Avoidable, Delayed or Under/ Overtransfusion (ADU) and Incidents Related to Prothrombin Complex Concentrate (PCC) n=365

11

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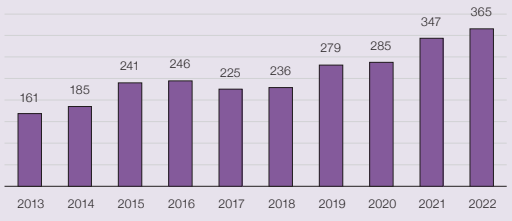
Abbreviations used in this chapter

ADU	Avoidable, delayed or under/overtransfusion
AF	Atrial fibrillation
AML	Acute myeloid leukaemia
BMS	Biomedical scientist
BP	Blood pressure
BSH	British Society for Haematology
CAS	Central alerting system
CPR	Cardio-pulmonary resuscitation
CT	Computed tomography
CML	Chronic myeloid leukaemia
DIC	Disseminated intravascular coagulation
DOAC	Direct acting oral anticoagulant
DOB	Date of birth
ECP	Extracorporeal photopheresis
ED	Emergency department
EWS	Early warning score
FBC	Full blood count
FFP	Fresh frozen plasma
GI	Gastrointestinal
GP	General practitioner
GVHD	Graft-versus-host disease
Hb	Haemoglobin
HSE	Handling and storage errors
ICH	Intracranial haemorrhage
ICU	Intensive care unit
ID	Identification
INR	International normalised ratio
IT	Information technology
ITP	Immune thrombocytopenia
LMWH	Low molecular weight heparin
IV	Intravenous
MAU	Medical admissions unit
MH	Major haemorrhage
MHP	Major haemorrhage protocol
NCA	National comparative audit
NHS	National Health Service
PCC	Prothrombin complex concentrate
SCD	Sickle cell disease
TACO	Transfusion-associated circulatory overload
UK	United Kingdom
VKA	Vitamin K antagonist

Headline data 2022

Number of reports n=365
Deaths n=15
Major morbidity n=10

ADU reports by year



Demographic data

Male n=161
Female n=196
Unknown n=8

Adults n=313
Paediatric n=40
Unknown n=12

Blood component data

Red cells n=263
Platelets n=43
Plasma n=14
Multiple components n=21
PCC n=21
Granulocytes n=1
Unknown n=2

Overview of ADU Cases

- Delayed transfusions n=205
- Avoidable transfusions n=121
- Under or overtransfusion n=18
- Incidents related to PCC n= 21

The number of reports submitted for delayed and avoidable transfusions has increased compared to 2021 (179 and 116 respectively). The under/overtransfusion category has decreased from 34 in 2021 partly due to a change in definition which can be found in that section.

Problems with staffing and workload were identified in many reports. Responses to human factors questions from reporters have highlighted issues relating to a mismatch between staffing and workload, as well as poor communication. These results are discussed further in the supplementary information on the SHOT website (https://www.shotuk.org/shot-reports/report-summary-and-supplement-2022/). Relevant to this, the Healthcare Safety Investigation Branch (HSIB) has published an interim report on the effect of staff well-being on patient safety, noting the extreme stress in ED (HSIB 2023) which probably impacts risk of errors. A study from the University of Bath also notes serious problems with staff stress and retention (Weyman et al. 2023).

The key SHOT messages and recommendations are covered in the respective chapters for each category.

Deaths related to transfusion n=15

There were 13 deaths related to delays, and 2 related to PCC administration.

Of the deaths related to delayed transfusion, there was 1 death that was definitely related (imputability 3), 3 probably related (imputability 2), and 9 possibly related (imputability 1). The 2 deaths where patients with ICH did not receive PCC were possibly related (imputability 1).

Major morbidity n=10

Major morbidity was cited in 10 reports.

- Delays n=6
- Undertransfusion n=1
- Overtransfusion n=1
- PCC n=2

Near miss cases n=14

- Delayed transfusion n=6
- Avoidable transfusion n=6
- Under or overtransfusion n=1
- PCC n=1

Problems with MHP activations n=64

In 64 cases in these categories, activation of the MHP was reported (half, 32, of these occurred out-of-hours).

- 41 delays (2 deaths both imputability 1, possible)
- 21 avoidable including 16 instances with use of O D-negative red cells
- 1 overtransfusion
- 1 PCC

Further information about these cases can be found in the respective chapters as well as in the supplementary information on the SHOT website (https://www.shotuk.org/shot-reports/report-summary-and-supplement-2022/).

Recommended resources

Avoidable, Delay and Under or Overtransfusion (ADU) Cumulative Data:
https://www.shotuk.org/resources/current-resources/data-drawers/avoidable-delay-and-under-or-overtransfusion-adu-cumulative-data/

UKTLC: Capacity planning guidance May 2021
https://www.shotuk.org/resources/current-resources/uktlc/

References

HSIB. Interim report explores impact of staff wellbeing on patient safety. (2023) https://www.hsib.org.uk/news-and-events/interim-report-explores-impact-of-staff-wellbeing-on-patient-safety/ [accessed 28 April 2023].

Weyman A, Glendinning R, O'Hara R, et al. Should I stay or should I go? NHS staff retention in the post COVID-19 world: challenges and prospects. (2023) https://www.bath.ac.uk/publications/should-i-stay-or-should-i-go-nhs-staff-retention-in-the-post-covid-19-world/attachments/NHS-staff-retention-IPR-report.pdf [accessed 28 April 2023].

11a Delayed Transfusions n=205

Authors: Paula Bolton-Maggs, Josephine McCullagh and Simon Carter-Graham

Definition:

Where a transfusion of a blood component was clinically indicated but was not undertaken or non-availability of blood components led to a significant delay (e.g., that caused patient harm, resulted in admission to ward, or return on another occasion for transfusion).

Key SHOT messages

- Delays accounted for the largest number of transfusion-related deaths across all SHOT reportable categories in 2022
- Poor communication at multiple points during the patient's care is common and exacerbates delays
- Patients should not die from anaemia or bleeding: irregular antibodies delay provision of compatible components and should be discussed with clinicians as soon as known
- Delayed recognition of bleeding increases morbidity and mortality. Low blood pressure should alert clinicians to consider haemorrhage
- MHP are either not activated when indicated or not followed correctly
- Staffing problems contribute to delayed transfusions

Recommendations

- Hospitals should review their MHP and test them with drills to ensure they are fit for purpose. All steps should be tested by simulation from end-to-end involving the transfusion practitioner and transfusion laboratory manager
- All MHP activations should be followed by a debrief to identify what went well and what did not, and this should include transfusion laboratory staff
- The MHP alert should require a single call to a dedicated telephone line which is then cascaded to all relevant departments
- Hospitals should review their staffing capacity plans for transfusion laboratories. This is an essential service where understaffing can contribute to adverse patient outcomes
- Laboratories must ensure their transfusion staff are contactable at all times for emergencies
- Hospitals should review their use and training of agency staff in areas where blood transfusion may take place
- When there are delays due to antibodies, or difficulty obtaining second samples etc., and the need for transfusion is urgent, laboratory staff should offer a 'Plan B' indicating what can be given immediately (O D-negative or O D-positive red cells) with appropriate monitoring

Action: Hospital transfusion committees

Introduction

Reports of delayed transfusions continue to increase (Figure 11a.1). Patients may die and this prompted publication of a CAS national alert, with actions for hospitals including review of their policies and procedures (SHOT 2022).

In 2022 many problems were related to inadequate staffing in both clinical and laboratory areas. The use of agency staff, inadequate skill mix, and poor transfusion training were contributory. ED were often reported as 'very busy' and the number of overall errors reported from the ED continues to increase (Figure 2.7 in Chapter 2: Participation in UK Haemovigilance).

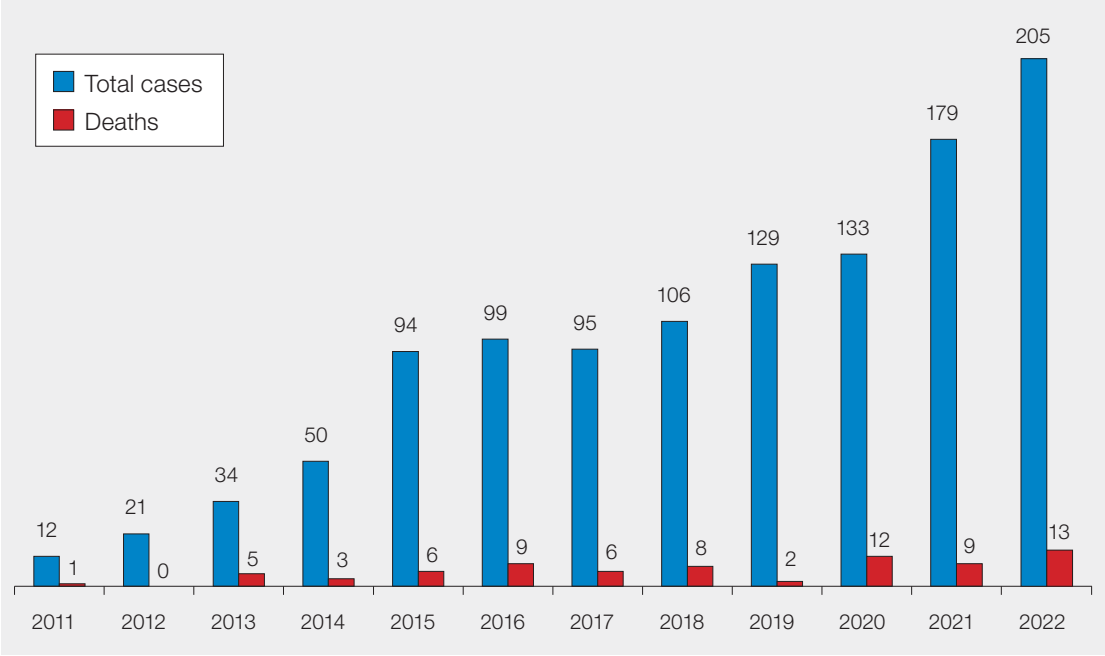


Figure 11a.1: Delayed transfusions by year 2011 to 2022

Key factors in delays

There were 205 delayed transfusions reported in 2022. The primary causes of these delays are detailed in Figure 11a.2. The most common cause of delays were communication, logistical and technical issues, however many cases had multiple errors.

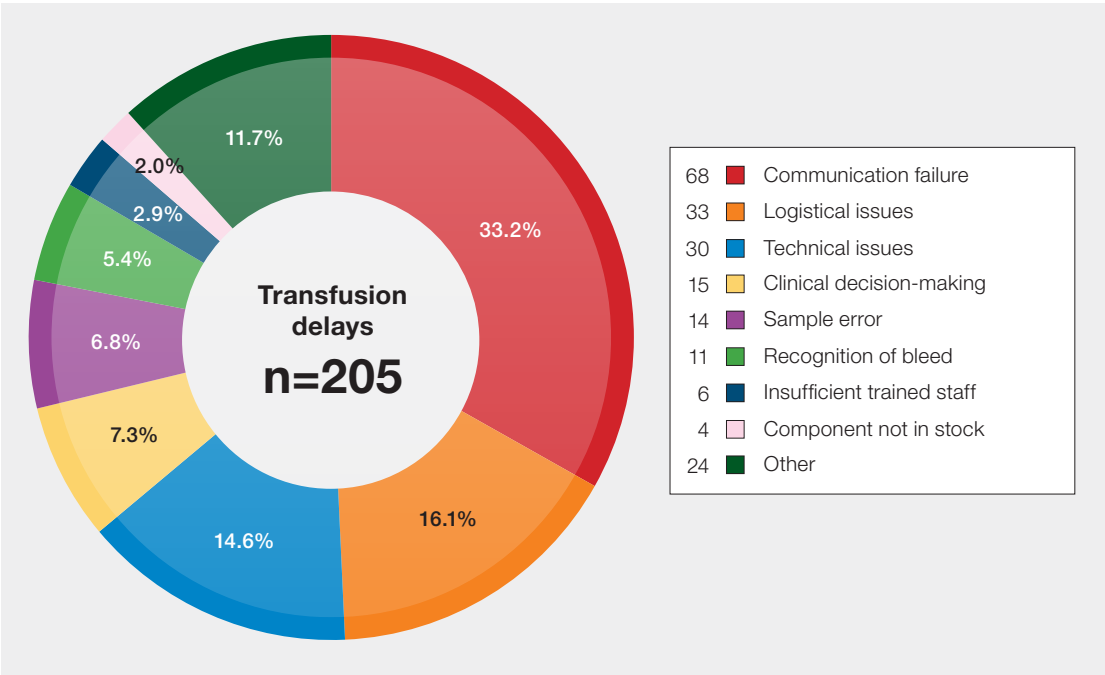


Figure 11a.2: Primary causes of delayed transfusions in 2022 (n=205)

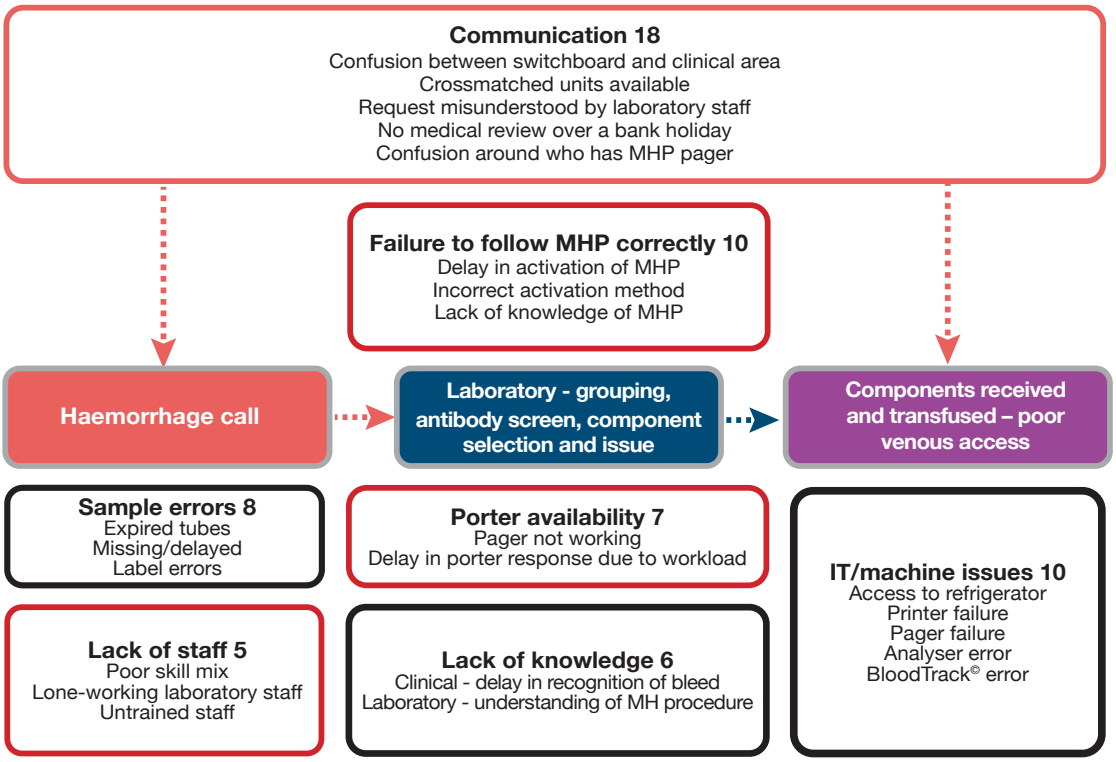
Gastrointestinal bleeding was reported in 27 cases; 5 deaths were related to the delayed transfusion. Recognition of bleeding and timely management is key to prevent delays in these patients.

Irregular antibodies often lead to delayed provision of red cells, noted in 24 cases of delay. Four patients died and of those 1 death was definitely related (imputability 3, see Case 11a.1), 1 death was probably related (imputability 2) and 2 were possibly related (imputability 1, see Case 11a.3).

Eleven cases resulted from delays in laboratory referral to a specialist laboratory.

MHP-related errors continue to cause delays. There were 41 reports of MHP activation including 6 obstetric cases and 14 cases of GI haemorrhage.

Figure 11a.3: Key factors contributing to delayed transfusions in 41 cases of major haemorrhage



MHP=major haemorrhage protocol; IT=information technology

HF contributing to delayed transfusion

- Communication problems were reported in 110 cases and were the most important contributory factor in 24 (21.8%)
- Failures in team function were cited as contributory in 62 (56.4%) cases
- Mismatch between workload and staff provision at the time of the incident was reported in 53 (48.2%)

In addition to answers in the HF section of the questionnaire, a review of cases demonstrated:

- Staff shortages were reported in 5 cases, and poor skill mix in 7 cases
- Busy units and departments were reported in 24 cases, 13 in ED or MAU and 4 in the laboratory
- Lone-working BMS in 6 cases
- Lack of transfusion-trained staff able to administer the transfusion in 12 cases
- Delayed escalation of an increasing EWS was noted in 3 cases

In 30 cases multiple factors were reported.

Learning points

- Urgent transfusions should not be delayed by lack of staff. The need should be escalated to acquire competent staff, or the patient transferred to a location where transfusion can be safely administered
- A pragmatic approach is required to risk-assess and train locum/agency staff to perform transfusion activities to ensure safe delivery of transfusion services

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Deaths related to transfusion n=13

There were 13 deaths reported due to delays. This compares with 9 deaths related to delays in 2021 and 12 in 2020.

- 1 was definitely related (imputability 3)
- 3 were probably related (imputability 2)
- 9 were possibly related (imputability 1)

In 4 cases the patients had irregular antibodies contributing to the delayed transfusion and death.

Case 11a.1: Delayed red cell transfusion and death in a patient with GI haemorrhage

An elderly person (known anaemia due to CML) was seen in the ED at 18:20 with coffee-ground vomit. Blood samples ('routine') were received in the laboratory 3 hours later (21:24), Hb 58g/L. Red cell units were requested (not identified as urgent) but irregular antibodies were detected, delaying provision of compatible units until 23:00. The MHP was activated at 23:40 and due to communication failures, the patient received emergency group O D-negative units (possibly incompatible); the patient was hypovolaemic, arrested and died.

Review noted that the ED was very busy. Transfusion and MHP training had been suspended due to COVID-19 pressures. Similar cessation of training was noted in another death due to delayed transfusion.

In 2 cases delayed provision of platelets contributed to death.

Case 11a.2: Delayed platelet transfusion in a patient with severe thrombocytopenia due to AML

An elderly man with AML had a Hb of 65g/L and platelets $2x10^9$/L at an outpatient visit. He was contacted to return for transfusion. Platelets were ready at 15:30. He attended the ED at 17:00, and fell at 19:30 sustaining a head injury. He was transfused platelets at about 22:30. He died of a subdural haematoma with brain herniation as a result of traumatic head injury following the fall. The 5-hour delay in platelet transfusion was considered contributory.

The ED was very busy and there were gaps in communication. The local review concluded that the haematology day unit was a more appropriate location for patients to wait for review of their blood counts to avoid such delays.

The second case is included in the supplementary information on the SHOT website (https://www.shotuk.org/shot-reports/report-summary-and-supplement-2022/).

Learning points

- Failure to communicate the urgency of requests leads to delays in blood component provision. Ensure that the request for samples and blood components is clear and that the urgency is stated
- Transfusion laboratory managers could consider education of clinical staff with a traffic light system detailing the meaning and time to red cell availability for 'emergency', 'urgent' and 'routine' requests
- Access to emergency components (red cells and platelets) should be clearly communicated to staff and form part of their MHP training

Case 11a.3: Delayed transfusion and death - sample errors and failure to recognise GI bleeding

A woman in her 60s, recently in hospital with myocardial infarction, was readmitted 3 weeks later at 04:10 with recurrent chest pain, vomiting and acute anaemia. Her Hb had fallen from 113g/L to 68g/L over 3 weeks. She was thought to have further myocardial infarction secondary to anaemia.

The first sample at 04:30 was rejected; transposed first and last names. The same error was repeated with a second sample at 08:26. The BMS made several unsuccessful attempts to contact the ED, unanswered telephone calls. Eventually new samples were received at 11:39; two red cell units were available at 13:36. However, the MHP was activated at 13:04 (Hb 34g/L) and four units of emergency O D-negative red cells were used. Despite this she died. Her anticoagulants had not been reversed and the GI bleeding was not identified until the very low Hb was recorded. A serious incident investigation was undertaken to establish what caused the delay in identification of GI bleeding; noted that the patient's first language was not English, and this may have been a contributory factor.

Another death in an elderly man with major GI bleeding occurred as a direct consequence of delayed transfusion. The pre-transfusion Hb was 38g/L, there was poor communication, confusion and a failure to escalate by the junior doctor.

Learning points

- Recognition of bleeding is crucial for timely and appropriate treatment
- GI bleeding is associated with a high risk of death in elderly patients. Low blood pressure is an important sign. Bleeding should be excluded before assuming the low BP is caused by something else
- Good handover information is essential especially when serious bleeding occurs out-of-hours
- It is essential to correctly identify patients and their samples; this can be a particular problem where the patient's first language is not English, and where there is also an alternative alphabet (such as Arabic) so that the spelling used in English may not be consistent on different occasions

Case 11a.4: Delayed transfusion due to haemolysis contributes to death

An elderly woman was admitted to the ED at 20:06 following collapse at home (chemotherapy 10 days earlier). Hypotension improved with IV fluids. Venous blood gas Hb was 54g/L. Blood tests were uninterpretable due to haemolysis (including blood group, antibody screen and crossmatch). The haematology consultant advised immediate transfusion of emergency group O red cells with steroid cover. At 03:13 prednisolone was given but no red cells. She suffered cardiac arrest at 05:10 with successful resuscitation but resuscitation was not attempted after another cardiac arrest. Death was considered 'possibly related' to this delay.

A further case is included in the supplementary information on the SHOT website (https://www.shotuk.org/shot-reports/report-summary-and-supplement-2022/). In total there were 24 cases of delays related to irregular antibodies in the patient.

Learning points

- When patients have irregular antibodies and require urgent transfusion clinicians should liaise with the transfusion laboratory staff and haematologist
- A 'Plan B' should be in place, i.e., use group O D-negative or positive (with close monitoring and steroids) rather than risk patient death from severe anaemia. Transfusion laboratories should have an SOP for concessionary release

Additional case reports of deaths possibly related (imputability 1) to transfusion can be found in the supplementary information on the SHOT website (https://www.shotuk.org/shot-reports/report-summary-and-supplement-2022/).

Major morbidity n=6

Of these, 2 cases involved young adults with SCD who deteriorated as a result of delayed transfusion.

A further case involved a patient with irregular antibodies which is discussed in the supplementary chapter; a child with a brain tumour whose platelet transfusion was delayed and developed ICH; delayed recognition and management of haemorrhage which resulted in a cardiac arrest call (the patient recovered with transfusion and surgery) and in the other case postoperative bleeding was associated with poor communication and multiple errors in the MHP.

Case 11a.5: Delayed transfusion in a patient with SCD associated with clinical deterioration

A patient with SCD, and a Hb of 64g/L, had two units of red cells authorised to be given as soon as available, but was not transfused until the following day. Nursing staff were unclear when the blood was meant to be given despite verbal handover the day before. The patient deteriorated with worsening chest pain and new oxygen requirement and subsequently required exchange transfusion.

Timely transfusion would likely have prevented deterioration.

The second case with SCD was similar, a delay of more than 12 hours receiving transfusion when he presented with acute chest syndrome. The patient needed exchange transfusion.

Learning points

- People with SCD benefit from specialist referral at an early stage of admission
- Junior medical staff should not hesitate to escalate for advice and discuss transfusion requirements with the transfusion laboratory

Case 11a.6: Delayed transfusion due to communication failures and lack of clarity in the MHP

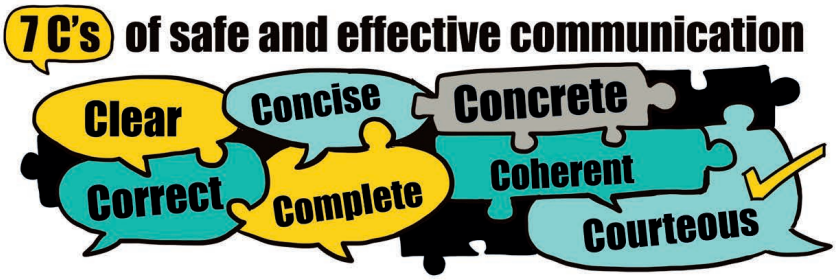
A woman experienced unexpected major bleeding the day after routine cholecystectomy (accidental damage to the portal vein) resulting in MHP activation. She was haemodynamically unstable with a pre-transfusion Hb of 36g/L. There was a 15-minute delay in the issue of red cells because the BMS was unclear about the patient location (transferred from ICU to theatre) and whether formal patient ID was needed. She received 15 units of red cells, six of plasma, one of platelets and fibrinogen.

There were several communication failures during the MHP. There was a lack of clarity and unfamiliarity with the MHP, and miscommunication across all three departments involved in the care of this patient.

In total poor communication was identified as contributory in 110 cases of delayed transfusions.

Learning points

- Poor communication frequently contributes to delayed transfusions. Be clear and concise
- MHP need drills covering each step of the process, including how to step down. Drills should also include obtaining blood packs



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Delays associated with the laboratory n=62

In 21/62 reports issues were noted with laboratory staff skills or knowledge and 9 cases reported a mismatch between workload and staff provision at the time of the incident. There were 15/62 delays that involved IT (16 clinical delays also involved IT). In 10 cases, delays were related to the presence of irregular antibodies or autoimmune haemolysis leading to delays in testing. Three of these were at the Blood Centre.

Learning points

- Laboratory staff working in transfusion must be adequately trained and competency-assessed
- Lone working out-of-hours is a risk factor for delayed transfusion
- Changes to routine practice, such as bank holiday working hours, should be clearly communicated to all staff

Information about responses related to HF questions can be accessed in the supplementary information on the SHOT website (https://www.shotuk.org/shot-reports/report-summary-and-supplement-2022/).

Near miss n=6

These included issues with storage in emergency and satellite refrigerators, and problems in the laboratory with sample validity (3 cases).

In 1 case staff in the ED made emergency units unavailable for 12 hours by trying to place a unit of patient-specific red cells in the refrigerator (this is not allowed). In another case the laboratory had failed to include details about irregular antibodies on serial reports in pregnancy so that when a MH was called at delivery the red cell units were incompatible but fortunately were not required. This was identified as an issue with the LIMS which made it difficult to add these results.

Conclusion

Delayed transfusion puts patients at risk and can contribute to death. Poor communication exacerbated transfusion delay in more than half the reported cases. Staffing shortages are a widespread problem in NHS hospitals and have been identified in many cases of delayed transfusion. Staff should escalate these issues to their managers and review their capacity plans. The recommended actions as per the SHOT CAS alert will help address preventable transfusion delays and improve patient safety. Patients should not die or suffer harm from avoidable delays in transfusion.

Recommended resources

SHOT Bite No. 8: Massive Haemorrhage Delays
https://www.shotuk.org/resources/current-resources/shot-bites/

SHOT Video: Delayed Transfusion in Major Haemorrhage
https://www.shotuk.org/resources/current-resources/videos/

SHOT Webinar: Every Minute Counts
https://www.shotuk.org/resources/current-resources/webinars/

2018 National Comparative Audit of Major Haemorrhage https://hospital.blood.co.uk/audits/national-comparative-audit/reports-grouped-by-year/2018-audit-of-the-management-of-major-haemorrhage/

Can you PACE yourself? The power of language to flatten hierarchy and empower multi-disciplinary healthcare teams in simulated critical scenarios
https://www.gloshospitals.nhs.uk/work-for-us/training-staff/gsqia/quality-improvements/Can-you-PACE-yourself/

15s30m stands for 15 seconds, 30 minutes – taking a few extra seconds at the start of a process can save someone a lot of time further along, reducing frustration and increasing joy at work.
https://fabnhsstuff.net/fab-stuff/15-seconds-30-minutes

References

SHOT. Preventing transfusion delays in bleeding and critically anaemic patients SHOT/2022/001 (2022) https://www.cas.mhra.gov.uk/ViewandAcknowledgment/ViewAlert.aspx?AlertID=103190 [accessed 28 April 2023].

11b Avoidable Transfusions n=121

Authors: Paula Bolton-Maggs, Catherine Booth and Simon Carter-Graham

Definition:

Where the intended transfusion is carried out, and the blood component itself is suitable for transfusion and compatible with the patient, but where the decision leading to the transfusion is flawed. Every unit transfused should be an individual decision, so this might include transfusion of multiple units where not all were appropriate/necessary.

Reporting should include:

- **Components that are not required or are inappropriate because of erroneous laboratory results, transcription errors, miscommunication or faulty clinical judgement**
- **Components that are for an inappropriate indication**
- **Transfusion of an asymptomatic patient with haematinic deficiency**
- **Avoidable use of emergency group O blood (D-negative or D-positive) where group-specific or crossmatched blood was readily available for the patient or the laboratory could have supplied a more suitable component, including use of group O when time would allow a more appropriate group to be remotely allocated from a remote release refrigerator system**

Key SHOT messages

- Group O D-negative units, a precious resource, continue to be used inappropriately
- Poor communication and flawed decision-making contribute to avoidable transfusions, including use of O D-negative units when crossmatched or group specific units were available
- Haematinic deficiencies are poorly recognised and managed inappropriately. Transfusion in patients with haematinic deficiency carries increased risk of TACO
- Transfusion decisions based on inaccurate blood results continue to be reported

Recommendations

- Unless the transfusion is an emergency, the pre-administration bedside checklist should include a review of the patient's Hb or platelet count and confirmation with the patient that they have given consent
- Centres using electronic authorising should consider pulling through laboratory results to the request form, to alert the prescriber to any discrepancies
- Blood authorisation charts should be designed to capture the indication for transfusion and any specific instructions, such as the circumstances under which transfusion should be given
- By authorising a blood component, the prescriber affirms they are requesting the correct component for the correct patient and have confirmed this is clinically necessary. Systems should be designed to make as many opportunities as possible to check that this is the case

Action: Hospital transfusion teams, UK medical schools, transfusion laboratory managers, clinical haematology teams

Introduction

There were 121 reports of avoidable transfusion compared to 116 in 2021 and 110 in 2020.

Deaths related to transfusion n=0

There were no deaths related to avoidable transfusions.

Major morbidity n=0

There were no cases of major morbidity related to avoidable transfusions.

Group	Red cells	Platelets	Plasma components	Multiple components	Total reports
Flawed decision	16	4	2	0	**22**
Decision based on inaccurate results	32	8	1	2	**43**
Failure to respond to change in circumstances	11	4	0	1	**16**
Transfusion without decision	5	1	0	1	**7**
Appropriate decision, inappropriate component	33	0	0	0	**33**
Total	**101**	**17**	**3**	**4**	**121**

Table 11b.1: Classification of avoidable transfusions

This year, the incidents reported have been mapped to the stage of the transfusion process and the staff members likely to be involved in the errors (Figure 11b.1).

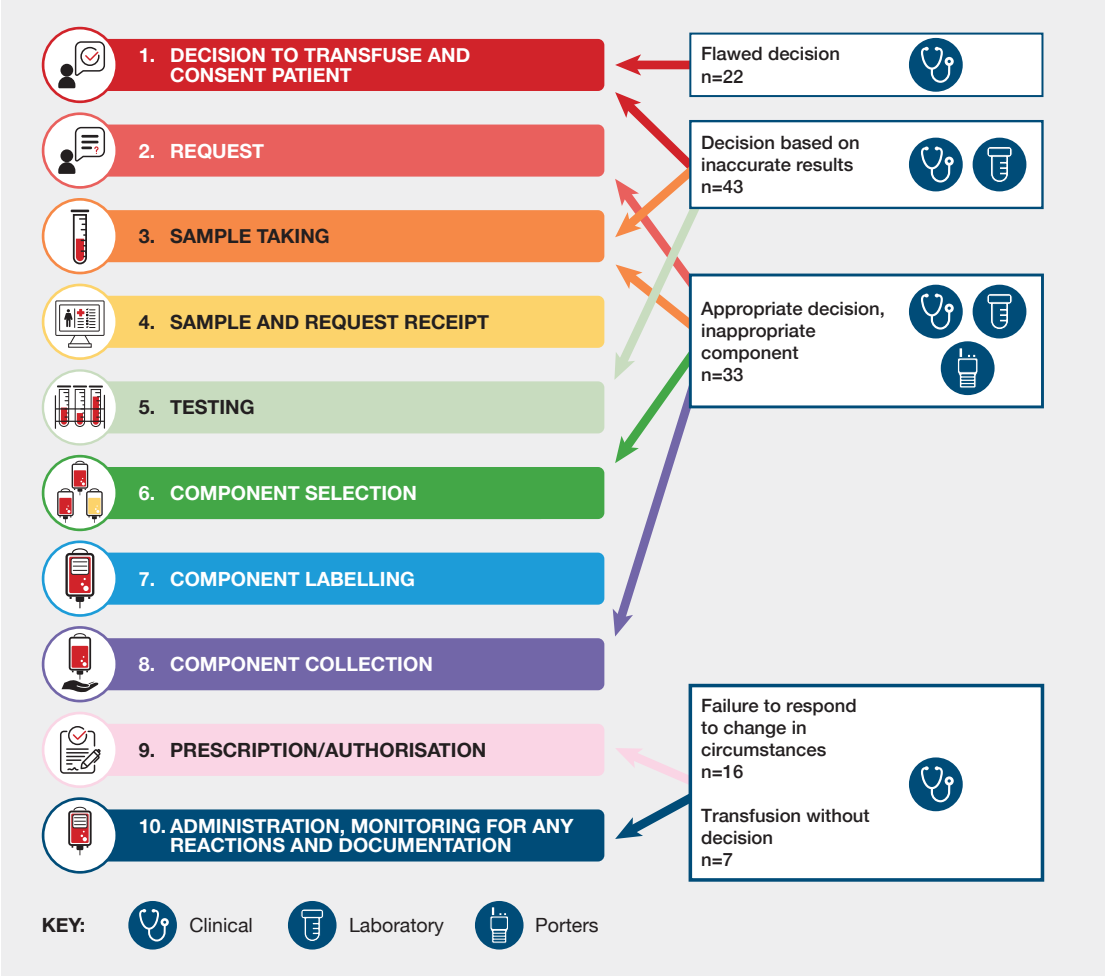


Figure 11b.1: Step in transfusion process with associated errors

Flawed decision n=22

Cases of flawed decision included: excessive transfusion for haematinic deficiency (n=6), transfusion of multiple units without review (n=7), transfusion above recommended thresholds (n=2), transfusion of platelets/plasma components to 'treat a number' in the absence of bleeding (n=3), misidentification of major haemorrhage (n=1), transfusion of a patient who had withheld their consent (n=3), all Jehovah's Witnesses.

Case 11b.1: Excessive transfusion for iron deficiency

A woman with menorrhagia, a Hb of 69g/L and moderate symptoms of anaemia received four units of red cells authorised by a junior doctor. One was warranted, but she should have been reviewed and Hb checked after each unit (or at the very least after two units). Her Hb was not measured until after the third unit and the result (Hb 105g/L) was not checked until after the fourth unit had been given. Her ferritin of 8micrograms/L was not acted on. There was a lack of understanding about the appropriate treatment of anaemia without transfusion. An anaemia clinic had been suggested but there was no funding.

Learning points

- Anaemia due to haematinic (vitamin) deficiencies is treated by replacing the missing vitamin. Transfusion should only be given where there is risk of haemodynamic instability, which is very unlikely in a young fit patient. If transfusion is essential, a single unit should be given followed by clinical review
- Clinicians authorising blood components for patients who cannot consent for themselves should check for any cautions or contraindications, just as they would check for allergies when prescribing a drug

Decision based on inaccurate results n=43

Cases where decisions were based on inaccurate results included: acting on old results (n=7), WBIT for FBC sample (n=4), use of another patient's results (n=2), misreading results (n=2), sample from drip arm (n=5), verbal handover of incorrect results (n=5), inaccurate results from a point-of-care device (n=4), spurious thrombocytopenia due to platelet clumping (n=3), other anomalous FBC results (n=11).

In 15 cases, these errors might have been prevented had there been a second check of the patient's laboratory parameters before proceeding with transfusion.

Case 11b.2: Results transcription error leads to unnecessary transfusion

An oncology patient received a transfusion of three units of red cells in a community hospital after a transcription error on the blood results recording page led to the platelet count of '80' being misread as the Hb. At the outpatient follow up appointment after transfusion, the Hb was over 200g/L.

Even if the Hb had been 80g/L, it is unlikely that three units would have been required.

Learning point

- There are multiple opportunities for an additional check of results prior to transfusion: at the time of the decision to transfuse, authorisation, release of units from the laboratory or immediately before administration. Systems making use of these checkpoints may be more likely to pick up erroneous decisions based on old or spurious results

Failure to respond to change in circumstances n=16

Cases where there was a failure to respond to change in circumstances included: components authorised for 'just in case' but transfused routinely (n=4), platelets given prophylactically for a procedure which

was cancelled (n=1), authorisation done in advance and recent results not checked (n=5), change in plan not communicated (n=3), transfusion already given but not documented (n=3).

Case 11b.3: Recent results not reviewed before commencing a transfusion prescribed in advance

A patient in their 80s with pure red cell aplasia was referred to the day ward for regular transfusion, two units of red cells every 2 weeks. She had recently been started on steroids. FBC was taken on arrival to the ward but transfusion of the first unit of red cells was started before the Hb result came back. The Hb was 140g/L and transfusion was stopped. Her Hb check 1 day before was also normal.

Learning points

- Where components are authorised 'just in case', e.g., for surgery, the authorisation should be accompanied by notes to explain under what circumstances these should be given
- Where authorisations are written in advance for patients attending for elective outpatient transfusions, there should be a routine step to check latest results and any change in patient circumstances before proceeding

Transfusion without decision n=7

Cases where patients were transfused without a formal written authorisation included: verbal handover of the plan to transfuse (n=3), transfusion prescribed for wrong patient (n=3), additional units given without prescription (n=1).

Case 11b.4: Miscommunication at verbal handover leads to a patient receiving an unnecessary red cell transfusion with an invalid prescription

A female (Patient 1) in her 50s was admitted to a haematology ward with AML and GvHD. Her Hb result on admission was 120g/L. She was due to receive ECP the following day, and there was a unit of red cells on standby in case they were required for this procedure. During a verbal handover Nurse 1 asked Nurse 2 to carry out two separate tasks; to obtain blood samples from Patient 1, and administer a red cell transfusion to Patient 2. Nurse 2 thought that they had been asked to transfuse Patient 1 and as there was a unit of blood in the refrigerator for Patient 1 (on standby for ECP), they collected this.

Pre-administration checks, including positive patient identification, checking the details of the patient with the ID band and prescription chart, and the final check of the compatibility tag with the ID band were carried out by two nurses. They did not notice the blood transfusion prescription dated 2 days previous to this and had not reviewed the patient's Hb result at any point. The red cells were administered. The patient suffered no ill effects from this avoidable transfusion.

This incident occurred on a very busy haematology ward which was full to capacity at the time. Nurse 2 thought they had understood what Nurse 1 had said when they took over the care of the two patients. They felt under pressure when asked to complete the requested tasks, as they were already caring for several other patients. The two nurses involved in the administration were already tired from previous long, busy shifts and there was a lack of staff at this particular time due to lunch breaks.

Learning points

- An authoriser should not authorise a blood component based on a verbal request without checking the indication and patient's results themselves
- Those administering transfusions should not rely on verbal handover but check there is a documented plan and completed authorisation before proceeding

Appropriate decision, inappropriate component n=33

Cases where an appropriate decision to transfuse was made but an inappropriate component was administered included avoidable transfusion of group O D-negative (n=28) and O D-positive (n=5) red cell units to patients with bleeding.

Thirty were due to clinical errors and 3 to laboratory error. Poor communication issues between the laboratory and clinical areas were implicated in 13 cases, while communication between different staff within the clinical area played a role in 7 cases.

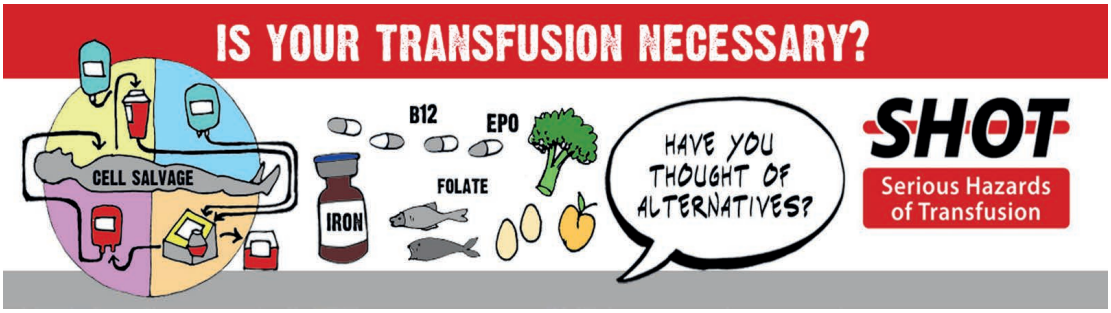
Crossmatched or group-specific units were available for 19 patients. In 7 cases, delays in taking a group and screen sample or mislabelled samples meant emergency units had to be selected. In 6 cases, a sample had been sent but the laboratory was not informed that the red cell units were required urgently. Three reports related to problems accessing group-specific units in remote refrigerators, 2 due to lack of trained staff and 1 due to an IT malfunction.

Case 11b.5: Multiple mislabelled samples result in prolonged use of group O D-negative units

A woman in her 20s was admitted to the ED following major trauma and issued an emergency trauma identity. The sample and request form did not match on the first set of two crossmatch blood samples received - Unknown Unknown on the sample, but a patient's name on request form. The second set of two samples both had unknown spelt incorrectly - Uknown on the sample. A third set of two blood samples was received 2 hours later. One did not have a DOB and was rejected. Group-specific blood components could only be made available after the seventh sample was received, resulting in prolonged use of emergency O D-negative blood.

Learning points

- Rules on correct sample labelling still apply in a major haemorrhage setting, including spelling of trauma ID names
- Taking samples promptly, delivering them to the laboratory and communicating their urgency are all central to provision of appropriate group-specific units



Near miss cases n=6

All of these were due to clinical errors, and 4/6 were discovered at the pre-administration checks.

The MHP was activated for an elderly woman with a GI bleed whose blood gas Hb was 43g/L but a repeat was 127g/L, so the MHP was cancelled (with wastage of a unit of O D-negative blood). The prescription was cancelled for two patients and detected at the pre-administration checks. A man in his 90s queried the need for a second unit which was then not given.

Conclusion

In a year where there have been shortages of blood components, particularly group O red cells, it is more important than ever that any transfusion given is clinically indicated and that group-specific components are given where possible. Including patients (where possible) in the decision to transfuse

is an important additional safety barrier, as a patient's questions might prompt greater scrutiny of the rationale for transfusion.

The largest number of reports related to patients receiving inappropriate transfusions based on incorrect laboratory results. These might have been prevented by an additional check of blood results prior to transfusion, which could be done at the stage of decision-making (e.g., a sense-check with a colleague, particularly if results are unexpected), authorisation (e.g., making use of IT systems to integrate laboratory results), issue from the laboratory (if BMS are empowered to question decisions) or administration (making review of results part of the pre-transfusion check).

Appropriate laboratory tests should be performed in patients with suspected iron deficiency to help direct onward investigation and management based on national gastrointestinal and gynaecology guidelines and local pathways within individual healthcare settings (BSH Fletcher et al. 2022). The 2019 national comparative re-audit of the medical use of red cells showed significant numbers of asymptomatic or only mildly symptomatic patients being transfused when their Hb levels are above the recommended thresholds. In this audit, one in five patients were transfused because of iron-deficiency anaemia and nearly 5% of transfusions were documented as given because of B12 or folate deficiency or both (NCA 2019). The 2021 national comparative audit of NICE Quality Standard QS138 helped identify areas where there were gaps in implementing patient blood management measures and recommended that hospitals explore barriers to the implementation of the NICE Quality Statements for Blood Transfusion (NCA 2021) (NICE 2016).

Clear lines of communication are central to an effective MHP, but this generally focuses on clinicians being able to rapidly contact the laboratory. To facilitate an effective switch to group-specific red cells, a defined communication channel from laboratory to clinical staff managing the haemorrhage is equally important. Local policies and processes must be in place and aligned with national guidelines for appropriate haematological management of major haemorrhage (BSH Stanworth et al. 2022).

SHOT
Serious Hazards of Transfusion

Recommended resources

E-learning modules:

Anaemia
Includes modules 'Anaemia - the only introduction you need', 'Anaemia in primary care patients', 'Anaemia in hospital patients' and 'Anaemia of inflammation and chronic disease'. Accessible via: https://hospital.blood.co.uk/training/clinical-courses/

Blood component use in major haemorrhage
https://www.e-lfh.org.uk/programmes/blood-component-use-in-major-haemorrhage/

The NHSBT O D-negative toolkit
https://hospital.blood.co.uk/patient-services/patient-blood-management/o-d-negative-red-cell-toolkit/

The A-E Decision Tree to facilitate decision making in transfusion
https://www.shotuk.org/resources/current-resources/

JPAC – Guidance for UK health professionals on consent for blood transfusion
https://www.transfusionguidelines.org/transfusion-practice/consent-for-blood-transfusion/guidance-for-healthcare-practitioners-involved-in-this-role

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Under or Overtransfusion n=18

11c

Authors: Paula Bolton-Maggs, Catherine Booth and Simon Carter-Graham

Definition:

A dose inappropriate for the patient's needs, excluding those cases which result in TACO and usually resulting in a haemoglobin or platelet level significantly outside the intended target range. Infusion pump errors leading to under or overtransfusion with clinical consequences (if no clinical consequences, then it is reportable as HSE)

Key SHOT messages

- More than 50% (10/18) cases in this category in paediatric patients. Volume calculation for transfusions in paediatric patients continues to be a concern
- Instances of overtransfusion continue to be reported where staff failed to check Hb increment following transfusions. This would help guide further transfusions

Recommendations

- Paediatric transfusion protocols should be readily available for reference by all clinical staff
- Staff who authorise paediatric transfusion should be trained so that they know how to calculate the correct dose of all components
- Major haemorrhage drills should include taking samples for intermittent Hb checks, using a blood gas analyser if appropriate (and quality-assured for that purpose)
- Mandatory transfusion training should include information about special patient groups where standard guidelines may not apply, such as haemoglobinopathy patients
- Specialist haematology advice should be sought for management of patients with haemoglobin disorders

Action: Hospital transfusion teams

Introduction

This year, recognising that there has been some confusion between cases of 'avoidable' transfusion and 'overtransfusion', the definition has been revised. Some cases reported in 2022 have been reclassified as avoidable, e.g., where a second unit was transfused that was not necessary. This has resulted in a smaller number classified this year as overtransfusion. As a result, 14 cases were recategorised from overtransfusion to avoidable transfusion.

There were 10 cases reported in children and these are discussed further in Chapter 23, Paediatric Cases. Errors in prescribing and administering blood components in children are common and hospitals should review their paediatric transfusion policy which must be aligned with national guidelines (BSH New et al. 2016).

Deaths related to transfusion n=0

There were no deaths reported related to under or overtransfusion.

Major morbidity n=2

Case 11c.1: Overtransfusion during major haemorrhage

An elderly woman had an estimated GI blood loss of about 500mL and was peri-arrest. A major haemorrhage call was made; she received six units of red cells and two of FFP. Her Hb post transfusion was 179g/L. There was no pre-transfusion Hb, and it was not assessed during the treatment.

Case 11c.2: Undertransfusion caused by a bleed back into red cell bag associated with peri-arrest in a man with GI bleeding

A man in his 60s was admitted with haematemesis and melaena and a Hb of 54g/L. The first unit of red cells was transfused but the bag was disconnected from the pump and put on the bed while he had an urgent CT scan at night and then needed to use the urine bottle. While the nurse was fetching the second unit, about 500mL bled back into the first bag; the patient complained of chest pain and a feeling of doom. An arrest call was put out; he received further transfusion and recovered.

A clamp on the line could have prevented the bleed back into the bag. The ward had a very poor skill mix. There were only two qualified nurses on duty overnight with a full ward and four patients who were actively bleeding. The nurse was exhausted and had to take time off work. She was a very experienced nurse but following a period of sick leave and counselling, she has resigned from her post.

Haematinic deficiency

Case 11c.3: Excessive transfusion for folate deficiency

A woman in her 70s and a low body weight of 29kg was admitted with symptoms of anaemia and a Hb of 61g/L. She received two units of red cells. On the following day she was reviewed by another consultant and was transfused a further two units. The post-transfusion Hb was 155g/L. Her anaemia was due to severe folate deficiency.

Every year SHOT receives reports of over or avoidable transfusion for haematinic deficiencies. Patients are put at unnecessary risk as severe anaemia is associated with an increased risk of transfusion-associated circulatory overload and death (see Case 17a.1 in Chapter 17a, Transfusion-Associated Circulatory Overload (TACO)). A single unit transfusion followed by reassessment is safer where symptoms indicate a limited transfusion to be appropriate.

Haemoglobin disorders n=2

Two patients with SCD were transfused excess red cells due to poor communication, staff misread the prescription in both cases.

One was an adult who was admitted with a sickle crisis and chest infection to a hospital unfamiliar with SCD (he was known to another tertiary centre). The laboratory was not informed of this diagnosis, so he did not receive appropriate phenotyped red cells; in addition, he received excessive transfusion requiring venesection. The other case involved a child with SCD who was overtransfused.

Near miss cases n=1

An incorrect volume was prescribed for a child without taking into consideration the child's body weight. The consultant identified the error on a ward round and prevented the transfusion of the second unit of red cells.

Conclusion

Transfusion in paediatric patients continues to be the main source of error reported in this section. Measures are needed to improve patient safety. This is a role for paediatricians and paediatric nurses as well as transfusion staff.

Blood loss in major haemorrhage in adults can be difficult to assess. Regular monitoring of blood parameters is recommended. Blood gas analysers may be used for this as long as they are quality assured for this purpose and the sample is handled correctly.

Unnecessary or excessive transfusion continues to be reported in patients with haematinic deficiencies, suggesting a reactive response in transfusing to correct anaemia rather than investigating and treating the cause (BSH Fletcher et al. 2022).

Recommended resources

SHOT Bite No. 4: Paediatrics
https://www.shotuk.org/resources/current-resources/shot-bites/

Key information from the BSH paediatric guidelines
https://www.shotuk.org/resources/current-resources/paediatric/

Reference

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11d Incidents Related to Prothrombin Complex Concentrate (PCC) n=21

Authors: Paula Bolton-Maggs, Josephine McCullagh and Simon Carter-Graham

Definition:

Hospitals are asked to report incidents related to PCC infusion where there was delay or inappropriate transfusion. (Allergic reactions should be reported to the MHRA through the yellow card scheme, https://yellowcard.mhra.gov.uk/).

Key SHOT messages

- Failure to administer PCC in a timely manner contributes to patient deaths
- Lack of clear understanding of the processes involved in ordering, procuring, and administering PCC has been identified as a common factor in the delays reported
- PCC dosing errors continue to be reported

Recommendations

- PCC are used mainly for oral anticoagulant reversal in an elderly vulnerable population. The ED should ensure they have a protocol for their use with clear instructions for dose and administration, and ensure that staff are appropriately trained in their use
- Use of PCC should be regularly audited for timeliness and appropriateness

Action: Medical directors of acute NHS Trusts/Health Boards

Introduction

PCC administration is an emergency treatment used for reversal of oral anticoagulants (warfarin and DOAC) which should be started within an hour of the decision being made and before the patient is transferred to other wards or departments. Patients with ICH are at high risk of death or serious sequelae and require urgent anticoagulant reversal.

PCC incidents were reported mainly in an elderly population, median age 71 years. There were 4 patients under 60 years of age. There were 12/21 reports of delayed PCC infusion. Other errors included administration of either under or over recommended doses.

All patients were taking anticoagulants, either warfarin or apixaban/edoxaban. Ten patients had ICH (8 delayed infusions and 2 received less than the recommended dosage).

Deaths related to transfusion n=2

There were 2 deaths possibly related (imputability 1) to failure to administer PCC in patients with ICH, both aged >80 years.

Case 11d.1: Failure to administer PCC to an elderly man with ICH

A request was made from the ED to the transfusion laboratory to issue PCC 1000IU to reverse warfarin for a patient with an acute subdural haematoma resulting from a fall. PCC was issued at

00:58 but never collected. At 12:25 the PCC was returned to stock by the transfusion laboratory. A verbal handover in the ED stated that the patient had received the PCC and was also documented wrongly in the patient notes. Failure to give PCC was considered contributory to his death.

Case 11d.2: Failure to give PCC for ICH due to misunderstanding of a new IT system

An elderly man on edoxaban for AF presented to the ED with a history of a fall at home. He sustained another fall in a cubicle in the ED hitting his head. A CT scan of his brain demonstrated ICH. PCC was prescribed on the new electronic patient record system (which had only been in use for a month) at 17:56 however the request was not automatically received in the laboratory. PCC was not issued until nearly 4 hours later at 21:39 when the laboratory was contacted by telephone. This delay was considered contributory to the patient's death.

The staff considered that training for the new system had been rolled out too rapidly and was inadequate.

Major morbidity n=2

Case 11d.3: Life-threatening delay in administration of PCC for GI haemorrhage

A woman in her 50s on warfarin (metallic heart valves) presented to the ED with melaena and a Hb of 48g/L. PCC was authorised by the on-call haematologist at 06:30 but not requested until much later, at 17:55. The patient was topped up with red cells but failed to receive PCC as the INR result was delayed (coagulation analyser recorded INR as >10 but was recorded on LIMS as 'unable to analyse' in error). She developed haemodynamic instability requiring transfer to ICU for inotropic support. Endoscopy was eventually done at 02:00.

A review identified the following concerns:

- Lack of understanding by both admitting and ward teams of the importance of immediate reversal of warfarin in the context of life-threatening bleeding
- Failure to appreciate that the risk of bleeding far outweighs the risk of thrombosis so the advice from cardiology consultant to the ward team that the INR should not be less than 2 was poor
- Delayed reporting of INR result
- Poor communication between the haematology consultant and the night team about administration of PCC and vitamin K

Case 11d.4: Incomplete dose of PCC given without prescription for a patient with ICH

A dose of 3000IU PCC was advised by the consultant haematologist for a patient with ICH; this correct dose was issued from the transfusion laboratory. At 21:58 the nursing notes documented that 3000IU had been given, but only 2000IU was given and not correctly recorded by an agency nurse working in a busy ED. The patient was admitted to ICU and made a full recovery. A vial of 1000IU PCC was returned to laboratory from ED 12 days after issue.

Delays n=12

Delays were caused by poor communication, transfer of patients between departments or setting inappropriately long infusion times. Patients with ICH experienced delays up to 12 hours.

Case 11d.5: Delayed PCC administration for ICH

A man in his 70s on anticoagulants for AF and with left sided weakness arrived in the ED at 02:01. At 07:15 it was noted that the patient had a long wait in ED. A CT scan showed ICH. At 10:40 the haematology registrar advised PCC which was issued, but not administered until 2 hours later, 11 hours after admission. There were delays in the prescribing, ordering, collection, and administration of the drug due to lack of knowledge (new nurse and agency nurse looking after the patient).

Case 11d.6: Delay in adequate reversal of anticoagulation following pelvic fracture

An elderly lady fell sustaining a fracture of her pelvis. She was on warfarin for AF and was admitted at 05:55. Scanning suggested active bleeding and at 08:21 the MHP was activated; a haematology registrar advised an inappropriately low dose of PCC (15IU/kg). A corrected dose of 50IU/kg was given 3 hours later. Death was not thought related to the suboptimal first PCC dose.

Additional factors included unfamiliarity of staff with PCC prescription and administration.

Additional cases can be found in the supplementary information on the SHOT website (https://www.shotuk.org/report-summary-and-supplement-2022/).

Learning points

- Medical and nursing staff working in the ED and medical/surgical admissions units should be trained in the use of PCC so that it can be administered without delay for anticoagulant reversal in the face of major haemorrhage
- PCC should be rapidly accessible, and consideration given to keeping a stock in the ED (note that this blood product must be fully traceable)
- Immediate reversal of anticoagulant should take place (and certainly within an hour) especially in cases of suspected ICH

Commentary

Fixed dose PCC?

The two PCC are currently only licensed for reversal of vitamin K antagonists. There is published evidence for benefit in haemorrhage in patients on DOAC (see references in Annual Report for 2021). There are specific reversal agents for DOAC demonstrated to be of benefit in ICH (Vestal et al. 2022).

Continued confusion about dose and rate of infusion suggest that a fixed dose regimen might be safer. The literature was reviewed in the Annual SHOT Report for 2021. It is not clear what the optimal fixed dose should be. Whether a fixed dose or weight-based regimen is used, follow up of the INR for patients on warfarin (who should also receive vitamin K) is essential to ensure the dose was adequate and to determine if further PCC is required.

Use of PCC for DOAC reversal

PCC may also be used for DOAC. A meta-analysis of reversal agents (PCC, idarucizumab and andexanet) for bleeding related to DOAC evaluated 60 studies with 4735 patients. Mortality of those with ICH was 20%; effective haemostasis was achieved in 75-81% and was similar for all agents and a particularly high thromboembolism rate was noted for andexanet (Gomez-Outes et al. 2021).

Ciraparantag is a new reversal agent in trial, a small synthetic molecule. In two randomised placebo-controlled, dose-ranging trials in normal adults, treated with either apixaban or rivaroxaban, haemostasis was assessed by whole blood clotting time. This agent resulted in dose-dependent reversal of both agents with minimal side effects. (Ansell et al. 2022).

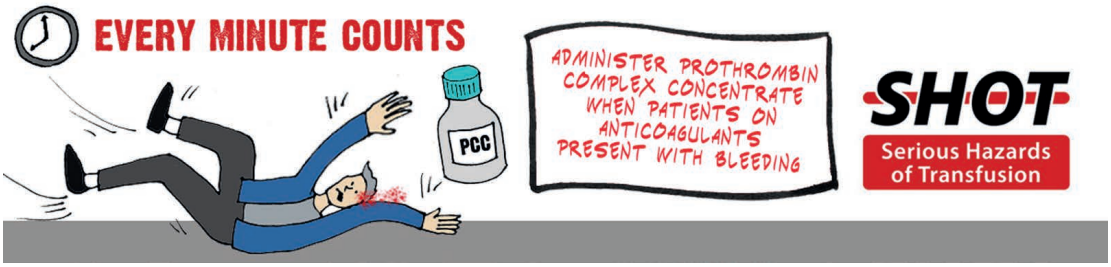
Near miss cases n=1

Two vials of PCC had transposed compatibility labels after a printer had been jammed; the labels were re-printed and applied to the wrong vials. The error was discovered at the pre-administration checks and the vials returned to the laboratory for re-labelling.

Conclusion

PCC are an important treatment for immediate reversal of vitamin K antagonists and other oral anticoagulants and should be given immediately a decision is made. All clinical staff involved in the acute care of patients with suspected serious haemorrhage, particularly ICH, who are eligible for reversal should ensure that they know how to obtain and how to administer PCC. Delay can contribute to death.

The SHOT CAS alert released in 2022 also addresses preventable PCC delays. One of the recommended actions was for all healthcare organisations to ensure their transfusion policies and procedures include agreed criteria where rapid release of PCC is acceptable without the initial approval of a haematologist.



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