

'Reducing risks for transfusion-associated circulatory overload'

Purpose of this document:

This document includes additional information to support the implementation of the National Patient Safety Alert to reduce risks for transfusion-associated circulatory overload (TACO) and improve patient safety. This is a UK wide alert issued through MHRA. TACO is a regulatory adverse reaction reporting category under the Blood Safety and Quality Regulations (2005).¹

List of abbreviations used in the document:

MHRA	Medicines & Healthcare products Regulatory Agency
NatPSA	National Patient Safety Alert
NBTC	National Blood Transfusion Committee
NCA	National Comparative Audit
NICE	National Institute for Health and Care Excellence
PBM	Patient Blood Management
TACO	Transfusion-associated circulatory overload

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*These questions have been added to the FAQ document after the alert was released following feedback

1. What is TACO and are there any validated criteria to help identify TACO? What is reportable to SHOT and MHRA?

TACO is defined as acute or worsening respiratory compromise and/or acute or worsening pulmonary oedema during or up to 12 hours after transfusion. Additional features include cardiovascular system changes not explained by the patient's underlying medical condition, evidence of fluid overload and a relevant biomarker.

The definition and criteria for reporting to SHOT and MHRA can be found at https://www.shotuk.org/reporting/

2. How common is TACO? How many cases are reported to SHOT annually?

SHOT started collecting reports relating to TACO in 2008, and although reported numbers have steadily increased since that time, it is thought that TACO remains under-reported. The 2022 Annual SHOT Report headline numbers were: 160 cases of TACO reported, 8 deaths, and 25 cases of major morbidity.

For further information on the incidence of TACO and the data related to reporting please see https://www.shotuk.org/resources/current-resources/data-drawers/transfusion-associated-circulatory-overload-taco-data-drawer/

3. Is the increasing trend in TACO cases reflective of increased cases or better reporting?

SHOT started collecting data on TACO in 2008 and since then, deaths and serious harm related to TACO have continued to be reported, with the numbers increasing each year. The increase in the number of cases reported to SHOT could be due to several factors such as:



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- an increased awareness of the pulmonary complications of transfusion following national comparative audit and educational initiatives
- improved haemovigilance reporting
- a potential increase in the number of TACO cases as higher numbers of elderly patients with comorbidities need transfusion support

Deaths and serious harm related to TACO continue to be reported to SHOT, with the numbers increasing each year. Review of TACO reported to SHOT between 2010-2022 found a total of 1336 reports. In this 13-year period, TACO contributed to 111 deaths accounting for 39.4% (111/282) of all transfusion-related deaths reported to SHOT.

The increasing trend in patient deaths and major morbidity due to TACO including cases of inappropriate management of chronic severe anaemia prompted this safety alert ².

4. What is the pathophysiology of TACO? What are the mitigating measures available to reduce the risk of TACO?

The pathophysiology of TACO is complex and likely multifactorial, with both an inflammatory component and volume-related factors. The understanding of risk factors for TACO has evolved over the years and the development of a risk assessment tool has helped recognise vulnerable patients and take appropriate actions.

The mitigating measures available for individuals at risk of TACO include:

- Avoiding unnecessary transfusions
- Appropriate dosing of red cells for transfusion
- Use single red cell units for transfusion and assess response or use red cell dosage calculator⁸
- Weight-based dosing and prescription for paediatric patients
- Appropriate use of diuretics if clinical features of fluid overload and/or presence of risk factors as outlined
- Slower infusion rates
- Closer monitoring, correcting underlying iron/haematinic deficiency and only transfusing where symptomatic in non-bleeding patients

5. How common is TACO in children and neonates? How many paediatric TACO cases have been reported to SHOT?

The incidence of TACO in children and neonates varies across published studies due to variations in practice and recording of these events. Additionally, diagnostic difficulties exist particularly in neonates who may have several other potential causes for respiratory deterioration. There could be potential under-reporting to SHOT.

In the 10 years between 2011 and 2021 there were 33 paediatric cases reported to SHOT of which 9 were neonates, 4 of whom were preterm. This is 2.3% of overall paediatric SHOT reports. The corresponding figure for adults is 5.8%. However, when corrected for an estimate of the denominator in terms of numbers of transfusion in children, the incidence appears to be broadly similar.

6. Is TACO different in paediatrics versus adults?

Analysis of paediatric and neonatal risk factors for TACO shows that 8/33 (24.2%) cases reported to SHOT between 2011 and 2021 were due to preventable error/s in the transfusion process. For example, miscalculation of volume required or errors relating to setting infusion pumps. Thus, getting the transfusion right in terms of volume is one of the critical steps in prevention of TACO in children. In the other 25 cases the same comorbidity and transfusion risk factors that are seen in adults are also present in children and neonates.



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7. Is there a TACO risk assessment tool for children?

No separate TACO risk assessment tool exists for neonates or children. However, similar risk factors and principles apply and the qualifying statement at the bottom of the adult tool remains relevant: "Due to the differences in adult and neonatal physiology, babies may have a different risk for TACO. Calculate the dose required for weight and observe the notes above."

8. How can we evaluate compliance to the recommendations in the TACO NatPSA to help plan actions?

A gap analysis tool has been developed that teams can use to identify gaps and initiate improvement plans in policies, processes and practices. This can be accessed on the SHOT website at this link: https://www.shotuk.org/resources/current-resources/safety-notices/

9. Has there been a National Comparative Audit for TACO? Where can I find this information?

In 2017, a NCA on blood transfusion audited practices relating to TACO in older adults. A total of 2461 inpatient transfusions and 2119 outpatient transfusions were evaluated. 89.2% patients were identified as having a risk factor for TACO in addition to age. Recommendations to improve practices included a formal pre-transfusion risk assessment for TACO and appropriate patient blood management⁴. The SHOT TACO risk assessment helps identify patients at risk of developing TACO and facilitates initiation of mitigating measures including better monitoring to enhance transfusion safety.

The TACO NCA from 2017 and recommendations can be found here:

https://hospital.blood.co.uk/audits/national-comparative-audit/reports-grouped-by-year/transfusion-associatedcirculatory-overload-audit-2017/

10. How do we assess the risk of TACO pre transfusion?

The use of a formal pre-transfusion TACO risk assessment was introduced in the 2015 Annual SHOT Report⁵. A question regarding the use of the TACO risk assessment and mitigating actions were added to the SHOT questionnaire for the 2019 reporting year. Severe anaemia was added to the TACO risk assessment following a signal observed in the haemovigilance data⁶.

It is important to recognise that in the absence of any single, robust, reliable, effective TACO preventive measure, the TACO pre-transfusion risk assessment helps identify patients at risk, institute mitigating measures listed on the alert and facilitates safe transfusion decisions <u>https://www.shotuk.org/resources/current-resources/.</u>

The TACO risk assessment can also be accessed on the Blood Assist App; this is available on smartphones or as a web-based application <u>https://nhsbtdbe.blob.core.windows.net/umbraco-assets-corp/21886/2021-0497-blood-assist-app-flyer.jpg.</u>

It is important to cover risks of TACO in transfusion consent discussions with patients and carers, for both inpatient and ambulatory transfusions^{15,16}. Adequate post-transfusion advice should be given along with information about when to seek medical help and contact details.

11. How were the TACO risk factors decided?

TACO risk factors were identified by performing a thematic analysis of adult TACO cases reported to SHOT and clinical papers relating to TACO. These are detailed in the 2015 Annual SHOT Report¹¹. The analysis was used to inform the development of the TACO risk assessment. The TACO risk assessment was validated the following year which showed that around 80% of adult TACO cases reported to SHOT had at least one risk factor identified by the TACO risk assessment¹². There were insufficient data to analyse neonatal and paediatric cases.



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12. How do we incorporate the TACO risk assessment into transfusion pathways and procedures in hospitals?

The TACO pre-transfusion risk assessment tool helps identify patients at risk of developing TACO and facilitates initiation of mitigating measures including better monitoring to enhance transfusion safety⁷.

This needs to be incorporated as part of pre-transfusion safety checks for all adult patients as part of blood authorisation procedure, either manual or electronic.

Where risks are identified, appropriate actions to mitigate these must be identified, implemented and documented.

13. How can I reduce the risk of TACO in patients with severe chronic anaemia?

Severe anaemia (e.g., following haematinic deficiency) was added to the TACO risk assessment following evidence previously observed in the data. Non-bleeding adult patients with severe chronic anaemia are particularly vulnerable to TACO even in the absence of additional risk and comorbidities that are known to predispose TACO. Single unit transfusions or weight-adjusted red cell dosing as appropriate to alleviate symptoms (not to normalise haemoglobin level) in patients with severe chronic anaemia based on available national and local guidelines should be considered. Managing severe chronic anaemia in non-bleeding patients using minimal/single unit transfusion support and anaemia management with iron therapy can reduce inappropriate transfusions and risk of TACO.

Patient blood management (PBM) measures are available via the Blood Assist App; Blood components App and national guidelines such as NICE⁹ and BSH guidelines^{10,13}.

The SHOT A-E decision tree to facilitate safe decision making in transfusion can be accessed at this link: <u>https://www.shotuk.org/wp-content/uploads/myimages/A-E-Decision-Tree-to-facilitate-decision-making-in-transfusion.pdf</u>

14. What tools are available to support weight-adjusted red cell dosing?

Weight-adjusted red cell dosing should be applied to non-bleeding patients who are not on a regular transfusion programme who are being transfused to meet a target Hb level (per NICE⁹, BSH guidelines^{10,13}).

A 'single unit and review' policy should be applied to all non-bleeding patients, even if the calculated dose is more than a single unit before transfusing further units. Patients with severe chronic anaemia (including iron deficiency) are a special case due to the increased risk of TACO and should receive minimal transfusion (often a single unit) to relieve any severe symptoms of anaemia as opposed to achieving a specific target Hb level. The paediatric transfusion formula remains the best way to calculate the volume of red cells for transfusing a child¹³.

A dose of 4mL/kg of donor red cells raises Hb concentration by approximately 10g/L¹⁷. Weight-adjusted red cell dosing is particularly important for patients with low body weight. Manual calculations are vulnerable to human error. There is a multi-platform browser-based application designed for weight-adjusted red cell dosing also alert to unnecessary transfusion please see <u>https://www.rcdcalculator.co.uk/.</u> It is important to note that it is validated for adult patients only and programmed with adult Hb triggers. The first page of the application explicitly advises against use in paediatric/neonatal patients, patients on regular transfusion programmes or those with active bleeding.

This ensures compliance with NICE NG 24, SHOT, NCA TACO recommendations, facilitating a personalised approach to 'right first time' patient blood management.

15. What are the NBTC indication codes and where can I find them?

The NBTC Indication codes⁸ should be used in conjunction with national guidelines ^{9, 10,11} and the transfusion decisions for each patient must be individualised considering risks and benefits to the patient.

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For further information please see: https://nationalbloodtransfusion.co.uk/recommendations

These can also be accessed via https://www.bloodcomponents.org.uk/

The NBTC Blood Components App can be accessed by searching 'Blood Components' in <u>Apple</u> or <u>Play</u> stores.

16. How should I investigate TACO cases and decide preventive actions?

The <u>TACO Incident Investigation Guidance Tool</u> was first launched in the 2020 Annual SHOT Report and its use continues to be a recommendation this year. Using the tool ensures a structured and comprehensive review of cases to support effective preventive actions. It is critically important that every case of TACO is used as an opportunity to improve practice and reduce risks for other patients. Structured investigation of these cases allows implementation of effective preventive actions and improved transfusion safety for future patients. The tool has been updated in March 2024.

For further information regarding TACO data and resources please access <u>https://www.shotuk.org/resources/current-resources/data-drawers/transfusion-associated-circulatory-overload-taco-data-drawer/</u>

17. How can I audit the use of the TACO risk assessment in my hospital?

Regular audits must be undertaken against standards in BSH, NICE and SHOT guidelines and recommendations.

Key themes to audit can include the following:

- Assessing indications and thresholds for transfusion
- Trending the number of TACO cases reported, identifying common themes and areas for improvement focusing on appropriateness of volume of transfusion, the effective use of the TACO risk assessment, use of patient blood management measures
- Evaluate management of chronic, severe anaemia (non-bleeding patients) in your organisation
- Check compliance with consent and the availability of patient information including the effectiveness of discharge communication

18. How and where can I access further TACO-related information & patient safety incident data?

Further information and related resources from SHOT relating to TACO can be accessed here: <u>https://www.shotuk.org/resources/current-resources/data-drawers/transfusion-associated-circulatory-overload-taco-data-drawer/</u>

19. How can we manage and achieve compliance with the TACO alert actions given the current workload/resources constraints?

It is within the remit of your organisations Risk and Quality Committees and the Hospital Transfusion Committee to support your efforts in ensuring that compliance for the national patient safety alert recommendations is achieved and sustained.

The following aspects should be considered as part of your action plan:

- Undertake the Gap Analysis/Action Plan (GAP), SHOT Safety Alert: Reducing risks for transfusionassociated circulatory overload and improving patient safety which will provide you with an overview of which actions required implementation and an opportunity to evaluate and review your current compliance <u>https://www.shotuk.org/resources/current-resources/data-drawers/transfusion-associatedcirculatory-overload-taco-data-drawer/</u>
- Incorporate any TACO-related audit questions into existing audit data sets e.g., transfusion audits, and ensure that these are monitored through audit governance processes



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- Escalate any resource/workload concerns to your Risk and Quality Committees and Hospital Transfusion Committees who are accountable for monitoring compliance with the recommendations in the safety alert and associated risk of non-implementation
- Consider placing identified risks arising from non-compliance gaps on your organisations risk register
- 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, midwifery, scientific and allied health professionals
- If relevant and in place, please refer to your local National Safety Alert Management Policy

20. Does the TACO risk assessment apply to patients with major haemorrhage?

SHOT data show that TACO is reported in patients with major haemorrhage. The TACO risk assessment acknowledges that the risk of delay or deferring transfusion may be greater than the risk of TACO in some situations, and this would include major haemorrhage. The operationalisation of the TACO risk assessment for specific patient groups or clinical presentations should be locally determined. A UK wide <u>CAS alert was issued in</u> <u>January 2022</u> to address preventable transfusion delays in bleeding and critically anaemic patients and patients should not die or suffer harm from avoidable delays in transfusion.

21. How does the alert affect patients on regular transfusion programmes?

SHOT data show that TACO is reported in this patient group. A TACO risk assessment should be performed before transfusion to identify ways to mitigate the risk. Single unit transfusion and use of conventional Hb targets in weight-adjusted red cell dosing may not be suitable for this patient cohort. Action 1b of the alert requires organisations to ensure their transfusion practices are compliant with national guidelines. These cover this patient group. Local transfusion policies and procedures should be in place to ensure appropriate transfusion management in this patient group.

It is important to note that the red cell dosage calculator that is currently available (<u>www.rcdcalculator.co.uk</u>) is not modifiable for individual Hb targets or alternative multiplication factors and therefore it is not suitable for patients on long-term transfusion management regimes, or for children. The red cell transfusion volumes for these patients should be calculated manually to suit specific individual needs.

It should be recognised that the alert is not an educational resource intended to be used by junior staff. It provides a framework for organisation to review local policies and procedures to reduce the risk of TACO in all patient populations they serve.

Please note that the questions 20 and 21 have been added to this FAQ document after the alert was released following feedback.





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- 7. TACO pre-transfusion risk assessment: <u>https://www.shotuk.org/wp-content/uploads/myimages/TACO-Checklist.jpg</u>
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- 13. BSH New HV, Berryman J, Bolton-Maggs PHB, et al. Guidelines on transfusion for fetuses, neonates and older children. Br J Haematol. 2016;175(5):784-828.
- 14. Guidelines from the advisory committee on the Safety of Blood, Tissues and Organs (SaBTO) on patient consent for blood transfusion accessed using this link: <u>https://www.gov.uk/government/publications/blood-transfusion-patient-consent</u>
- 15. Transfusion consent resources developed by the UK and Ireland Blood Transfusion Network can be accessed at this link: Consent for Blood Transfusion (transfusionguidelines.org)
- 16. Safe transfusion- right blood, right patient, right time and right place from the JPAC Transfusion Handbook can be accessed using this link: <u>https://www.transfusionguidelines.org/transfusion-handbook/4-safe-transfusion-right-blood-right-patient-right-time-and-right-place.pdf</u>



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Contact details:

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