

# NMA course

**The SHOT Team**

## Haemovigilance



# Objectives



- ✓ Discuss the role of SHOT and the haemovigilance process in UK
- ✓ Understand the role of haemovigilance in improving transfusion safety and the role of the NMA within this process
- ✓ Apply knowledge to a SHOT reported incident

# Haemovigilance



A set of surveillance procedures from the collection of blood and its components to the follow up of the recipients

To collect and assess information on unexpected and undesirable effects resulting from the therapeutic use of labile blood components

To prevent their occurrence or recurrence

# Role of SHOT

Transfusion pathway is complex, involving a wide variety of teams both clinical and laboratory





## Analysis

SHOT collects and analyses information on transfusion reactions and adverse events from all healthcare organisations in the UK



## Experts

Input from working experts and steering group members



## Components

Red cells, plasma, cryoprecipitate, platelets, anti-D Ig administration, immune anti-D cases and prothrombin complex concentrates



## Aims

Where risks and problems are identified, SHOT produces recommendations to improve patient safety

**Identify transfusion recipients where extra care is needed**

Transfusions as day cases, vulnerable patients: Age groups, sickle/thalassemia, transplant/shared care

**Recognise improper practices**

Avoidable, delayed, over-transfusions, wastage

**Identify areas for improvement**

Safety critical steps, NM  
Investigating incidents  
Highlighting gaps in transfusion training and education



**Improving transfusion safety**

**Better transfusion decisions**

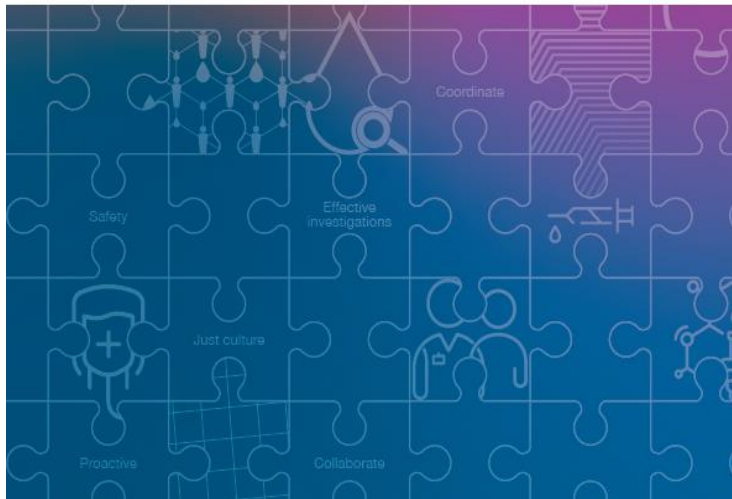
SHOT data and recommendations

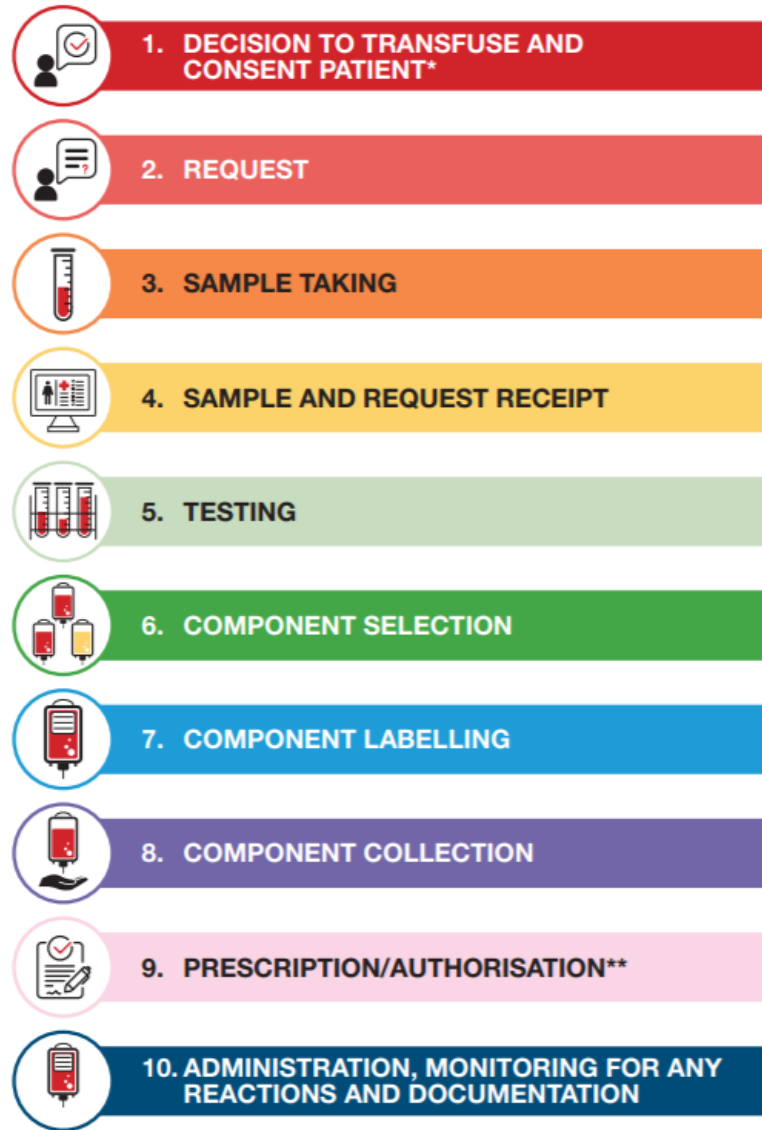




# ANNUAL SHOT REPORT 2023

SHOT is affiliated to the Royal College of Pathologists  
This report is produced by SHOT working with MHRA





*\*Note that the pre-transfusion sample may have been taken in advance (for e.g. pre-op) while the decision to transfuse is made at a later date.*

*\*\*Once the decision to transfuse has been made, the prescription/authorisation may be written at variable times during the sequence but must be checked at the final stage.*

*Staff are encouraged to use the SHOT Safe Transfusion Checklist with every transfusion episode.*

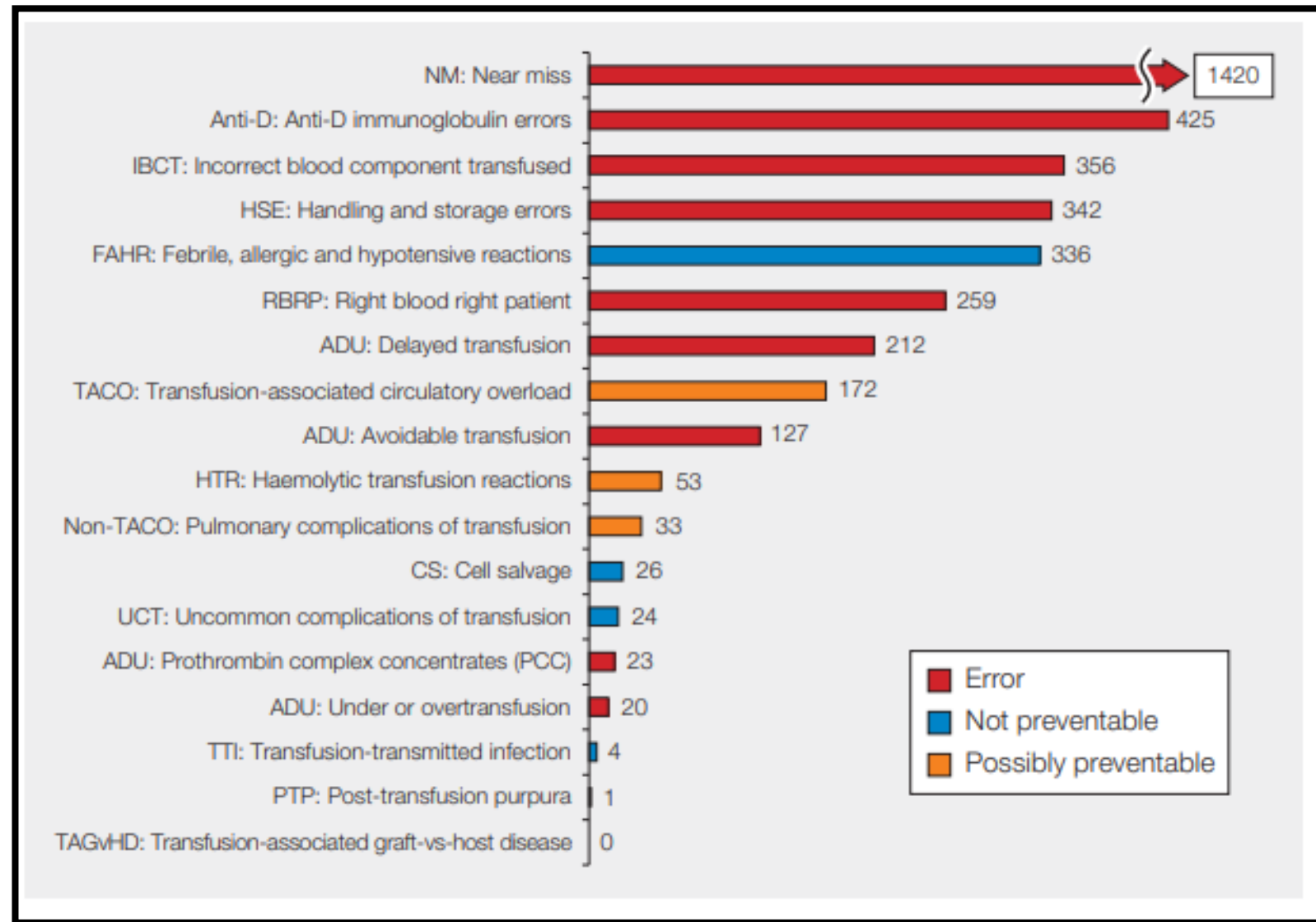
**Critical points in the laboratory**

*Misidentification of patients is a significant cause of avoidable harm. Patient identity must be verified effectively and accurately at every step in the transfusion pathway. All staff must be aware of the importance of correct patient identification and this must be confirmed in accordance with local policies.*

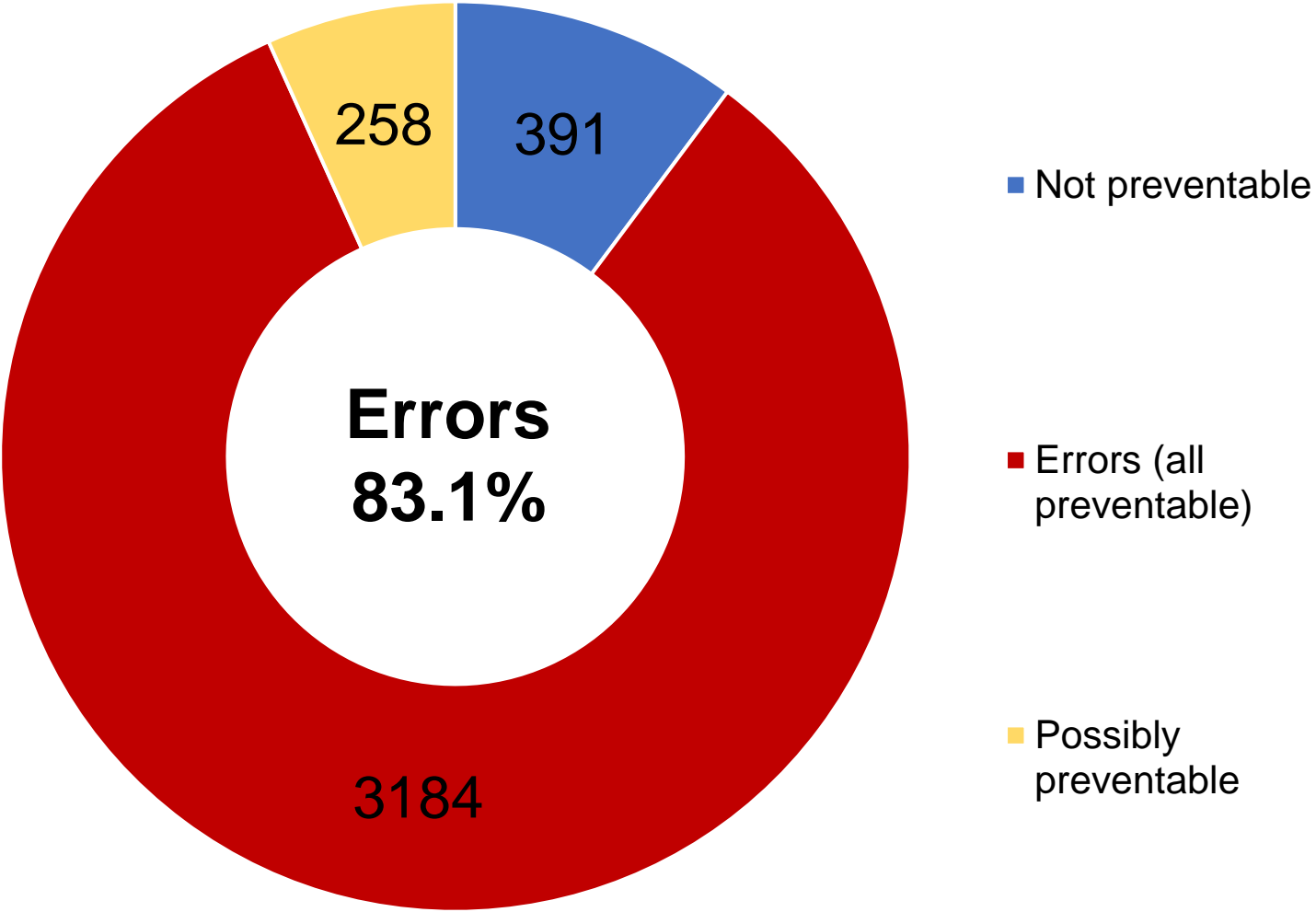
**Critical points where positive patient identification is essential**



# Summary data for 2023



Errors account  
for most  
reports in  
2023  
(n=3184/3833)



**Staffing issues, mismatch with workload, skill mix**

**Staff knowledge, training issues; HFE awareness and application**

**Complicated/complex processes resulting in workarounds; pandemic spillover of practices**

**Challenges with resources: IT, equipment**



**Recurrent themes in analysed incidents**

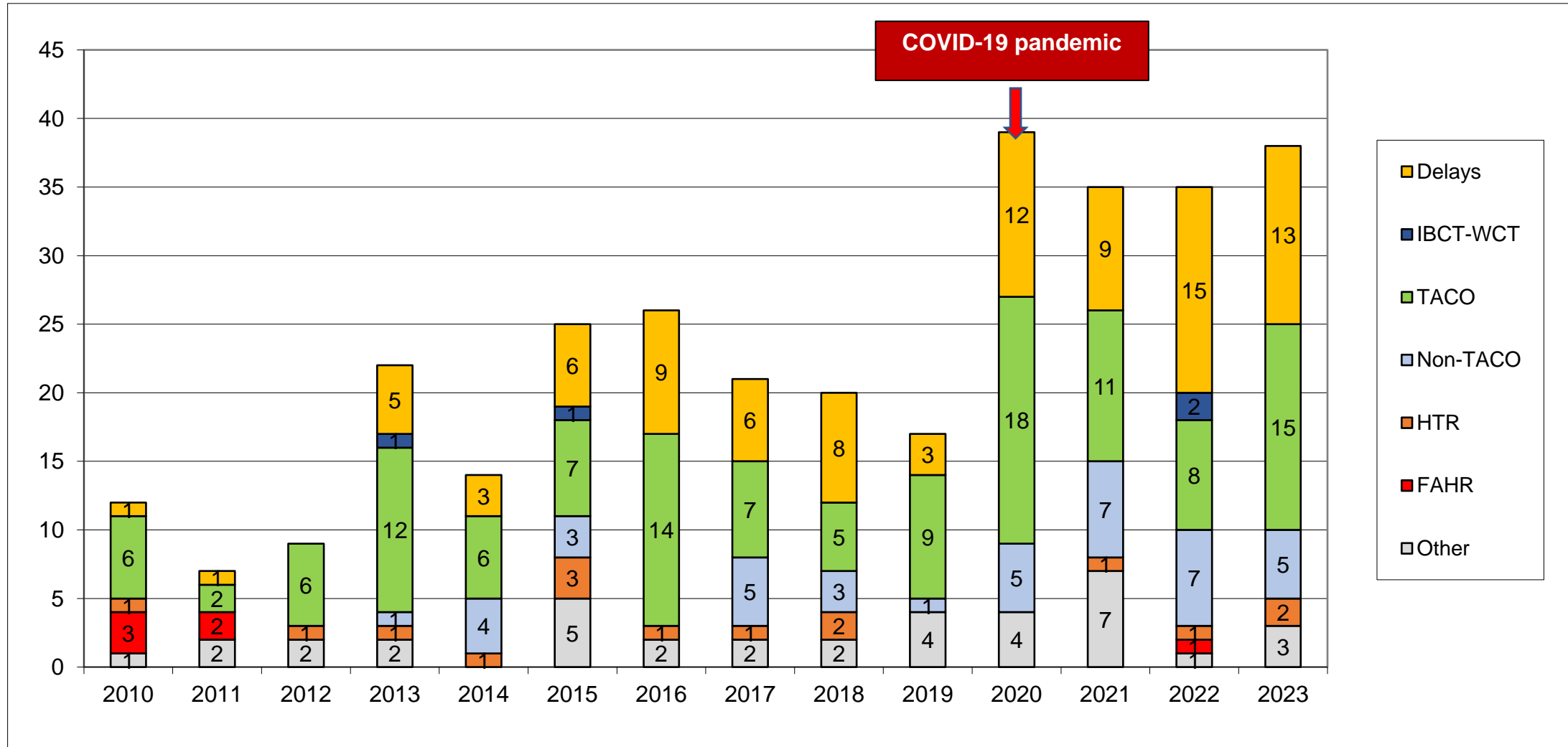
**IT issues: suboptimal implementation, poor training of staff**

**Overreliance on IT  
Complacency, alert fatigue,  
warning flags not heeded**

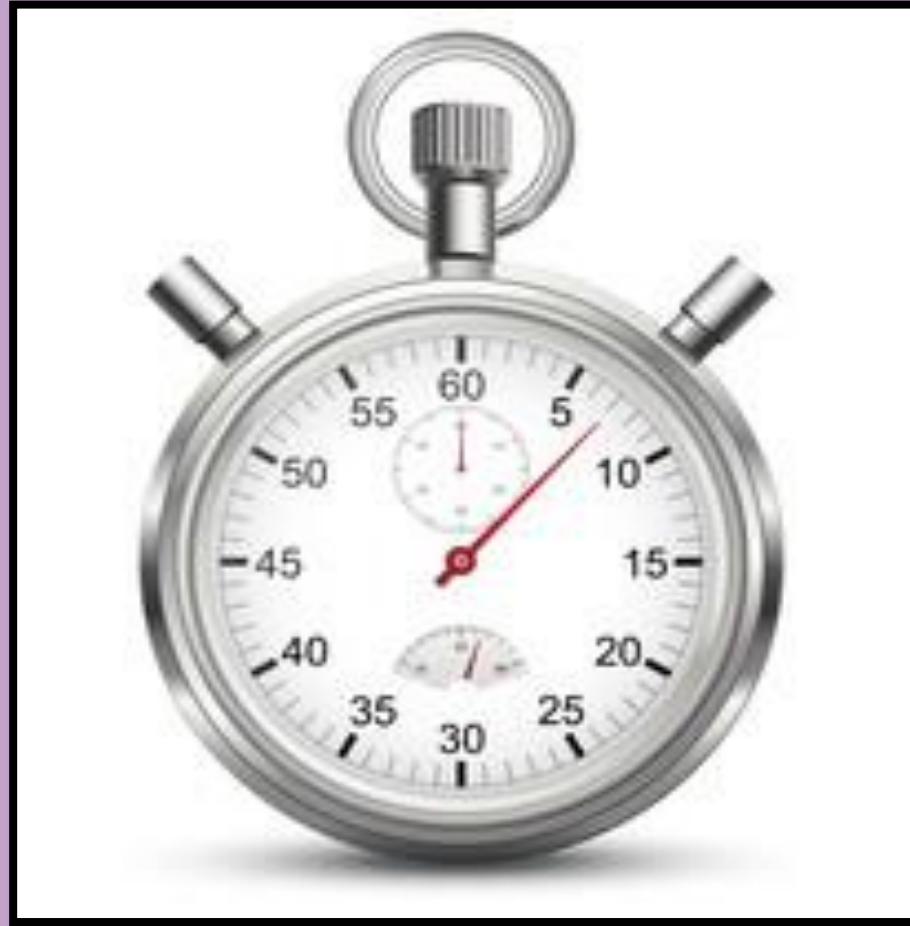
**Communication issues including suboptimal handover**

**Safety culture, leadership**

# Transfusion-related deaths 2010 to 2023 (n=320)

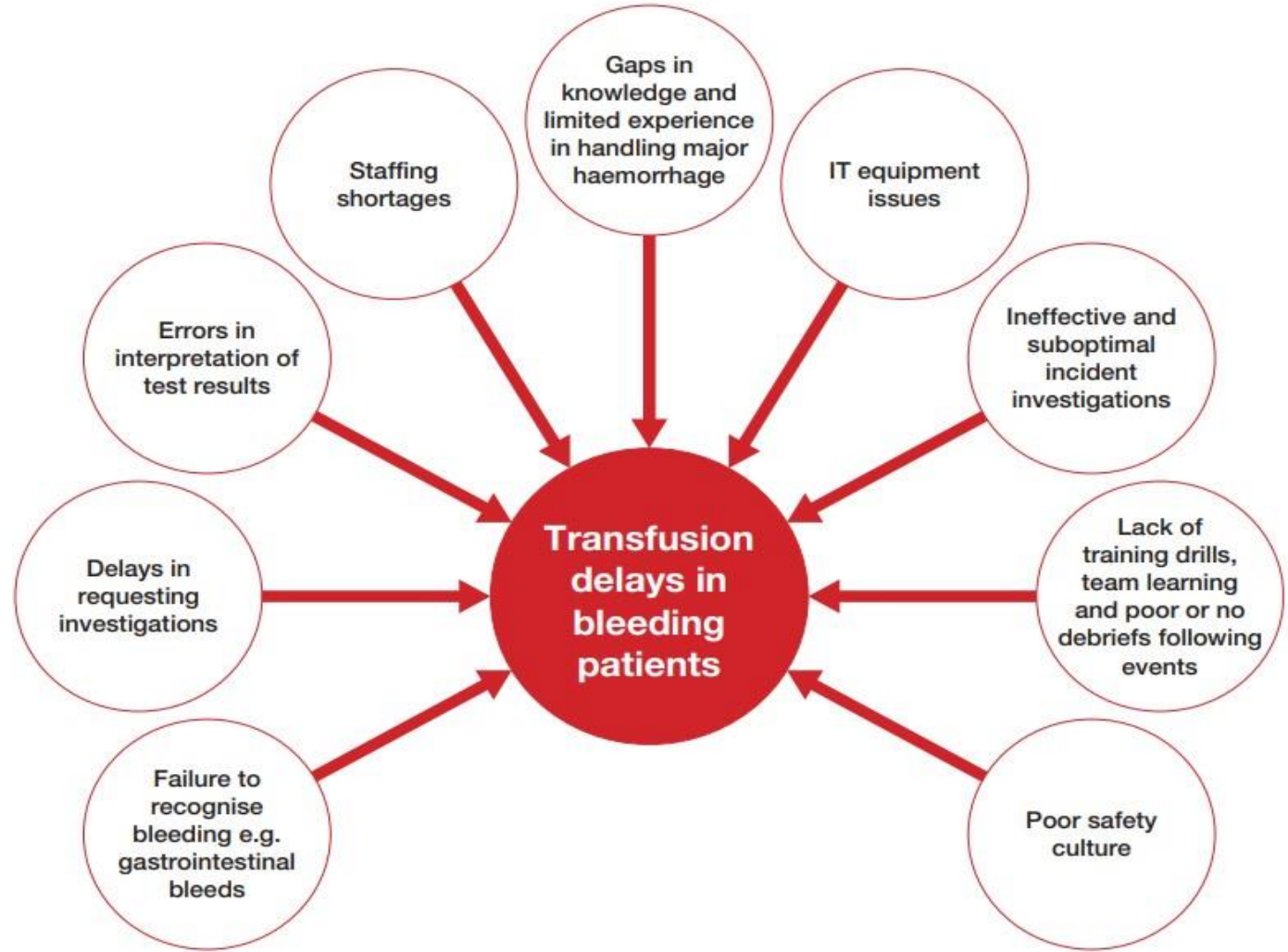
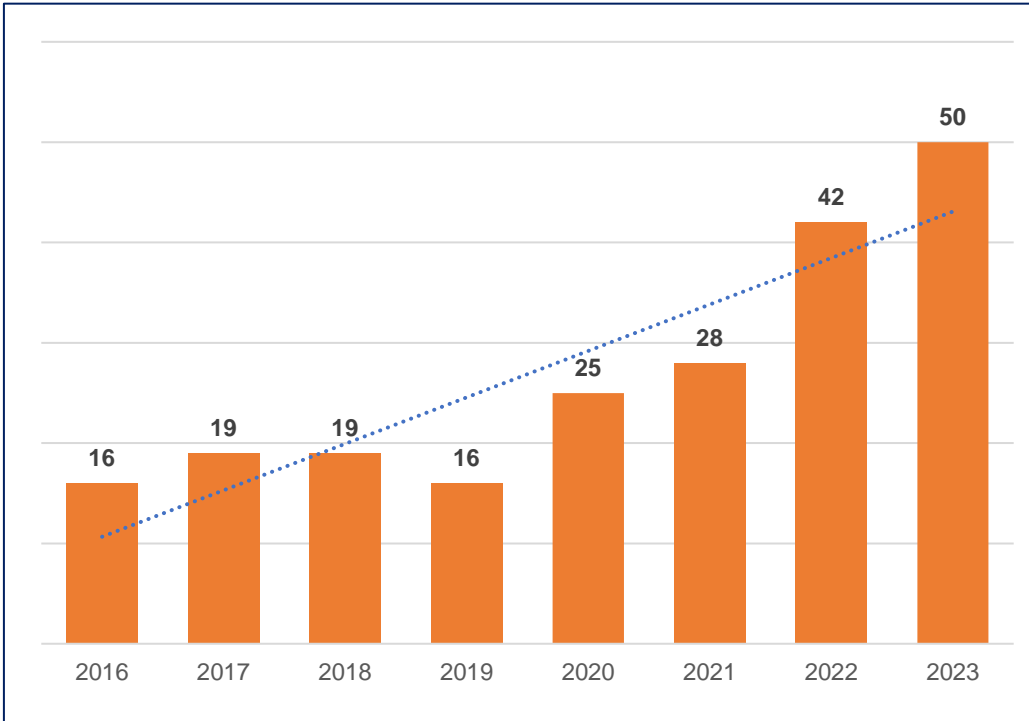


# Delayed transfusions

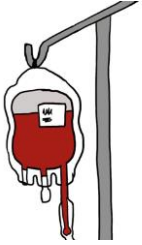




# Major Haemorrhage delays



# Urgent need for blood during surgery - pager failure



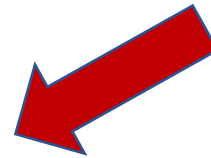
*Theatre staff needed blood during repair of an AAA for a man in his 80s but could not contact the BMS due to pager failure*



*The delay was 30 minutes and was thought to have contributed to the patient's death*



*Major haemorrhage drills should include testing of communication channels and equipment*



*Clinical staff must be able to reach transfusion laboratory staff in case of emergencies*

## 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.**



# Incorrect Blood Component Transfused



### Key points to note:

- 7 ABOi red cell transfusions and 3 ABOi plasma transfusions reported in 2023 (one of which was in a neonate)
- No deaths reported directly related to ABOi
- Two cases of major morbidity and one minor morbidity; no clinical reaction in the rest
- Primary errors were noted in the following areas: Collection (4), Administration (3), Component selection (2) and sample taking (historical WBIT=1)

### ABOi transfusions in 2023 (n=10)







### Safe Transfusion Practice: Transfusion Checklist

Transfusion Request	Signature to confirm
<b>Ensure that:</b>	
The reason for transfusion is documented in the patient record	
Details on the transfusion authorisation (prescription) sheet are completed and any specific requirements documented	
All fields on the transfusion request form are completed and the form is signed	
The identity details on the transfusion sample are completed correctly and samples labelled at the patient's bedside. These must be handwritten unless electronic systems are available that generate and print a label at the bedside from the patient ID band are available	
The patient has (and where appropriate family/carers have) received information, has agreed to the transfusion, and this is documented <b>Or</b> In cases where the patient is unconscious and/or unable to consent and the blood component is given in patient's best interest, ensure this is documented in the patient's notes, and information given retrospectively	
The laboratory is informed of the degree of urgency of the request	
<b>Pre-Transfusion Checks</b>	



## CAS Alert

### Safe Transfusion Practice: Use a bedside checklist

09 November 2017

Alert reference number: CEM/CMO/2017/005

Since the first report in 1997 the UK national haemovigilance surveillance programme, Serious Hazards of Transfusion (SHOT), has repeatedly identified that patients are harmed, and some die, as a result of being given the incorrect type of blood.

In 2014 a patient died as a result of an ABO-incompatible transfusion in a high profile case. The nurse collected, then administered a unit intended for another patient with a similar name. This would have been prevented if the final bedside check had been undertaken correctly.

There were seven ABO-incompatible transfusions reported to SHOT in 2015, and three in 2016. All of these were preventable. In addition to the risk of ABO-incompatible transfusion, patients may have other specific, and sometimes critical, transfusion requirements such as irradiated blood, CMV negative serology blood and extended phenotype blood.

Two critical points occur in preparation for transfusion; the first is to correctly identify the patient and label the sample when taking blood for a pre-transfusion blood sample, and the second is to check the details on the unit of blood and the patient's identity at the point of transfusion.

Evidence from SHOT shows that the bedside check performed at the point of transfusion is not always undertaken correctly and that this puts patients at risk of serious complications or death. SHOT therefore recommends a structured process with a **bedside checklist** which must confirm the following:

- Positive patient identification including first name, family name and date of birth; unless impossible, this should be done by asking the patient to state their names and date of birth
- Unique identification number (hospital number, NHS number or equivalent)
- Check that it is the correct and compatible component (against the prescription and label on the component) for this patient at this time
- Check that the component meets any specific requirements for that patient

### Actions

**Who:** All organisations providing NHS funded care which involves the provision of blood transfusions.

**When:** Immediate



Organisations should assess their bedside systems (including electronic systems) to ensure a confirmatory step is in place where the individual performing the checks must sign to say all steps have been followed.



This alert (and supporting information) should be circulated to all relevant staff, including to community nursing staff and midwives who may be involved in the transfusion of blood products in the community.

# Patient Identification



# THE SAMPLE CIRCLE



All samples must be labelled at the patient side  
using positive patient identification.

Unlabelled blood samples **MUST NOT** leave the **SAMPLE CIRCLE**.

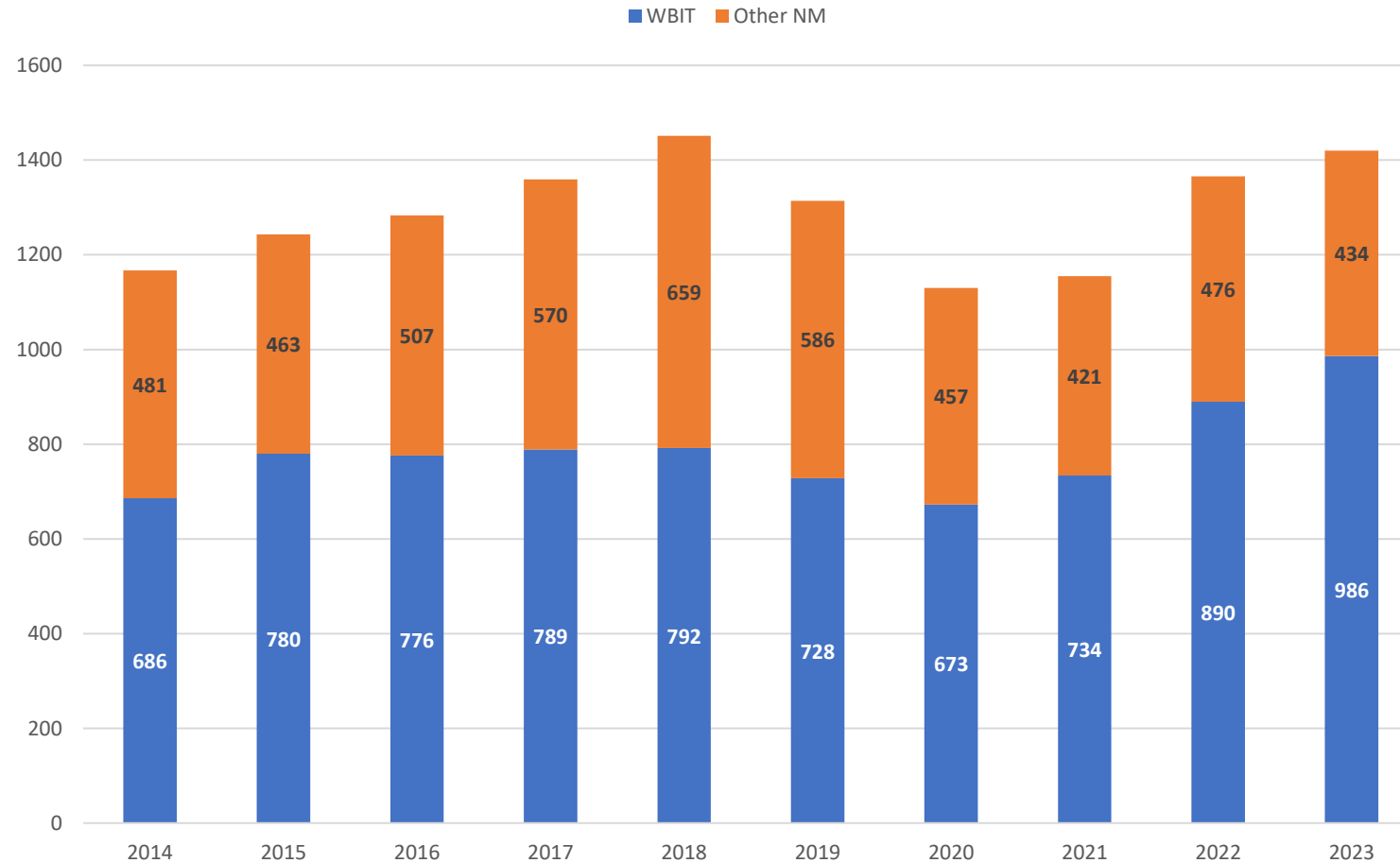
Unlabelled blood samples outside the circle should be disposed of.

# Wrong Blood In Tube



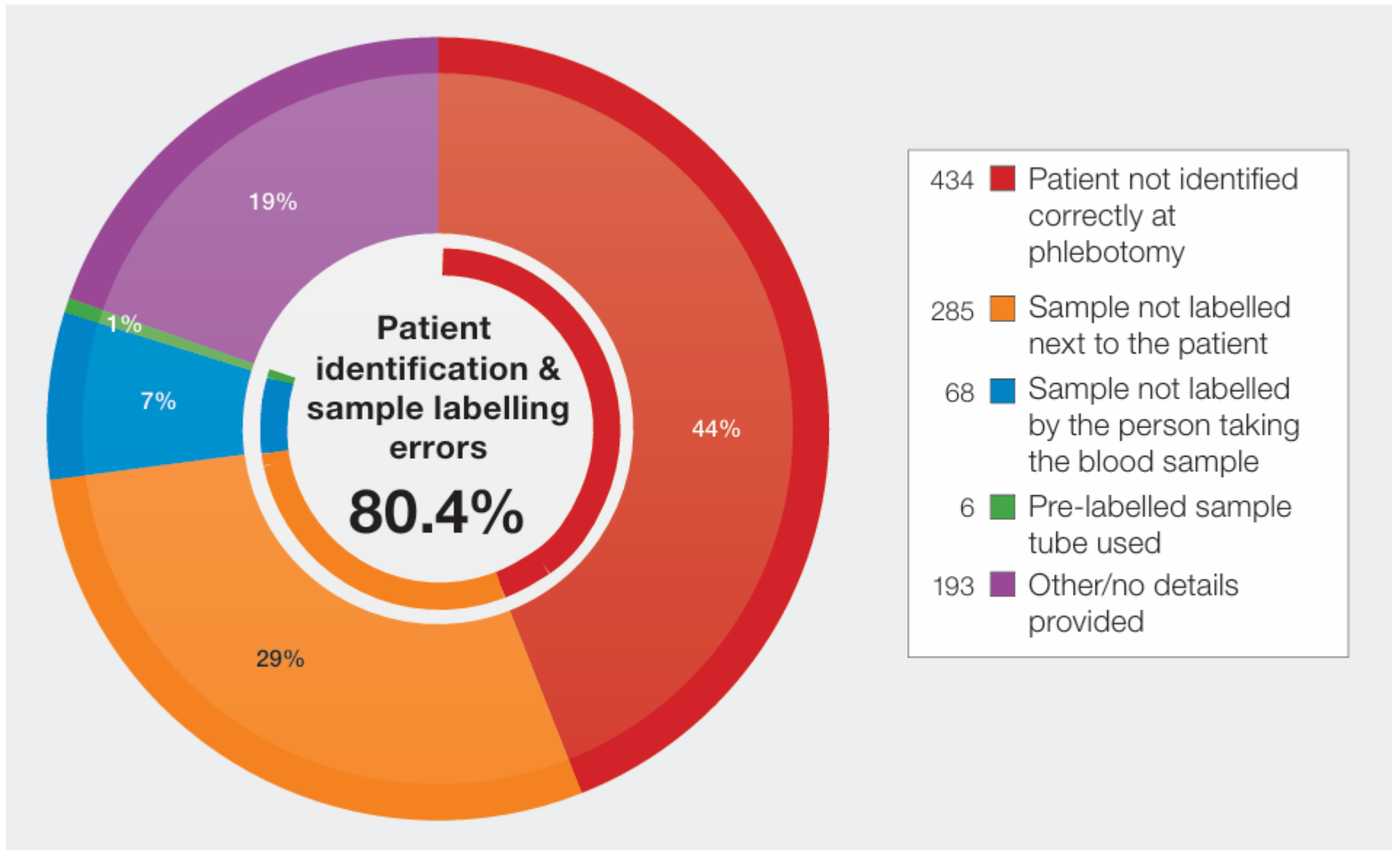


# A decade of near miss and WBIT reports 2014-2023








## Primary errors leading to WBIT in 2023 (n=986)



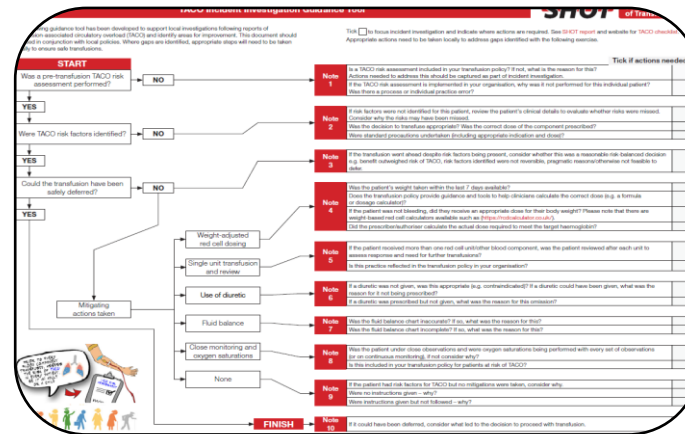
# Pulmonary complications of transfusion



Pulmonary complications of transfusion remain a leading cause of transfusion-related mortality and morbidity, contributing to >50% of transfusion-related deaths reported to SHOT from 2013 to 2022

	Does the patient have any of the following: diagnosis of 'heart failure', congestive cardiac failure (CCF), severe aortic stenosis, or moderate to severe left ventricular dysfunction?			Review the need for transfusion (do the benefits outweigh the risks)? Can the transfusion be safely deferred until the issue is investigated, treated or resolved?	
	Is the patient on a regular diuretic?			<b>If Proceeding with Transfusion: Assign Actions</b>	<b>TICK</b>
	Does the patient have severe anaemia?			Body weight dosing for red cells	
	Is the patient known to have pulmonary oedema?			Transfuse a single unit (red cells) and review symptoms	
	Does the patient have respiratory symptoms of undiagnosed cause?			Measure fluid balance	
	Is the fluid balance clinically significantly positive?			Prophylactic diuretic prescribed	
	Is the patient receiving intravenous fluids (or received them in the previous 24 hours)?			Monitor vital signs closely, including oxygen saturation	
	Is there any peripheral oedema?			<b>Name (PRINT):</b>	
	Does the patient have hypoalbuminaemia?			<b>Role:</b>	
	Does the patient have significant renal impairment?			<b>Date:</b>	<b>Time (24hr):</b>
<b>Signature:</b>					

Due to the differences in adult and neonatal physiology, babies may have a different



The 2023 reporting year recorded **172** 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.


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


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


# Omitted TACO risk assessment led to overtransfusion and TACO, with no structured investigation performed


 A patient weighing 64kg was admitted to a ward with severe symptomatic microcytic hypochromic anaemia (Hb 47g/L)


 Pre- transfusion CT scan showed: pulmonary fibrosis and a small pleural effusion. Patient has multiple co-morbidities

 A TACO risk assessment was not performed, and a fluid balance chart was not in place

 Initially transfused uneventfully with 2 units of red cells, and post-transfusion Hb was 65g/L

 Then given a 3<sup>rd</sup> unit of red cells. Became wheezy, hypertensive, tachycardic, pyrexial and had rigors. Oxygen saturation reduced to 75% and had peripheral pitting oedema

 Post-transfusion chest X-ray showed consolidation thought to be caused by aspiration pneumonia and new bilateral infiltrates consistent with pulmonary oedema

 Patient received oxygen via continuous positive airway pressure, a diuretic, hydrocortisone, bronchodilator and antibiotics. Was transferred to HDU and later recovered



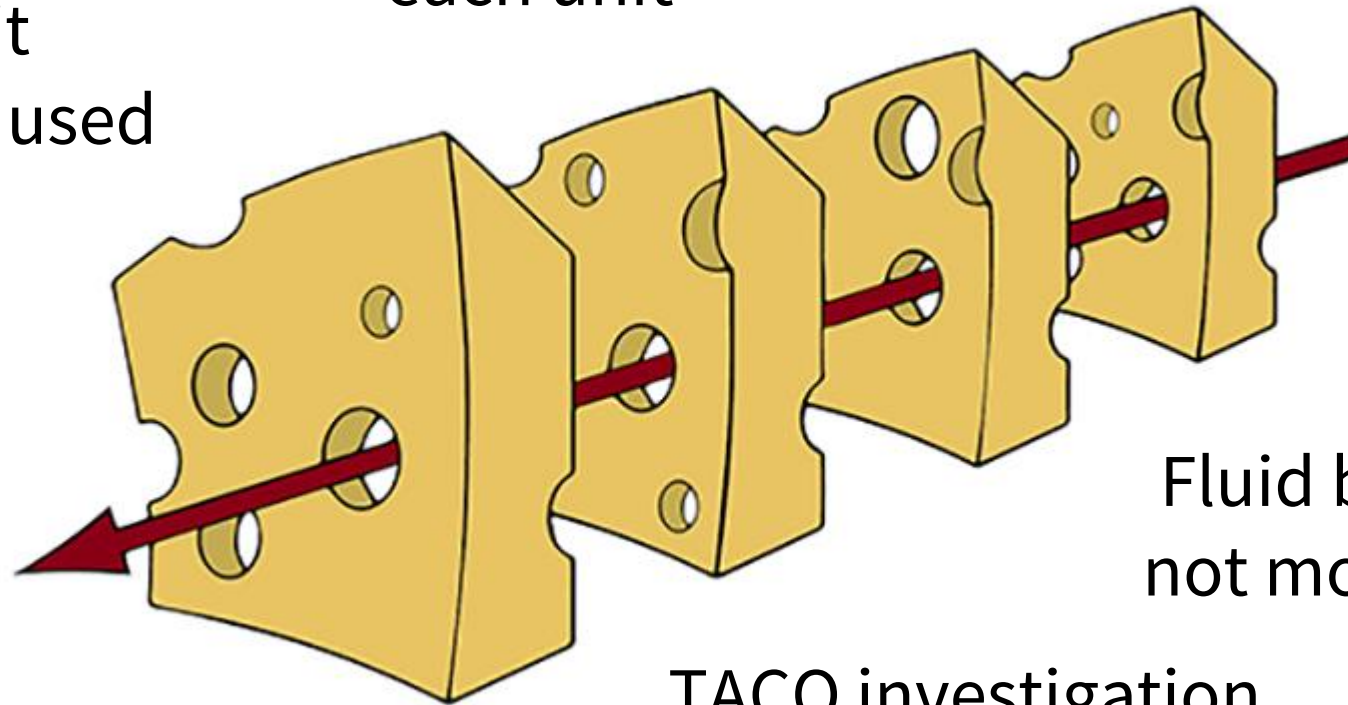
TACO due to over transfusion requiring HDU admission

Single unit approach not used

Not reviewed after each unit

TACO risks not identified

TACO risk assessment not completed



Fluid balance not monitored

No implementation of PBM (Fe therapy)

TACO investigation tool not used



Prophylactic diuretic



Fluid balance measurement



Single unit transfusion and review



Body weight dosing



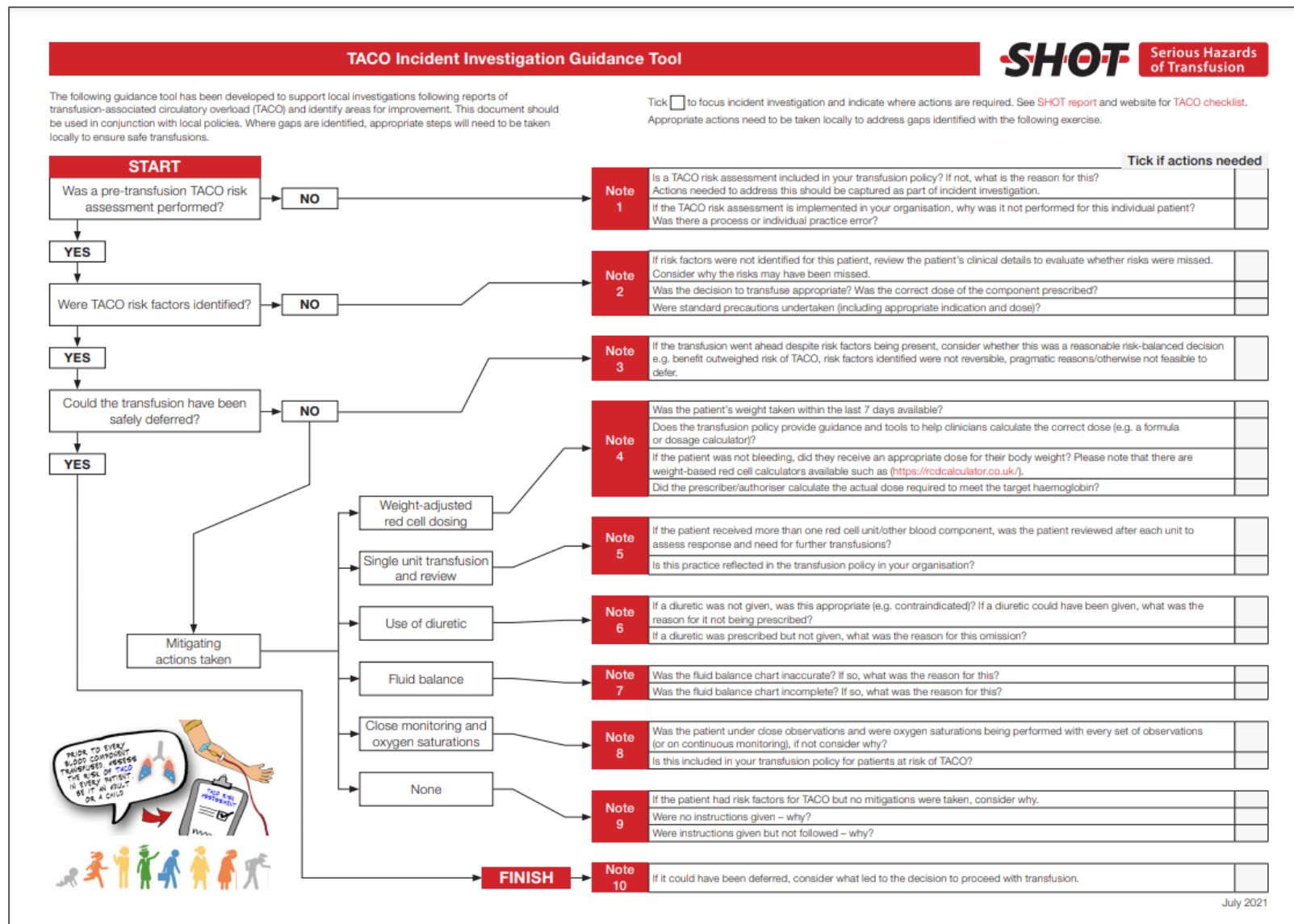
Vital signs monitoring



Alternatives to transfusion

These measures would have helped mitigate the risk for this transfusion episode and help in planning future transfusions. It also represents an opportunity to improve practice and reduce risk for all future patients

A **TACO investigation guidance tool** has been developed and can be accessed from 'Current resources' on the SHOT website





**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: <b>NHS and Independent (acute and specialist) sector where transfusions are carried out.</b>			
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:	Actions required
<p><b>Transfusion delays are preventable. Patients should not die or suffer harm from avoidable delays in transfusion.</b></p> <p>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.</p> <p>Delays in provision and transfusion of blood during major haemorrhage have been identified repeatedly in Annual SHOT Reports<sup>1</sup>. Delays are compounded by failure to recognise bleeding, communication failures and the presence of red cell antibodies in the patient blood sample<sup>1</sup>.</p> <p>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%<sup>2,3</sup>. Urgent provision of blood may be needed for patients with severe anaemia. Laboratory testing may be complicated by the presence of the autoantibodies.</p> <p>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)<sup>4</sup>. Delays or omissions in administration can result in serious morbidity (such as expansion of an ICH) or death<sup>5,6</sup>. Poor communication, patient transfer between departments, dosage calculation and perceived need for consultant approval contribute to PCC delays<sup>1</sup>.</p>	<p><b>Local organisations must have:</b> <b>Actions to be completed as soon as possible and no later than 15 July 2022.</b></p> <ol style="list-style-type: none"> <li>Reviewed and updated policies and procedures to cover:             <ol style="list-style-type: none"> <li>Rapid release of blood components and products for major haemorrhage, AIHA and reversal of anticoagulants.</li> <li>Compliance with SHOT<sup>1</sup>, NICE<sup>4</sup> and BSH<sup>7</sup> recommendations.</li> <li>Agreed criteria where rapid release of PCC is acceptable without the initial approval of a haematologist.</li> <li>Concessionary, rapid release of the best matched red blood cells for patients with red cell antibodies.</li> <li>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.</li> <li>Treatment of patients who refuse transfusion of blood components and/or products.</li> </ol> </li> <li>Reviewed, updated, and implemented training programmes to include:             <ol style="list-style-type: none"> <li>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.</li> <li>Major haemorrhage drills, simulations and debriefs into regular staff training activities, including clinical and laboratory teams.</li> <li>Concessionary, rapid release of the best matched red blood cells for patients with red cell antibodies.</li> <li>A process for recording participation and identifying dates for re-training.</li> <li>Treatment of patients who refuse transfusion of blood components and/or products.</li> </ol> </li> <li>Implemented processes to audit and investigate all transfusion delays, using appropriate investigation tools to identify system factors for improvement.</li> </ol>



For further detail, resources and supporting materials see: [www.shot.org](http://www.shot.org)  
For any enquiries about this alert contact: [SHOT@nhsbt.nhs.uk](mailto:SHOT@nhsbt.nhs.uk)

**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: <b>NHS and Independent (acute and specialist) organisations where transfusions occur</b>			
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:	Actions required
<p>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. <b>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.</b><sup>1</sup> 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:</p> <ul style="list-style-type: none"> <li>cardiac dysfunction</li> <li>renal dysfunction</li> <li>low body weight</li> <li>hypalbuminaemia</li> <li>pre-existing fluid overload</li> <li>high volume in relation to body weight</li> <li>severe chronic anaemia</li> <li>women with severe pre-eclampsia</li> </ul> <p><b>Non-bleeding adult patients with severe chronic anaemia are particularly vulnerable to risk of TACO.</b> 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.<sup>2,3</sup></p> <p><b>TACO risk reduction measures include:</b></p> <ul style="list-style-type: none"> <li>avoiding unnecessary transfusions</li> <li>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<sup>4</sup>) and assessing response</li> <li>consideration of weight-adjusted red cell dosing for patients of low body weight (including children)</li> <li>avoiding transfusions in excess of recommended infusion rates</li> <li>administering a diuretic when appropriate</li> <li>monitor vital signs closely, including oxygen saturation</li> </ul> <p>Further supporting information about TACO and this alert can be found in the supporting FAQ document.<sup>5</sup></p>	<p><b>Actions to be completed as soon as possible and no later than 4 October 2024:</b></p> <ol style="list-style-type: none"> <li>Review and update <b>policies, procedures and processes</b> to ensure:             <ol style="list-style-type: none"> <li>All transfusions are compliant with recommendations from British Society for Haematology (BSH),<sup>6,7</sup> SHOT,<sup>8</sup> and NICE<sup>9</sup></li> <li>A TACO risk assessment is undertaken utilising the SHOT risk assessment tool<sup>10</sup> prior to transfusions<sup>10</sup></li> <li>Appropriate mitigation measures are initiated for individuals at risk – see FAQ document<sup>5</sup></li> <li>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<sup>10</sup></li> <li>Inclusion of guidance on timely management of TACO, including the use of diuretics, oxygen, and other supportive measures<sup>10</sup></li> <li>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</li> <li>Use of the structured TACO incident investigation tool<sup>11</sup> from SHOT</li> </ol> </li> <li>Review, update, and <b>implement training programmes</b> to include:             <ol style="list-style-type: none"> <li>Use of TACO pre-transfusion risk assessment tool<sup>10</sup></li> <li>Appropriate use of mitigation measures – FAQ document<sup>5</sup></li> <li>Management of severe chronic anaemia in non-bleeding patients using minimal/single-unit transfusion support, and anaemia management with iron therapy where appropriate</li> <li>Recognition and prompt management of TACO, importance of timely interventions and escalation of care as appropriate</li> <li>Empowerment of clinical staff and biomedical scientists to question practices of prescribing/requesting blood components</li> <li>A process for recording participation and identifying dates for re-training</li> <li>Knowledge and awareness to report TACO cases locally, as well as to MHRA and SHOT by hospital transfusion teams</li> </ol> </li> <li><b>Undertake regular audit</b> on the use of the TACO risk assessment tool for adult patients<sup>10</sup>, 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</li> </ol> <p><b>*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.</b></p>

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](mailto:info@mhra.gov.uk) or [SHOT@nhsbt.nhs.uk](mailto:SHOT@nhsbt.nhs.uk)



# Febrile, Allergic and Hypotensive Reactions

**THINK BEFORE PRESCRIBING**

**FEBRILE AND ALLERGIC REACTIONS NEED DIFFERENT TREATMENTS**

**STERIODS**

**ANTI-HISTAMINE**

**PARACETAMOL**

**SHOT**  
Serious Hazards of Transfusion

**USE THE RIGHT TREATMENT FOR THE RIGHT PATIENT AT THE RIGHT TIME**

**No deaths  
related to  
FAHR in 2023**

**119 cases  
with major  
morbidity  
related to  
FAHR in 2023**

**336** Febrile and allergic reactions in 2023

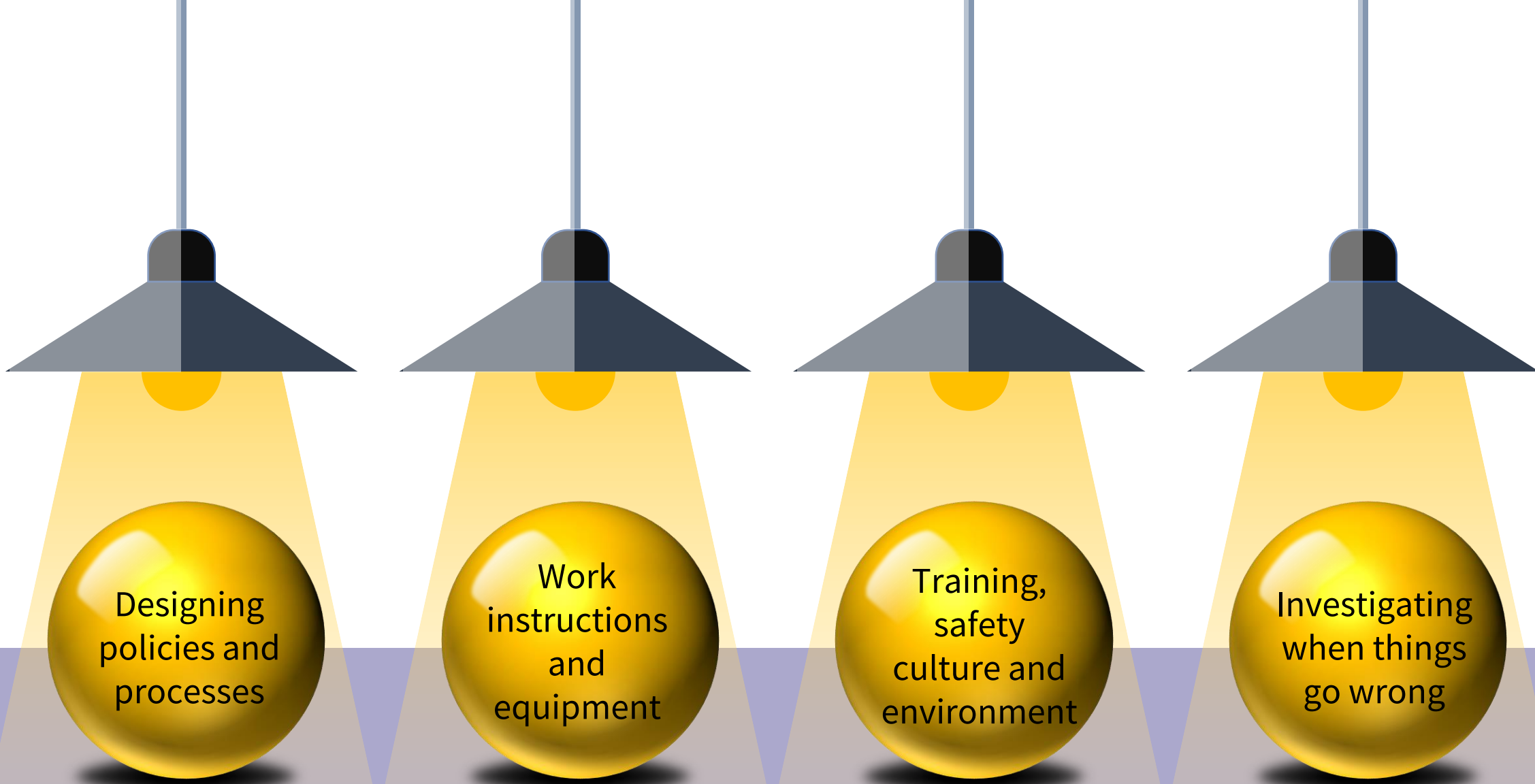
**50** severe allergic reactions in 2023

Difficulties in accurately categorising events continue

Red cells usually associated with febrile reactions

Plasma and platelets more commonly cause allergic reactions

Inappropriate use of antihistamines with or without steroids seen



Human Factors principles are important in all these aspects of transfusion safety



# Human Factors resources developed by SHOT

Learn more

- [Human Factors](#)
- [HFIT Training Package](#)
- [Human Factors Resources](#)

## Human Factors



As three quarters of all incidents reported to SHOT are related to errors, we would like to understand more about why these occur. Errors in transfusion practice may be related to workplace features. What are the human factors that contribute to errors in transfusion practice?

Patient safety incidents and errors in transfusion can lead to fatal outcomes. Effective investigation of these incidents is essential to optimise learning and take action to prevent further incidents occurring.

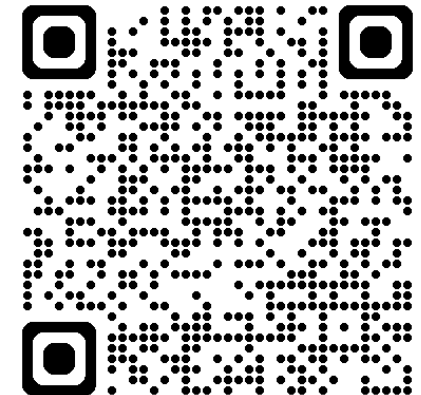
In 2021, we incorporated and amended The Yorkshire Contributory Factors Framework (YCFF) into our Human Factors Investigation Tool (HFIT). This Framework has an evidence base for optimising learning and addressing causes of patient safety incidents by helping SHOT, clinicians, risk managers and patient safety officers identify contributory factors incidents. It is anticipated that the HFIT questions will take around 15 minutes to complete.

The underlying aim is not to ignore individual accountability for unsafe practice, but to try to develop a **more sophisticated understanding** of the factors that cause incidents. These factors can then be addressed through changes and recommendations in systems, structures and local working conditions. Finding the true causes of patient safety incidents offers an opportunity to address systemic flaws effectively.

### Human Factors

As three quarters of all incidents reported to SHOT are related to errors, we would like to understand more about why these occur. Errors in transfusion practice may be related to workplace features, communication, and IT systems, and organisational pressures.

It is important to answer every question as this will allow SHOT to interpret practices, and gain understanding of all the factors involved



# SHOT **A**cknowledging **C**ontinuing **E**xcellence in Transfusion



- Learning from all events and experiences including excellence
- Appreciative enquiry
- Making visible the hidden work people do to successfully navigate problems
- Build resilient teams and systems

# What can you do?

Report any errors or concerns to  
Transfusion Practitioner

Ensure a safe environment for transfusions

Be a champion for transfusion  
safety/promote a safety culture

# 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**



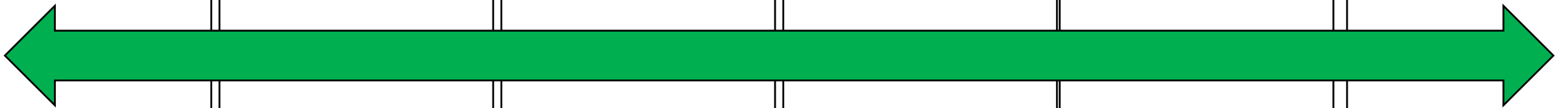
**Review your hospital transfusion policies**



**Carry out a consent review and use of checklist / SRNM**

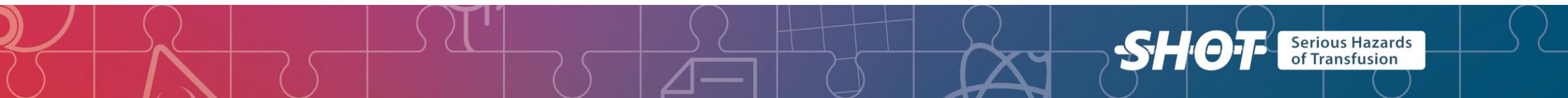
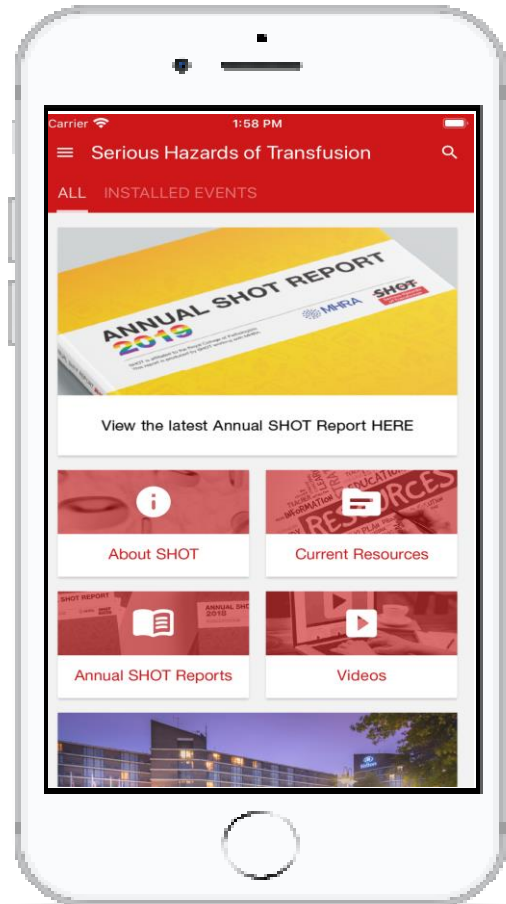


**Carry out a review of your Trust's SHOT reports**





# SHOT App



# Acknowledgements

- **The reporters and hospital staff who share their incidents**
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**For further information visit:** [www.shotuk.org](http://www.shotuk.org)



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