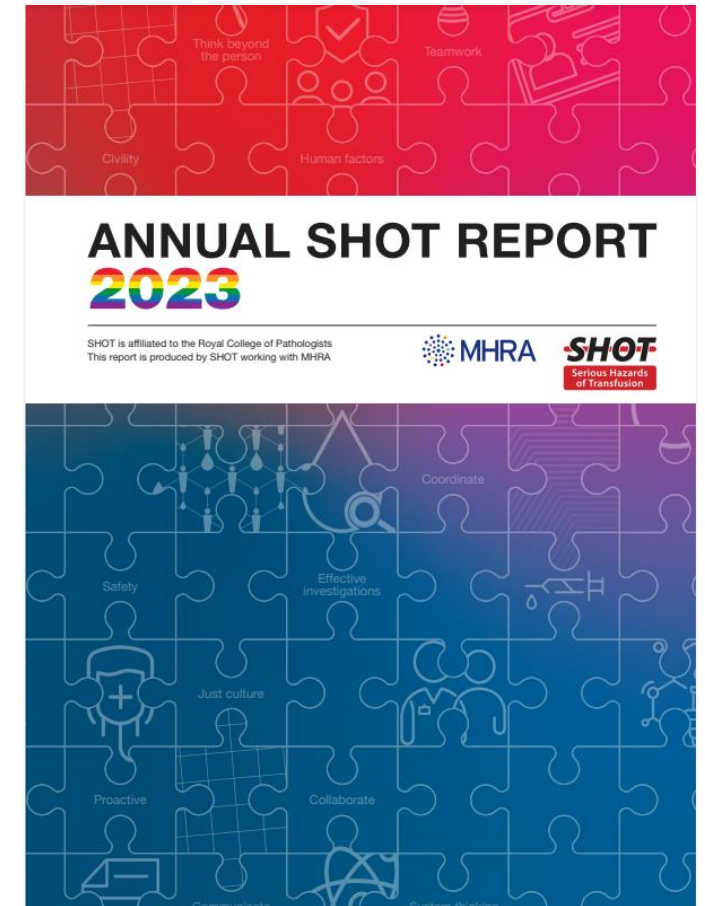


# Learning from transfusion errors

## Incident investigation



Nicola Swarbrick Laboratory Incident Specialist  
Caryn Hughes, SHOT Operations Manager

# Learning Outcomes



Explain how haemovigilance (HV) and transfusion practice impact patient safety



Describe tools used in incident investigation, and the impact of appropriate incident investigation



Evaluate cases of good and insufficient investigation

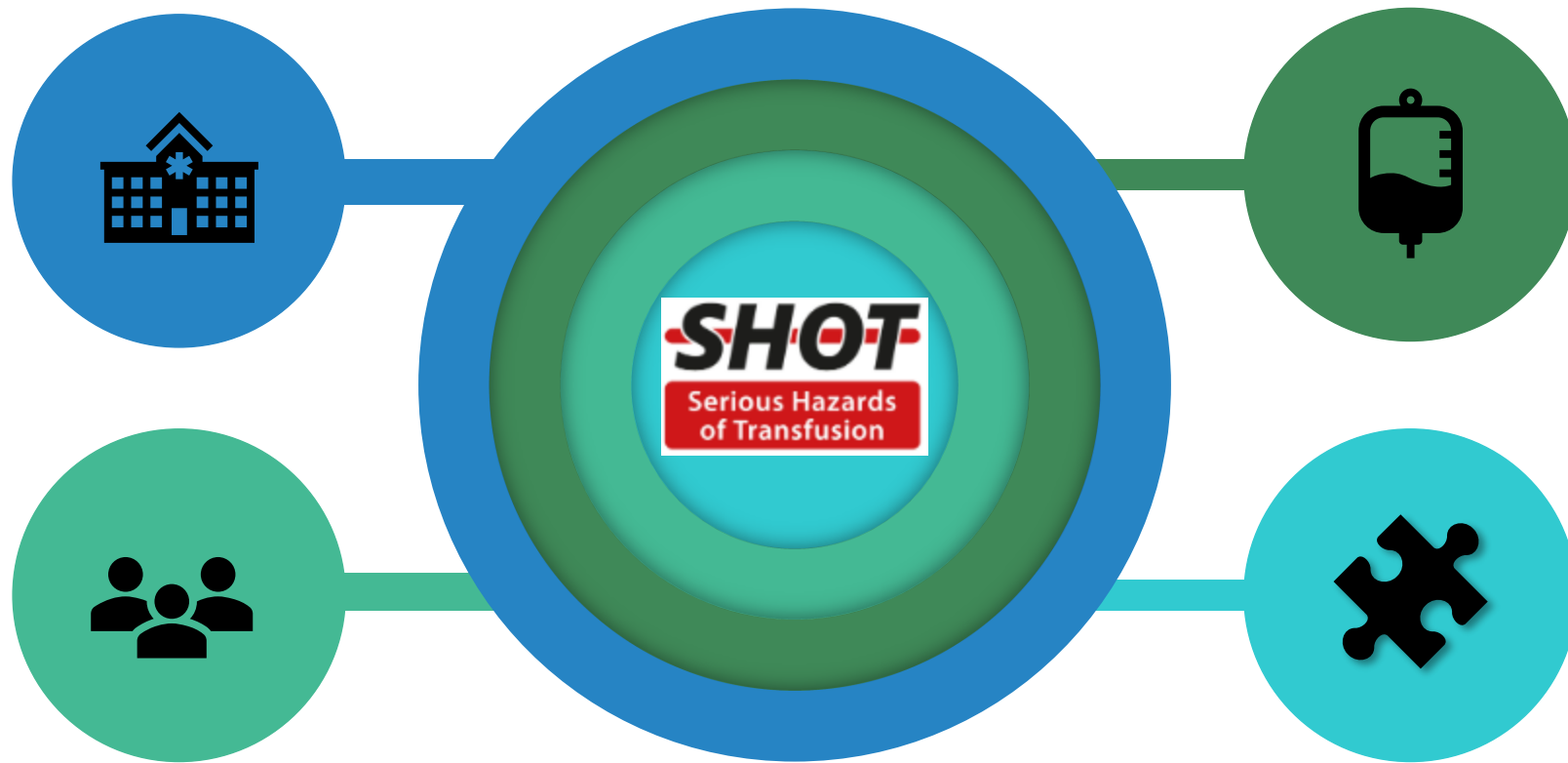
# Role of SHOT

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



**Transfusion reactions and adverse events from whole UK**

**All components, anti-D immunoglobulin and prothrombin complex concentrates**

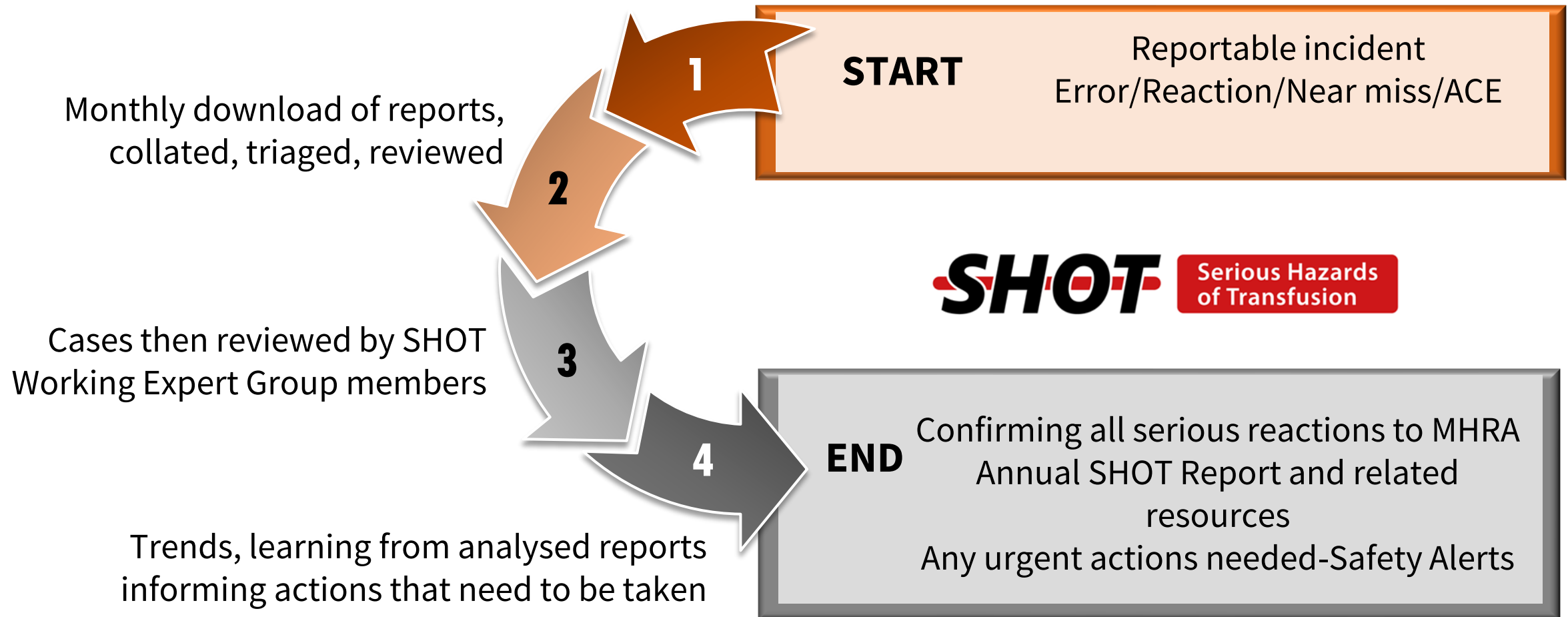


**Transfusion community expert input**

**Recommendations and education**

# Flow of haemovigilance information in the UK

Nominated person/s submit reports via SABRE/SHOT portal

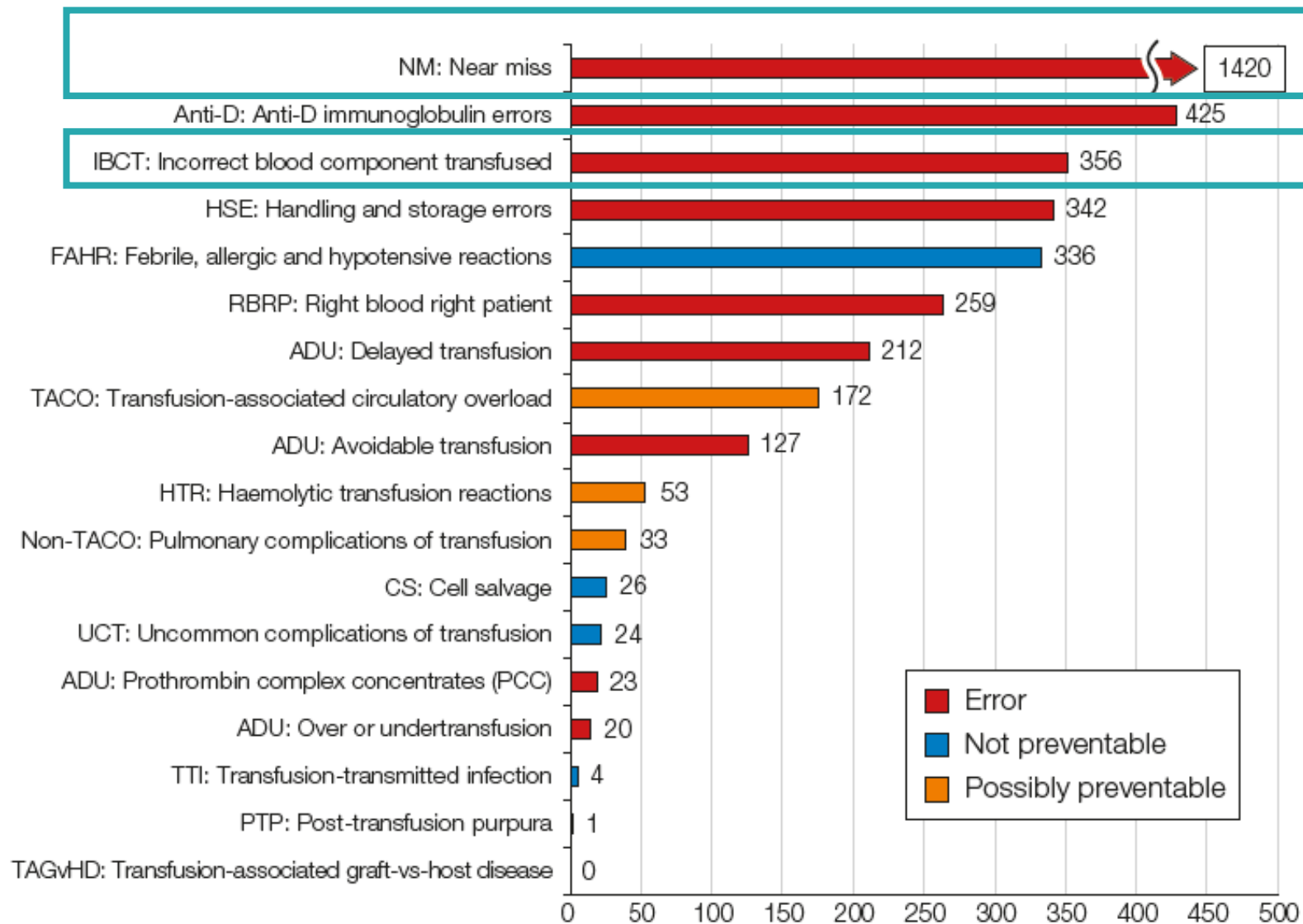


Errors account for most reports in 2023 (n=3184/3833)



3184 ■ Errors (all preventable)  
 391 ■ Not preventable  
 258 ■ Possibly preventable

Summary data for 2023, all categories (includes RBRP and NM) (n=3833)



■ Error  
 ■ Not preventable  
 ■ Possibly preventable

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

**Staff knowledge, training issues; HFE awareness and application (dirty dozen)**

**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 incidents



Image from: [https://www.123rf.com/stock-photo/wrist\\_bands.html?sti=m2mns1yu6rqowx8sp2/](https://www.123rf.com/stock-photo/wrist_bands.html?sti=m2mns1yu6rqowx8sp2/)

# Why is this trend continuing?

Inadequate resources

Sub-optimal system designs

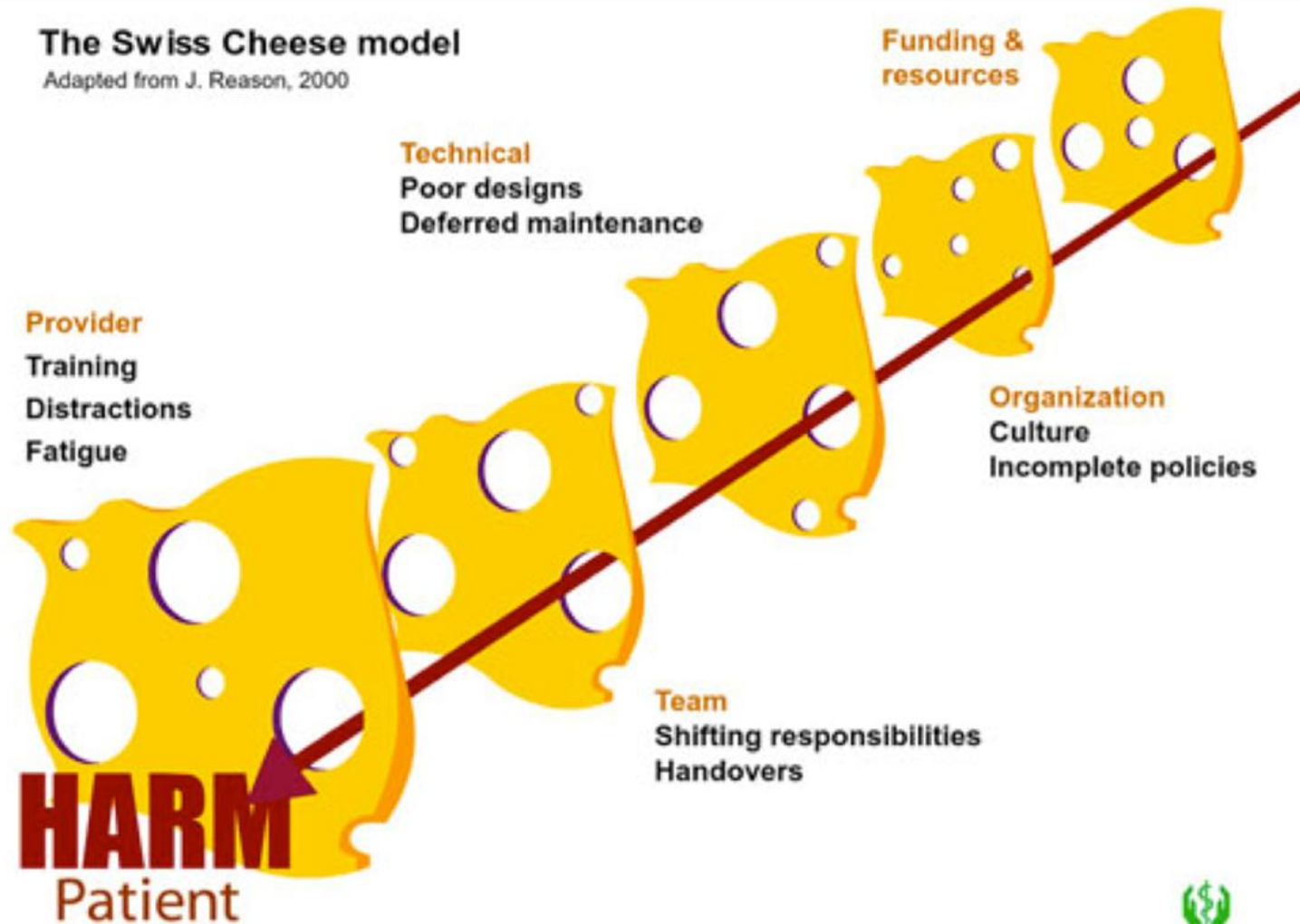
Sub-optimal incident investigations

Ineffective preventative actions

Lack of sustained improvements & learning from events

## The Swiss Cheese model

Adapted from J. Reason, 2000



# How can we improve our investigation process?

**Are we asking the right questions?**

**Are we optimising learning?**

**Are staff trained to use investigation tools?**



**Are we identifying the right actions?**

**Are staff aware of human factor principles?**

**Are we sharing the lessons learnt?**

# Warning signs of suboptimal incident investigations



## Inferences

Investigations conclude human error or blame one or more individuals as causing the event



## Process failures

Investigations not completed in a timely manner, not involving all stakeholders, attribution bias



## Systems view

No contributing factors identified, lack of supporting data or information



## Interventions

Interventions are not SMART and do not appear to address the system vulnerabilities identified



## Impact

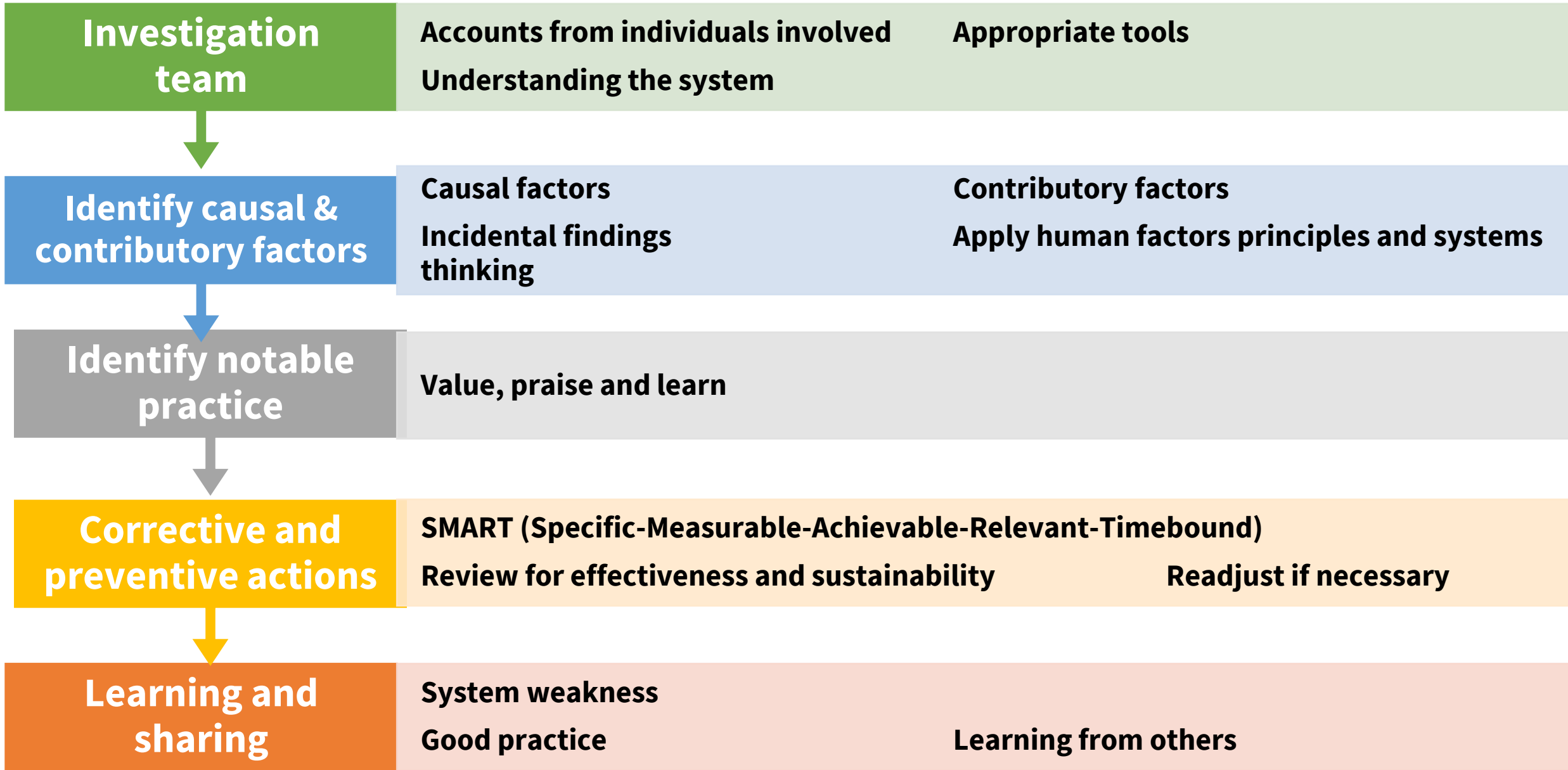
There is little confidence that implementing and sustaining agreed interventions will significantly reduce the risk of future occurrences of similar events

**Poor leadership, poor safety culture and lack of shared learning from incidents**



Investigation process

# Investigation process



# Investigation Team



Who do you need?

Subject matter expert  
Investigation trained individual



How are you going to meet?

Round table  
Virtual



How are the individuals involved included?

Support (via line management)  
Accounts (written accounts/asking open ended questions)

**Ask how, what, why, where, when, before asking who**



# Investigation Tools



## Timeline

- Detail
- Questions to be answered



## Process mapping/policy mapping

- Identify weakness



## Human factors

- SHOT HFIT, Incident Decision Tree, Fishbone



- Causes
- Contributory factors
- Incidental findings

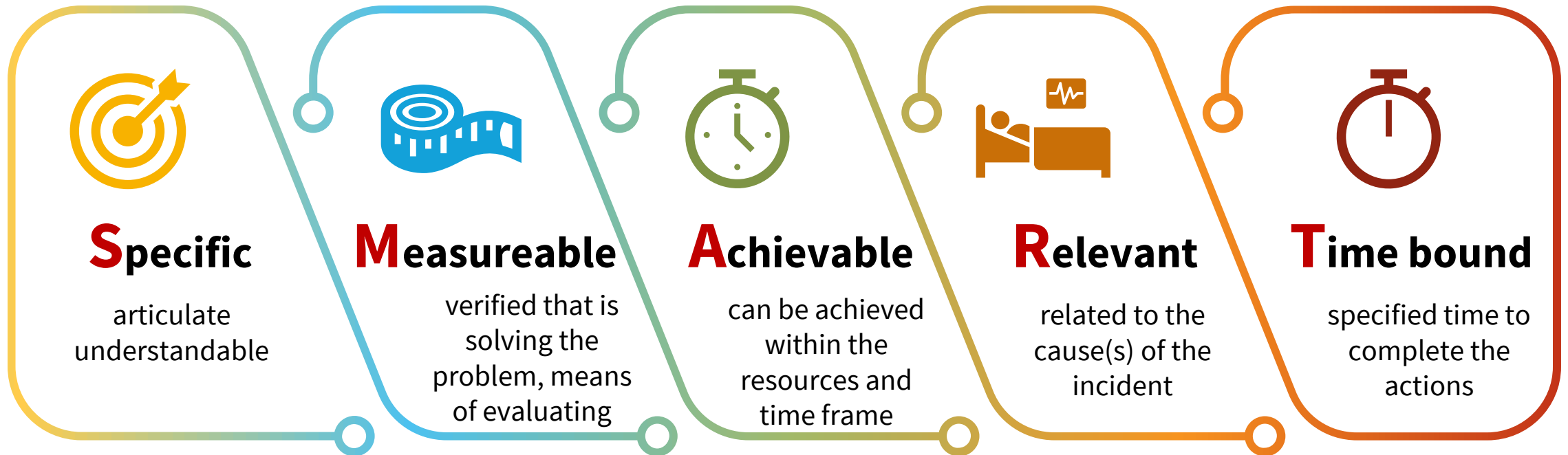
NHS England Patient Safety  
Incident Response Framework  
(PSIRF)

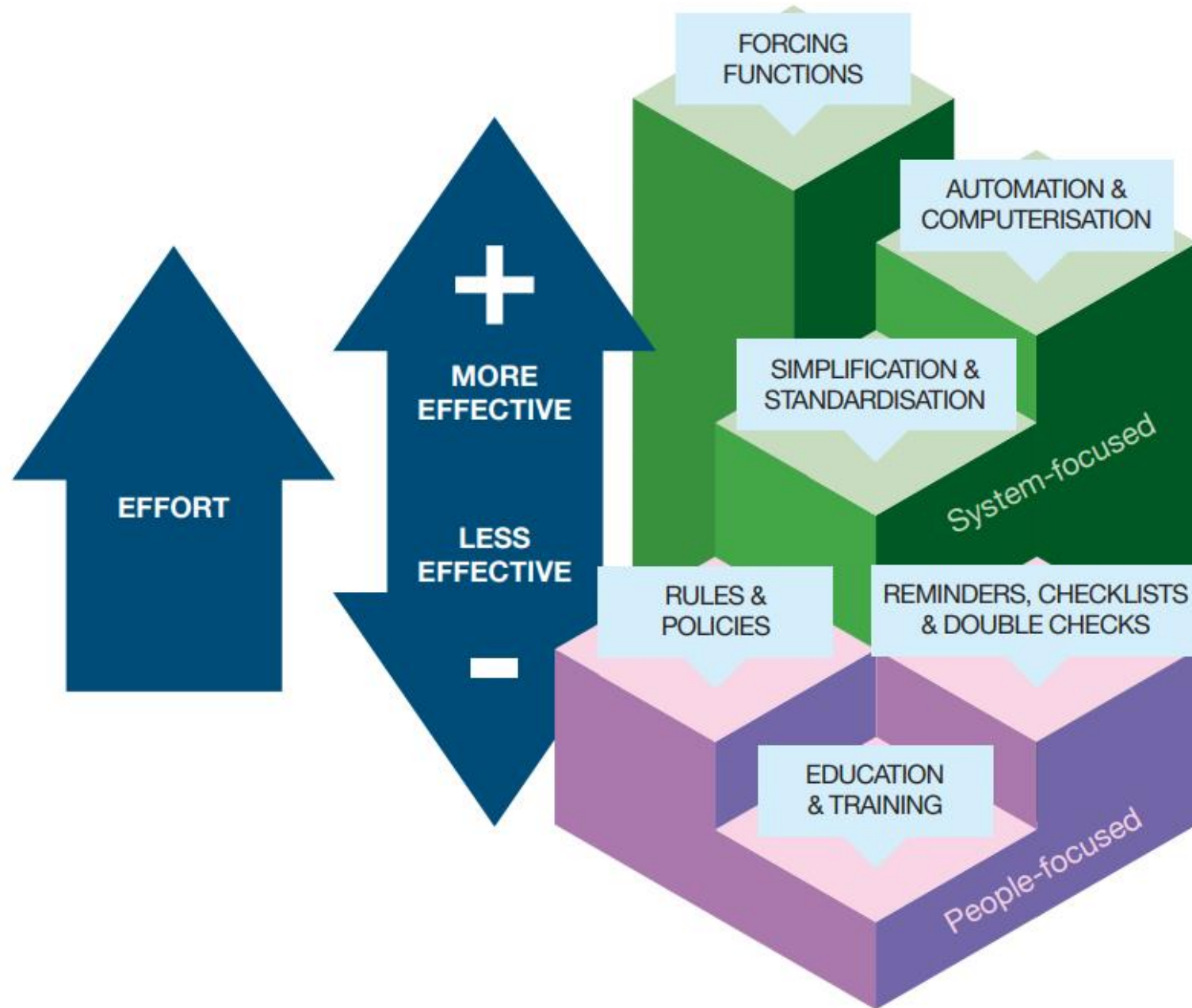
# Time line of events

Date	Time	Step	Error	Questions/Follow up	Person
12/06/24	09:05	Patient arrived in Theatre assessment			DS
12/06/24	09:30	Wrist band attached to patient			DS
12/06/24	09:55	Phlebotomist takes GS sample without verbal confirmation of ID	DOB incorrect on request form and sample	Check competency	HS
12/06/24	10:15	Sample received and booked into Transfusion LIMS	ID error not detected	Check competency	PD
12/06/24	10:45	GS authorised. Sample ID checked	ID error not detected	2 <sup>nd</sup> check completed?	GO
12/06/24	12:05	Theatre 4 ring Transfusion and request 2 RBC			JS
12/06/24	12:30	2 RBC issued, units and LIMS match	Sample checked prior to EI. ID error not detected	Why sample not checked?	GO
12/06/24	13:30	Units collected and transferred to theatre fridge			GO



# SMART Corrective and Preventive Actions





*Adapted from the figure in 'From Discovery to Design: The Evolution of Human Factors in Healthcare' by Joseph A. Cafazzo and Olivier St-Cyr in the Healthcare Quarterly 15 (Special Issue) April 2012: 24-29. doi:10.12927/hcq.2012.22845*

**Human factors is  
“The scientific  
discipline concerned  
with the understanding  
of interactions among  
humans and other  
elements of a system”**



# Human factor influences



Poor  
Communication



Complacency



Lack of  
Knowledge



Distraction



Stress



Lack of  
Resources



Pressure



Lack of  
Teamwork



Loss of  
Awareness



Accepting the  
Norms



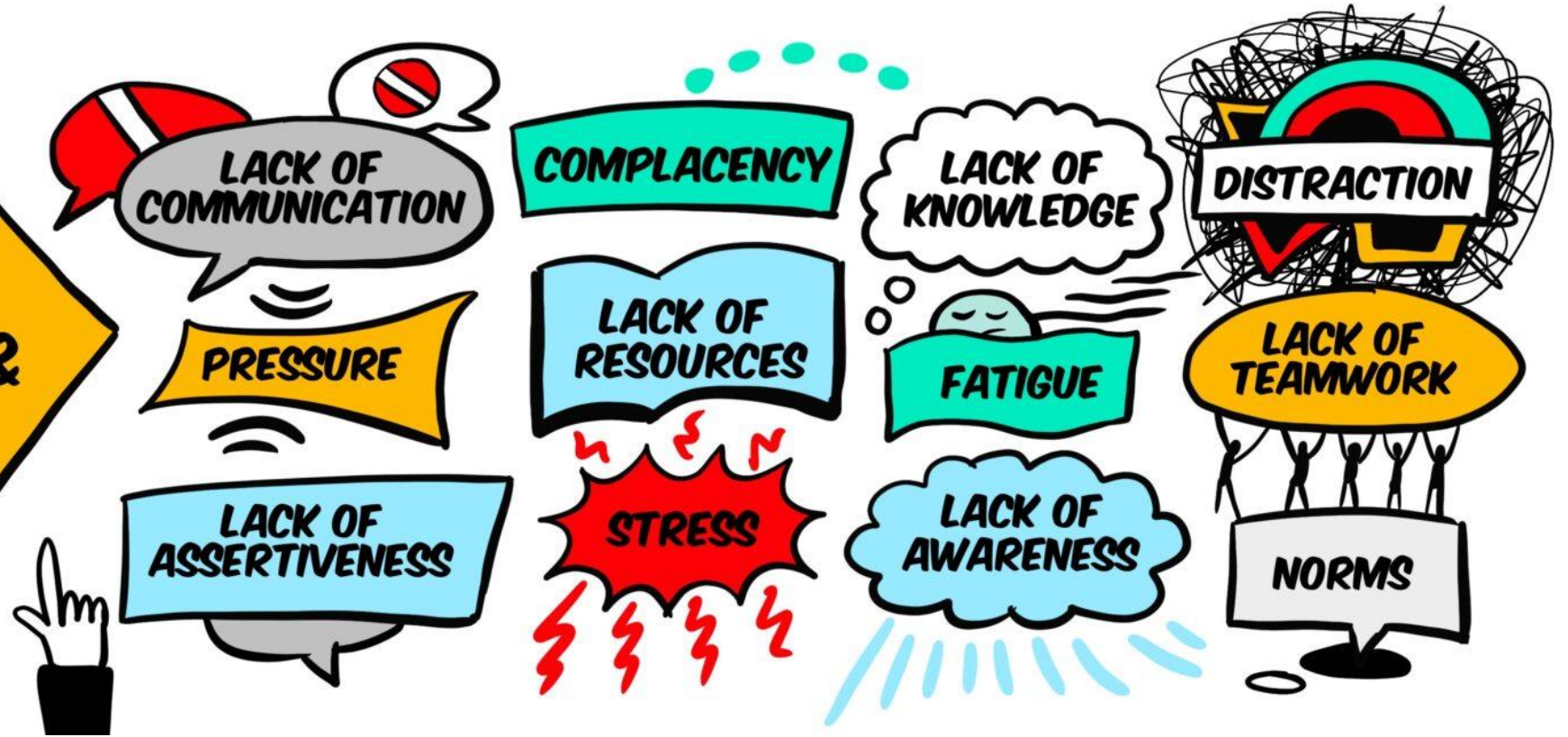
Fatigue



Lack of  
Assertiveness



# Learning point







Important to remember

**HUMAN FACTORS  
IS NOT THE SAME AS  
HUMAN ERROR**



**LOOK BEYOND  
THE PERSON**

# Why is understanding Human Factors important?

---

Reduction in errors

Improving safety

Reduction in waste

Better patient, donor, staff experiences

Increase in staff engagement

Improved staff wellbeing



# Definitions WAI v WAD

---

**“Work-as-imagined (formal work)  
is what designers, managers, regulators, and  
authorities believe happens or should happen”**

**“Work-as-done (informal work)  
is what people have to do to get the job done. It is  
what actually happens”**

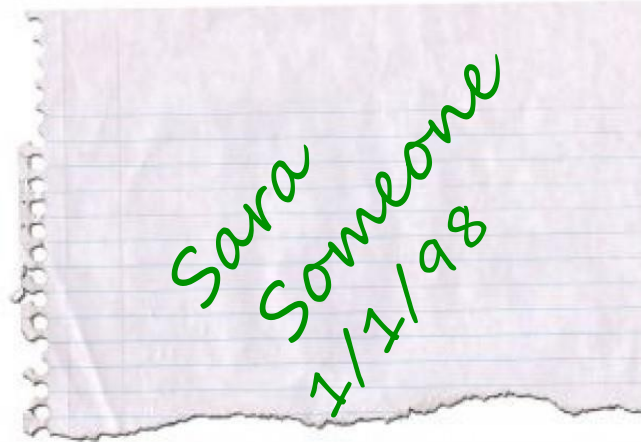
# WAI

# V

# WAD

## Policy

Take patient's details to collect blood



Pictures from internet, uncredited

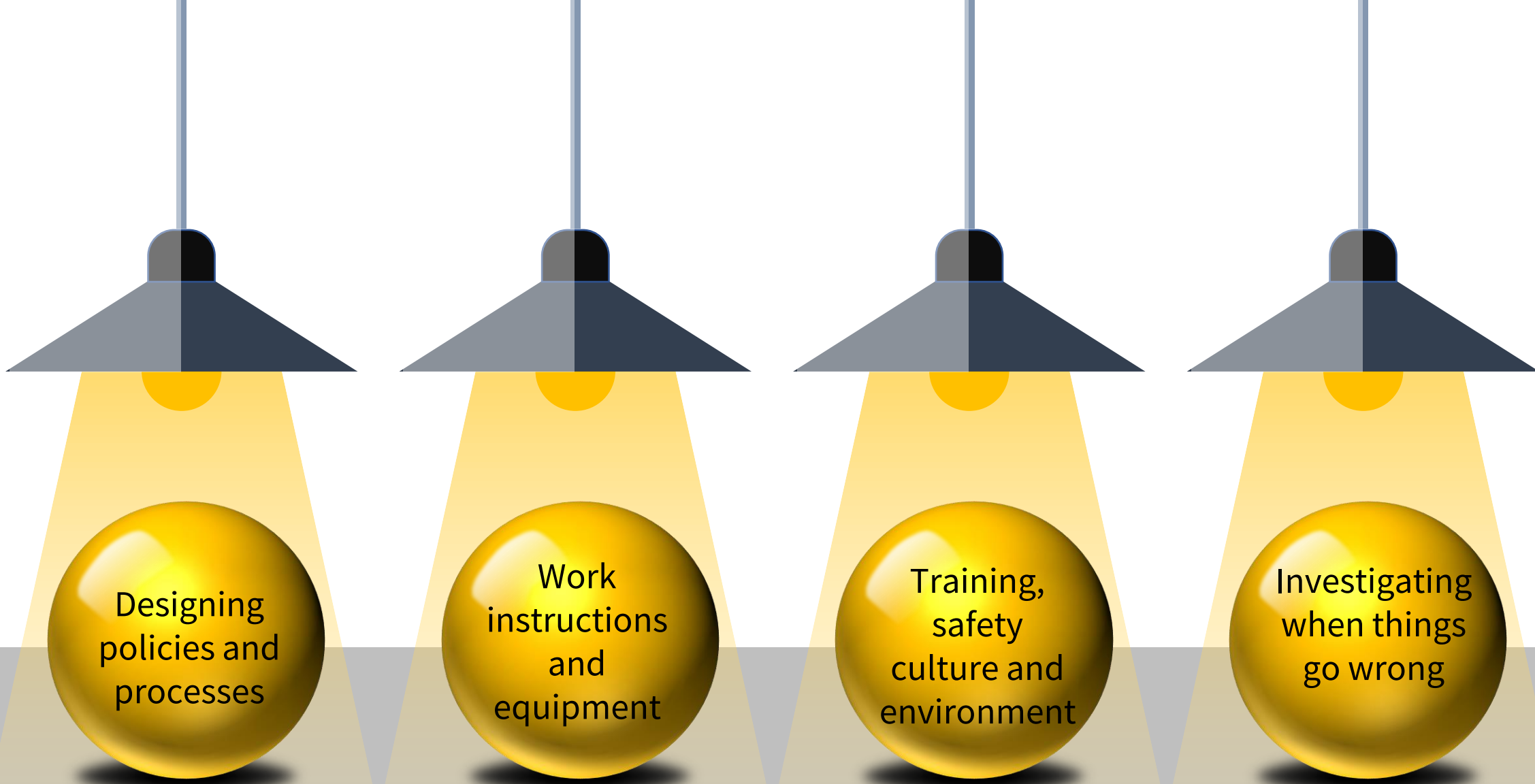
### DRUG CHART

Name Sarah Somebody  
DOB 1/1/96 Hosp No 123456

Date	Medication (Print Generic Name)	Dose	Route	Frequency	Time	Signature	Print Your Name	Contact	Sign	Continued on discharge?	Type / Abb	Duration?	Discharge?
3/16	Oxycodone	10-20mg	PO	PRN		[Signature]	[Name]		[Signature]				
5/10	Oxycodone IR	10-20mg	PO	PRN		[Signature]	[Name]		[Signature]				
11/10	Oxycodone IR	10-20mg	PO	PRN		[Signature]	[Name]		[Signature]				

DRUG CHART (continued)

DRUG (Printed Name)	(Oxycodone)	DOSE	10-20mg
DRUG (Printed Name)	Oxycodone IR	ROUTE	PO
DIRECTIONS/INDICATION	q1h PRN		
DOCTOR'S SIGNATURE	[Signature]	DR'S NAME/STAMP	
START DATE	11/4/5	CEASE DATE	



Designing  
policies and  
processes

Work  
instructions  
and  
equipment

Training,  
safety  
culture and  
environment

Investigating  
when things  
go wrong

HFE principles are important in all these aspects

## PSIRF and impact on haemovigilance reporting and investigation of transfusion incidents in England, UK

### Summary infographic:

#### PSIRF and impact on haemovigilance in England

Recording transfusion incidents: **NO change**

Reporting to local Quality Management Systems and external reporting to SHOT and MHRA: **NO change**

Investigating incidents/What to investigate: **NO change**

While PSIRF replaces the Serious Incident Framework in England, the investigation of transfusion incidents must comply with Blood Safety Quality Regulations and Good Practice Guidance. Hence **NO change** to what needs to be investigated in transfusion.

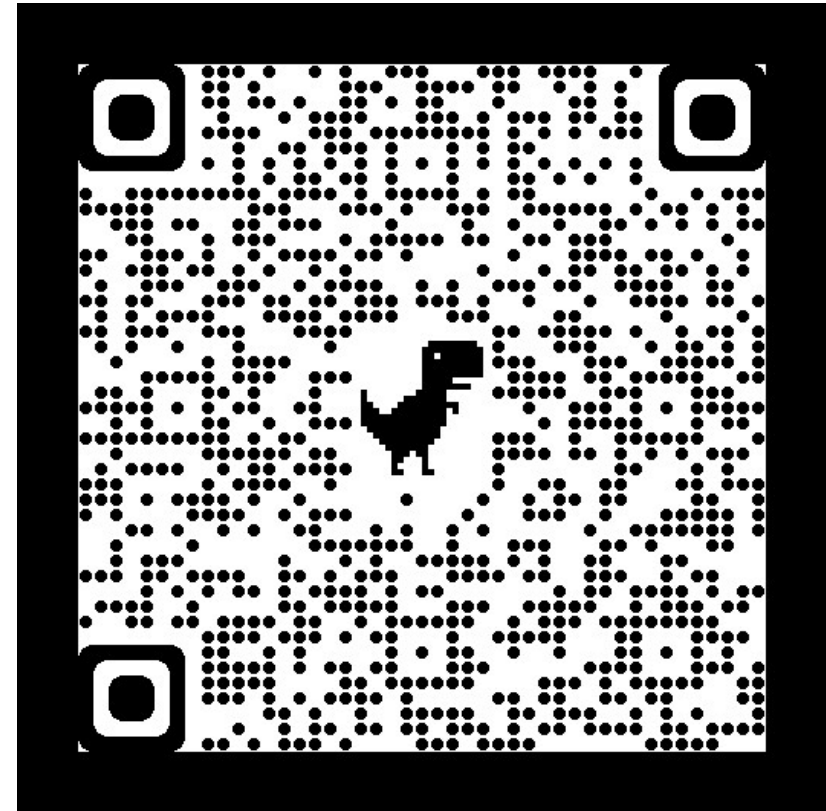
While PSIRF is less prescriptive, transfusion incidents must be managed in accordance with BSQR and GPG

How to investigate: Change in terminology but principles are the same; **NO significant change**

PSIRF moves away from RCA and emphasises a systems approach to incident management and interventions. While BSQR and GPG state RCA as the methodology for investigating incidents, guidance is clear that a systems approach with application of human factors principles and identifying effective system focussed interventions are vital with a just, learning culture. MHRA and SHOT support and promote these principles to enhance transfusion safety and optimise learning from haemovigilance.

**SHOT, MHRA and NHS England support the compassionate engagement and involvement of those affected by safety incidents. Lessons learnt from incidents must be shared widely.**

*If any questions, please contact [shot@nhsbt.nhs.uk](mailto:shot@nhsbt.nhs.uk), [sabre@mhra.gov.uk](mailto:sabre@mhra.gov.uk) and/or [patientsafety.enquiries@nhs.net](mailto:patientsafety.enquiries@nhs.net)*



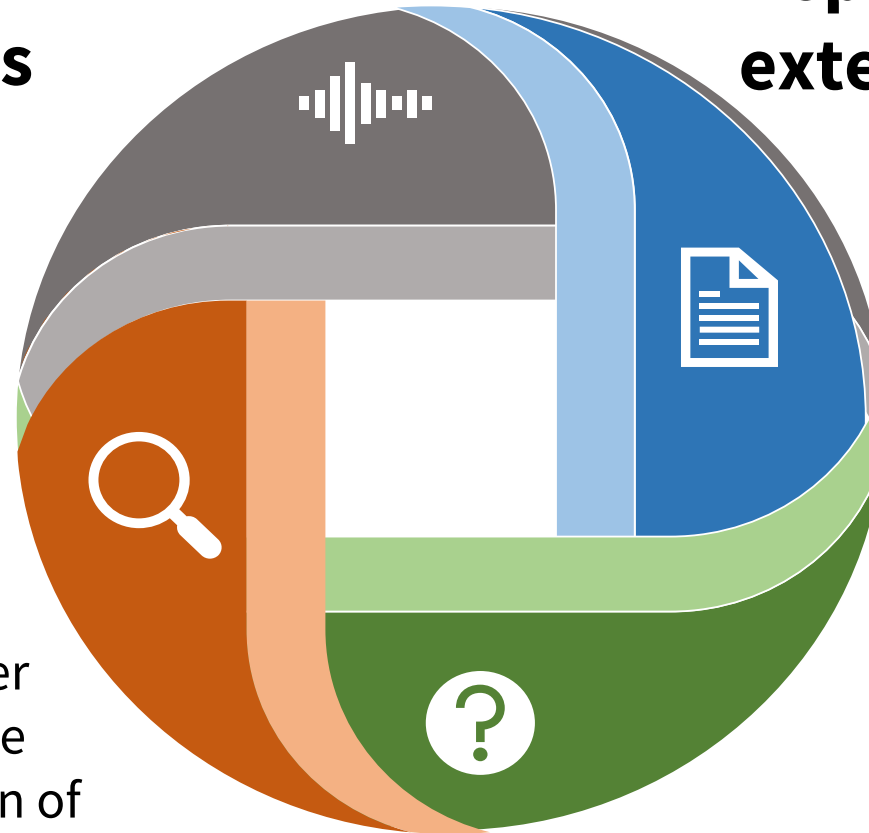
# Key highlights: PSIRF and impact on haemovigilance

## Recording transfusion incidents

**No change**

## How to investigate

Methodology (RCA vs SEIPS/other learning tools)- focus on effective learning from incidents, application of HFE, systems thinking, quality over quantity



## Reporting to local QMS and externally to SHOT and MHRA

**No change**

## What to investigate/Threshold

Investigation of transfusion incidents must comply with BSQR and GPG requirements

**No change**

# Optimising learning from transfusion incidents

1

Using human factors principles and systems thinking (different models/frameworks)

2

Asking the right questions, investigator training

3

Intervention hierarchy-choosing system oriented, long-term solutions

4

Safe and effective implementation of IT vein to vein supported by staff training

5

Involving patients in aspects of personal and organisational safety

6

Promoting awareness of human factors, cognitive bias, capacity planning

7

Aligned with rest of the NHS – patient safety strategy, PSIRF

8

Promoting just, learning safety culture, non-punitive approach



# Action examples

Deficiency noted in investigation – staff not trained to respond to fridge temperature excursion alert

## Good action



Create training plan and competency assessment covering fridge alerts and deliver training to all staff



Target date – within 4 weeks (Ensure staff trained prior to lone working shift)



Action by – transfusion laboratory manager



Evidence – signed training and competency assessment documents

## Suboptimal action



Include in next staff training session



Target date – within 6 months



Action by – transfusion laboratory



None recorded

**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:**

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

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

Delays in provision and transfusion of blood during major haemorrhage have been identified repeatedly in Annual SHOT 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>.

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.

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>.

- Actions required**
- Local organisations must have:**  
**Actions to be completed as soon as possible and no later than 15 July 2022.**
- Reviewed and updated policies and procedures to cover:
    - Rapid release of blood components and products for major haemorrhage, AIHA and reversal of anticoagulants.
    - Compliance with SHOT<sup>1</sup>, NICE<sup>4</sup> and BSH<sup>7</sup> recommendations.
    - Agreed criteria where rapid release of PCC is acceptable without the initial approval of a haematologist.
    - Concessionary, rapid release of the best matched red blood cells for patients with red cell antibodies.
    - 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.
    - Treatment of patients who refuse transfusion of blood components and/or products.
  - Reviewed, updated, and implemented training programmes to include:
    - Recognition of bleeding, importance of communication, processes for activation of major haemorrhage protocols and rapid access to blood components and products in clinical staff training programmes.
    - Major haemorrhage drills, simulations and debriefs into regular staff training activities, including clinical and laboratory teams.
    - Concessionary, rapid release of the best matched red blood cells for patients with red cell antibodies.
    - A process for recording participation and identifying dates for re-training.
    - Treatment of patients who refuse transfusion of blood components and/or products.
  - Implemented processes to audit and investigate all transfusion delays, using appropriate investigation tools to identify system factors for improvement.



For further detail, resources and supporting materials see: [www.shot.org](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:**

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.**<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:

- cardiac dysfunction
- renal dysfunction
- low body weight
- hyponatraemia
- 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.<sup>2,3</sup>

**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<sup>4</sup>) 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.<sup>5</sup>**

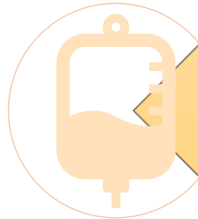
- Actions required**
- Actions to be completed as soon as possible and no later than 4 October 2024:**
- Review and update **policies, procedures and processes** to ensure:
    - All transfusions are compliant with recommendations from British Society for Haematology (BSH),<sup>6,7</sup> SHOT,<sup>8</sup> and NICE<sup>9</sup>
    - A TACO risk assessment is undertaken utilising the SHOT risk assessment tool<sup>1</sup> prior to transfusions<sup>10</sup>
    - Appropriate mitigation measures are initiated for individuals at risk – see FAQ document<sup>5</sup>
    - 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>11</sup>
    - Inclusion of guidance on timely management of TACO, including the use of diuretics, oxygen, and other supportive measures
    - 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
    - Use of the structured TACO incident investigation tool<sup>11</sup> from SHOT
  - Review, update, and **implement training programmes** to include:
    - Use of TACO pre-transfusion risk assessment tool<sup>1</sup>
    - Appropriate use of mitigation measures – FAQ document<sup>5</sup>
    - Management of severe chronic anaemia in non-bleeding patients using minimal/single-unit transfusion support, and anaemia management with iron therapy where appropriate
    - Recognition and prompt management of TACO, importance of timely interventions and escalation of care as appropriate
    - 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
    - Knowledge and awareness to report TACO cases locally, as well as to MHRA and SHOT by hospital transfusion teams
  - Undertake regular audit** 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
- \*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](mailto:info@mhra.gov.uk) or [SHOT@nhsbt.nhs.uk](mailto:SHOT@nhsbt.nhs.uk)

# Case 1

Incorrect blood group  
transfused to post-  
transplant recipient

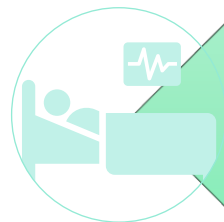
# Case 1 – Incorrect group issued post-transplant



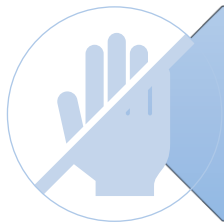
Transfusion laboratory issued incorrect ABO red cells to patient post allo-HSCT



LIMS had warning flag in place on patient record, but not heeded by BMS when issuing red cell units



BMS working night shift rushing to complete work remaining from late shift



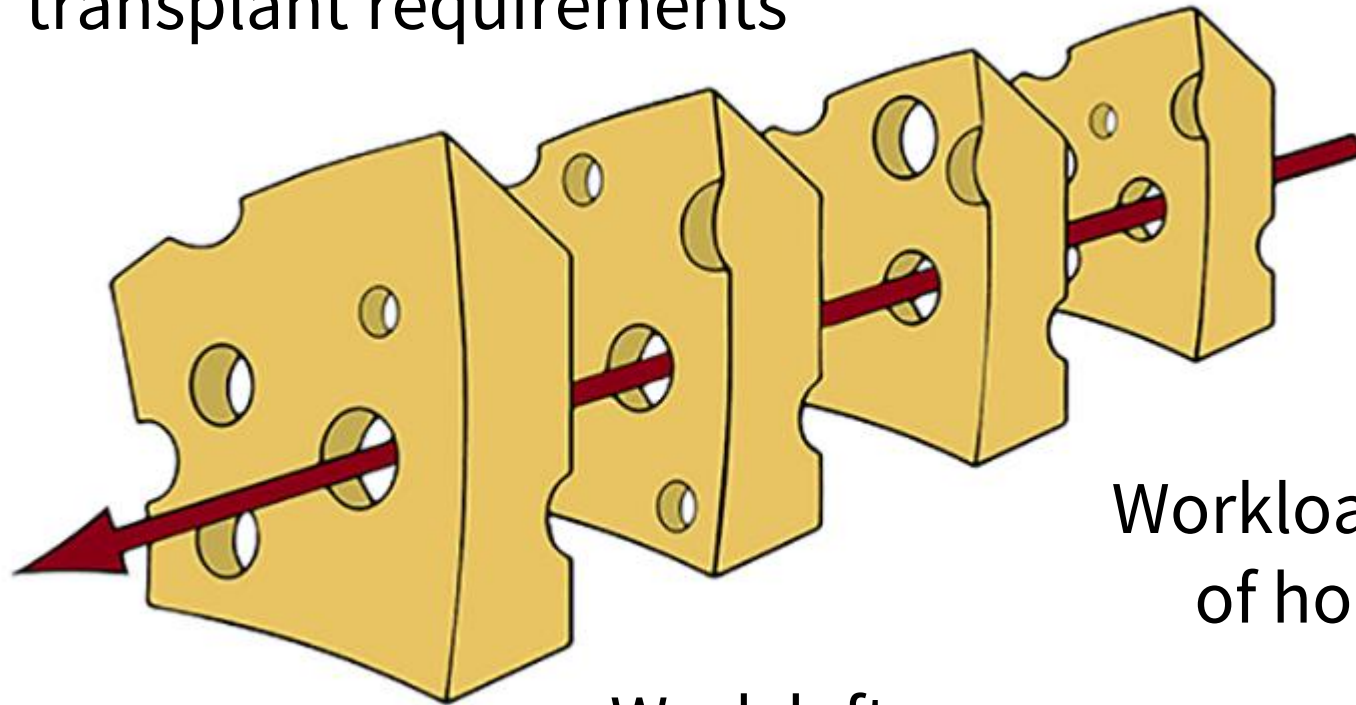
Very thorough investigation

ABO  
incompatible  
red cell  
transfusion

SOP not  
clear

Insufficient knowledge of  
transplant requirements

No LIMS algorithms for  
transplant patients



Alert in place,  
but not clear

Workload out  
of hours

Work left over was  
seen as a failure

Rushing

# Case 1 continued....



Transplant training session, competency and assessment in place but ineffective so redesigned, simulation exercises for transplant and LIMS alerts/flag



Review of all transplant patients/ Updated flag colours and moved icon to front and centre. Updated LIMS rules to, reworded alert




Increased formal handovers 2xday. Improved visibility of workload on LIMS. Increased rotation of shift working BMS into transfusion


# Case 2


Missed opportunities to identify TACO risks and implementation of mitigating actions


# Case 2– 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



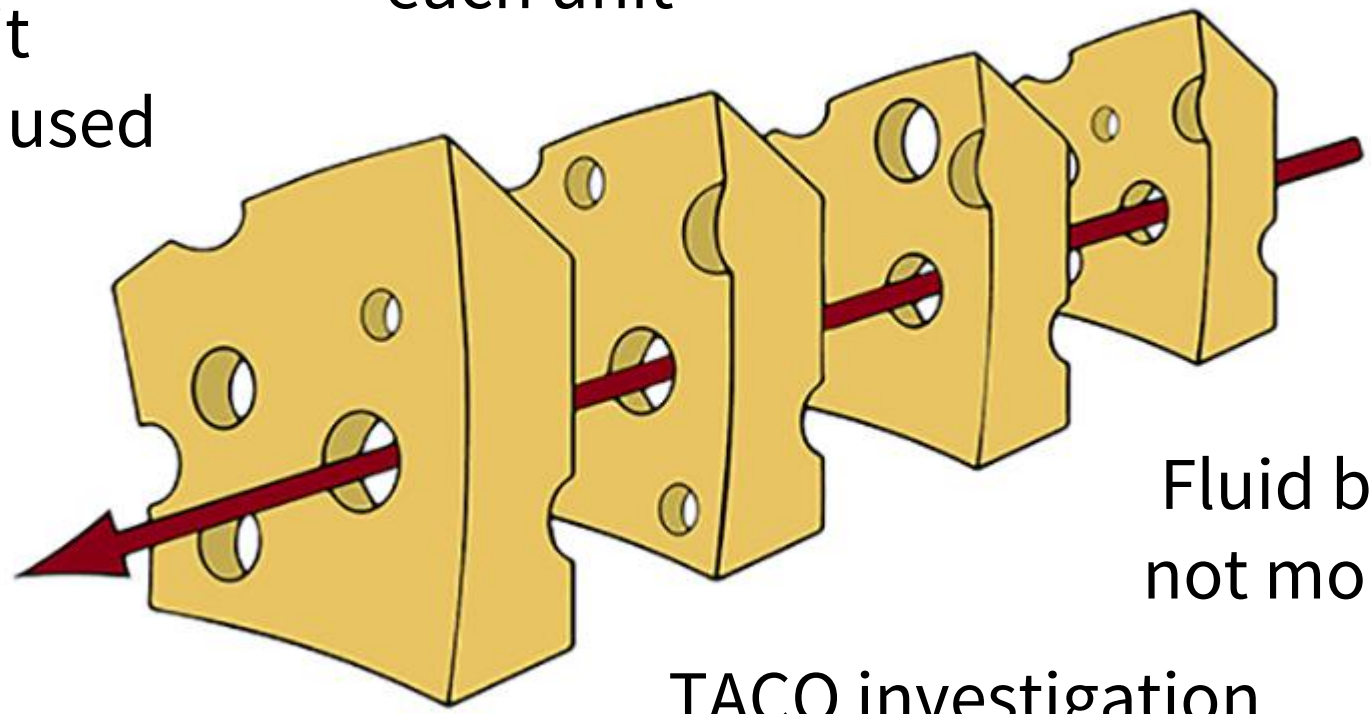
TACO due to over transfusion requiring HDU admission

Single unit approach not used

Not reviewed after each unit

TACO risks not identified

TACO risk assessment not completed



Fluid balance not monitored

TACO investigation tool not used

No implementation of PBM (Fe therapy)

## Case 2 continued.....



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

# Learning Outcomes



Explain how haemovigilance (HV) and transfusion practice impact patient safety

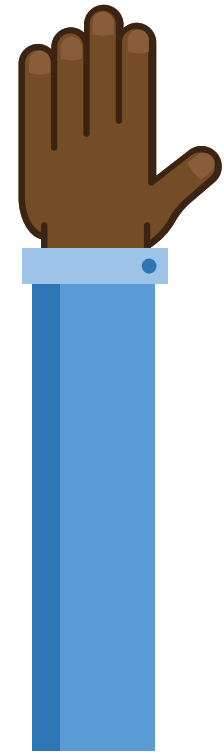
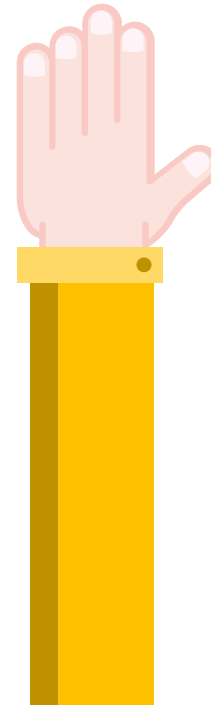
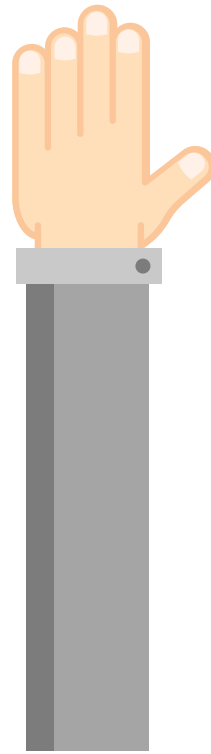
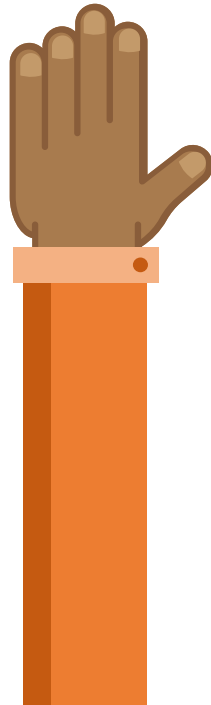
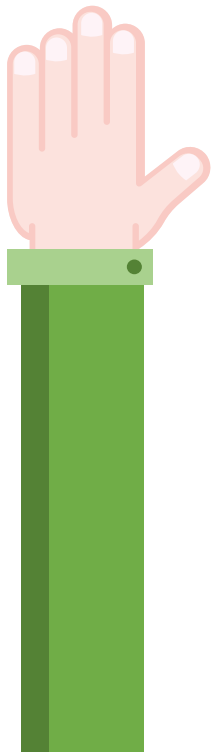


Describe tools used in incident investigation, and the impact of appropriate incident investigation



Evaluate cases of good and insufficient investigation

# Any questions?





- Many more resources, including the 2023 Annual SHOT Report are available on the SHOT website [www.shotuk.org](http://www.shotuk.org)
- In particular our educational resources
  - SHOT Bites
  - SHOTcasts
  - Webinars
  - Videos (Laboratory errors)
  - Email signatures





## Acknowledgements

- The SHOT team
- The Steering Group and Working Expert Group members
- The vigilant reporters and hospital staff who share their incidents
- **For further information visit:** [www.shotuk.org](http://www.shotuk.org)