National Patient Safety Alert

SHOT Serious Hazards of Transfusion

Medicines & Healthcare products Regulatory Agency

Reducing risks for transfusion-associated circulatory overload

Date of Issue:	4-Apr-24	Reference No:	NatPSA/2024/004/MHRA

This alert is for action by: **NHS and independent (acute and specialist) organisations where transfusions occur**

This is a safety critical and complex National Patient Safety Alert that is relevant across many departments and professions. Implementation 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, midwifery, scientific and allied health professionals.

Explanation of identified safety issue:

Transfusion-associated circulatory overload (TACO) is defined as acute or worsening respiratory compromise and/or acute or worsening pulmonary oedema during or up to 12 hours after transfusion, with additional features including cardiovascular system changes not explained by the patient's underlying medical condition, evidence of fluid overload and a relevant biomarker. **TACO is one of the most common causes of transfusion-related deaths in the UK and cases have increased substantially in recent years. Identifying risk factors for TACO prior to transfusion allows initiation of appropriate mitigating measures.**[1] TACO deaths are potentially preventable. TACO can occur in any individual of any age, including elderly people, children, and neonates. The risk is increased by the following factors:

- cardiac dysfunction
- renal dysfunction
- low body weight
- hypoalbuminaemia
- pre-existing fluid overload
- high volume in relation to body weight
- severe chronic anaemia
- women with severe pre-eclampsia

Non-bleeding adult patients with severe chronic anaemia are particularly vulnerable to risk of TACO. Errors in prescription for blood components have been reported in children and can contribute to TACO. Pulmonary complications of transfusion within this group can be difficult to identify, particularly in neonates. There should be awareness of TACO as a potential cause of respiratory deterioration following transfusion in this group.[2,3]

TACO risk reduction measures include:

- avoiding unnecessary transfusions
- single-unit transfusion or transfusing only the minimum number of units (or weight-adjusted red cell dose) needed to meet the haemoglobin (Hb) target (using red cell calculator[4]) and assessing response
- consideration of weight-adjusted red cell dosing for patients of low body weight (including children)
- avoiding transfusions in excess of recommended infusion rates
- administering a diuretic when appropriate
- monitor vital signs closely, including oxygen saturation

Further supporting information about TACO and this alert can be found in the supporting FAQ document.[5]

Actions required

Actions to be completed as soon as possible and no later than 4 October 2024:

1. Review and update **policies, procedures and processes** to ensure:
   a. All transfusions are compliant with recommendations from British Society for Haematology (BSH),[6,7] SHOT,[8] and NICE[9]
   b. A TACO risk assessment is undertaken utilising the SHOT risk assessment tool[1] prior to transfusions*
   c. Appropriate mitigation measures are initiated for individuals at risk – see FAQ document[5]
   d. Patients and carers should be informed of TACO as a significant potential complication of transfusion and likely symptoms, as part of complying with Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO) consent for transfusion guidance[10]
   e. Inclusion of guidance on timely management of TACO, including the use of diuretics, oxygen, and other supportive measures
   f. Clear communications on discharge to patients and staff involved in the care of the patient about blood components and/or blood products administered and any complications such as TACO
   g. Use of the structured TACO incident investigation tool[11] from SHOT
2. Review, update, and **implement training programmes** to include:
   a. Use of TACO pre-transfusion risk assessment tool*
   b. Appropriate use of mitigation measures – FAQ document[5]
   c. Management of severe chronic anaemia in non-bleeding patients using minimal/single-unit transfusion support, and anaemia management with iron therapy where appropriate
   d. Recognition and prompt management of TACO, importance of timely interventions and escalation of care as appropriate
   e. Empowerment of clinical staff and biomedical scientists to question practices of prescribing/requesting blood components
   f. A process for recording participation and identifying dates for re-training
   g. Knowledge and awareness to report TACO cases locally, as well as to MHRA and SHOT by hospital transfusion teams
3. **Undertake regular audit** on the use of the TACO risk assessment tool for adult patients*, consent practices, management of chronic severe anaemia, avoidable transfusions, volume of red cell transfusion and communication of information at discharge to relevant teams involved in the care pathway including patients

It is important to note that the TACO risk assessment tool has not been formally validated for paediatric age groups, but the risk factors are similar. Careful attention to appropriate volume and rate of transfusion is vital.

For further detail, resources and supporting materials see: https://www.gov.uk/drug-device-alerts and https://www.shotuk.org/

For any enquiries about this alert contact: info@mhra.gov.uk or SHOT@nhsbt.nhs.uk

Failure to take the actions required under this National Patient Safety Alert may lead to CQC taking regulatory action

Additional information:

Further information and patient safety incident data:
The MHRA are regulated by the Secretary of State to collect information regarding Serious Adverse Reactions (SAR) under Sections 7 (e) (ii), for Blood Establishments and Section 9 (f) (ii), for Hospital Blood Banks under the Blood Safety and Quality Regulations 2005 (as amended). SHOT provide the MHRA with consultant clinical input to ensure the correct classification of SARs, including TACO.

Review of TACO events analysed by SHOT between 2010 and 2022 found a total of 1336 reports. In this 13-year period, TACO contributed to 111 deaths, accounting for 39.2% (111 in 283) of all transfusion-related deaths reported to SHOT. The increasing trend in patient deaths and major morbidity due to TACO, with 8 deaths and 25 patients with major morbidity in 2022,[8] prompted this safety alert. In 2022, there were 3 cases in the under-18 age group, including neonates.[8]

The use of a formal pre-transfusion TACO risk assessment was introduced in the 2015 Annual SHOT Report.[12] A question regarding the use of the TACO risk assessment and mitigating actions was added to the SHOT questionnaire for the 2019 reporting year. In 2022, the TACO risk assessment was not used in 60.6% (97 in 160) of reported TACO cases. Where a TACO risk assessment was performed in 29 of 57 (50.9%), the need for a mitigating action was demonstrated. In most cases, appropriate actions were taken, however, in some cases additional measures could also have been performed.

Severe anaemia was added to the TACO risk assessment following evidence emerging in the data.[13] Non-bleeding adult patients with severe chronic anaemia are particularly vulnerable to TACO, even in the absence of additional risk and comorbidities known to predispose to TACO. From the 2022 SHOT data, 39 of 160 cases had Hb lower than 60gL; of these 39 cases, 7 were of severe anaemia due to haemorrhage or erroneous Hb measurement, 32 had severe chronic anaemia and 7 of these had clear evidence of iron deficiency.

The TACO structured investigation tool was first launched in the 2020 Annual SHOT Report and continues to be a recommendation.[11,13] The pulmonary reactions questionnaire in the SHOT database (Dendrite) has been updated to include a question as to whether it was performed. A structured review and incident investigation should be undertaken for every case of TACO to optimise organisational and individual patient-safety measures.

TACO is a regulatory reporting category under the Blood Safety and Quality Regulations (2005).[14] The National Blood Transfusion Indication codes[15] should be used in conjunction with national guidelines[6,7,8,9] and the transfusion decisions for each patient must be individualised considering risks and benefits to the patient. Information, recommendations, resources, and further references to support implementation of this alert are available in the FAQ document[5] on the TACO cumulative data page[2] on the SHOT website.

References:

1. TACO pre-transfusion risk assessment (previously referred to as the TACO checklist). First published on 07 July 2016, updated one published on 07 July 2020.
2. SHOT. Cumulative data from SHOT relating to TACO. Last updated April 2024.
3. Narayan S (Ed). Poles D and other, on behalf of the SHOT Steering Group. The 2021 Annual SHOT Report (2022). Published 06 July 2022. See within TACO chapter.
4. Grey S, and others. A web-App for weight-adjusted red cell dosing: post-development implementation and clinical effectiveness. British Journal of Haematology: 2018; volume 181: abstract 146. online 16 April 2018 (Further information about the red cell calculator can be found at this link https://www.rcdcalculator.co.uk/)
5. TACO. FAQ document to support the National Patient Safety Alert, NatPSA/2024/003/MHRA.
6. Robinson S, and others. The administration of blood components: a British Society for Haematology Guideline. Transfusion Medicine: volume 28, pages 3 to 21.
7. New HV, and others. Guidelines on transfusion for fetuses, neonates and older children. British Journal of Haematology: 2016; volume 175, pages 784 to 828.
8. Narayan S (Ed). Poles D and others, on behalf of the SHOT Steering Group. The 2022 Annual SHOT Report (2023). Published 04 July 2023.
9. NICE. Blood transfusion. Guideline NG 24. Published 18 November 2015.
10. Guidelines from the Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO) on patient consent for blood transfusion. Published 17 December 2020.
11. SHOT. TACO Incident Investigation Tool TACO-Incident-Investigation-Guidance-Tool-2024-A4-v34.pdf (shotuk.org). Published March 2024.
12. Bolton-Maggs PHB (ed), Poles D, and colleagues, on behalf of the SHOT Steering Group. The 2015 Annual SHOT Report (2016). Published 07 July 2016. See within TACO Chapter.
13. S Narayan (Ed) D Poles et al. on behalf of the Serious Hazards of Transfusion (SHOT) Steering Group. The 2020 Annual SHOT Report (2021). https://doi.org/10.57911/FN15-ME02. Published July 2021. See within the pulmonary complications chapter.
14. The Blood Safety and Quality Regulations 2005. UK Statutory Instruments 2005, number 50. ISBN 0110990412.
15. National Blood Transfusion Committee. Recommendations, Documents and Resources. Indication codes for transfusion.

Stakeholder engagement

Serious Hazards of Transfusion (SHOT) Haemovigilance Scheme Working Expert and Steering Group; Transfusion Specialty Advisory Committee of the Royal College of Pathologists; UK and Ireland Blood Transfusion Network with representatives from all UK 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 and NHS England and representatives from Scottish and Welsh Governments and the Department of Health Northern Ireland.

NHS England

Department of Health www.health-ni.gov.uk

NHS National Services Scotland

Llywodraeth Cymru Welsh Government

Please check website https://www.gov.uk/drug-device-alerts/national-patient-safety-alert-reducing-risks-for-transfusion-associated-circulatory-overload-natpsa-slash-2024-slash-004-slash-mhra for when actions should be ceased or advice to check for date restriction are lifted.