

Preventing transfusion delays in bleeding and critically anaemic patients.

Date of Issue: 17-Jan-22 Reference No: SHOT/2022/001

This alert is for action by: NHS and independent (acute and specialist) sector where transfusions are carried out.

Access to blood components and products is a complex safety critical issue that is relevant across many departments and professions. Implementation of this alert should be coordinated by an executive leader (or equivalent role in organisations without executive boards) and supported by their designated senior leads for medical, nursing and pathology teams.

Explanation of identified safety issue:

Transfusion delays are preventable. Patients should not die or suffer harm from avoidable delays in transfusion.

The urgent provision of blood components and/or blood products is vital for life threatening bleeding and severe anaemia as described in the three situations below. A rapid, focused approach is required as delays can result in preventable death or end-organ damage.

Delays in provision and transfusion of blood during major haemorrhage have been identified repeatedly in Annual SHOT Reports¹. Delays are compounded by failure to recognise bleeding, communication failures and the presence of red cell antibodies in the patient blood sample¹.

Autoimmune haemolytic anaemia (AIHA) is a relatively uncommon disorder caused by autoantibodies directed against the patient's own red blood cells, with an estimated prevalence of 17:100,000 and a mortality rate of 11%^{2,3}. Urgent provision of blood may be needed for patients with severe anaemia. Laboratory testing may be complicated by the presence of the autoantibodies.

Anticoagulation is associated with an increased risk of bleeding which can be life/limb or sight threatening. Rapid reversal of anticoagulation in these cases is mandatory and delays impact patient safety. Prothrombin Complex Concentrates (PCC) are human blood products recommended for use as first line treatment for warfarin reversal (and for some other oral anticoagulants) when patients present with severe, life threatening bleeding. PCC should ideally be given within an hour once the anticoagulant reversal decision is made, particularly in patients with intracranial haemorrhage (ICH)⁴. Delays or omissions administration can result in serious morbidity (such as expansion of an ICH) or death^{5,6}. Poor communication, patient transfer between departments, dosage calculation and perceived need for consultant approval contribute to PCC delays1.

Actions required

Local organisations must have:

Actions to be completed as soon as possible and no later than 15 July 2022

- Reviewed and updated policies and procedures to cover:
 - Rapid release of blood components and products for major haemorrhage, AIHA and reversal of anticoagulants.
 - b. Compliance with SHOT¹, NICE⁴ and BSH⁷ recommendations.
 - Agreed criteria where rapid release of PCC is acceptable without the initial approval of a haematologist.
 - d. Concessionary, rapid release of the best matched red blood cells for patients with red cell antibodies.
 - e. Criteria and pathways for laboratory escalation to a haematologist where transfusion is urgent, and the presence of antibodies might delay release of red blood cells.
 - f. Treatment of patients who refuse transfusion of blood components and/or products.
- 2. Reviewed, updated, and implemented training programmes to include:
 - Recognition of bleeding, importance of communication, processes for activation of major haemorrhage protocols and rapid access to blood components and products in clinical staff training programmes.
 - b. Major haemorrhage drills, simulations and debriefs into regular staff training activities, including clinical and laboratory teams.
 - c. Concessionary, rapid release of the best matched red blood cells for patients with red cell antibodies.
 - d. A process for recording participation and identifying dates for re-training.
 - e. Treatment of patients who refuse transfusion of blood components and/or products.
- 3. Implemented processes to audit and investigate all transfusion delays, using appropriate investigation tools to identify system factors for improvement.

For further detail, resources and supporting materials see: www.shot.org

Additional information:

Further information and patient safety incident data

Deaths and serious harm related to delayed transfusion continue to be reported to <u>Serious Hazards of Transfusion</u> (the UK haemovigilance scheme), with the numbers increasing each year. Review of delayed transfusions reported to <u>Serious Hazards of Transfusion</u> (SHOT) between 2010-2020 found a total of 809 reports. In this 11-year period, transfusion delays contributed to 54 potentially preventable deaths accounting for 25.5% of all transfusion deaths reported to SHOT. The increase in reports of delayed transfusion with 12 deaths in 2020² prompted this safety alert.

There were 133 cases of delayed transfusion reported in the 2020 Annual SHOT Report. In this report 12 patient deaths are described, including 2 infants after elective biopsy. Delays in running the major haemorrhage protocols occurred in 26 cases, and in 1 case involving a child there was a failure to activate the protocol. Delayed transfusion in major haemorrhage resulted in major morbidity in 6 cases. In 8 cases, transfusions were delayed for patients with complex antibodies (3 of these had AIHA) due to difficulties with laboratory testing. These delays resulted from the need to refer samples to specialist centres, poor communication and lack of understanding of concessionary release of red cells. There were 11 reports of delayed PCC infusion. Although no patients died due to PCC delays in 2020, one death was reported in the 2019 Annual SHOT Report.

Traceability of blood components is a legal requirement under the <u>Blood Safety and Quality Regulations</u> (2005). PCC are blood products and must also be traceable. Processes for rapid access to, and administration of emergency blood components and products must ensure that traceability is maintained.

Unintentional administration of the wrong blood component, where there is an ABO blood group incompatibility, can result in death and this is preventable. This is a <u>National Health Service (NHS) Never Event for England</u>, Wales and Northern Ireland. In Scotland these cases would be reported as Red Incidents through the Scottish National Blood Transfusion Service. Positive patient identification using a <u>pre-administration checklist</u> must be ensured during emergency transfusions.

Information, recommendations, resources and further references to support implementation of this alert are available in Chapter 12 of the <u>2020 Annual SHOT Report</u>, <u>educational video</u> and summary documents for <u>major haemorrhage</u> and <u>PCC</u>.

References

- 1. Narayan S (Ed) Poles D et al. on behalf of the Serious Hazards of Transfusion (SHOT) Steering Group. The 2020 Annual SHOT Report (2021).
- Hill, Q.A., Stamps, R., Massey, E., Grainger, J.D., Provan, D., Hill, A. and (2017), The diagnosis and management of primary autoimmune haemolytic anaemia. Br J Haematol, 176: 395-411. https://doi.org/10.1111/bjh.14478
- 3. Hill, Q.A., Stamps, R., Massey, E., Grainger, J.D., Provan, D., Hill, A. and (2017), Guidelines on the management of drug-induced immune and secondary autoimmune, haemolytic anaemia. Br J Haematol, 177: 208-220. https://doi.org/10.1111/bjh.14654
- 4. NICE (2015) Guideline NG 24 Blood transfusion. Prothrombin complex concentrate. Thresholds and targets. https://www.nice.org.uk/guidance/ng24/chapter/Recommendations#prothrombin-complex-concentrate-2
- 5. Sweidan AJ, Singh NK, Conovaloff JL, et al. Coagulopathy reversal in intracerebral haemorrhage. Stroke Vasc Neurol 2020;5(1):29-33
- 6. Narayan S (Ed) Poles D et al. on behalf of the Serious Hazards of Transfusion (SHOT) Steering Group. The 2019 Annual SHOT Report (2020).
- 7. British Society for Haematology. Haematological Management of Major Haemorrhage (2015). h.org.uk/guidelines/guidelines/haematological-management-of-major-haemorrhage/

Stakeholder engagement

- Serious Hazards of Transfusion (SHOT) Haemovigilance Scheme Steering Group
- Transfusion Specialty Advisory Committee of the Royal College of Pathologists
- UK and Ireland Blood Transfusion Network with representatives from all Blood Services
- UK Transfusion Laboratory Collaborative group
- National Blood Transfusion Committees for England, Scotland, Wales and Northern Ireland
- British Society for Haematology Transfusion Task Force