Serious Hazards of Transfusion (SHOT)

Non-medical authorisation course





Learning objectives:

By the end of this session with the additional of the E learning delegates will be able to:

- Describe the role of SHOT in the UK haemovigilance system, including its function in collecting, analysing, and disseminating transfusion-related incident data.
- Understand the role of Non-Medical Authorisation (NMA) practitioners in haemovigilance, including their contribution to transfusion safety, clinical decision-making
- Apply SHOT data to clinical practice by analysing case studies that illustrate key transfusion risks such as TACO, Delays and IBCT, and identifying lessons learned to improve patient safety.



Join the Vevox session

Go to vevox.app

Enter the session ID: 144-502-585

Or scan the QR code



What was the total number of reports submitted to SHOT in 2024?

4,250	
	0%
4,972	
	0%
5,033	
	0%
5,500	
	0%



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4,250

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5,033

0%

5,500

RESULTS SLIDE SETION SE

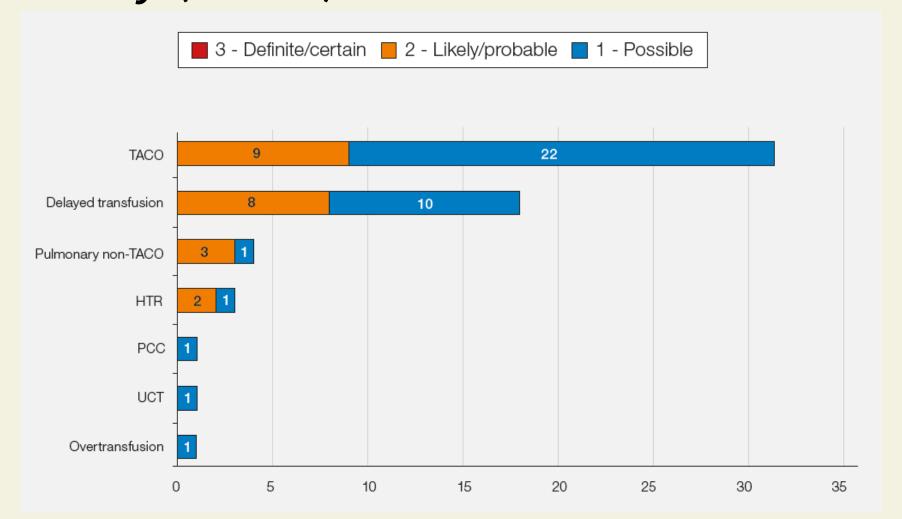
Beyond Incidents: ACE Reports

- SHOT also captures Acknowledging Continuing Excellence (ACE) reports
- Highlights good practice and promotes a Safety-II approach
- Resources and learning tools available via the SHOT website





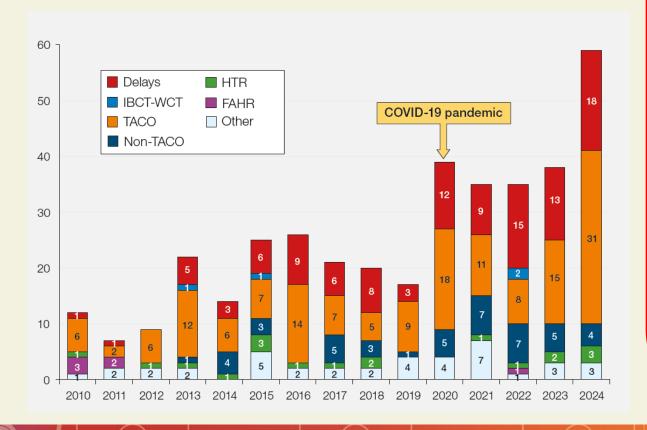
Transfusion related deaths in 2024 with imputability (n= 59)





Deaths related to transfusion 2010-2024 (n=379)

by SHOT category



Important to note:

TACO and delays are the most common causes of transfusion-related deaths in the UK year on year

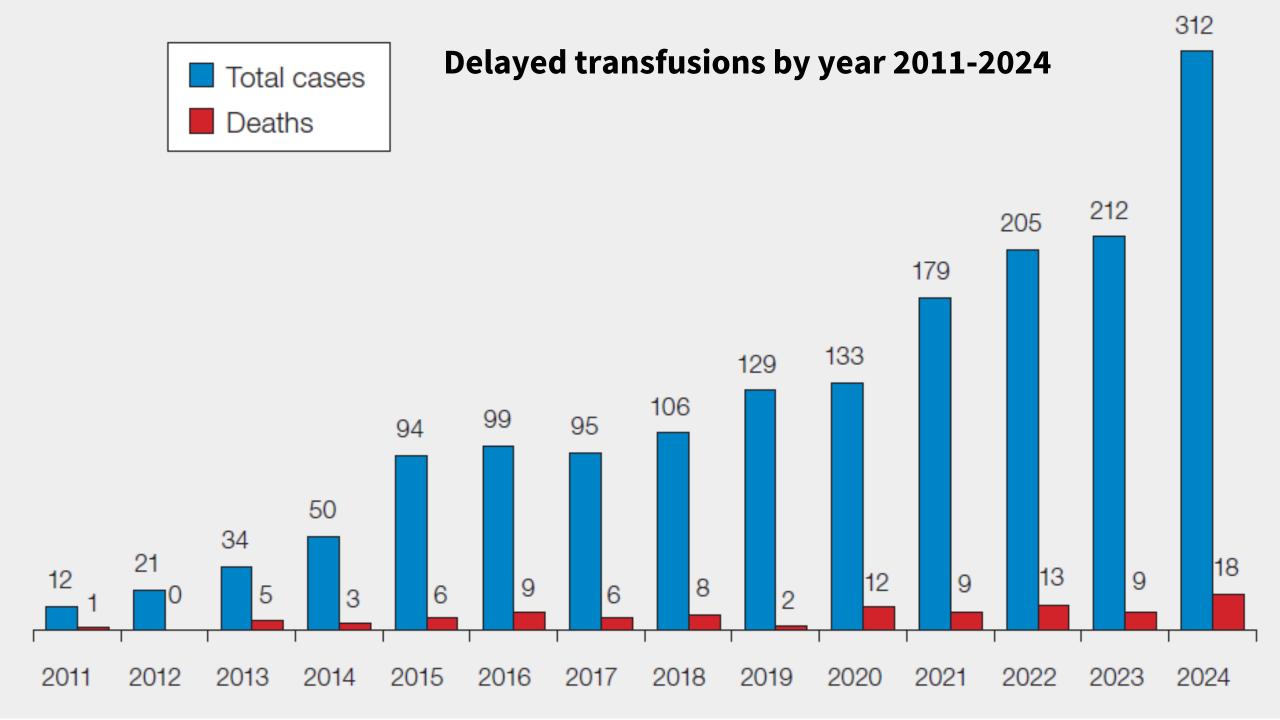
Absolute number of deaths reported have increased post COVID with a further steep increase in 2024 - this could be due to multiple factors

Deaths reported



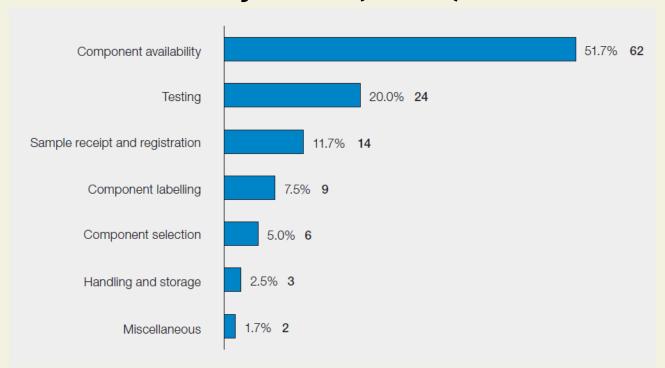
2013 = 0.80 per 100,000 components issued 2024 = 2.68 per 100,000 components issued





Laboratory errors resulting in transfusion delays n=120 (was 56 in 2023)

Laboratory errors (n=120)



Key themes:

- Communication issues
- Problems with handover
- Availability of blood components

Transfusion: A Life-Saving Therapy — But Not Without Risk

Key Considerations

- •Transfusion is not risk-free even in well-functioning systems.
- •The safest transfusion is the one not given but only if the patient can safely go without it.
- •Clinical judgement is vital: withholding transfusion must never result in preventable harm or death.

Vulnerable Groups

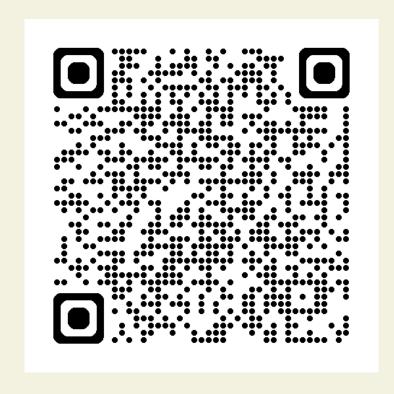
- •Adults: Especially those with comorbidities or undergoing complex procedures.
- •Paediatrics: Smaller blood volumes increase sensitivity to errors and reactions.
- Sickle Cell Patients:
 - Higher transfusion exposure.
 - Increased risk of alloimmunisation, delayed haemolytic reactions, and hyperhaemolysis.
 - Require tailored transfusion strategies and vigilant monitoring.

Safe Practice Principles

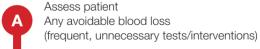
- Balance benefit vs risk for every transfusion decision.
- Use alternatives where appropriate (e.g. iron therapy, cell salvage).
- Ensure informed consent includes discussion of risks.
- Prioritise haemovigilance and continuous improvement.



The A-E Decision Tree to facilitate decision making in transfusion

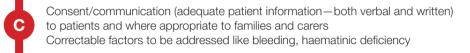


The A-E Decision Tree to facilitate decision making in transfusion Assess patient



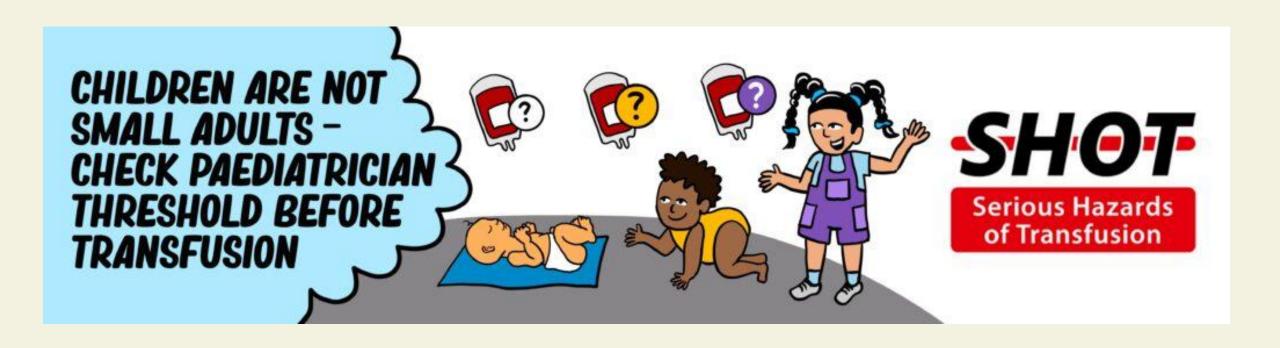
Blood results (all) reviewed including trends – valid and reliable?

Best treatment option—is transfusion the best treatment option? If yes, what components needed, how many, what order and any specific requirements needed?

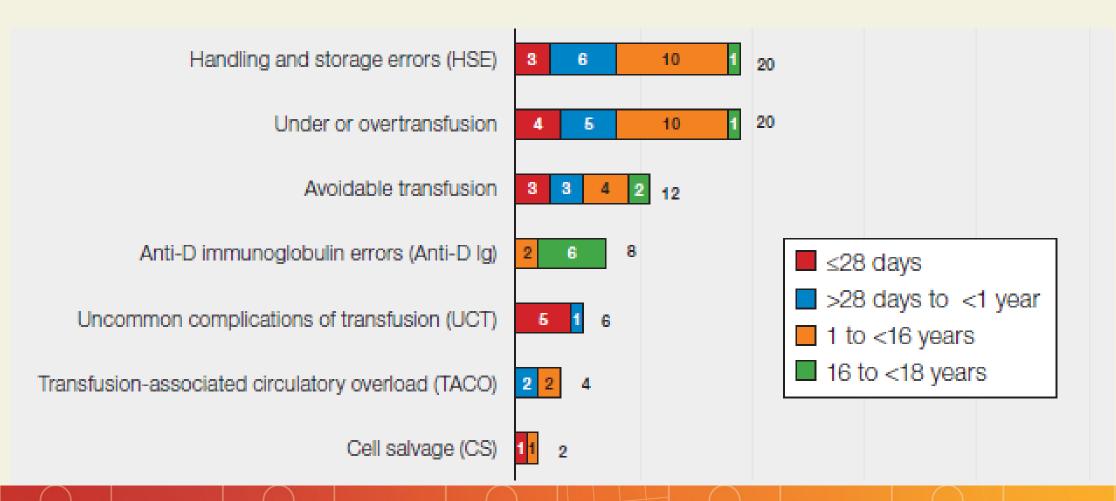


Do not forget other measures (vitamin K, tranexamic acid, cell salvage, etc)
Do not hesitate to question colleagues regarding decisions made and ask for rationale
Do not forget to document in patient's notes and in discharge summaries

Ensure timely communications to laboratory- need to be clear, concise and accurate Ensure all relevant transfusion checklists including TACO risk assessment and actions arising thereafter have been completed Evidence based decisions made weighing risks, benefits and options available Ensure patient receives adequate post-transfusion information if transfusion given as a day case



SHOT paediatric summary data 2024; n=202





Paediatric major morbidity by SHOT reporting category 2011-2024





SHOT reports: Error common themes

Patient identification



Over (or under transfusion): Prescribing and administration errors





Neonatal use of Adult O D Negative units



Laboratory errors; Neonatal compatibility and







Communication errors



Failure to meet special requirements



Acting on erroneous results



Delays in transfusion: Massive haemorrhage





Case Study





Patient Profile: Mrs. A, 37 years old, at 30 weeks gestation, presenting with shortness of breath, fatigue, and palpitations.



Medical History: Known coronary heart disease with previous stent placement; currently on low-dose aspirin.



Pre-transfusion Findings: Haemoglobin critically low at 55 g/L.



Vital Signs: Tachycardia (HR 115 bpm), hypotension (BP 95/60 mmHg), increased respiratory rate (RR 24), and SpO₂ 95% on room air.



What are your key considerations?

Has informed consent been obtained and documented?	
	0%
Has the risk of Transfusion-Associated Circulatory Overload (TACO)	
	0%
What is the transfusion strategy and any mitigations?	
	0%
All the above	
	0%



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RESULTS SLIDE Serious Hazards of Transfusion



which of the following is essential when obtaining informed consent for transfusion in a pregnant patient with CHD?

Only verbal consent is required

	0%
Risks, benefits must be explained, tailored to her condition and alternatives if appropriate	
	0%
Consent is not needed if MDT has agreed	
	0%
Written consent is mandatory in all case	
	0%





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RESULTS SLIDE SETION SE

What does the SHOT TACO Risk Assessment Tool help clinicians evaluate?

Blood group compatibility	
	0%
Risk of haemolytic transfusion reactions	
	0%
Risk of transfusion circulatory overload and mitigation strategies	
	0%
Need for platelet transfusion	
	0%



Join at: **vevox.app** ID: **144-502-585**

What does the SHOT TACO Risk Assessment Tool help clinicians evaluate?

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Risk of haemolytic transfusion reactions	
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Risk of transfusion circulatory overload and mitigation strategies	
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RESULTS SLIDE SETIONS HAZARDS OF TRANSFUSION

What is one recommended mitigation strategy for a patient identified as high risk for TACO?

Transfuse both units rapidly	
	0%
Use whole blood instead of red cells	
	0%
Transfuse one unit at a time with reassessment	
	0%
Avoid monitoring during transfusion	
	0%



What is one recommended mitigation strategy for a patient identified as high risk for TACO?

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RESULTSSLIDE

ID: 144-502-585



vyrrat other consideration should be made writer selecting blood components for a pregnant patient?

Use of irradiated blood

	0%
CMV-negative status is preferred to reduce foetal infection risk	
	0%
Whole blood is preferred for volume replacement	
	0%
Platelets should be given routinely in anaemia	
	0%





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RESULTS SLIDE Serious Hazards of Transfusion

Patient review:



6 hours later you come back to review the patient



The patient has not started to received any of the red blood cell.



There was a misunderstanding regarding who should request the red cell units from the transfusion laboratory. You assumed the nurses would request the blood as this was routine practice in the clinical area where you have previously worked.



Conversely, the nurses assumed the authoriser would be requesting the blood as this was routine practice on the current ward.



with of the following actions would best support role clarity and prevent delays in transfusion? (tick all that apply)

Assume the same transfusion workflow applies across all wards

	0%
Clarify local transfusion responsibilities during team handover	
	0%
Use a standardised transfusion checklist or protocol	
	0%
Wait until the patient asks about the delay	
	0%
Clearly document who is responsible for requesting blood component	
	0%



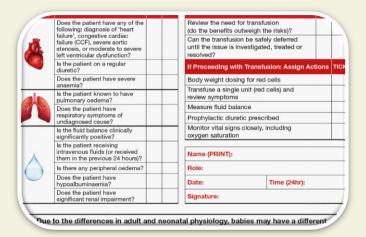
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RESULTS SLIDE Serious Hazards of Transfusion

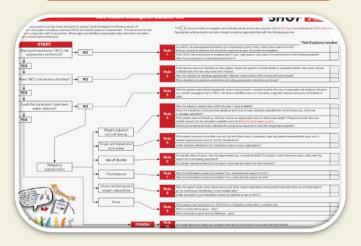
TACO pre-transfusion risk assessment



The 2024 reporting year recorded **188** TACO cases which is the highest ever reported to SHOT.

A TACO pre-transfusion risk assessment should be utilised whenever possible prior to every transfusion, especially in vulnerable patients.

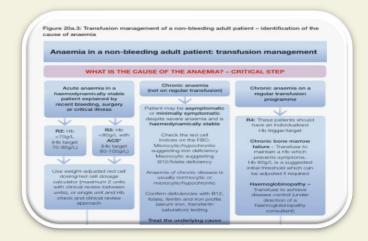
TACO investigation guidance tool



It is important that all TACO cases are used as a learning opportunity to prevent or mitigate TACO in other patients.

A TACO investigation guidance tool available from 'Current resources' on the SHOT website helps optimise learning from these events

Anaemia in a non-bleeding adult patient



Patients with severe chronic anaemia should receive only minimal red cell transfusion with the aim of alleviating symptoms as opposed to aiming for a Hb correcting to meet a target Hb level





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

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%23. 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 in 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.

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

For any enquiries about this alert contact: SHOT@nhsbt.nhs.uk

Actions required

Local organisations must have: Actions to be completed as soon as possible and no ater than 15 July 2022

- Reviewed and updated policies and procedures to
 - a. Rapid release of blood components and products for major haemorrhage, AIHA and reversal of anticoagulants.
 - b. Compliance with SHOT¹, NICE⁴ and BSH⁷ recommendations.
 - c. Agreed criteria where rapid release of PCC is acceptable without the initial approval of a
 - 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
 - Treatment of patients who refuse transfusion of blood components and/or products.
- 2. Reviewed, updated, and implemented training programmes to include:
 - a. 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.

1/2

tools to identify system factors for improvement.

Implemented processes to audit and investigate all transfusion delays, using appropriate investigation







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 f fluid overload and a relevant biomarker. TACO is one of the most common causes of transfusionrelated 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.23

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 calculator4) and assessing
- consideration of weight-adjusted red cell dosing for patients of low body weight (including
- avoiding transfusions in excess of recommended infusion rates
- administering a diuretic when appropriate
- monitor vital signs closely, including oxygen

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:

- Review and update policies, procedures and processes to
- a. All transfusions are compliant with recommendations from British Society for Haematology (BSH), 6,7 SHOT,8 and
- b. A TACO risk assessment is undertaken utilising the SHOT risk assessment tool1 prior to transfusions1
- c. Appropriate mitigation measures are initiated for individuals at risk - see FAQ document5
- 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 guidance¹⁰
- e. Inclusion of guidance on timely management of TACO, including the use of diuretics, oxygen, and other supportive
- 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
- Review, update, and implement training programmes to
- a. Use of TACO pre-transfusion risk assessment tool*
- b. Appropriate use of mitigation measures FAQ document⁵ 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
- 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
- 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





Paediatric TACO 2024





4 cases



~2% of TACO cases



1 resulted in mortality



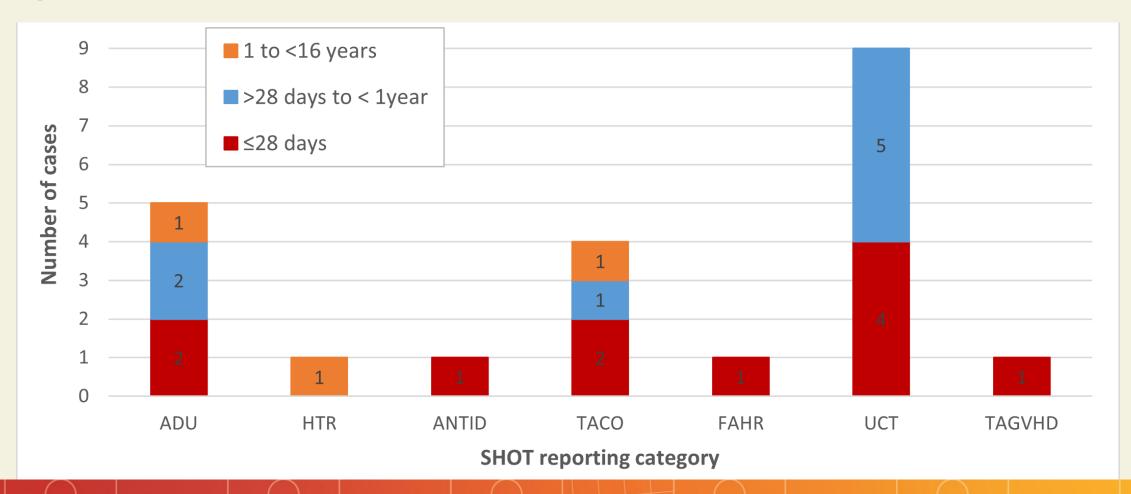
1resulted in major morbidity

Learning points

- TACO is likely under recognised in children.
 Although a formal TACO pre-transfusion risk
 assessment for children does not exist it is
 known from previous SHOT data that many of
 the same adult risk factors apply
- TACO can occur with small or appropriate volumes of component

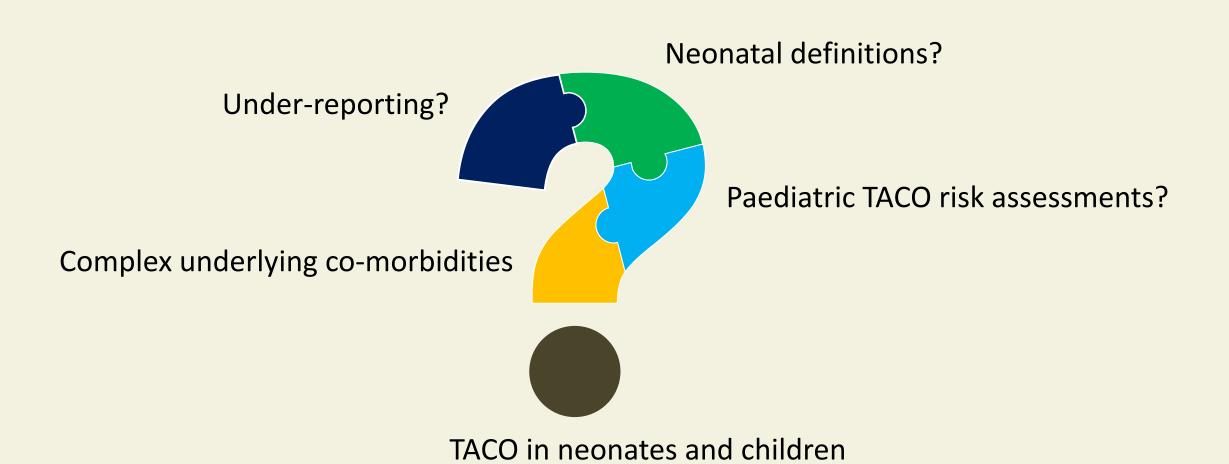


Paediatric deaths by category and age group: 2010-2024





Paediatric challenges and unanswered questions









1. Transfusion safety



2. Transfusion information technology and equipment



3. Supporting staff to work safely



4. Staff education and training



5. Safety culture



6. Patients as safety partners



7. Haemovigilance and risk management



8. Governance



1. Transfusion safety



Anaemia management



Performing TACO pre-administration assessment



Management of reactions



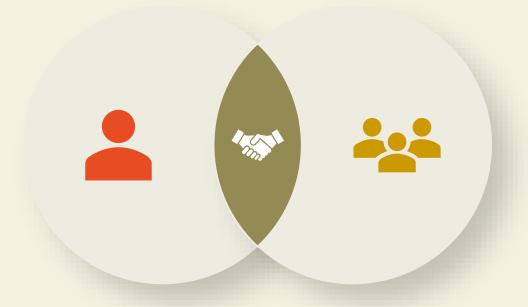
Monitoring outcomes



Patient awareness upon discharge

Patient background and event

Haematology/oncology patient with a complex transfusion history.

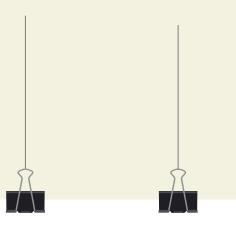


Presence of multiple clinically significant red cell antibodies

Patient received 3 units of red cells that did not meet her documented specific requirements



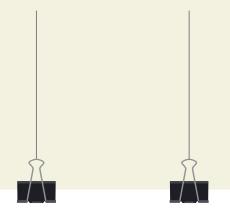
Reasons attributed to this incident are:





Documentation

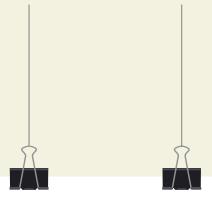
Requesting clinician failed to complete specific requirement of the request form.





Integration

Patient's historical record not showing on new upgraded LIM system



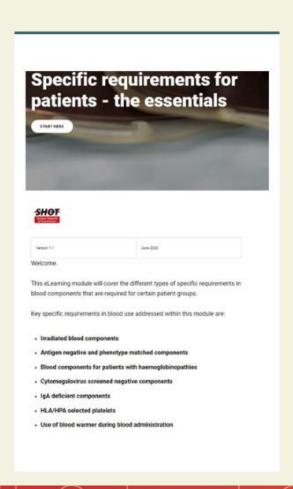


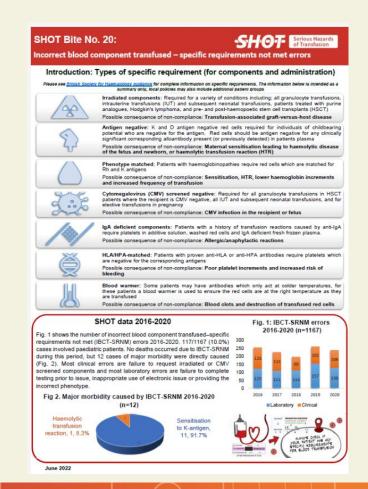
Oversight

Laboratory staff
failed to check
historical
specific requirement
flag from legacy LIM
data



Incorrect Blood Component Transfused (IBCT) resources from SHOT



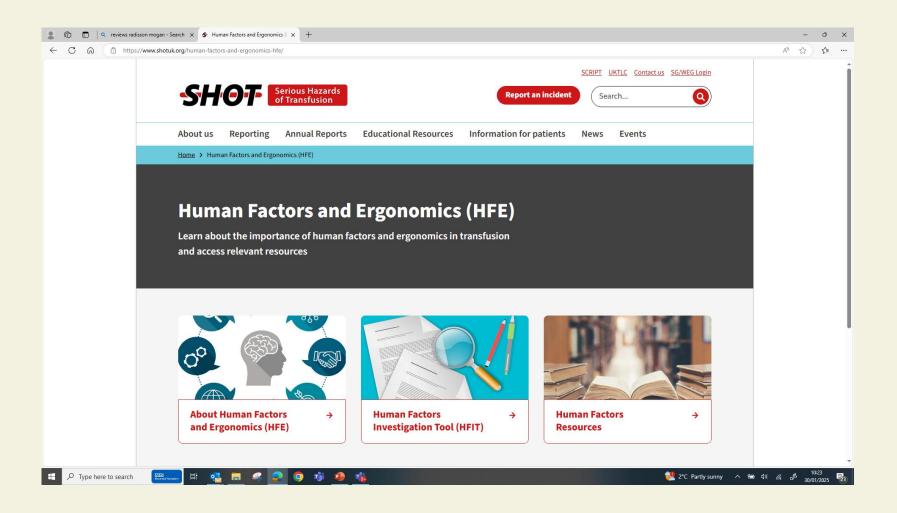


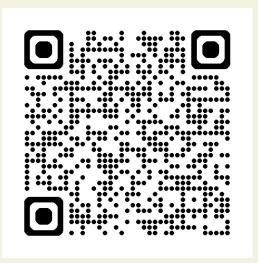


Remember Positive Patient Identification is essential



Human Factors resources developed by SHOT





'My Transfusion' patient app

- For adult patients receiving transfusion and their carers/relatives
- Covers the transfusion
 journey, transfusion risks,
 benefits and alternatives for
 patients
- Based on current national guidelines
- Created with insights from patients and healthcare professionals



What can you do?

Report any errors or concerns to Transfusion Practitioner

Ensure a safe environment for transfusions

Be a champion for transfusion safety



Suggested activities



Spend some time with a haemovigilance reporter when they are completing a SHOT report



Attend a hospital transfusion committee meeting



Attend an investigation meeting



Review your hospital transfusion policies



Carry out a consent review and the use of pre-transfusion checklist / SRNM

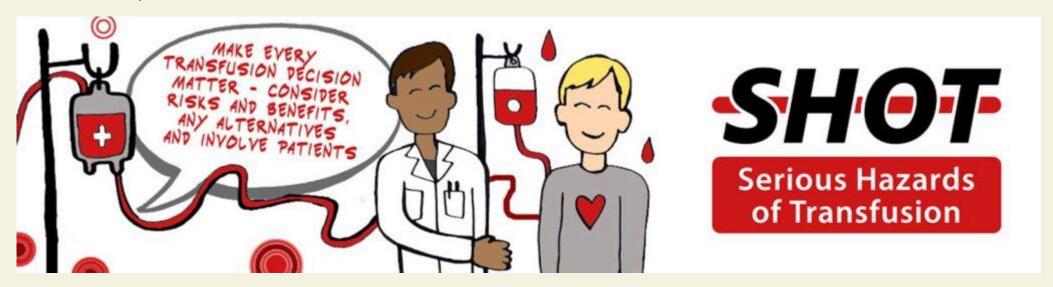


Carry out a review of your Trust's SHOT reports

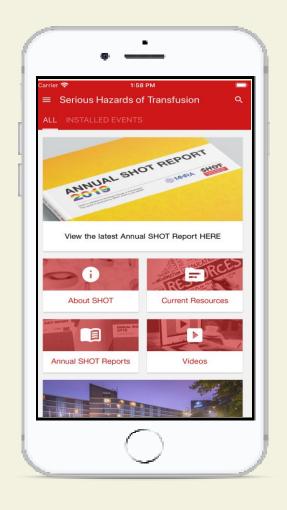


Take away messages

- Take some time to read the SHOT data
- Remember TACO pre-transfusion risk assessment, especially on our high-risk vulnerable patients
- Correct prescribing of blood components for infants and children is vital
- Make every transfusion count



SHOT App







Acknowledgements

- The reporters and hospital staff who share their incidents
- The SHOT Steering Group and Working Expert Group members
- MHRA haemovigilance team
- The UK Forum for funding

For further information visit: www.shotuk.org



