quality processes in the laboratory are vital for detecting WBIT, but patient safety relies on vigilance and quality checking by all staff involved in transfusion. If processes were undertaken accurately at the time of sampling there would be many fewer potential WBIT.

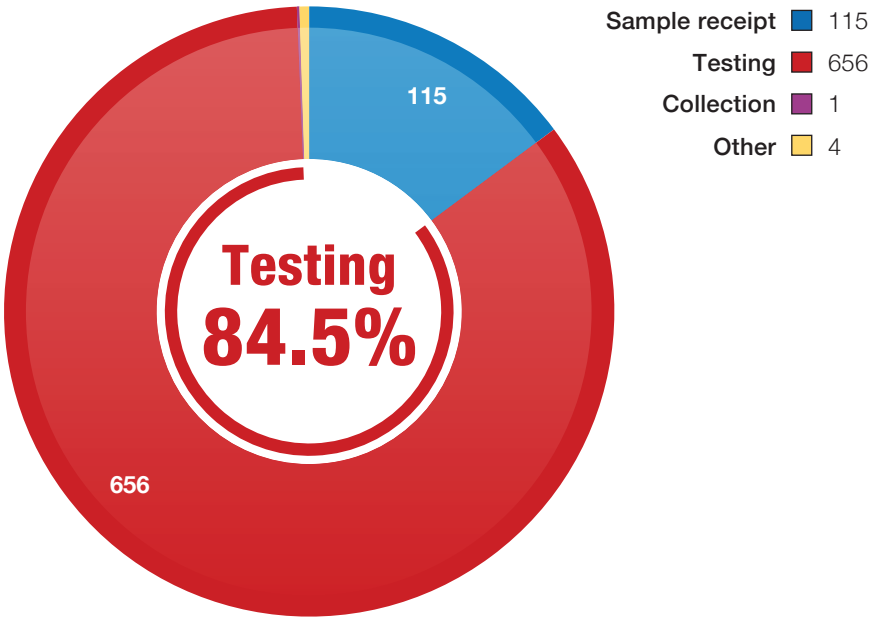


Figure 10.7: Point in the process where a wrong blood in tube incident was detected*

**includes 1 WBIT incident that could have led to avoidable transfusions and is included in Chapter 11b, Avoidable transfusion*

Additional tables showing the subcategorisation of near miss errors consistent with those in previous Annual SHOT Reports (2010–2015) can be found in the supplementary information on the SHOT website www.shotuk.org.

Information technology (IT)-related IBCT-WCT cases n=29

Laboratory n=26 and clinical n=3

Use of warning flags or alerts n=17 and failure to consult the historical record n=4

There were nine cases where a warning flag was in place but not heeded, one case where the flag was not updated and four where the historical record was not consulted.

There were a further seven cases where, had a flag been in place, the error might not have occurred.

11 of these 'wrong blood' incidents were in HSCT or solid organ transplant (SOT) patients.

Transfusion laboratories supporting allogeneic HSCT units need to use the LIMS to support complex specific requirements plus a change in blood group and hence a requirement for different blood components at different stages following the transplant. The LIMS does not replace laboratory expertise and knowledge about this specialised area and, of course, effective communication between the clinical area and the laboratory.

Incorrect result entered manually n=2

Both cases had anomalous groups that had to be interpreted and entered manually to allow issue of blood. One case with a weak D was transfused group A D-positive blood instead of AB D-positive blood during a postpartum haemorrhage because a lone worker had interpreted the group incorrectly and the blood was required urgently. A second case had an anomalous reverse group that was under investigation but a lone worker manually entered the interpretation O D-positive instead of O D-negative

on two successive samples and then issued blood for surgery to an elderly male patient. In the second case the LIMS incorrectly permitted electronic issue (EI) despite a manually edited result.

Electronic blood management systems n=2 and online blood ordering system (OBOS) n=1

In one case an adult emergency O D-negative unit was removed from a satellite refrigerator and given to a neonate. There had already been a delay and the collector needed help logging onto the system to access the refrigerator, so when neither the paediatric nor the adult emergency units could be successfully scanned out of the refrigerator the adult unit was taken to prevent further delay.

In another case the kiosk alerted the collector that the wrong blood was being collected but an inexperienced BMS responding to the alarm thought it was a cold chain alert instead of a wrong blood alert and allowed the blood to be collected.

Case 10.8: Two electronic systems fail to prevent D-positive blood being transfused

Blood was ordered for an exchange transfusion for a B D-negative patient with sickle cell disease using the OBOS and B D-positive blood was selected stating (in the comments box) that O D-negative blood could be substituted if necessary. Six units of O D-positive were provided, crossmatched and transfused. The LIMS did not prevent issue of D-mismatched blood and this error was not detected until the next transfusion was due when an unexplained mixed field was detected on the pre-transfusion sample (see Chapter 24 Haemoglobin Disorders: Update).

Computer downtime n=2

In one case D-positive blood was selected and given to a D-negative male surgical patient during planned computer downtime because the analyser result was misread. The reporter classified this transfusion as 'routine' which should ideally be avoided during planned computer downtime. Another series of errors occurred when selecting red cells and FFP because the computer screen froze and needed rebooting during a busy time when responding to an unexpected catastrophic haemorrhage during an invasive but routine procedure. IT failure can be extremely stressful for staff and very distracting when responding to an emergency.

Learning point

- In haemopoietic stem cell and solid organ transplant the elements requiring some IT control include the ability to
  - flag the date of the haemopoietic stem cell or solid organ transplant
  - store the recipient and donor blood groups as well as the current blood group
  - support the issue of each blood component of the correct group and specific requirements

Some, but not all, IT systems can be configured to achieve this and it would be helpful to share good practice to improve the care of these patients and prevent errors

Blood issued against wrong patient ID n=1

In this case, platelets were requested for the wrong patient with the same surname. The unit was transfused without a complete check of patient ID band.

Near miss IBCT-SRNM cases n=121

The near miss incidents related to patients' specific requirements show similar learning points to the full incidents which led to a transfusion of components where specific requirements were not met.

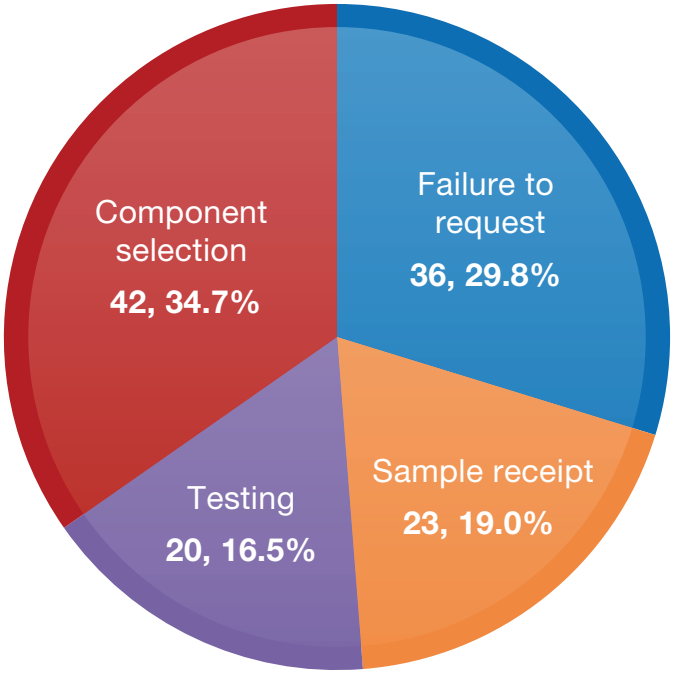


Figure 10.8: Near misses that could have led to IBCT-SRNM n=121

In 2016 there was an increase in near miss SRNM cases, 121 compared to 97 in 2015. Failures to notice requests for specific requirements at sample receipt were 23 in 2016; 7 in 2015.

Additional tables showing the subcategorisation of near miss errors consistent with those in previous Annual SHOT Reports (2010–2015) can be found in the supplementary information on the SHOT website www.shotuk.org.

IT-related IBCT-SRNM cases n=161

Laboratory n=73 and clinical n=88

Use of the historical computer record: laboratory n=15 and clinical n=21

There were 15 laboratory cases where the historical record was not consulted, or not linked to the current record, when selecting suitable blood components for transfusion. In 13 cases the blood selected was not of the correct phenotype either because the patient had historical antibodies but a negative antibody screen, or because there were other red cell antigens that should have been selected for. In one case non-irradiated blood components were issued because the historical record was not identified or merged and in another case non-CMV tested blood was issued to a pregnant woman.

There were 21 clinical cases where the historical record was not consulted or linked to the current record. On four occasions, non-phenotyped blood was selected for a patient in error. On 11 occasions non-irradiated blood components were issued in error. There were four clinical cases where a woman was being transfused electively in pregnancy and non-CMV-screened blood was transfused and two cases where HEV-unscreened blood was provided for a transplant patient.

Warning flags not in place, not heeded or not used: laboratory n=45 and clinical n=67

In 11 cases a warning flag was in place on the LIMS but was not heeded. This resulted in five patients not receiving irradiated components, one not receiving MB-FFP and two not receiving HEV-screened components as required. There were three cases who did not receive appropriate antigen-negative blood.

In a further 19 cases a warning flag was not activated, or updated with current information. This resulted in 11 non-irradiated components, four patients did not get HEV-screened components and four antigen-negative requirements were not met.

In 82 cases flags were not used but might have prevented errors had they been in place. The largest category here includes 40 clinical cases and a further five laboratory cases where flags could have been used to prevent the issue of non-irradiated components. There were 15 cases where a flag had not been used to highlight the need for HEV-screened components and no laboratory flag in seven cases to alert the requirement for MB-FFP or SD-FFP for those born after 1 January 1996. In three cases the need for HLA-matched platelets or red cells was missed and in 11 cases there was no flag to highlight the need for phenotyped blood. The final case was an unsuitable sample that the LIMS did not flag up as it was not working.

Case 10.9: Flags can only be set correctly if clinicians can agree

A patient with chronic lymphatic leukaemia (CLL) and anaemia had bendamustine treatment 3 years ago. The transfusion was organised by the FY1 doctor and when the request arrived in the laboratory the BMS noted that, although there was no flag on the LIMS, of two previous transfusions one had been irradiated and one had not. The BMS phoned to ask if irradiated blood was required and the ward staff stated 'no' but when the FY1 discussed the transfusion with the consultant haematologist it became clear that lifelong irradiated components were required. The LIMS was subsequently updated with a warning flag.

Electronic issue n=20

Electronic issue should be entirely dependent on the LIMS algorithm and there were 20 cases this year where blood was issued electronically where the patient was not eligible. The majority of these cases (n=17) have already been included within the numbers in the subheadings above. Most of these resulted in blood of the wrong phenotype being issued to patients with current or historical antibodies.

Case 10.10: No information in LIMS to identify non-eligibility for EI

A shared care patient with HbSC disease was transfused prior to routine surgery. The current antibody screen was negative so blood was crossmatched by EI and the patient had a preoperative exchange transfusion. After the transfusion, the details on the patient's condition and history of red cell antibodies detected in the past by another hospital was discovered so the patient should have had a serological crossmatch with antigen-negative blood.

Case 10.11: Computer algorithm does not control eligibility for EI: still need to set manual flag

A patient post HSCT was identified as having received blood by EI on three separate occasions. The laboratory policy is to crossmatch blood serologically for these patients. The error was detected during an audit of specific requirements. The flag relating to the HSCT had been correctly set to ensure the correct group and other specific requirements were met but the additional flag required to prevent EI had not been included.

Learning point

- Electronic issue (EI) is a safe and efficient way of providing safe and timely blood for transfusion but the computer algorithm needs to have access to all the relevant information on which to base eligibility for EI. Any change to laboratory information management system (LIMS) or patient administration system (PAS) including upgrades, replacements, mergers or hospital number changes should include the historical information on blood groups, antibodies and specific requirements including conditions such as sickle cell disease, haemopoietic stem cell transplant and solid organ transplants so that those ineligible for EI or remote issue can be determined accurately

The remaining SRNM-related IT cases consisted of:

- Wrong record selected on LIMS/PAS n=1
- Other equipment failure n=1
- Incorrect result or data entered manually n=2
- Electronic blood ordering/OBOS n=6

Recommendation

- There should be an industry standard based on the British Society for Haematology (BSH) and Medicines and Healthcare Products Regulatory Agency (MHRA) guidance for laboratory information management systems (LIMS) and electronic blood management systems (EBMS) to support electronic issue which should apply to blood components provided from the laboratory and from remote issue refrigerators and should, where possible, have limited manual intervention

Action: Software/IT/equipment providers/manufacturers with the UK transfusion laboratory collaborative

Critical steps in the transfusion process

The emphasis this year is to highlight the errors occurring at each of the nine steps in the transfusion process to enable more efficient learning points to be made. Rather than focussing on the outcome, we can learn from the root cause of the error and ensure improvement is made in that area of practice.

Figure 10.9 shows the different steps undertaken by both clinical and laboratory staff, each step incorporates independent checks at every point that should, if carried out correctly, be able to identify any errors made earlier.

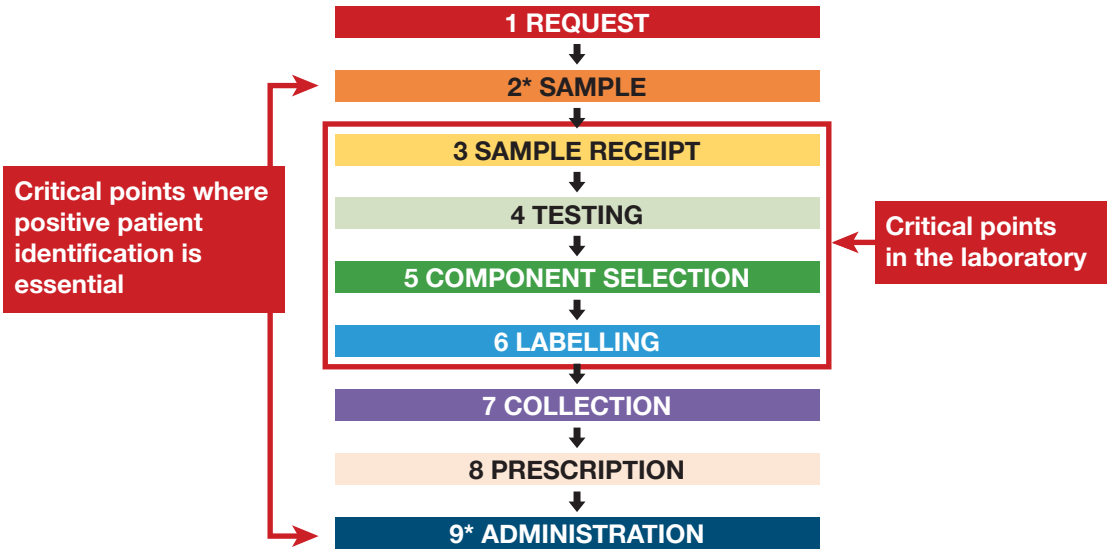
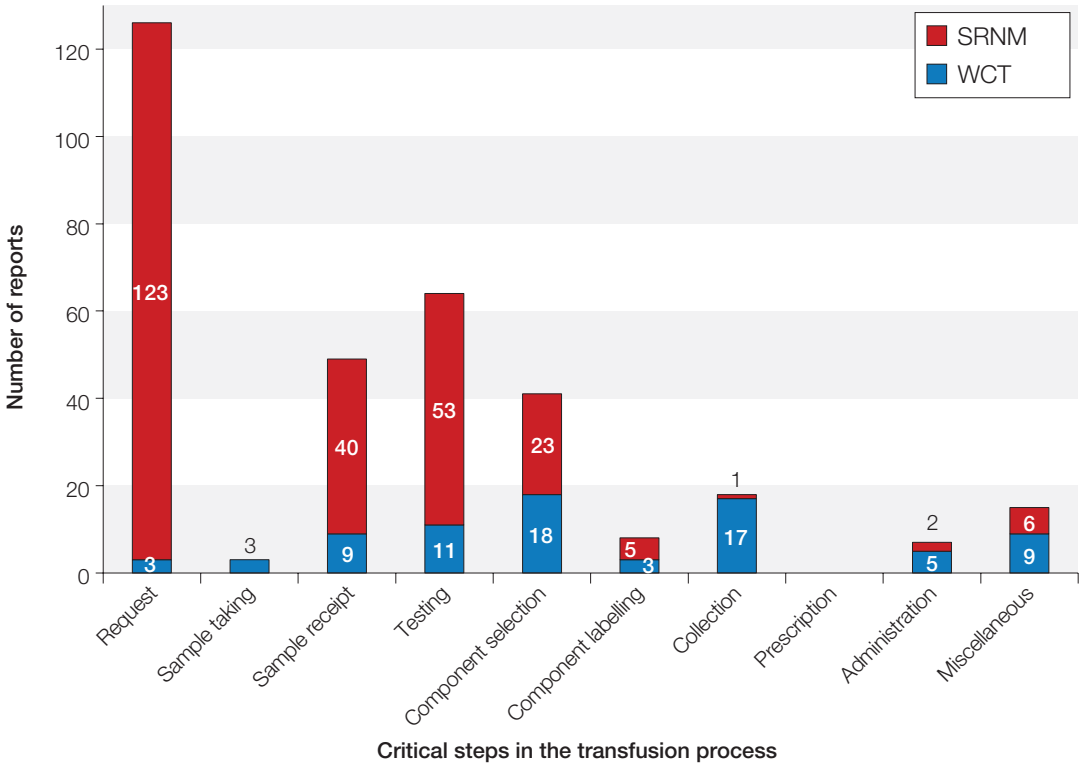


Figure 10.9: Transfusion process (nine steps)

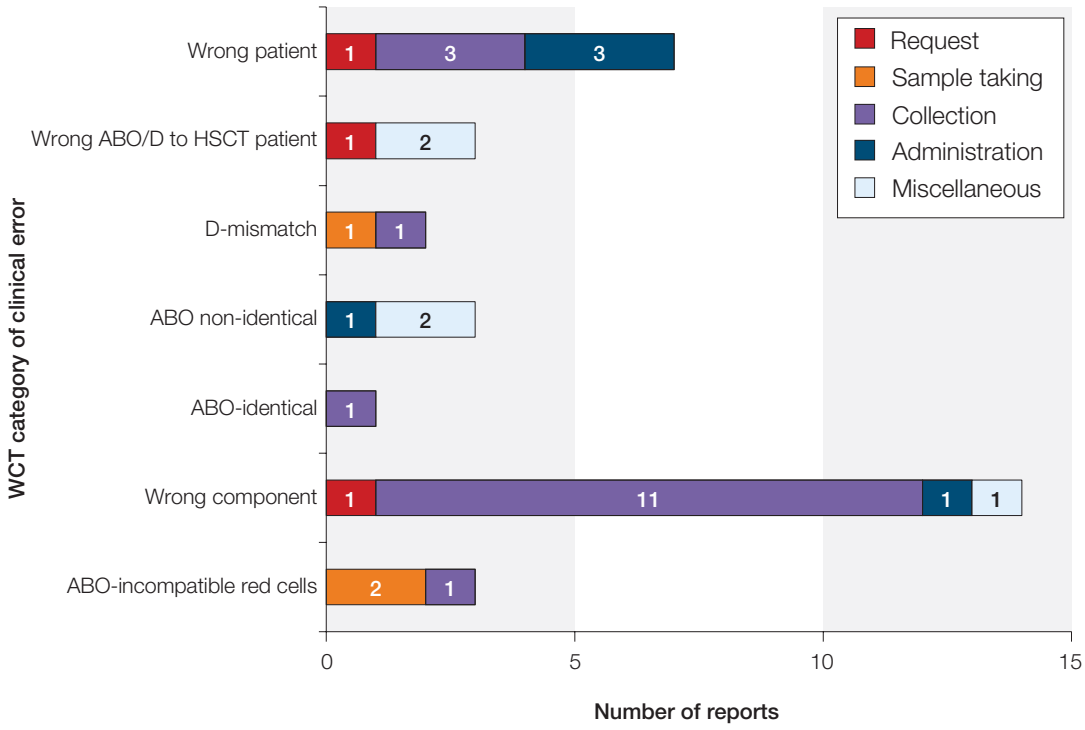
Note: Once a decision to transfuse is made, the authorisation or prescription may be written at variable times during this sequence, but must be checked during the final stage

Figure 10.10: Errors where the wrong component was transfused or specific requirements were not met in the transfusion process n=331



Figures 10.11 and 10.12 illustrate the step in the transfusion process where the primary error took place and the category for both clinical and laboratory steps.

Figure 10.11a: Clinical errors resulting in wrong component transfused n=33



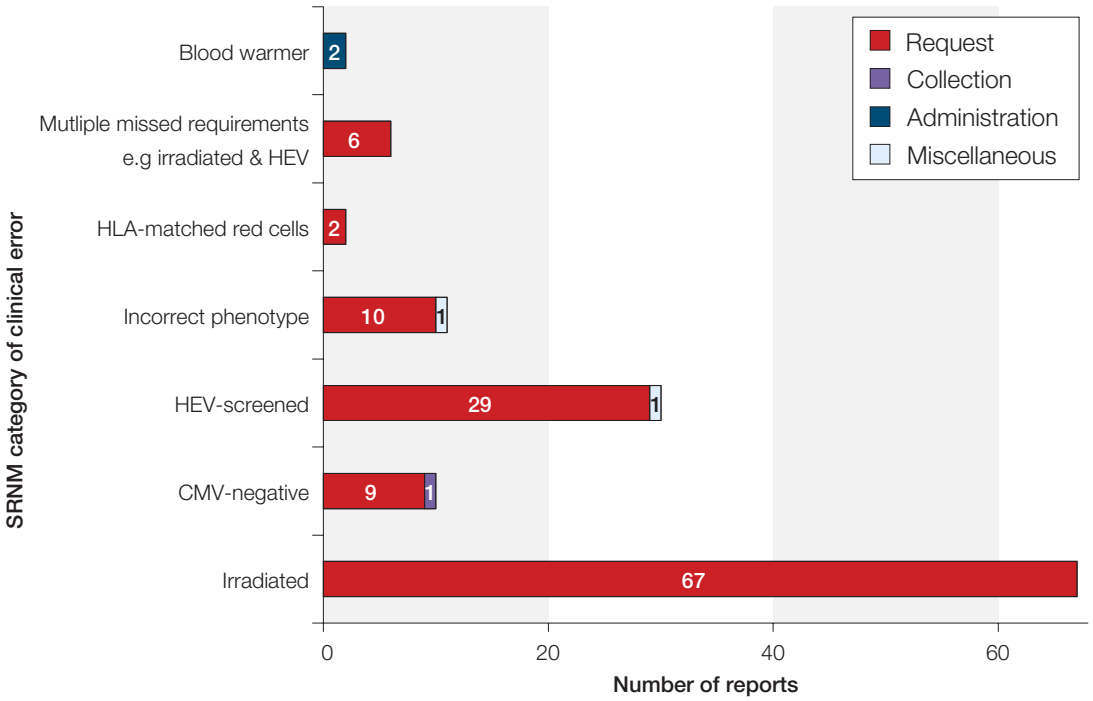


Figure 10.11b: Clinical errors leading to specific requirements not being met n=128

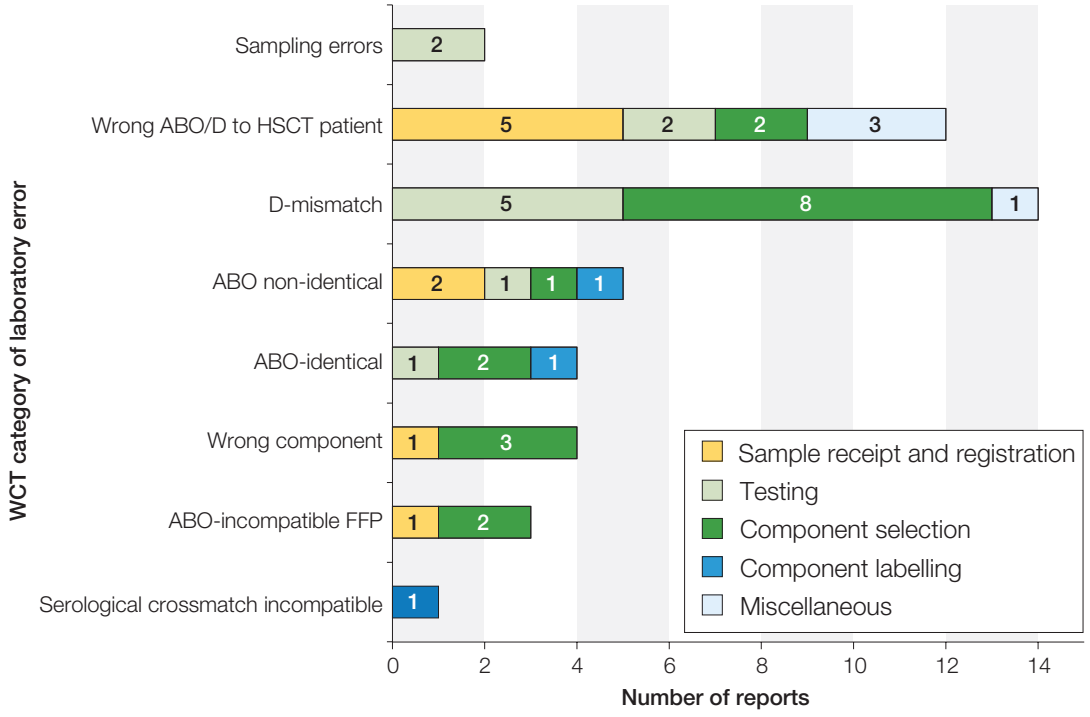


Figure 10.12a: Laboratory errors resulting in wrong component transfused n=45

**Sampling errors associated with 2-sample rule or invalid sample when performing ABO/D grouping*

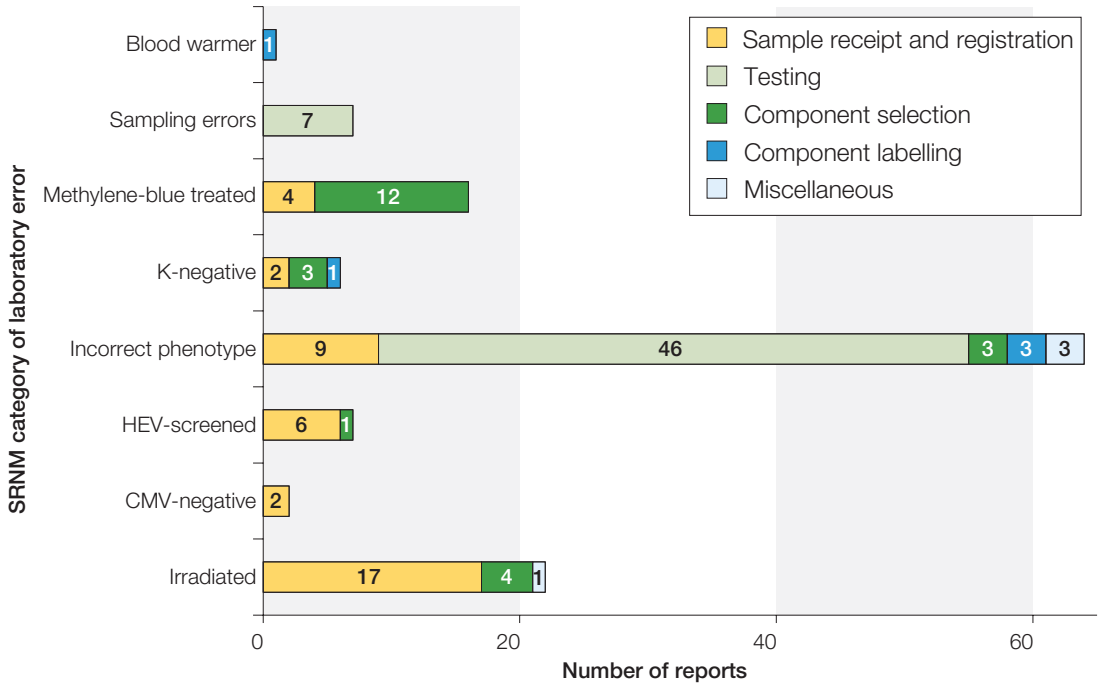


Figure 10.12b: Laboratory errors resulting in specific requirements not being met n=125

Step 1: Request errors n=128

The request is the first of the nine steps in the transfusion process following the decision to transfuse. It is essential that clinical staff ensure all necessary information is complete and correct according to national guidance and includes any relevant factors, where known, that influence transfusion requirements, including current diagnosis, any co-morbidities, pregnancy status and any clinical requirements (BSH Harris et al. 2017).

Despite several opportunities to identify the error at the remaining eight steps of the transfusion process 96.1% (123/128) specific requirements were missed.

Request errors can be further divided by method of requesting, where known:

- 16 verbal
- 17 computer-generated specific requirements request forms
- 56 written transfusion request forms
- 13 other including 5 by electronic request/prescription form
- 26 unknown

Wherever possible, communication should be in written or electronic format to minimise the risk of misinterpretation or transcription errors which may be associated with verbal communication (BSH Harris et al. 2017).

Common themes at step 1 include:

- Failure to complete and communicate that the patient was pregnant or had a known haemoglobinopathy. Often these patients are admitted through the ED where clinical staff may be unaware of the significance of the patient's underlying condition when requesting blood components
- Failure to identify a requirement for irradiated and/or HEV-screened components accounted for 79.7% (102/128) of SRNM. The recommendation for HEV-screened components for specific patients (SaBTO 2015) has proved difficult for hospitals to implement as captured by reports submitted to

SHOT. However, the reasons are similar to errors associated with failure to provide irradiated blood, with an initial failure to recognise the need for a specific requirement. Notably there may be a lack of awareness/knowledge, lack of information communicated from shared-care hospitals, or the patient has a historical diagnosis that requires a specific requirement

It is important to note that many patients are exposed to non-irradiated and/or non HEV-screened blood components on more than one occasion and in one case a patient received 486 non-irradiated blood components due to failure to recognise a historical diagnosis of Hodgkin lymphoma.

Clinical haematology teams should continue to ensure that patients at risk of transfusion-associated graft versus host disease (TA-GvHD) are made aware of their need for irradiated cellular components and provide written information and a specific alert card, but it is essential that adequate processes are also in place to educate/train both medical and nursing staff of all grades about specific requirements.

Learning points

- Clear communication channels should be developed with the local transfusion laboratory, pharmacy and shared-care hospitals to further minimise the risk of transfusion-associated graft versus host disease (TA-GvHD) to patients
- The use of an aide memoire for specific requirements on the reverse of written requests forms, prescription forms, on electronic request systems or at the final bedside check may help reduce the number of specific requirements not met (SRNM)

Figure 10.13a and 10.13b provide some examples of an aide memoire for specific requirements.

NHS Blood and Transplant

Before each unit is transfused, ensure you check If the patient requires:

Transfusion Special Requirements Checklist

- Irradiated Components (Pre HSC donation or transplant- allo donor 14 days pre and during harvest, allo recipient from conditioning and post HSC transplant on GvHD prophylaxis, auto within 7 days harvest and from conditioning to 3 months post transplant or 6 months if TBI, HLA products, neonates post IUT, Hodgkin's Disease, Aplastic anaemia on ATG (rabbit) or for HSC, Live liver and renal donors 7 days pre and during transplant. Patients who have received: Fludarabine, cladribine, nelarabine, bendamustine, deoxycoformycin, clofarabine, alemtuzumab, chlorodeoxyadenosin, ATG, ALG, alemtuzumab/campath, muromonab, SCID, DiGeorge syndrome and Wiskott Aldrich syndrome)
- CMV Negative Components (Neonate up to 28 days post delivery, pregnancy)
- HbS Negative Components (Sickle Cell Disease (SCD), Neonates)
- Kell Negative Components (Women of childbearing potential)
- HEV Negative Components (3 months pre planned SOT or date of listing, post SOT on immunosuppressants, acute leukaemia unless/until not for HSC, 3mths pre allo HSC to 6 mths post or while immunosuppressed, Extra corporeal procedures for above indications)
- High Titre Negative Components (A, B or AB patients receiving O component and AB receiving A or B)
- Methylene Blue/ Solvent Detergent Components (if born after 01/01/96)

Figure 10.13a: Indications for specific requirements included on an aide memoire card, the Therapeutic Apheresis Service, NHS Blood and Transplant

Figure 10.13b: Indications for specific requirements provided on the reverse of the transfusion prescription chart, The Christie, Manchester

The Christie NHS
NHS Foundation Trust

DOES YOUR PATIENT NEED BLOOD PRODUCTS WITH SPECIAL REQUIREMENTS?

Patient Condition/Treatment	Irradiated Blood Products Required	Commence	Additional Information
Autologous Bone Marrow Transplant/ Peripheral Blood Stem Cells	**Yes** Continue for 6 months post BMT/PBSC Or lifelong if had purine analogue chemotherapy	7 days before stem cell harvest 7 days before transplant	It is not necessary to irradiate fresh frozen plasma or cryoprecipitate **All patients requiring irradiated blood products must be given an information leaflet and card which they must carry at all times in case they require blood products at another hospital. These are available in your ward area, the transfusion lab or from the Transfusion Practitioner** Discuss with attending Haematology consultant when required.
Allogenic Bone Marrow Transplant/ Peripheral Blood Stem Cells	**Yes**	7 days before conditioning for transplant	
Hodgkin's Disease	**Yes**	From diagnosis - indefinitely	
Has received Purine Analogue Chemotherapy i.e. Fludarabine, Cladribine, Bendamustine and Deoxycoformycin, Clofarabine	**Yes**	From start of Chemotherapy - indefinitely	
Has received Alemtuzumab (MabCampath), Antithymocyte Globulin (ATG) and Antilymphocyte Globulin (ALG)	**Yes**	From start of Chemotherapy - indefinitely	
New Leukaemia Patients	**No,** unless fall into any of the above		**Pregnant patients must receive CMV - products**

Patient Condition/Treatment	Hepatitis E negative products required	Commence	Additional Information
New Leukaemia Patients	**Yes**	From diagnosis - until a decision is made not to transplant	**All patients requiring HEV negative blood products must be given an information leaflet. These are available in your ward area, the transfusion lab or from the Transfusion Practitioner.**
Allogenic Bone Marrow Transplant/ Peripheral Blood Stem Cells	**Yes**	3 months prior and 6 months post transplant - until patient is no longer immunosuppressed	
Patients awaiting solid organ transplant	**Yes**	3 months prior to transplant or the date listed for transplant	
Patients who have had solid organ transplant	**Yes**	Until stopping immunosuppressants	
Extra corporeal procedures	**Yes**	Dialysis, extra corporeal circulatory support is included if within above indications	

Any questions contact: Consultant Haematologist
Transfusion Laboratory 0161 446 3287 Transfusion Practitioner 0161 446 3055

The Hospital Transfusion Team 2016

Step 2: Taking the blood sample n=3

Positive patient identification is essential when taking a sample for pre-transfusion compatibility testing and is the first of the two critical patient identification steps in the transfusion process. Taking the correct blood from the correct patient and labelling the sample tube correctly at the patient's side at this step can prevent wrong components being transfused. A second sample should be taken if a historical group is not available complying with national guidelines (BSH Milkins et al. 2013). This is essential to confirm the blood in the labelled sample is from the correct patient.

Sample errors led to 2 ABO-incompatible red cell transfusions (Cases 10.3 and 10.4) and one D-mismatch.

Step 3: Sample receipt n=49

As the first of the four critical laboratory steps, it is essential to ensure that the right investigation is performed on the right patient on the right sample at the right time (depending on the patient's transfusion history). The SOP for sample acceptance by the laboratory must define locally agreed and minimum acceptable identification criteria and the course of action to be followed when these criteria are not met and should comply with national guidelines (BSH Harris et al. 2017).

Sample receipt and registration errors are divided into three categories, demographic data entry errors, failure to heed available historical information and missed information on the request form. There were:

- 27 where laboratory staff did not heed available historical information
- 22 missed important information on request forms

Errors associated with sample receipt are discussed in more detail in Chapter 7, Laboratory Errors.

Step 4: Testing n=64

The correct test/analysis is performed to ensure that the safe provision of blood components is undertaken in full compliance with local and national guidelines (BSH Milkins et al. 2013).

There were 2/64 testing errors that resulted in major morbidity, Case 10.2 and a transcription error in D-grouping resulting in development of anti-D in the patient.

Testing errors are divided into the following four categories of errors, technical, transcription, interpretation, and procedural. For IBCT there were:

- 6 transcription errors
- 12 interpretation errors
- 46 procedural errors

Errors associated with testing are discussed in more detail in Chapter 7, Laboratory Errors.

Step 5: Component selection n=41

Component selection should ensure that the correct components (together with the correct specific requirements) are selected to comply with the patient's requirements and the clinical request.

There were 3/41 selection errors that resulted in serious harm. One selection error resulted in a 4-day-old baby with HDFN receiving incompatible red cells and requiring further exchange transfusion, Case 10.1.

Errors associated with component selection are discussed in more detail in Chapter 7, Laboratory Errors.

Step 6: Labelling, availability and handling and storage errors (HSE) n=8

These are final laboratory steps before the components are available for collection by the clinical staff and so the last opportunity to ensure that the correct component leaves the laboratory. The correct component needs to be labelled with the correct four (or five) key patient identification criteria; i.e. first

name, surname, date of birth, unique patient identification (ID) identifier and address if in Wales (BSH Milkins et al. 2013). Components need to be accessible and available for the time required, if this is not possible then the clinical area needs to be informed. The components need to be handled and stored correctly as indicated in the guidelines for blood transfusion services in the UK (JPAC 2013).

In one case a patient was transfused serologically-crossmatched incompatible units (not ABO-incompatible) due to a labelling error, see Case 10.7 and Chapter 24, Haemoglobin Disorders: Update. Errors associated with component labelling, availability and HSE are discussed in more detail in Chapter 7, Laboratory Errors.

Step 7: Collection n=17

This step requires that a trained and competent healthcare worker take authorised documentation containing the patient's core identifiers to the designated storage site. These documents should be checked with the laboratory-generated label attached to the blood component (BSH Harris et al. 2017).

Collection as the primary error is the most common cause for wrong components transfused 51.5% (17/33) and this step can be further divided to demonstrate some learning points.

Collection of blood components in these cases was carried out by a number of different healthcare workers

- 4 healthcare supporter workers
- 4 porters
- 7 registered nurses
- 2 unknown

In 13/17 staff were trained and competent but two stated their competency had expired. A further two had not received training or competency-assessment for collection and the remaining two were unknown.

In 7/17 the staff member did not formally check against paperwork and in 8/17 the formal check against paperwork was completed. In the remaining two cases it was unknown what checks had taken place.

In two cases more than one unit was collected at once for more than one patient. In cases where collection was carried out by non-registered staff, it was clear they were not aware of or did not remember the storage conditions or the visual difference between the different components.

Case 10.12: Unknown patient rushed to theatre with reliance that the final checks would be done at the patient's side

Four units were scanned out of the ED refrigerator to go to theatre with the patient and to be placed in the refrigerator in theatres. The need was urgent and the staff member scanned the units out without the necessary checks but relying on the fact that the blood would be checked at a subsequent step in the transfusion process prior to administration. In theatres a unit of blood was given that was incorrect, but colleagues assured the clinical team that the unit had already been checked and was ready to be administered.

The root cause investigation revealed:

- Actions were performed based on a verbal assurance without confirmatory checking
- Actions were performed but incomplete as further checks should take place downstream in the patient pathway
- Communication breakdown during patient transit meant that staff members thought that a unit had been fully checked and was ready to use

In addition to the above it was noted that the situation was extremely busy with conflicting attention required from the staff involved, and a lack of leadership during the trauma call.

Learning points

- Staff unfamiliar with blood components should be fully trained to recognise the difference in appearance of the different blood components and to know their storage conditions
- Where possible only one unit for one patient should be collected at a time (BSH Harris et al. 2017)
- Reliance on colleagues should not replace the checks required by each individual at each step of the transfusion process

Step 8: Prescription n=0

This step is identified in Figure 10.9 as step 8, but the prescription may be written at different points in the transfusion process and should be completed and checked prior to the final administration step.

Prescription did not appear as the primary error in any cases, however it is possible errors made earlier in the transfusion process could have been detected at this stage or when making reference to the prescription.

Step 9: Administration n=6

This is the final opportunity to prevent patients receiving the incorrect component or missing their specific requirement due to errors earlier in the transfusion process, therefore it is essential that the final administration check must always be conducted next to the patient by the healthcare professional who is going to administer the component (BSH Harris et al. 2017).

In six cases administration featured as the primary error: in 4/6 cases staff failed to notice that it was the wrong component during the checking procedure, one of which was checked away from the patient at the nurses' station. In 2/6 further cases staff failed to adhere to an instruction on the prescription for a blood warmer.

Two cases involved one nurse in the checking procedure and in the remaining 4 it was unknown, however, if local policy requires a two-person check, national guidance suggests each person should complete all the checks independently (double independent checking) (BSH Harris et al. 2017).

Double independent checking is resource-hungry by taking two nurses away from other tasks with a risk of being distracted in a busy environment or in the emergency situation when there is added pressure to rush. Double checking in this way can also provide a false sense of security, each believing the other person is checking everything correctly.

A clinical review of checklists (Winters et al. 2009) suggests that the use of **verification checklists** may be more helpful when time is short and competing priorities distract our attention. Thus a 'static sequential verification' checklist requires a **challenge and response** and is completed together rather than independently. This may be more effective than the current two-person independent or single person check. For example, the nurse responsible for administering the blood component performs the task and the second person challenges the completion of each step by reading them from the checklist, the nurse performing the task must respond to confirm completion of each step.

Learning point

- The use of a five-point checklist at the patient's side immediately prior to connecting the transfusion as recommended (Bolton-Maggs et al. 2016) is an essential step. The two-person dependent check should be explored further

Miscellaneous n=15 (7 clinical and 8 laboratory)

There were 15 cases where the primary error was not associated with the nine steps in the transfusion process.

Clinical n=7

There were 2 cases where specific requirements were not met where blood was required urgently:

- A clinical decision made to give non-HEV-screened blood to an allogeneic HSCT patient
- A patient with a gastrointestinal haemorrhage admitted via ED; discovered post transfusion that the patient required HbS-negative components

There were 5 cases of wrong components transfused:

- 2 cases involved transcription of incorrect blood groups from one document to another
- 1 case involved shared care of a neonate (group B) who had received multiple group O units at a previous hospital. The receiving hospital was not informed of this multiple transfusion so the neonate grouped as O and received group O plasma inappropriately
- 1 case involved misidentification of an unknown patient who received blood labelled for another patient who had never even been in the ED. The error occurred when ambulance staff identified the unknown patient with the wrong details
- 1 case of lack of knowledge, a neonatal unit was used for an intrauterine transfusion see Chapter 22, Paediatric Summary

Laboratory n=8

There were 4 cases where laboratory staff did not action notifications promptly, therefore patient records were not accurately maintained. In 3 cases this resulted in the wrong ABO/D group being given to HSCT patients and one where laboratory staff failed to provide irradiated units, see Chapter 23, Summary of Incidents Related to Transplant Cases.

There were a further 3 cases where the Blood Service issued incorrect/unsuitable components and did not inform the laboratory, one of these resulted in major morbidity.

A patient with sickle cell disease required 10 red cell units. A flag preventing release of red cells from the remote issue refrigerator was not applied to the patient record because the BMS did not have the right IT privilege access.

Additional miscellaneous cases are discussed in more detail in Chapter 7, Laboratory Errors.

Importance of team work

The following demonstrate that multiple errors and missed opportunities to detect an earlier error could prevent incorrect blood components transfused.

- 21/170 (12.4%) cases where primary error originated in the laboratory could have been detected in the clinical area
- 72/331 (21.8%) errors could have been detected at administration, 30/72 where the primary error was in the laboratory and 42/72 where the primary error originated in the clinical area
- 710/818 (86.8%) cases of near miss where the primary errors in the clinical area associated with request or sample taking were detected by laboratory staff and prevented an IBCT, Chapter 12, Near Miss Reporting (NM)

Case 10.13: A renal dialysis patient received two units of red cells that were crossmatched but were not intended for transfusion nor prescribed: four opportunities for detection (clinical)

A regular dialysis patient required two units of platelets prior to a minor surgical procedure to investigate haematuria. Two units of platelets were requested but the crossmatch box was ticked. Following a conversation between laboratory and clinical staff about the tick in the crossmatch box, red cells were crossmatched and issued. Platelets were prescribed before the procedure but not red cells. The healthcare assistant (HCA) was trained and competency-assessed to collect blood components, but red cells were collected instead of the prescribed platelets and then administered by the registered nurse.

Error 1: Request – two units of platelets were requested correctly, but the crossmatch box was also ticked. Clinical staff were not aware that crossmatch was only required for red cells.

Error 2: Component selection – the BMS checked with the clinical staff, but failed to speak to an appropriately trained member of staff. Red cells were issued and made available for collection.

Error 3: Collection – the HCA was trained to collect blood components but there was a gap between theory and practice. She was not aware of the visual difference between red cells and platelets nor that platelets were only located in the laboratory and not in the remote refrigerator.

Error 4: Prescription – prescription of platelets clearly stated pre-procedure, red cells were not prescribed and therefore not indicated for transfusion.

Error 5: Administration – a failure to follow hospital policy. Nursing staff were also unfamiliar with the visual appearance of platelets because it was rare for them to be administered on the dialysis unit.

Case 10.14: Primary error in laboratory: wrong component transfused, where there were five opportunities for detection (laboratory)

A unit of red cells was commenced in error instead of the prescribed plasma. The laboratory prepared the wrong component type following a telephone request. It was noted that laboratory staff were very busy and had inadequate staffing levels at the time of the incident. Two registered nurses checked the red cells but did not refer to the prescription so failed to notice it was the wrong component type, and should have been plasma. Verbal evidence from the ward manager confirms all patient details were checked correctly but the prescription form was not checked.

This case demonstrated six errors:

Error 1: Sample receipt and registration – the laboratory prepared the wrong component type following a telephone request.

Error 2: Component selection – the laboratory staff selected the wrong component as they did not document the telephone request appropriately.

Error 3: Component labelling – while labelling, the laboratory staff did not detect that the wrong component had been selected.

Error 4: Collection – the prescription was not consulted before or during the component collection.

Error 5: Prescription – there was no documented evidence of these checks as the component was never prescribed therefore the prescription record was not completed.

Error 6: Administration – the transfusion policy was not adhered to by ward staff in terms of bedside checking procedure. Two registered nurses checked the component but did not refer to the prescription and failed to notice the wrong component during the final bedside check.

Learning points

- Investigating, reviewing and reporting incidents from a team perspective including various disciplines, for example, consultant haematologists, nursing, laboratory, pharmacy, junior medical staff can encourage team work and help to identify specific areas of error in the transfusion process
- Consider the following:
  - Identify the step where the error occurred
  - Identify the first step where the error could be detected
  - Identify subsequent or previous steps (if present) where the error could be detected or prevented
  - Identify specific actions to prevent the same error occurring

Commentary

Although the transfusion process is defined into separate clinical and laboratory steps (Figure 10.9) it is everyone's responsibility to ensure they complete their part of the process fully and with care. Each step incorporates independent checks and each staff member should ensure they complete the necessary checks at their step in the process as they can help to detect any errors that may have occurred earlier before the blood component reaches the patient.

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