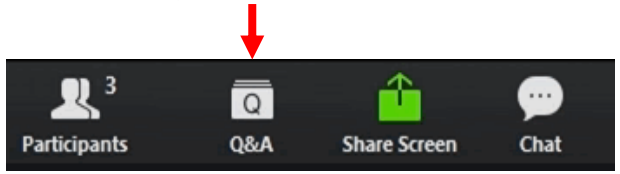
Optimising learning from incidents – joint SHOT, MHRA and UKTLC webinar

- Your microphone is muted by the host and will remain muted throughout the session
- Please type any questions into the **Q&A** box below, do not use the chat facility for questions
  - Questions will either receive a response through Q&A or will be answered live



- The session will finish with a poll for your immediate feedback

Thank you for attending!

Music: https://www.bensound.com

Panellists for this webinar

Dr Shruthi Narayan, SHOT Medical Director and Consultant Donor Medicine, NHSBT

Dr Alison Watt, HFE expert and SHOT Steering Group member

Emma Milser, SHOT Haemovigilance/Patient Blood Management Specialist

Dr Jennifer Davies, UKTLC Deputy Chair, Transfusion Laboratory Manager, Royal Devon University Healthcare NHS Foundation Trust, Deputy Chair of UK Transfusion Laboratory Collaborative and SHOT SG/WEG member

Kerry Dowling, UKTLC chair and Blood Transfusion Laboratory Manager, Blood Transfusion Laboratory Manager University Hospital Southampton NHS Foundation Trust

Caryn Hughes, SHOT Operations Manager

Chris Robbie, MHRA Haemovigilance specialist

Webinar discussions moderated by SHOT team members:
Nicola Swarbrick, Raquel Lopez, Caryn Hughes and Emma Milser


thank you

Outline of this webinar

- Overview and background from SHOT
- Insights from MHRA
- Application of human factors principles – HFIT and illustrative cases
- Input from UKTLC re survey results and standards relevant to incident investigation
- Holistic approach to safety, available resources and conclusions
- Q&A – all panellists

Learning objectives

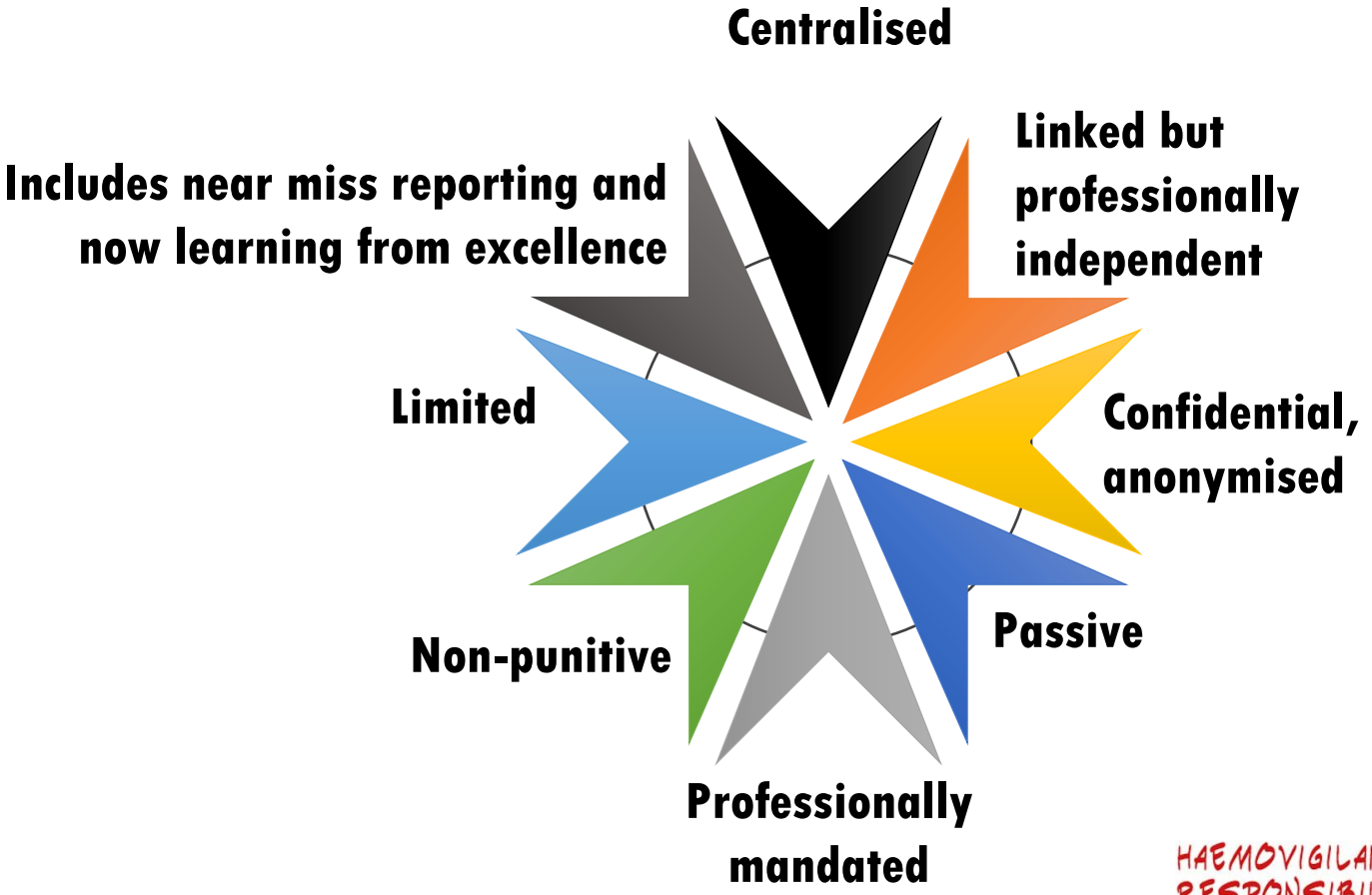
Understand the importance of effective incident investigation

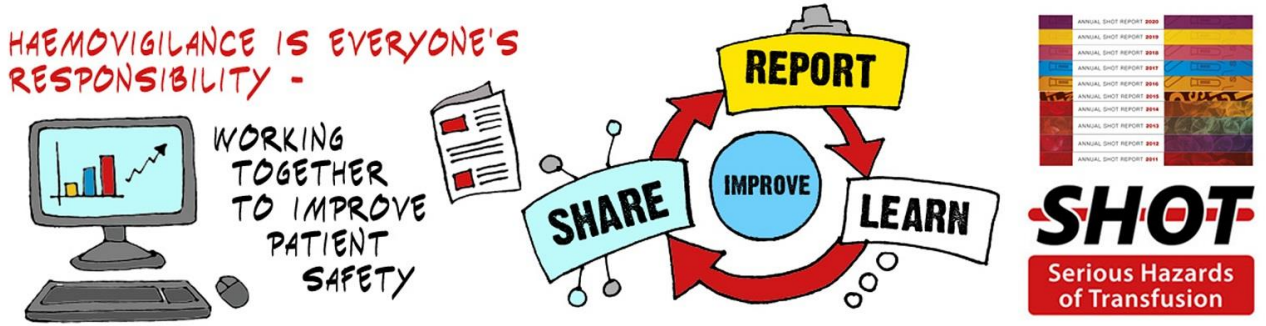
Identify how optimising learning from incidents contributes to transfusion safety

Explore contributory factors and effective corrective and preventative actions

Explore some illustrative case studies

SHOT – UK haemovigilance system

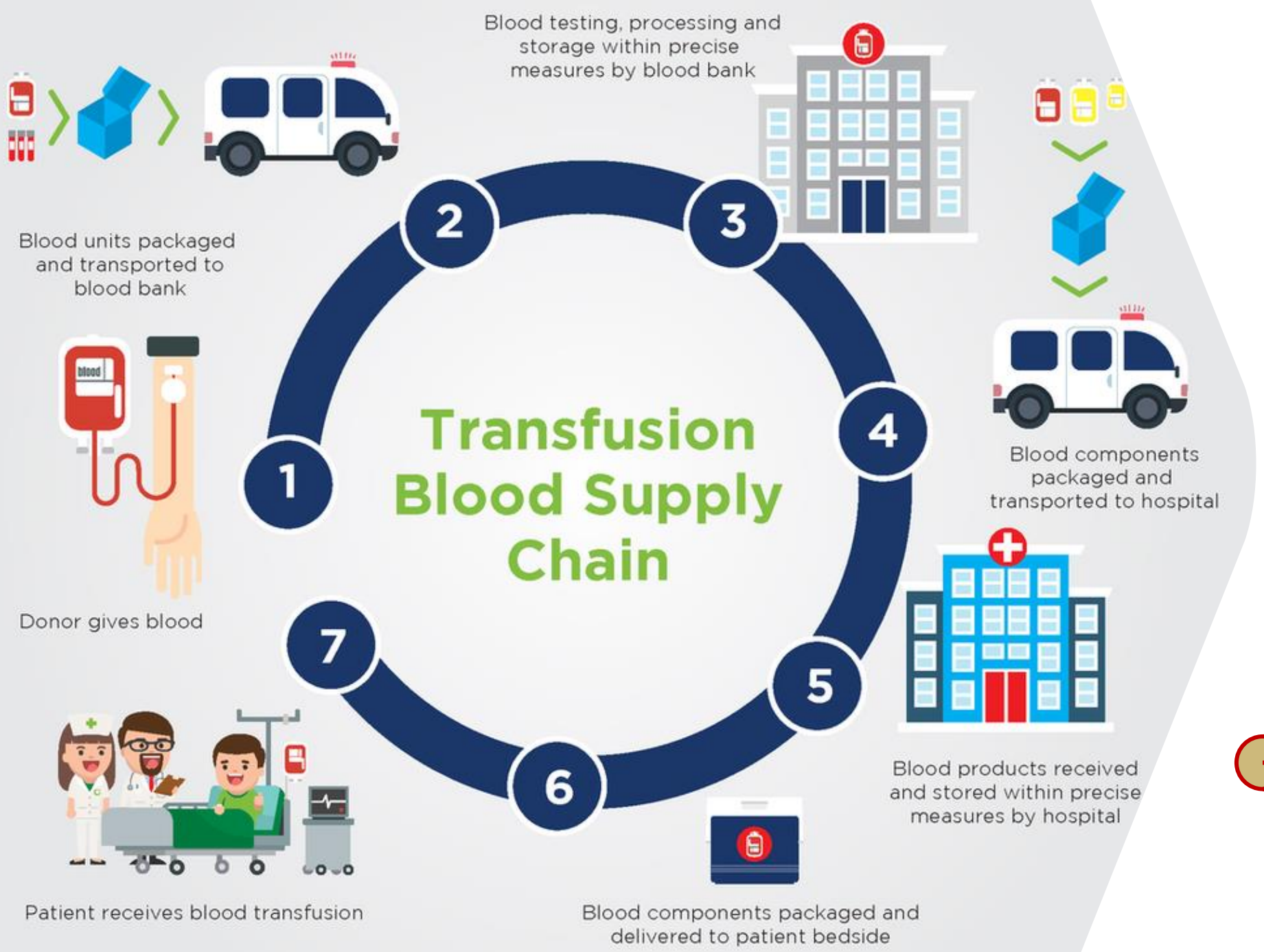




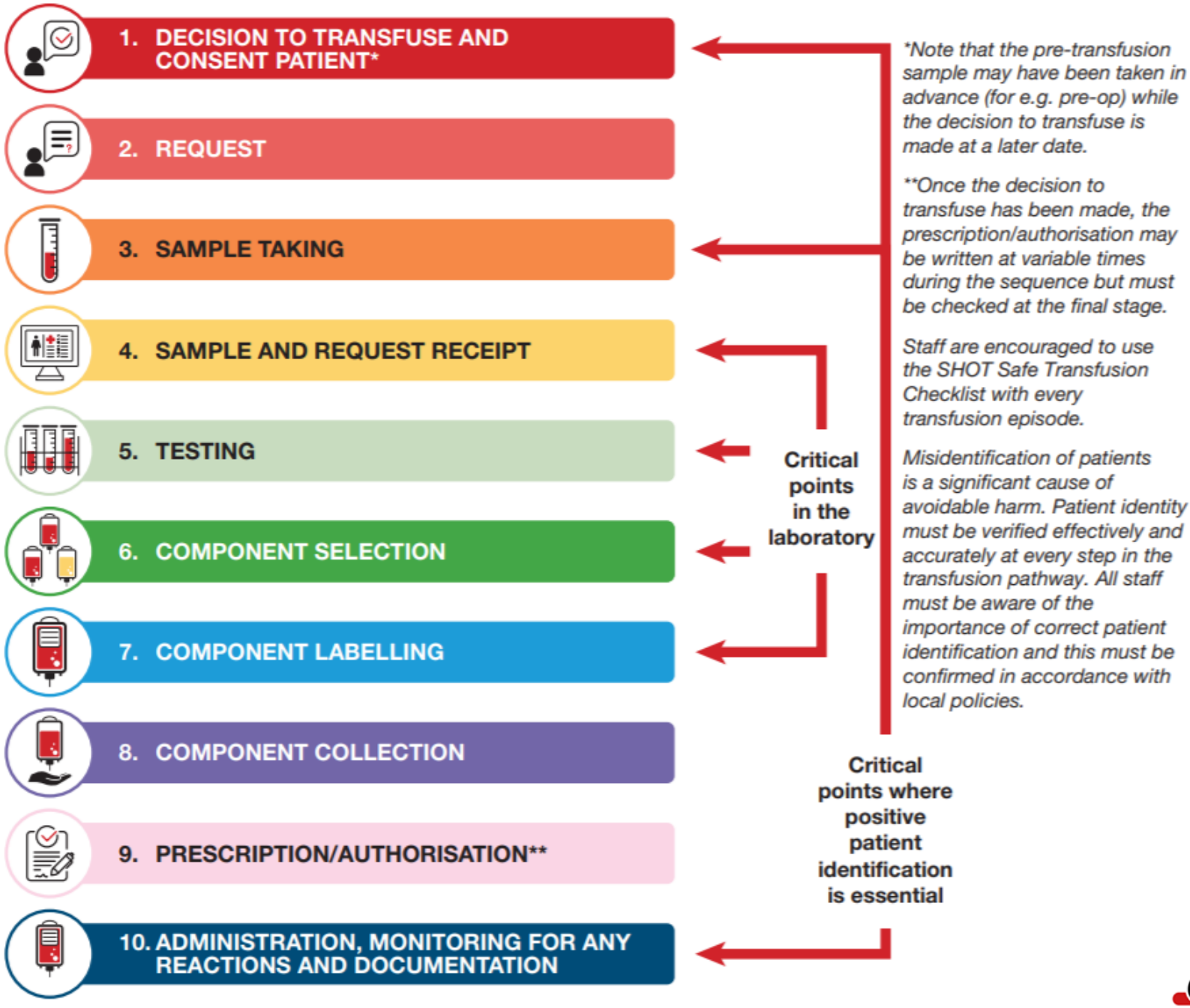
Improving transfusion safety

SHOT Serious Hazards of Transfusion

The basic premise of a national haemovigilance system is the development of a coordinated approach to the continuous improvement of the safety, availability and appropriate use of blood and blood products and related activities across all organisations involved in the transfusion chain.

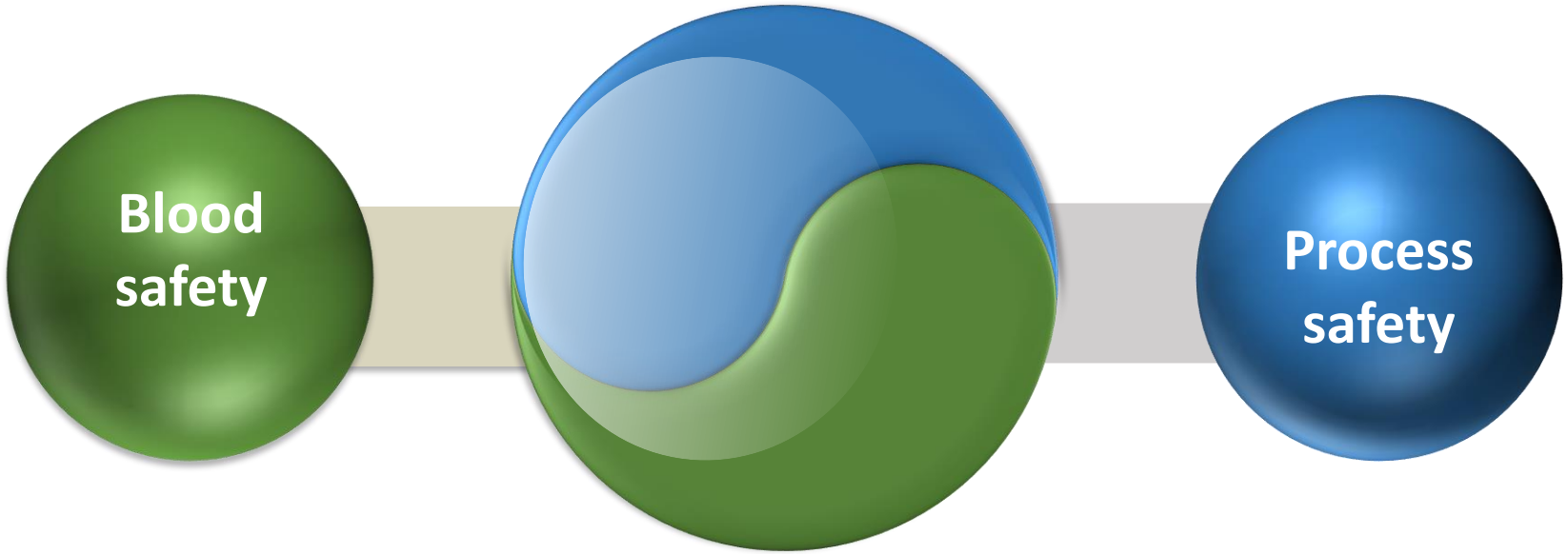


Transfusion is a complex, multistep process requiring effective communication between teams, good coordination and collaboration to ensure safety



SHOT Serious Hazards of Transfusion

Transfusion safety

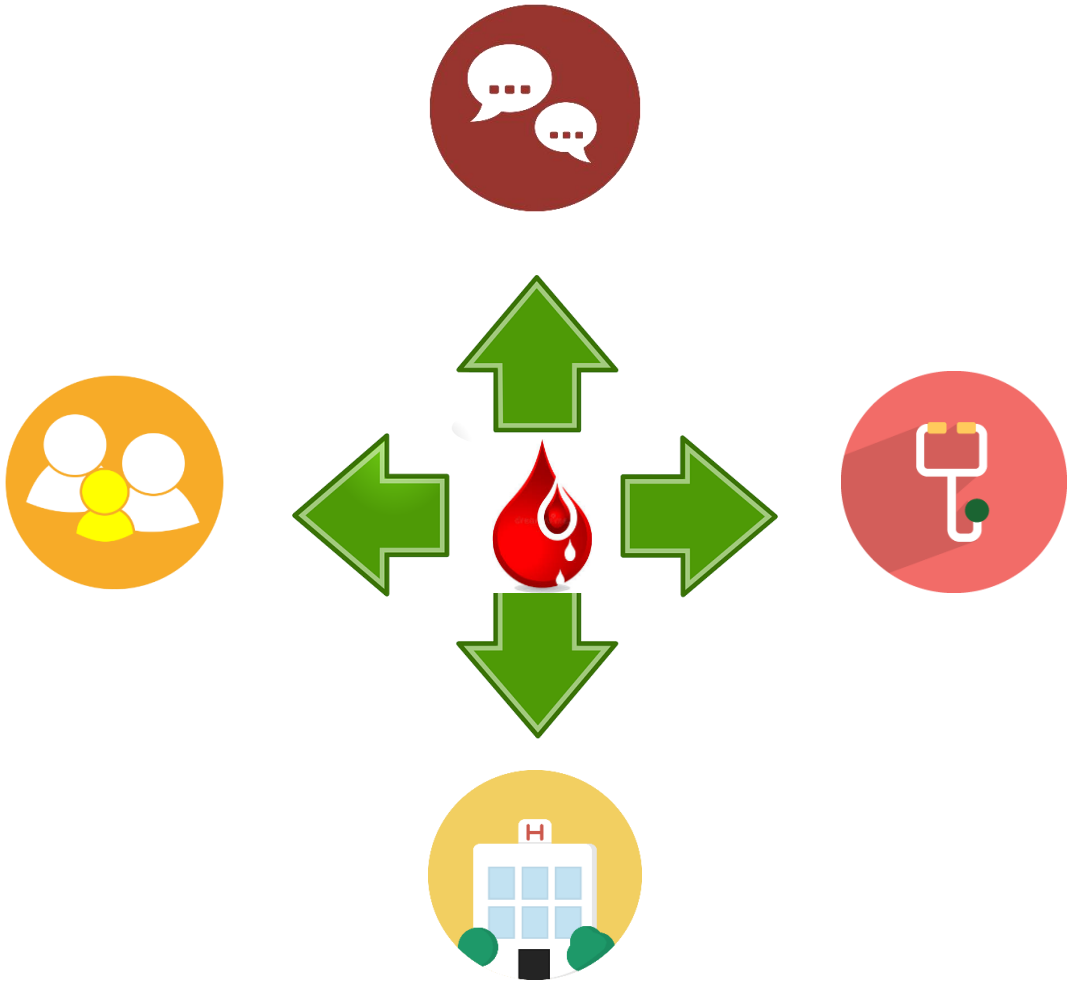


Transfusion safety is not just about safe blood components, it is also about process-based safety.

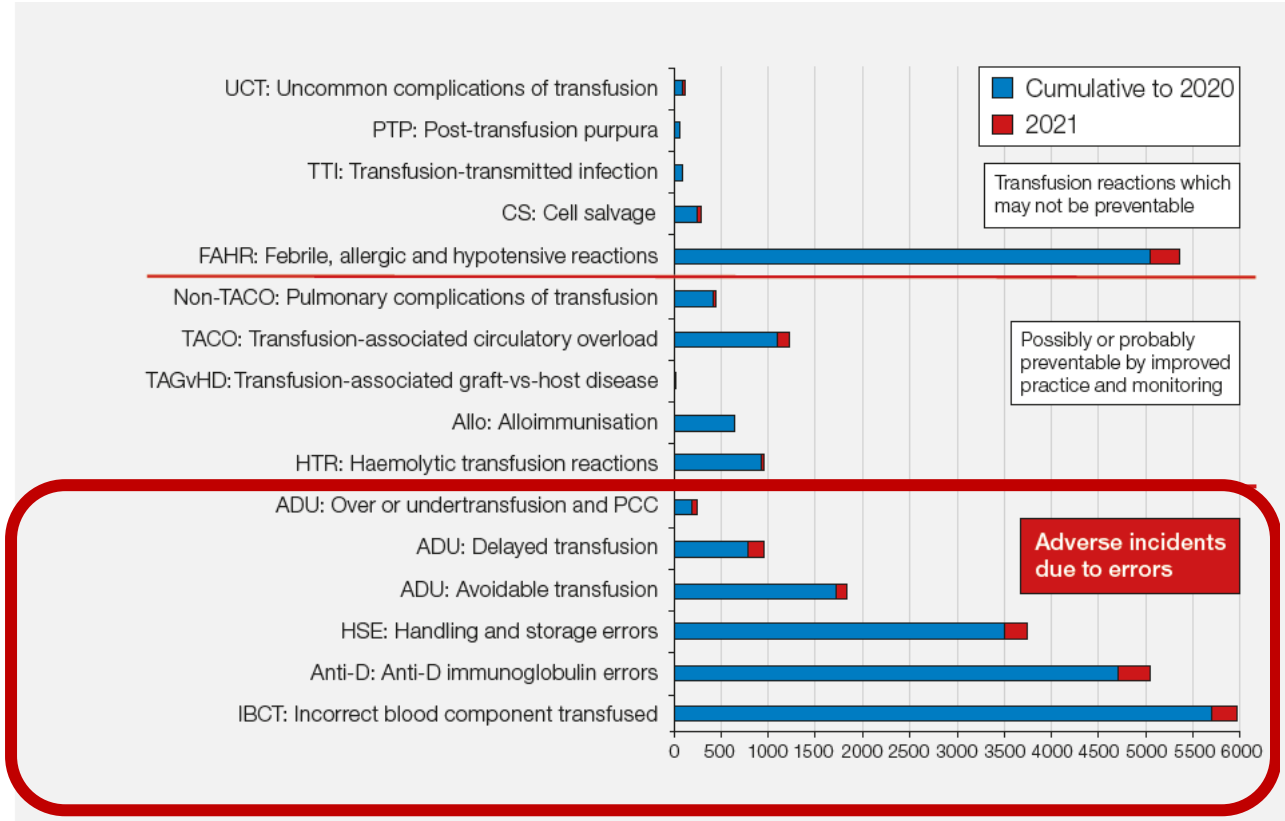
Transfusion incidents

Image from: https://www.123rf.com/stock-photo/wrist_bands.html?sti=m2mns1yu6gqowx8sp2|

What potential impacts do transfusion incidents have?

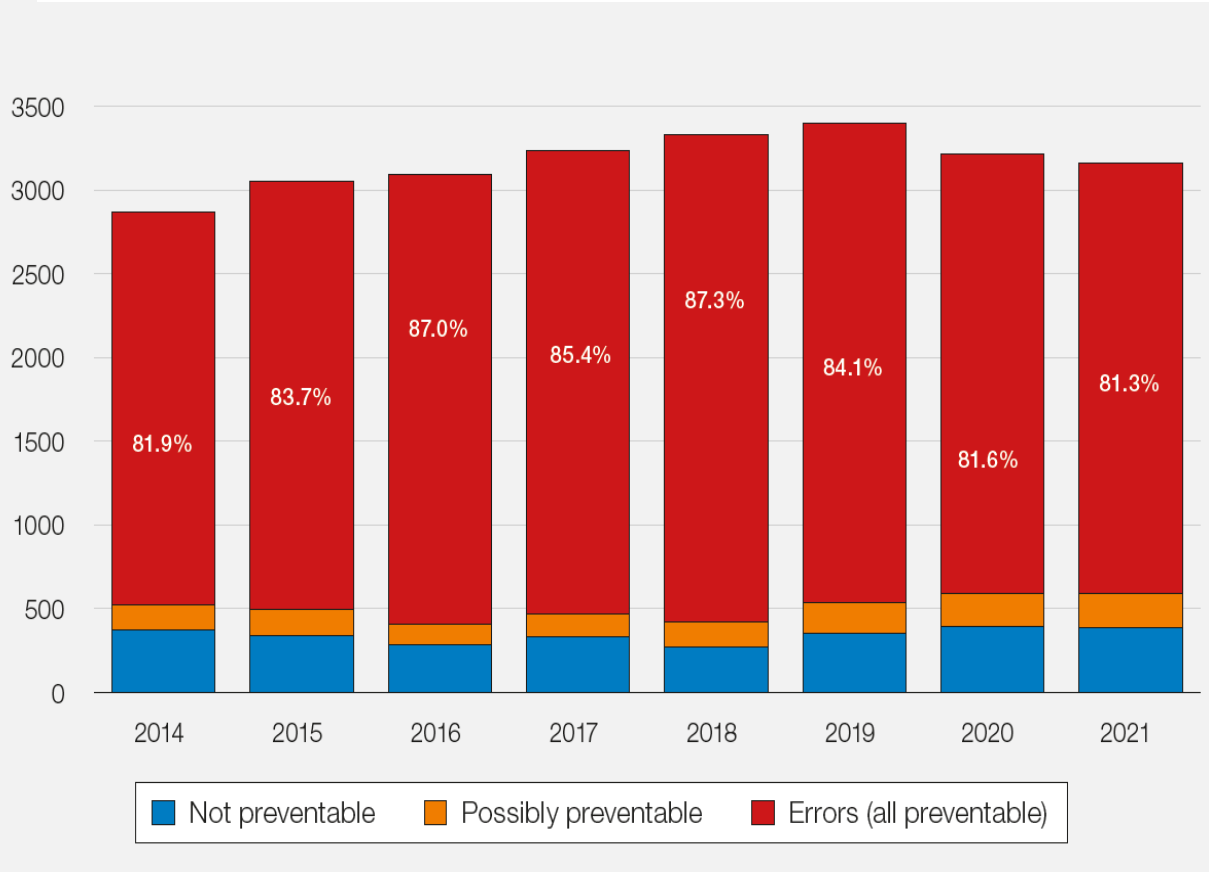


Cumulative data for SHOT categories 1996-2021



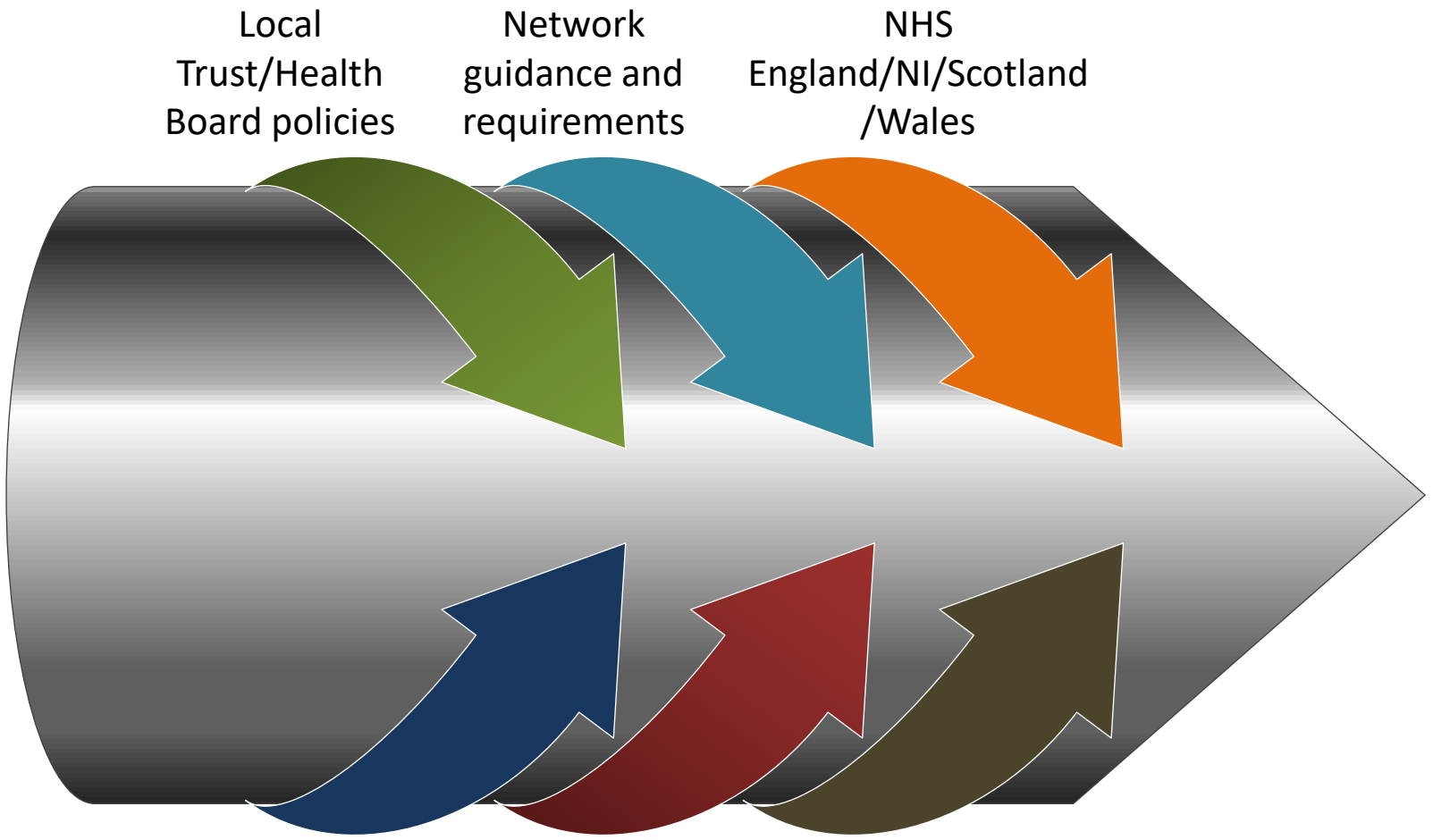
*Data on alloimmunisation is no longer collected by SHOT since 2015

Errors as a percentage of total reports 2014- 2021



Potential reasons for continuing trend in adverse events reported to SHOT

Influences on policies, procedures and practices



Investigating and learning from safety incidents

Medicines & Healthcare products Regulatory Agency

SHOT/MHRA incident investigation webinar

Chris Robbie, MHRA Haemovigilance specialist
SHOT Working Expert and Steering Group

2023

Blood Safety and Quality Regulations

2005 Regs define the terms SAE and SAR

2006 Amendment 12 B inserts requirements for reporting SAEs and SARs

Medicines & Healthcare products Regulatory Agency

Key points

- All relevant information
- As soon as known
- Identify “preventable causes”
- Submits a Confirmation on completion of the investigation

EUROPEAN UNION

COUNCIL OF EUROPE

CONSEIL DE L'EUROPE

Good practice guide

EU Member States shall ensure, according to Directive 2005/62/EC, that the quality system in place in all blood establishments complies Good Practice Guidelines with the standards and specifications set out in the Annex to that Directive

- In other words

- The GPG applies to the implementation of the BSQR!

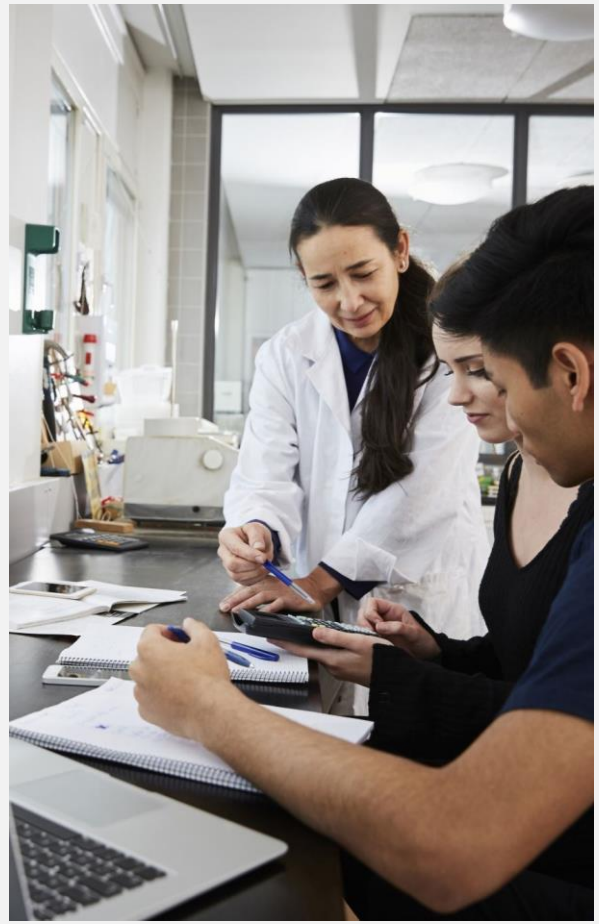
Medicines & Healthcare products Regulatory Agency

Key points of the GPG

An appropriate level of root-cause analysis should be applied

If the true root cause(s) of the issue cannot be determined, consideration should be given to identifying the most likely root cause(s)

Where human error is suspected or identified as the cause, this should be justified having taken care to ensure that process, procedural or system-based errors or problems have not been overlooked



Key points continued

Appropriate corrective actions and/or preventive actions (CAPAs) should be identified and taken

The effectiveness of such actions should be monitored and assessed in accordance with quality risk management principles.

Further detail is found in Chapter 9

Common problems with SABRE reports

Late reporting

- Delayed Notification
- After completion of investigation
- Delayed Confirmation
  - Trust-wide SUI investigations often delay the legal reporting requirements unnecessarily

Delays result in

- Failure to remember detail
- Loss of witness information
- Risk of repeat error
- Lack of scrutiny/ input from Haemovigilance experts

Common problems with SABRE reports

Lack of detail

- Poorly written and described
- Reports conclusions only
  - No information how those conclusions were reached

Lack of depth to investigation

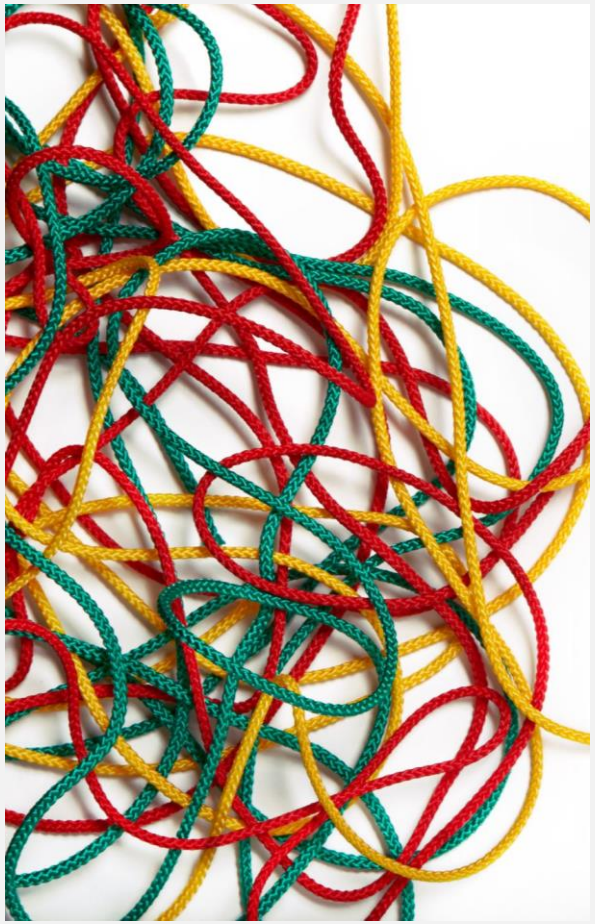
- RC does not investigate beyond “human error”
- System failures overlooked

Increases the risk of repeat errors and potential patient harm

Common problems with SABRE reports

Corrective measures

- Do not address RC that have been identified
- Place unnecessary responsibility of an error on an individual
- Do not improve aspects of the QMS
- Are incomplete



Corrective measures

Corrective measures

- Address **all** causative factors
- Use reflective practices as part of the investigation, not CAPA
- Ensure elements of the process, documentation, training, environment, staffing, workload, etc are improved before concluding human error
- Don’t leave CAPA unfinished (Committing to review an SOP is not the same as reviewing an SOP and re-writing it)

Common Inspection findings

2 **The Management of deviations was deficient in that:**

2.1 The assessment of Incident Root Cause and CAPA did not adequately reflect potential harm.

2.2 The incidents reviewed showed insufficient evidence of an appropriate level of investigation of root cause and implementation of CAPA.

2.3 There was no justification for the late closure of incidents.

2.4 There was no formal process for requesting investigation extensions and associated impact risk assessments.

2.5 There was no justification for the allocation of incident investigation and close out times.

2.6 SABRE reports were not made “as soon as known”

2.7 There was no detailed trending of incidents.

Reference: CoE GPG 9.4.2, 9.4.3, 9.4.4. 9.4.5, 9.4.6, 9.4.7, 9.4.8

Insights from SHOT- Human factors and Ergonomics principles and incident investigations

Common themes from analysed reports

WARNING FLAGS

VALIDATION AND IMPLEMENTATION

STAFFING ISSUES

UPGRADING OF LIMS

OVER RELIANCE ON IT

INTEROPERABILITY

SYSTEM DOWNTIMES

ALGORITHMS AND RULES

TRAINING

The dirty dozen

Poor Communication

Complacency

Lack of Knowledge

Distraction

Stress

Lack of Resources

Pressure

Lack of Teamwork

Loss of Awareness

Accepting the Norms

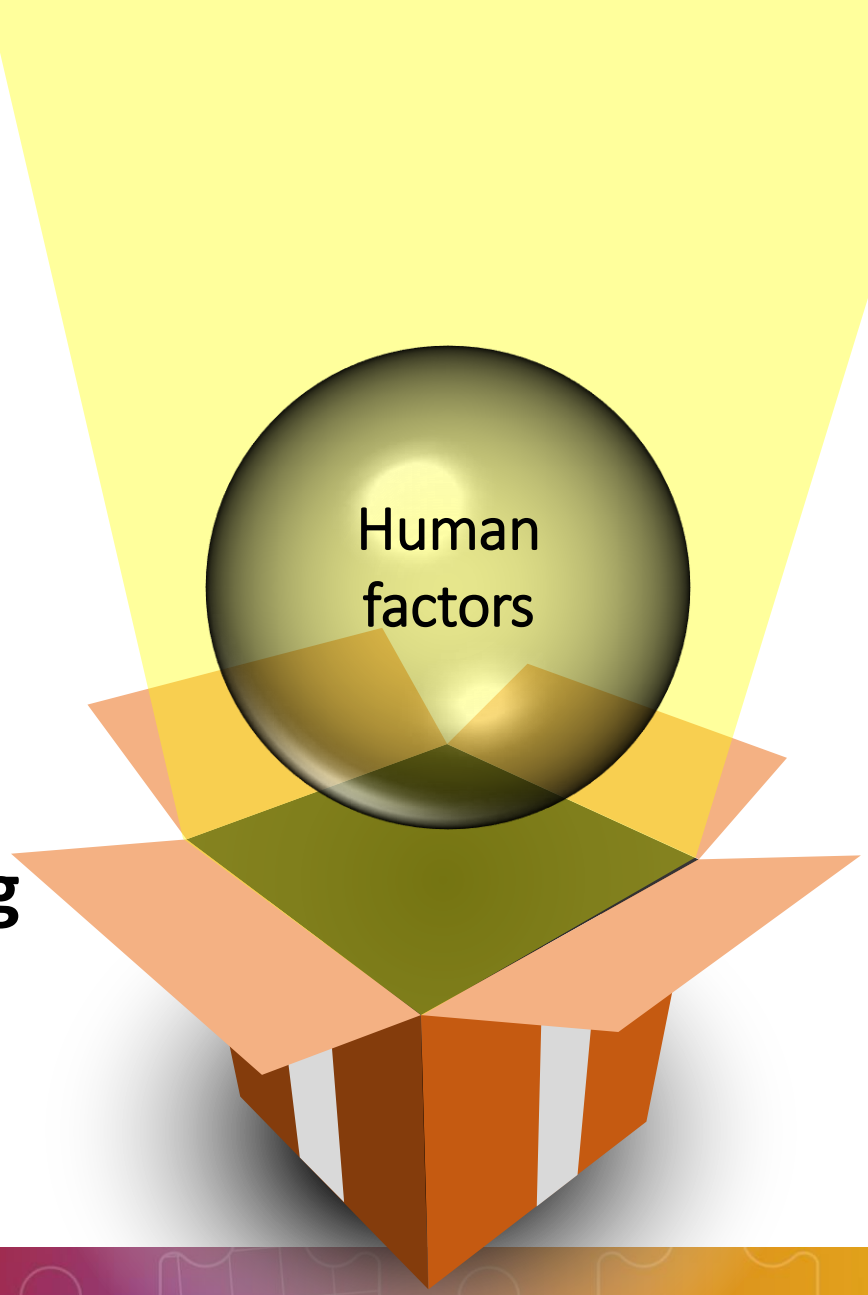
Fatigue

Lack of Assertiveness

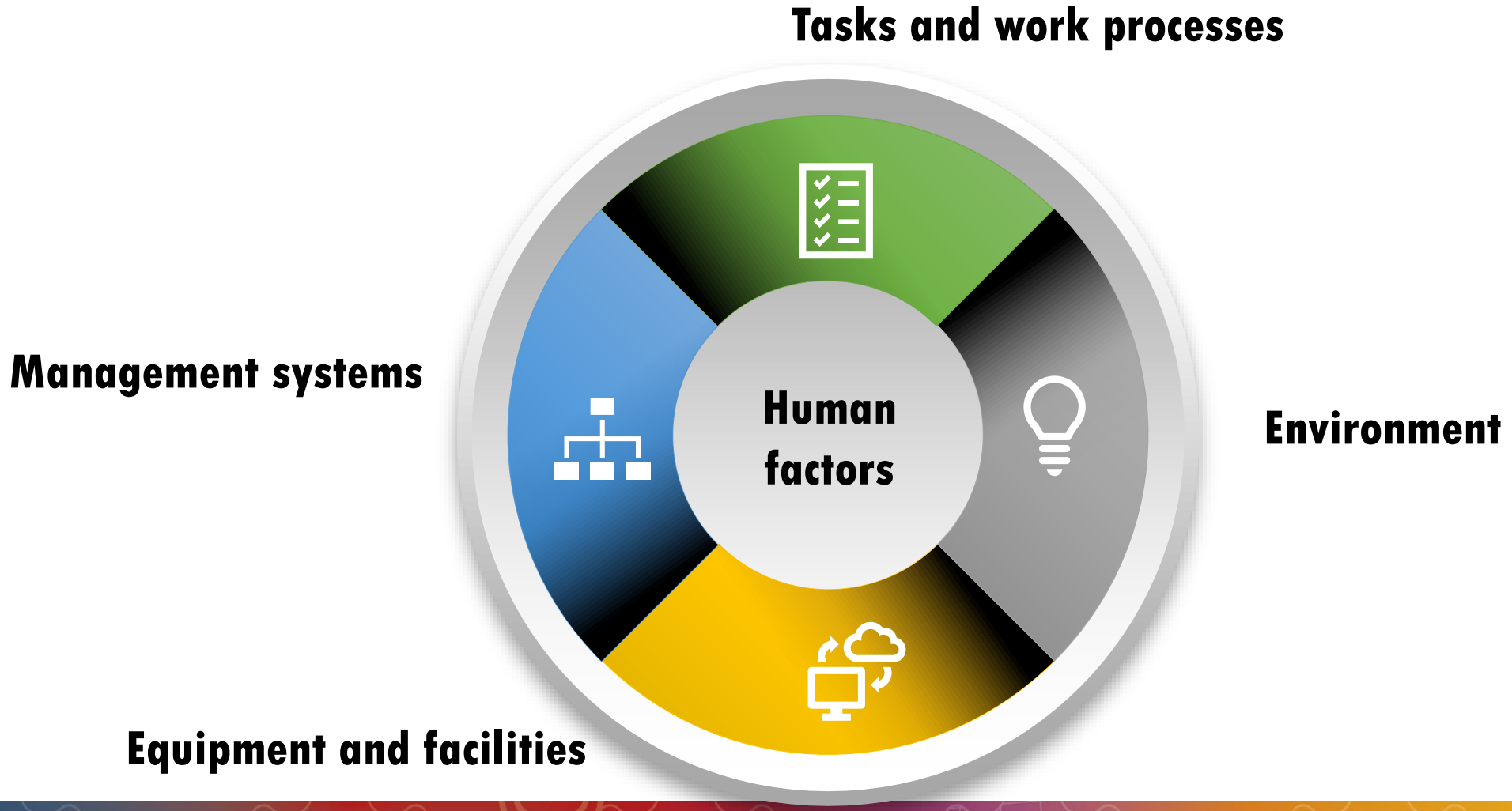
These recurring themes in the serial Annual SHOT Reports and a high incidence of preventable errors prompted the HFE work from SHOT

Human factors

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



‘Human factors’ does not mean focusing on humans alone



Why Human Factors?

Reduction in errors

Reduction in waste

Increase in staff engagement

Improved staff wellbeing

Better patient, donor, staff experiences

Improving safety

SHOT Serious Hazards of Transfusion

Human Factors is
not
Human error

Important to recognise

Why is human error not an acceptable conclusion following an incident investigation?

When human error is involved in an adverse event, the very occurrence of a human error implies that it can happen again. Human error is inevitable.

It is therefore important to understand the system factors facilitating human error and to develop system solutions.

If one well-intentioned, well-trained staff member working in their typical environment makes an error, there are system factors that facilitated the error.

Solutions that are only people focussed are all weaker solutions- they don't address the probability that the event will occur with other staff in similar circumstances. A high-profile event today may be forgotten in the future.

Our goal as part of learning from incidents is to increase safety in the long term and not allow a similar event to occur.

‘Human error’: Words shape worlds

Human error?

‘Human error’ points to individuals in a complex system

‘This is not to say that people are not responsible for their actions – of course they are. What is relevant is the difference between normal variability in human performance, and what we define as recklessness. Labelling either as ‘human error’ is not helpful.’- Steven Shorrock

SHOT
Serious Hazards of Transfusion

Address systems issues

Need to understand how systems work and address deficiencies

https://safetydifferently.com/the-use-and-abuse-of-human-error/

Human factors principles are important in all these aspects

SHOT Serious Hazards of Transfusion

2

2014 – **SHOT began collaboration with Loughborough University** to improve safety of transfusion processes across UK

1

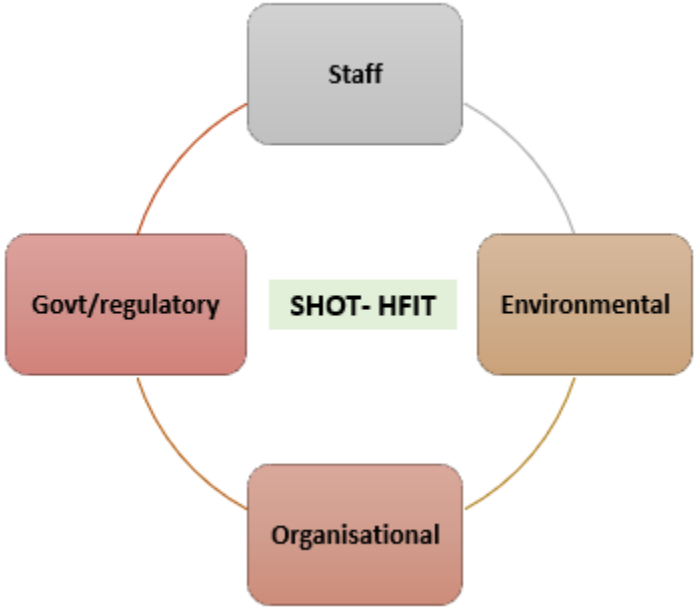
2013 - Annual SHOT Report
1st HF recommendation

Process redesign: Annual SHOT data consistently demonstrate errors to be the largest cause of adverse transfusion incidents. In line with human factors and ergonomics research it may be better to redesign the transfusion process

4

3

2016 – SHOT **introduced bespoke human factors investigation tool (HFIT)** because no model was ideal



2015 - **reviewed past SHOT cases** using various existing best practice HF models

7 HF models evaluated

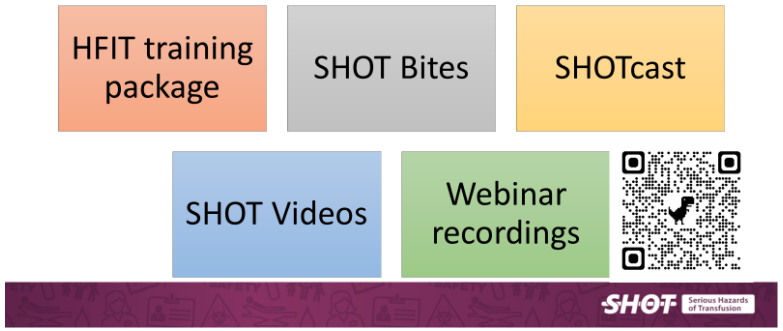
1. SRK Skills Rules Knowledge	**2. Active & Latent** Swiss Cheese Model	**3.AcciMap** Accident Mapping
4. HFACS HF Analysis and Classification System	**5. STAMP** Systems Theoretic Accident Modelling and Processes	
6. FRAM Functional Resonance Analysis Method	**7. SEIPS 2.0** Systems Engineering Initiative for Patient Safety 2.0	

6

5

2018 - Data from HFIT + use of learning package showed **slight reduction in staff blame**, so added link to HF videos for further education and created complementary resources

HF resources developed by SHOT



2017 - Data from 2016 HFIT over emphasis of blaming staff for incidents, so **introduced self-tuition package to enhance understanding of HF**

	Staff member	Environment	Organisation	Government/ regulatory
Total sum of scores assigned to each	16,891	5,087	3,862	1,141
Percentage assigned to each	62.6%	18.9%	14.3%	4.2%

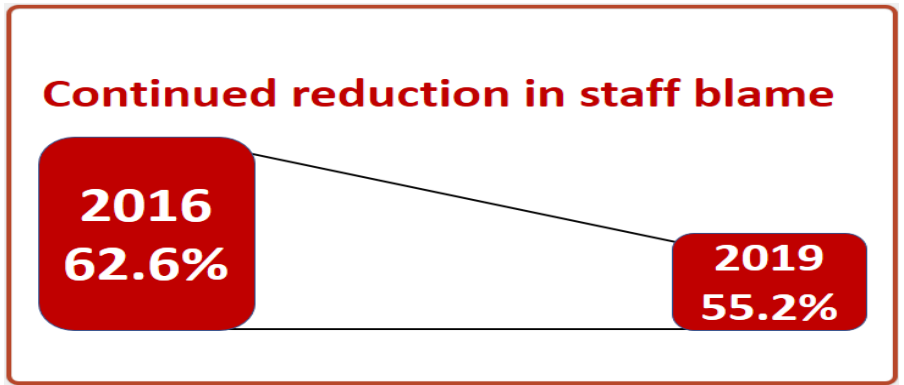
> 60% culpability assigned to staff members

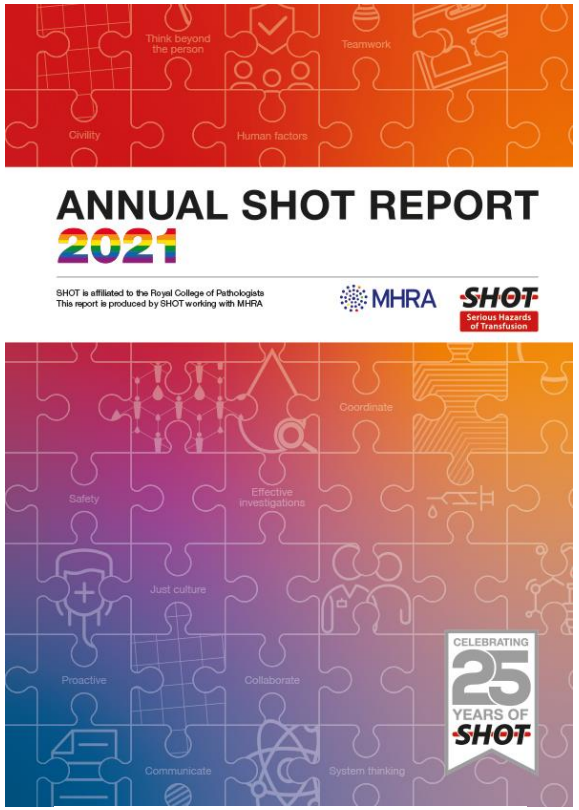
8

2020 – **published Loughborough collaboration in PhD thesis** showing impact of HFIT data and related SHOT HF initiatives. Combined Safety-I and Safety-II approach

7

2019 - Data from HFIT + use of learning package + use of videos showed **continued reduction in staff blame**





SCAN ME

SHOT Serious Hazards of Transfusion

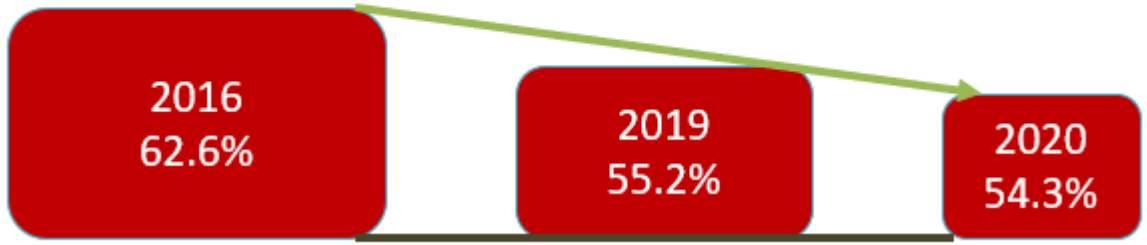
10

2022 – **published 1st analysis new HFIT** showing reduced staff blame and more system and organisational factors being considered

9

2021 - published final analysis of all 5 years of original HFIT and **amended the HFIT based on the Yorkshire Contributory Factors Framework (YCFF)**

Continued reduction in staff blame- statistically significant



SHOT
Serious Hazards of Transfusion

SHOT Working Expert and Steering Group

Loughborough University

MHRA

NHSEI- SEIPS work with a Never Event

SHOT Office Team

All reporters from across NHS organisations

All 4 UK Blood Transfusion Services

All professional organisations working in transfusion medicine

International: IHN, ISBT, WHO

Key:
MHRA – Medicines and Healthcare products Regulatory Agency
NHSEI – NHS England and Improvement
SEIPS – System Engineering Initiative for Patient Safety

IHN – International Haemovigilance Network
ISBT – International Society of Blood Transfusion
WHO – World Health Organisation

SHOT promoting use of human factors (HF) principles in transfusion

SHOT webinar on HF

Incident investigations

Learning from near miss and excellence

HF in Transfusion course

Virtual & interactive

Case-based discussions

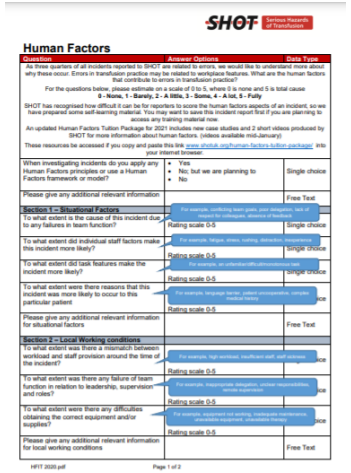
Accreditation being sought from CIEHF

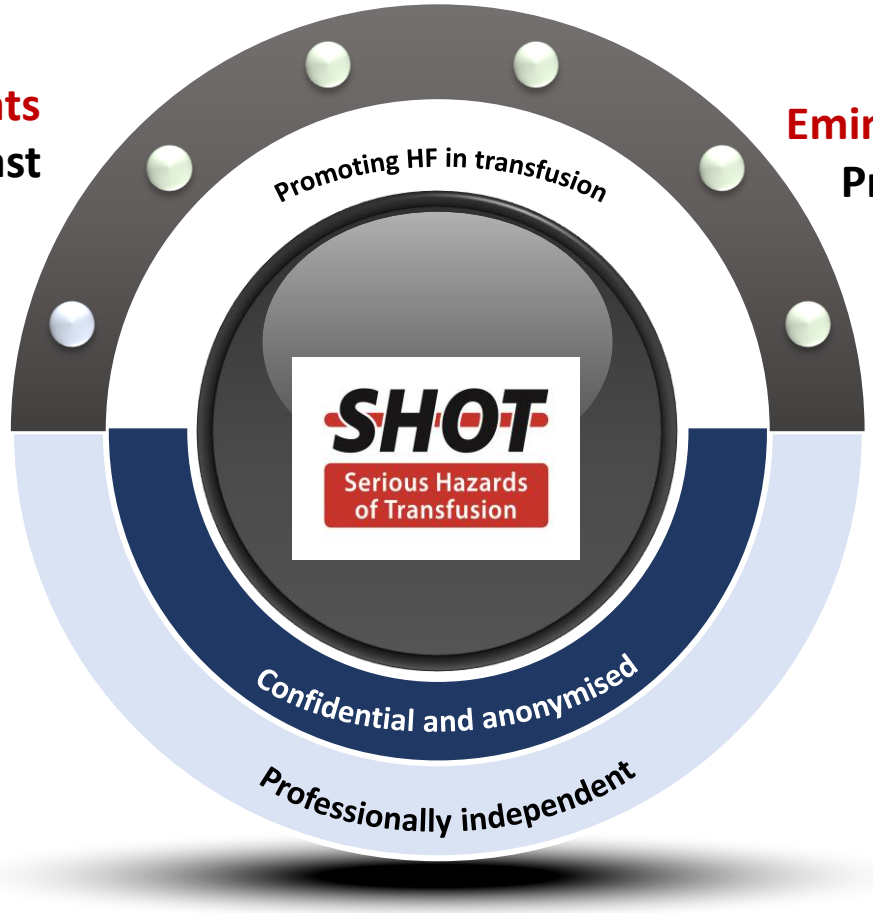
HF related resources in various formats

SHOT Bites, SHOT videos, SHOTcast

HF Investigation Tool + tips

and HF chapter in Annual SHOT Report





Eminent speakers at Annual SHOT Symposia

Prof Eric Hollnagel, Prof Sidney Dekker

Prof Rob DeBoer, Steven Shorrock

Demonstrating enhanced learning

By applying systems thinking and

HF principles to incident analysis

PEN Patient Experience Network

Recognitions and Awards

HSJ PATIENT SAFETY AWARDS 2022

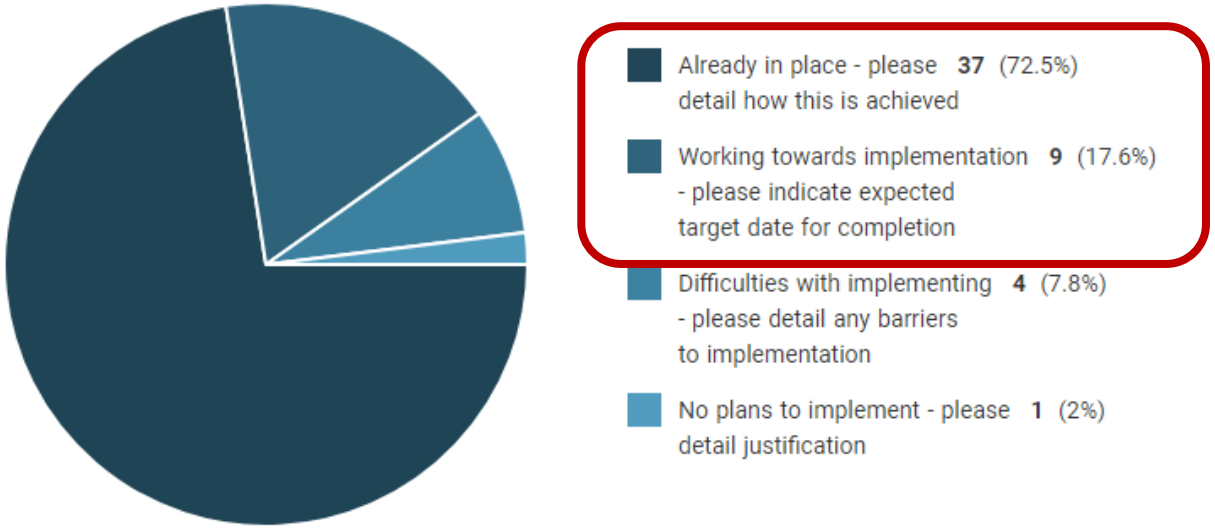
2022 WINNERS JUDGING PARTNERSHIP ALUMNI CONTACT US FAQS CONGRESS

WINNER: Serious Hazards of Transfusion, SHOT - Improving transfusion safety by applying human factors principles in the UK

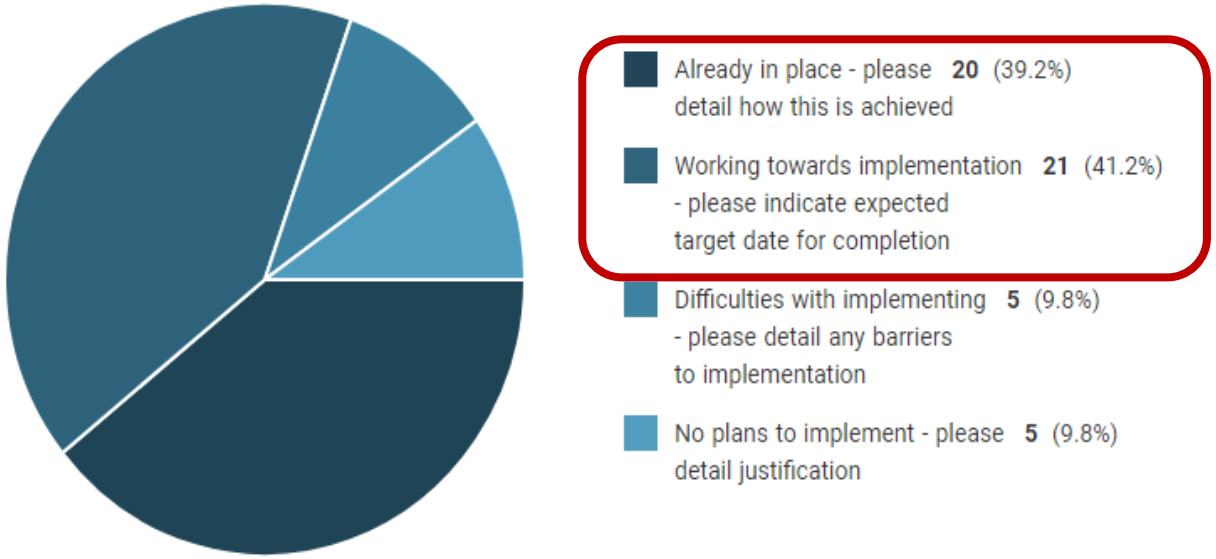
2021 Annual SHOT Report Recommendations survey- Ensure that staff involved in incident investigations receive adequate training in using human factors principles-based investigation frameworks and identifying effective corrective and preventative actions

Encouraging!

Progress with implementation in LABORATORY AREAS



Progress with implementation in CLINICAL AREAS



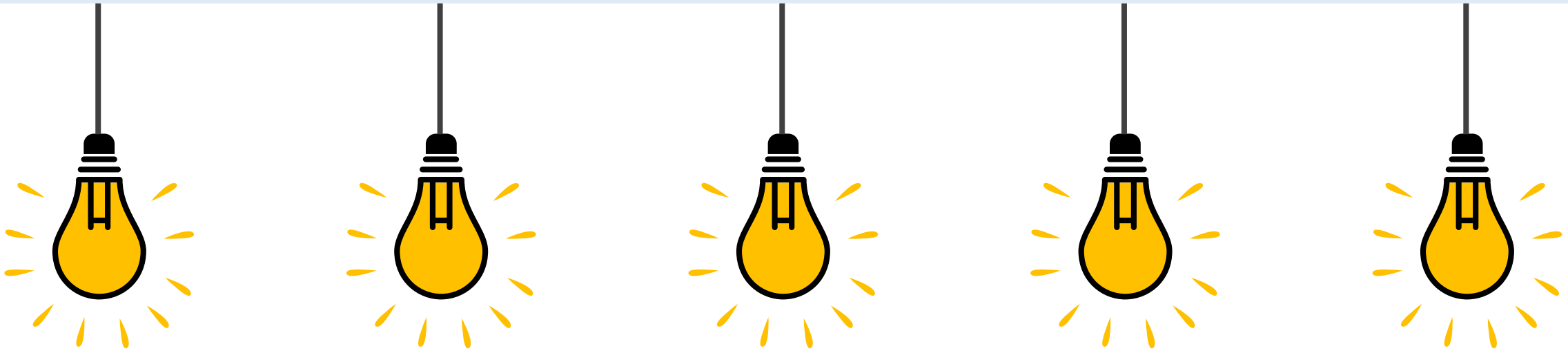
SHOT HFE Recommendations

Staff involved in investigating incidents should be fully trained in techniques for effective investigations, including an understanding of human factors methods

Investigations should identify, and include improvement actions, for all the contributory factors involved

The nine key principles outlined in the white paper titled ‘Learning from Adverse Events’ published by the Chartered Institute of Ergonomics and Human Factors (CIEHF, 2020) should be applied to investigating transfusion incidents in order to help with understanding a human factors perspective. A link to the paper is in the chapter resources section

Key messages from HFE analysis in recent Annual SHOT Reports



Attribution bias

Incident investigators should analyse all evidence as impartially as possible

Human factors

Incident investigations need to incorporate questions using HF principles

Missed opportunities

Systemic causes need to be identified to build robust long term solutions

Training and support

Staff need to be trained in basics of HF and have access to HFE expert

Vein to vein audit

Staff encouraged to participate in a HF based v2v audit

Overview of incident investigations- key principles

Why investigate?

- Mitigate impact of incidents and identify contributory factors
- Identify strengths and weaknesses in processes
- Make improvements to processes
- Learn from mistakes and victories
- Build future improvements to the QMS
- Ensure patient safety from a robust QMS and safe component

It is NOT to BLAME individuals for the errors made

Incident Investigation

Initial assessment

What went wrong?

Why it went wrong?

What can be done to stop it going wrong again?

Remedial Actions

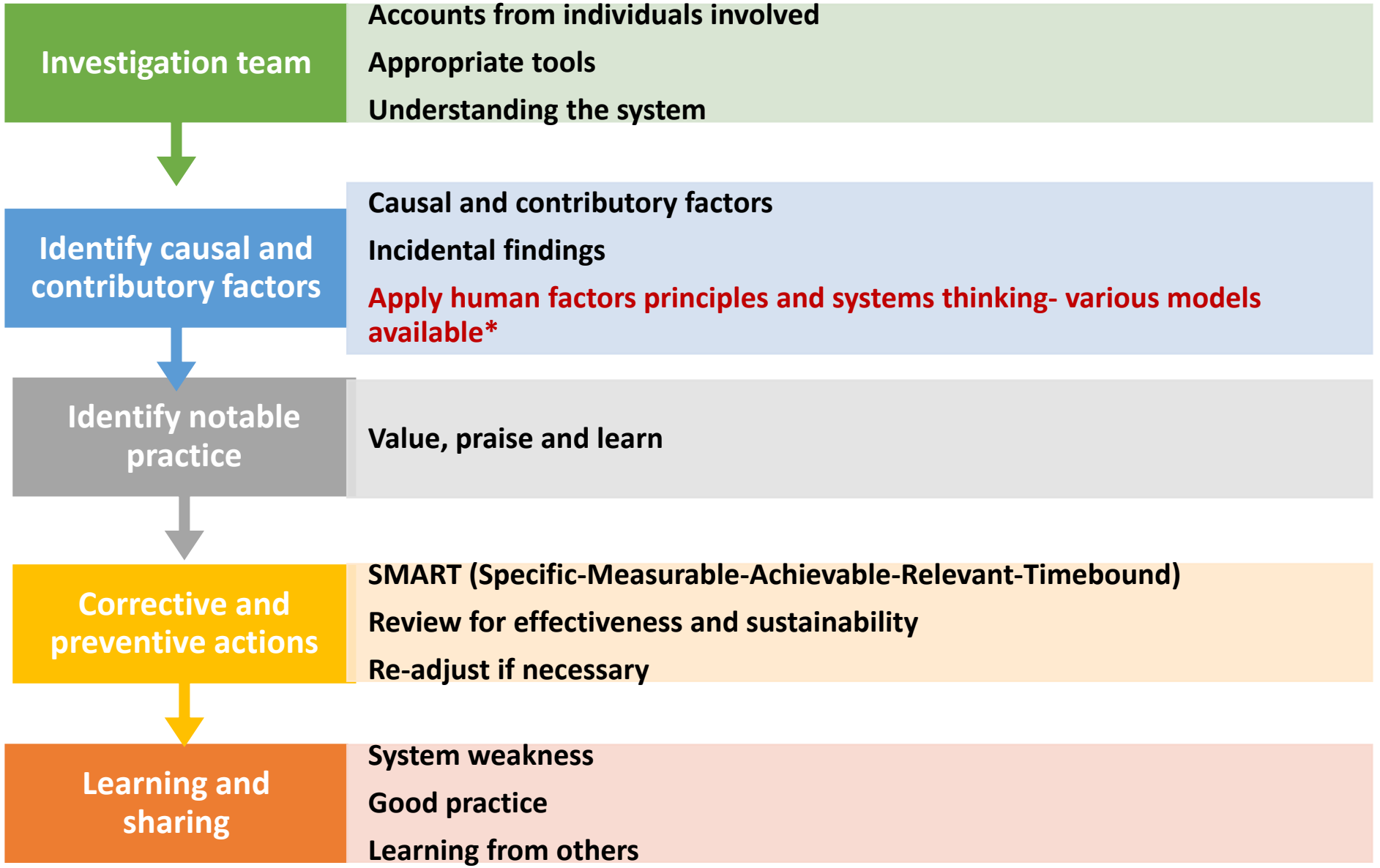
Actions taken immediately to ensure risk to patient is minimised

Is the patient safe?
Is the future patient safe?

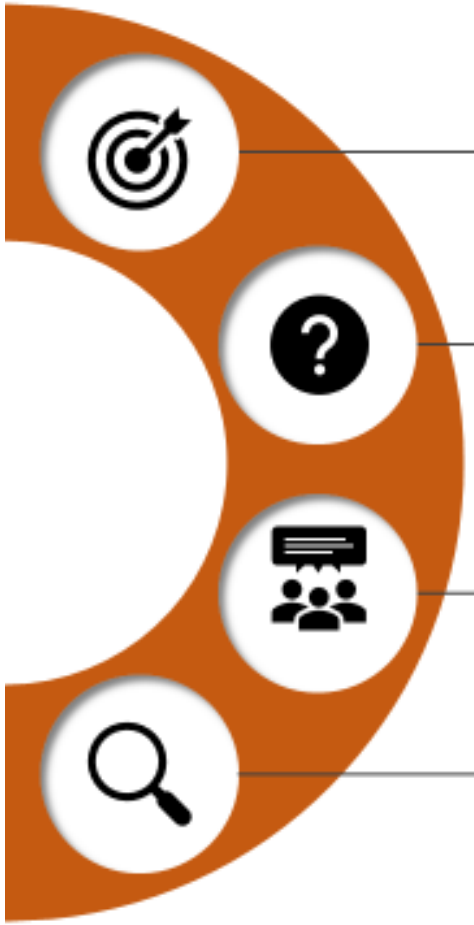
Does the service/task need to be suspended?

What can be done to make the system safe during the investigation?

Investigation process



Frameworks/Models incorporating human factors



PEAR
People, Environment, Actions, Resources

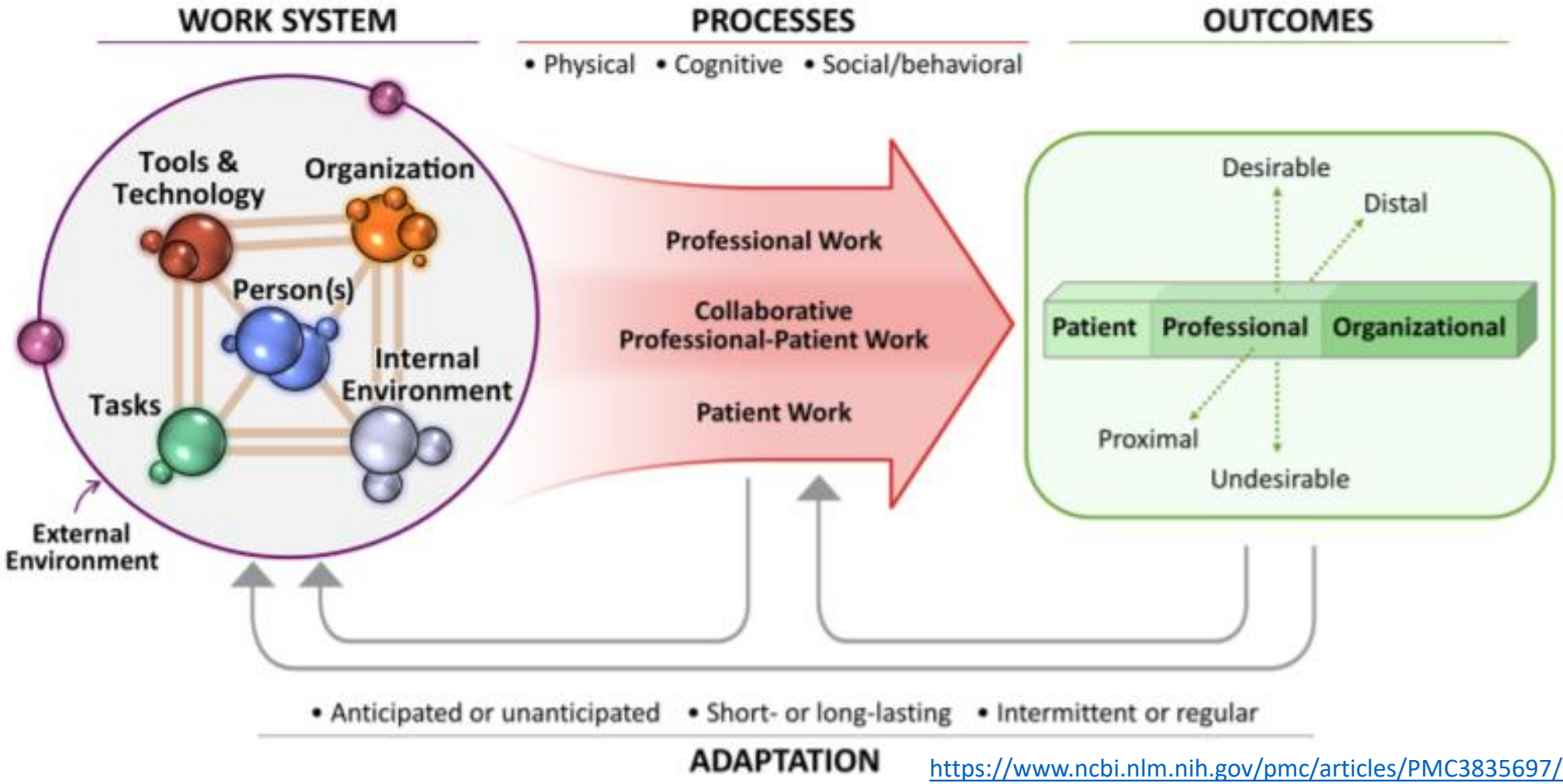
SHELL and SHEEP
Software, Hardware, Environment, Liveware
Systems, Human Interaction, Environment, Equipment, Personal

HFACS
Human Factors Analysis and Classification System
(based on James Reason's Swiss Cheese Model)

Others: The London Protocol, Yorkshire Contributory Factors Framework, etc

HFIT from SHOT has been updated based on the Yorkshire framework

HF offers a systems view: SEIPS 2.0 model

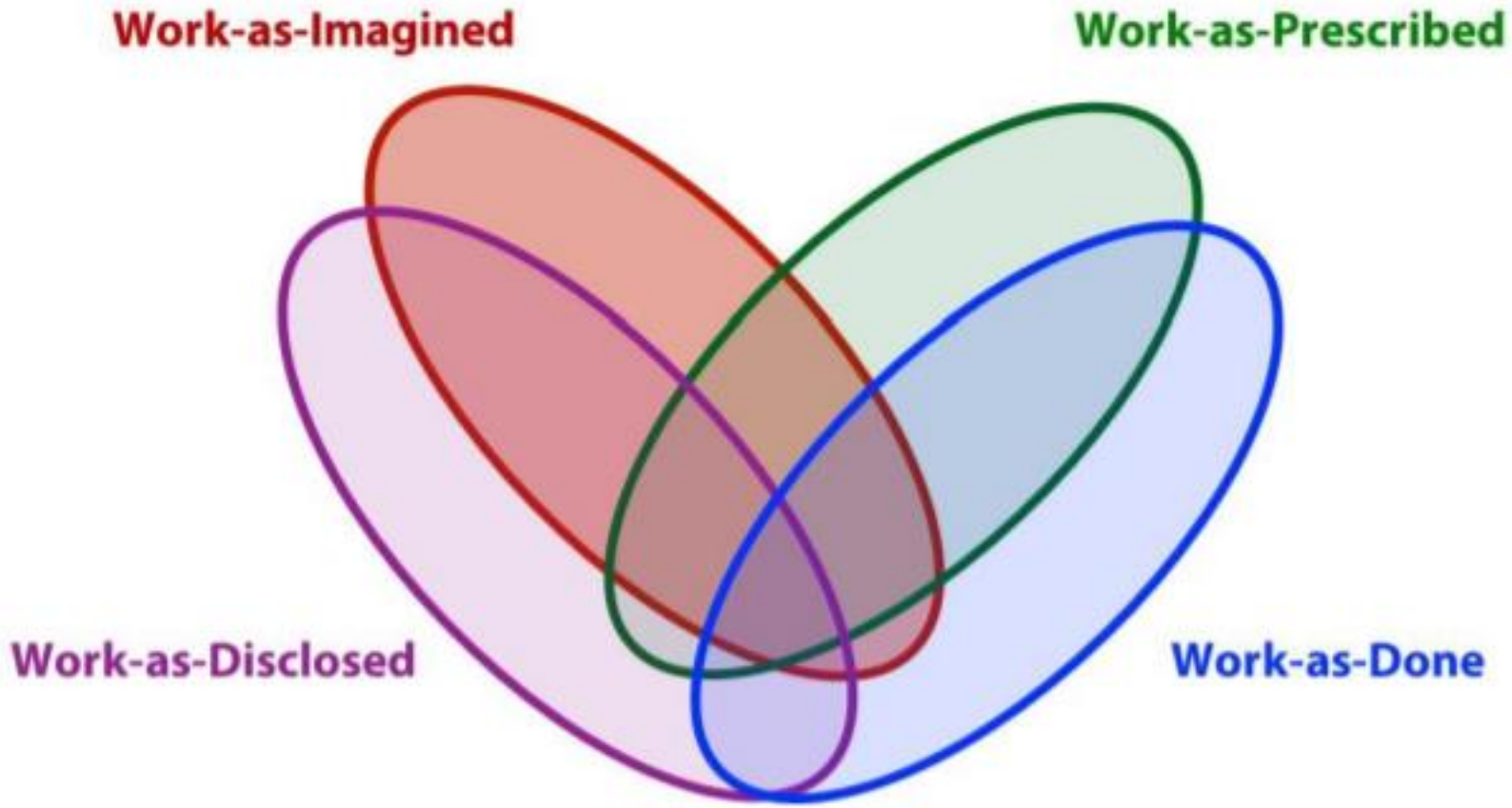


https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3835697/pdf/nihms521772.pdf

- **The Systems Engineering Initiative for Patient Safety (SEIPS) models** provide a framework for integrating HFE in health care quality and patient safety improvement
- This is one of the available systems-based investigation models, and helps investigators to consider the full range of contributory factors across a system and to identify important findings
- Recommendations targeted at system changes can then be made that are more likely to produce sustained safety improvements
- Systems-based safety investigations can positively influence safety culture in organisations

Systems-based investigation of patient safety incidents: https://doi.org/10.7861/fhj.2021-0147

The Four Varieties of Human Work



http://safetysynthesis.com/onewebmedia/Shorrock_Paper.pdf

Definitions WAI v WAD

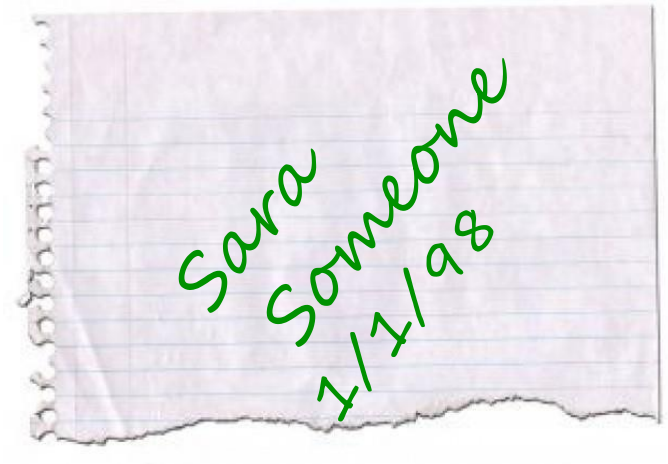
**"Work-as-imagined (formal work)
is what designers, managers, regulators, and
authorities believe happens or should happen"**

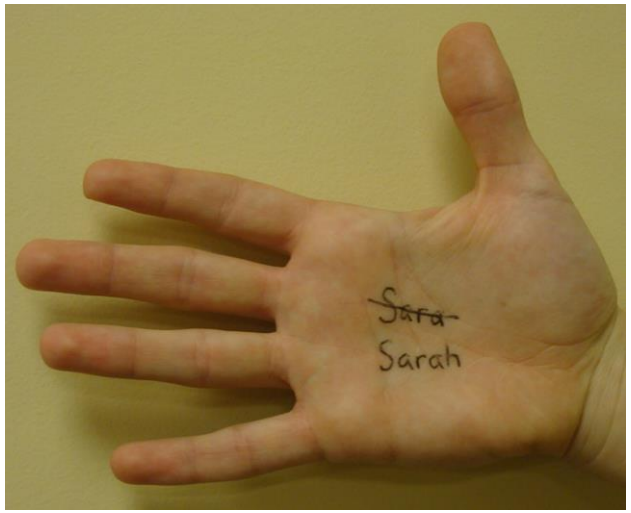
**"Work-as-done (informal work)
is what people have to do to get the job done.
It is what actually happens"**

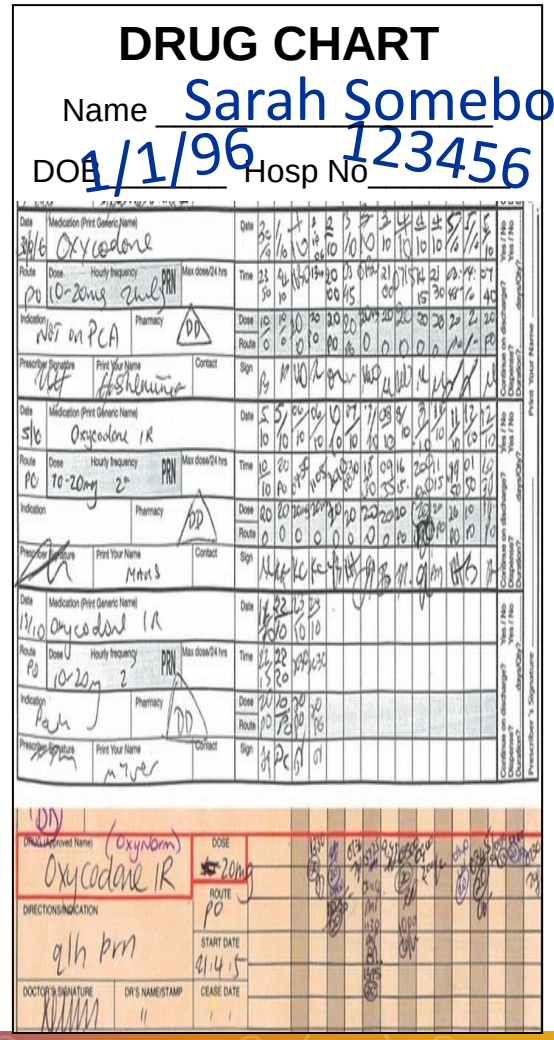
WAI v WAD

Policy

Take patient's details to collect blood







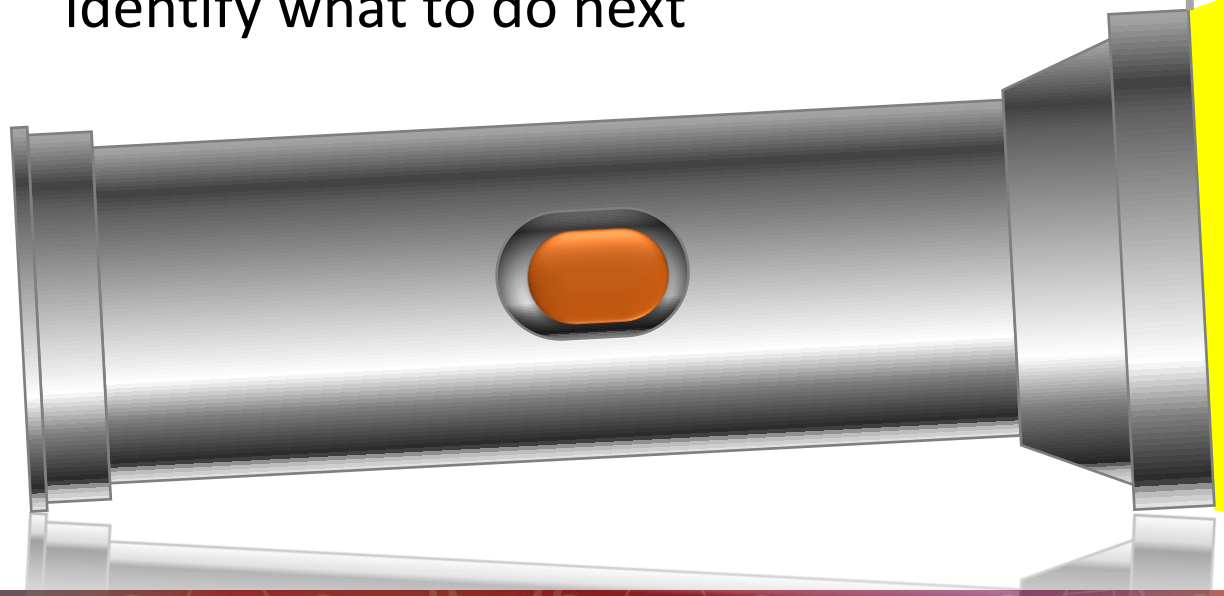
Pictures from internet, uncredited

Slide courtesy: Dr Alison Watt

SHOT Serious Hazards of Transfusion

Plugging the gap

Only by considering the varieties of human work can we hope to understand what's going on and identify what to do next



The key aspect of bridging this gap should be designing for work as done and develop user centered/human-centered processes

Corrective and Preventive Actions

- **S**pecific – articulate and understandable
- **M**easurable - verified that is solving the problem, means of evaluating
- **A**chievable– can be achieved within the resources and time frame
- **R**elevant- related to the cause(s) of the incident
- **T**ime bound– specified time to complete the actions

Action examples

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

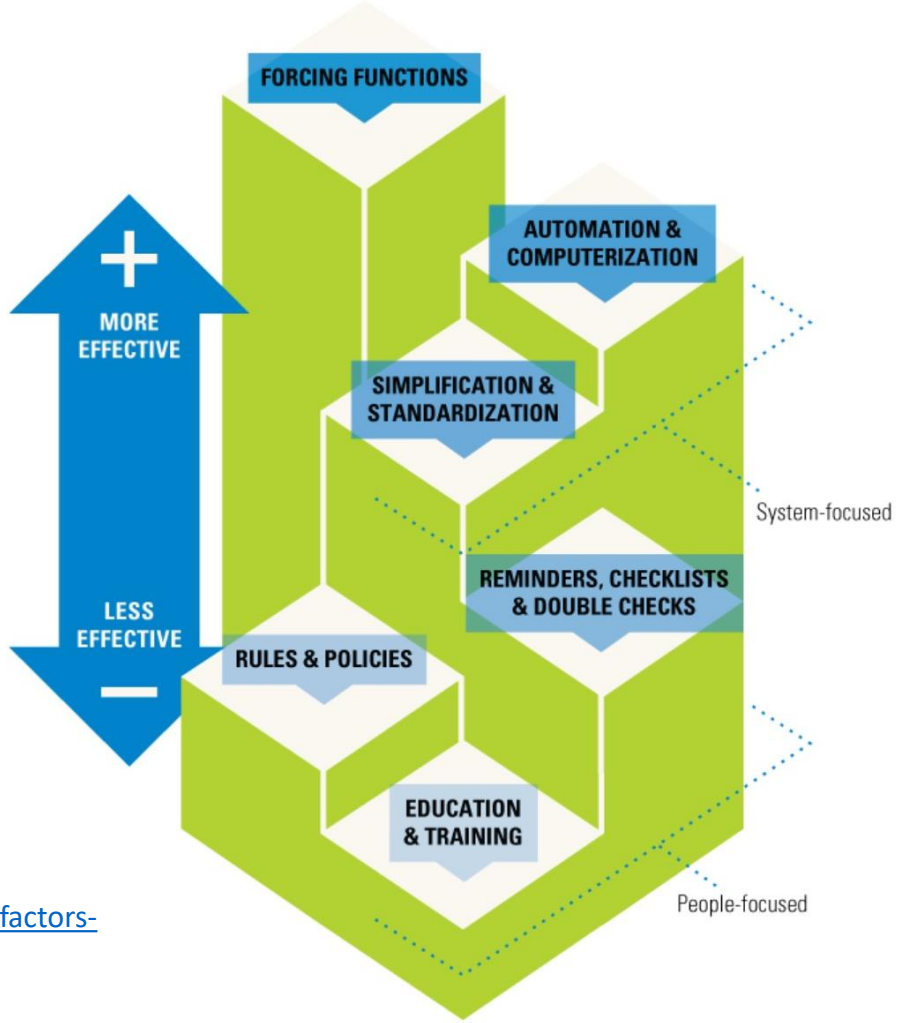
Good action

- 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

Poor action

- Include in next staff training session
- Target date – within 6 months
- Action by – transfusion laboratory
-

The Hierarchy of Intervention Effectiveness



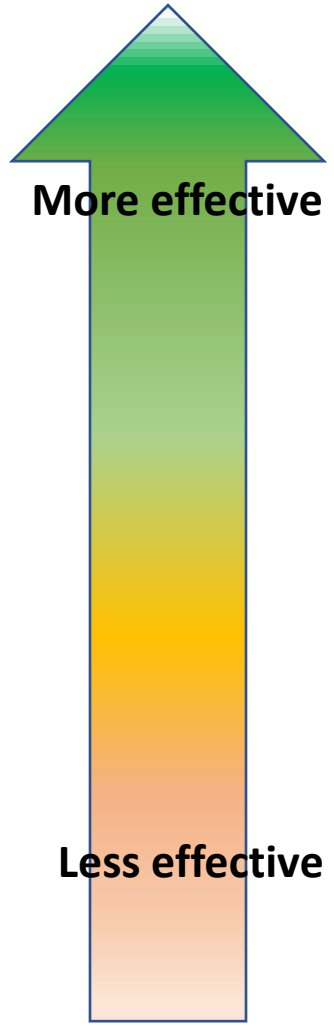
https://www.longwoods.com/content/22845/healthcare-quarterly/from-discovery-to-design-the-evolution-of-human-factors-in-healthcare

Intervention Hierarchy

Forcing functions: robust process that include barriers and fail-safes, automation, and computerisation. These are the most effective barriers but are usually the hardest to implement. Reliance on systems to ensure safe practice, but can be subject to technology complacency, flag fatigue and short cuts if not set up correctly.

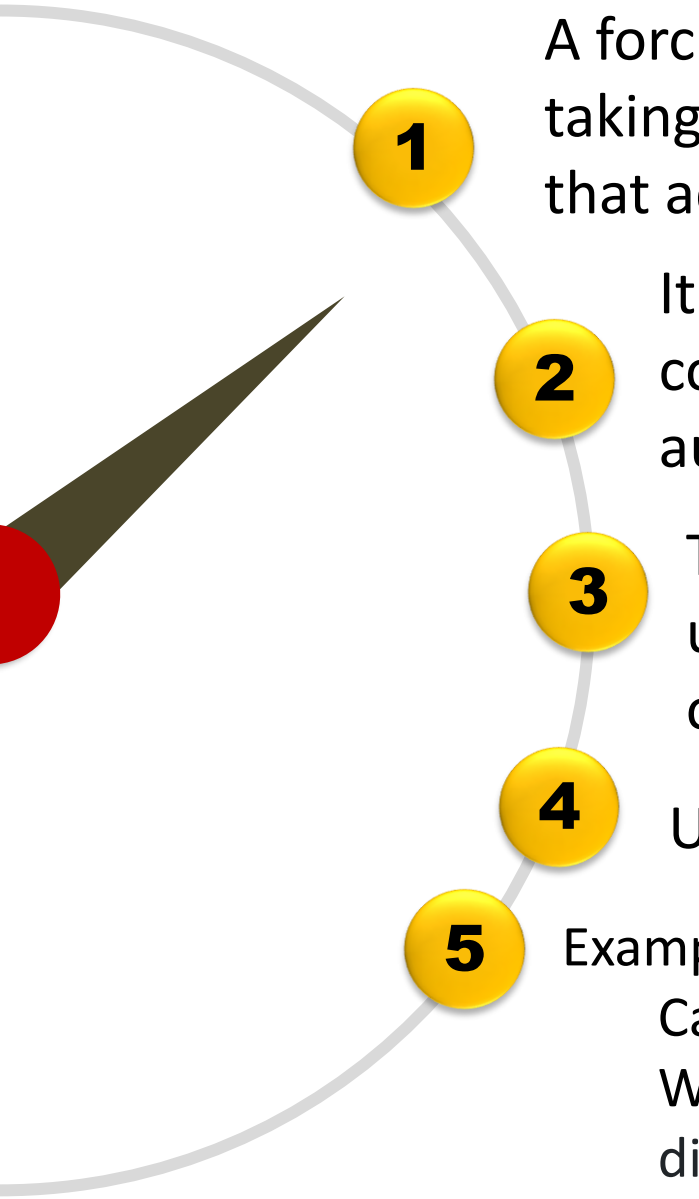
System focussed: standardisation, protocols and procedures, warnings, alerts, reminders, checklists, and robust checking. Partial reliance on humans and partial reliance on systems. Can be used as interim measures whilst more effective forcing functions are being explored.

People focussed: education and training, rules, and policies, even if applied to teams rather than individuals these are known to be ineffective. They are easy to implement and often used as the first line of defence. Reliant on humans to remember safe practice.



What is a forcing function?

SHOT Serious Hazards of Transfusion



1. A forcing function is an aspect of a design that prevents the user from taking an action without consciously considering information relevant to that action
2. It forces conscious attention upon something ("bringing to consciousness") and thus deliberately disrupts the efficient or automatised performance of a task
3. This is an aspect of a design that prevents an unintended or undesirable action from being performed or allows its performance only if another specific action is performed first
4. Useful in safety critical work processes
5. Examples:
   - Can’t start a microwave without closing the door
   - Websites with good password creation tools utilise forcing functions by disabling the button until the password criteria are met

Examples of forcing function in transfusion

LIMS prevents release of ABO incompatible blood by block to assigning to the patient record

Blood fridge has electronic lock that restricts access to trained staff only

Haemobanks that only allow access to the emergency O units, or unit for the patient on the pick-up slip

Blood fridge will not open to accept a unit without label verification confirming the right label is on the bag

Effective Interventions

Making the most of your interventions: The following guide can help ensure that the interventions identified are effective and fit for purpose:

Process

As simple as possible, as complex as necessary

Fail-safes and barriers (visual and physical) to error

Check points for safety

Reviewed for fitness for purpose

LIMS & Automation

Functionality utilised to its full potential

Appropriate rules and meaningful alerts

Alerts not easily overridden with audit trail of override reasons

SOPs

Clear and concise instructions for methodology

Clear escalation pathways and instructions for discrepancies

Regular review and updates

Training

Planned and delivered to all relevant staff

Clear learning outcomes

Follow up for learning assurance/ regular sessions

Checklist

Clear purpose for design

Utilise best practice

Succinct reminder not an explanation of process

Clear pause points for use

Review the effectiveness

Learning from Near Misses (NM

Near Misses

Near Misses may occur many times before an actual harmful incident. Wrong blood in tube incidents continue to be the most frequently reported NM

Organisational culture

A learning, resilient, high reliability organisation will endeavour to learn from Near Misses

NM as learning opportunities

NM represent error-prone situations and have been picked up by vigilant staff and processes. These also need to be investigated thoroughly to help build robust systems and prevent real events

↑Link to HSIB report on WBIT

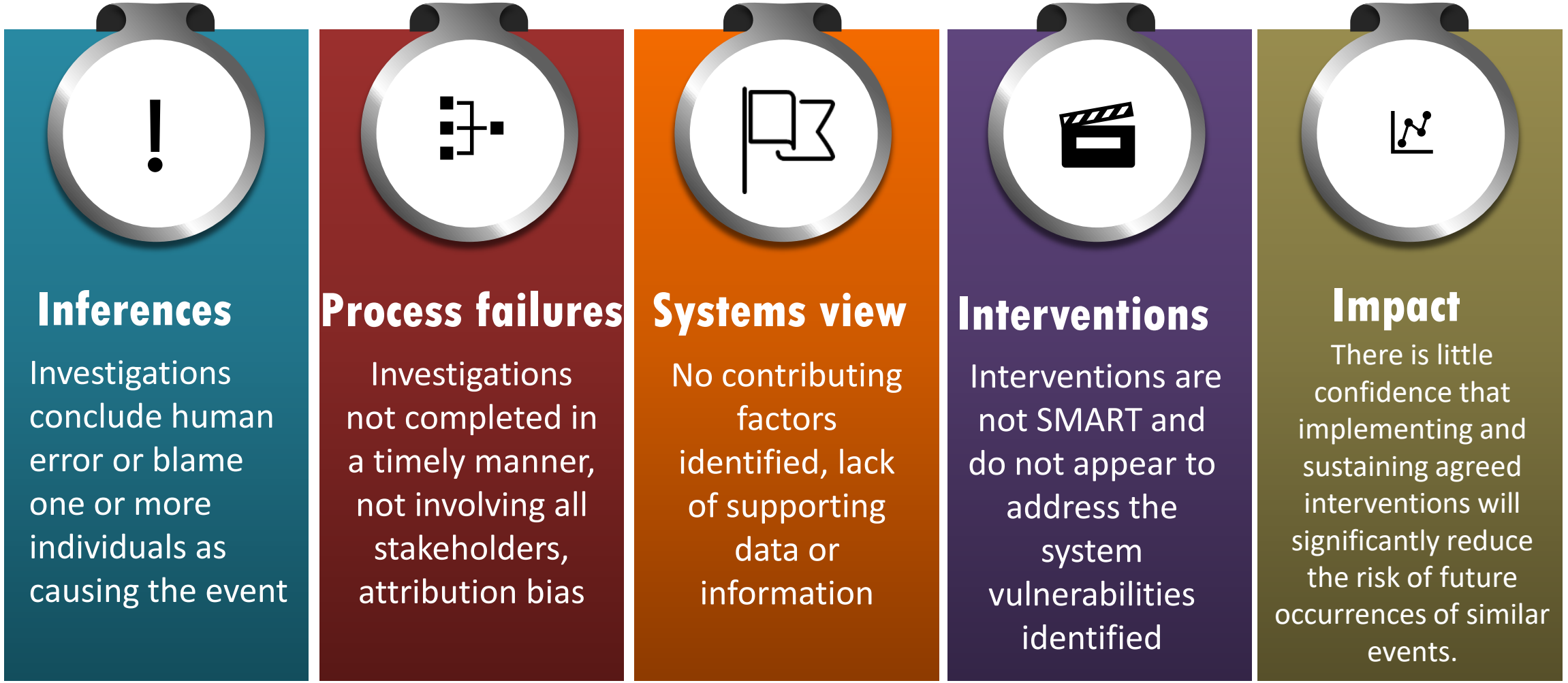
Safety is everyone's responsibility

Raising awareness, improving patient/donor education and involving donors/patients in decision making and checks where possible is vital

Share the learning

- Individual involved
- Organisation
- National
- International

Warning signs of suboptimal incident investigations



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

Case 1- ABOi platelet transfusion given to a patient

A unit of platelets was requested for a patient with non-Hodgkin lymphoma and critical site bleeding

Laboratory staff issued group O platelets by mistake for a group A patient

Ward staff completed the pre-transfusion checks and transfused the unit

Error was identified by the laboratory, the ward notified and advised not to give the unit but it had already been transfused

BMS involved was experienced in transfusion but was a new member of staff. They assumed that they were to take the platelets from the top shelf of the stock incubator

The LIMS flagged that group O platelets were being selected for a group A patient but the BMS overrode the warning

The BMS could not explain why they issued mismatched platelets. It was discovered that although the BMS had most competencies up to date they did not have competency for issue

The patient did not suffer any untoward harm

Case 1- ABOi platelet transfusion given to a patient

Staff		Occurred during night shift Workload issues Competency
Environmental		Layout of platelet storage area Assumption bias
Organisational		Lone working System and communication failures
Government/ regulatory		Insufficient NHS funding leading to inability to increase staff levels to cope with increased work loads and changes in work patterns

Case 2: Delay in urgent transfusion caused by lack of labels in the remote refrigerator printer

A man with gastrointestinal bleeding came to theatre, shocked with hypotension and tachycardia and a haemoglobin (Hb) of 70g/L

Staff had to wait for the transfusion laboratory staff to come to theatre to put the labels in

The second telephone call was made by the anaesthetic consultant who said they needed someone to 'come now'

It was supposed to send a remote alert when it reached a low threshold

He was eligible for electronic issue, but staff were unable to release blood from the electronically controlled refrigerator as there was no paper in the printer for the compatibility tags

During the first telephone call requesting help the staff were told the transfusion laboratory staff were in the middle of handover

The label printer does not generate a local nor remote alert when empty and was designed to count a specified number of printed labels

Access to the printer was open to anyone, and is easily knocked, resulting in misalignment of the feed

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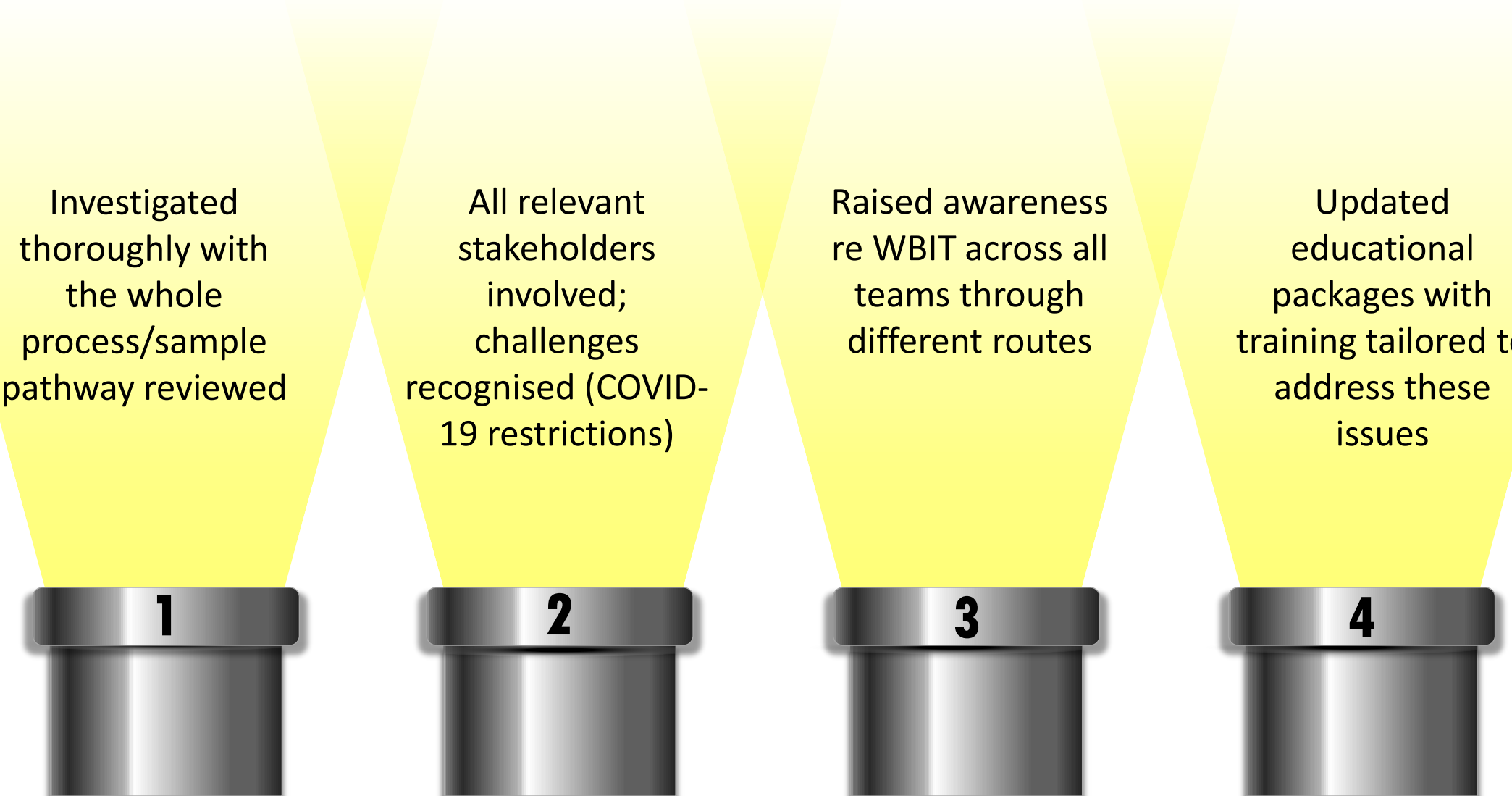
Case 3: Avoidable platelet transfusion following a WBIT with a thorough incident investigation

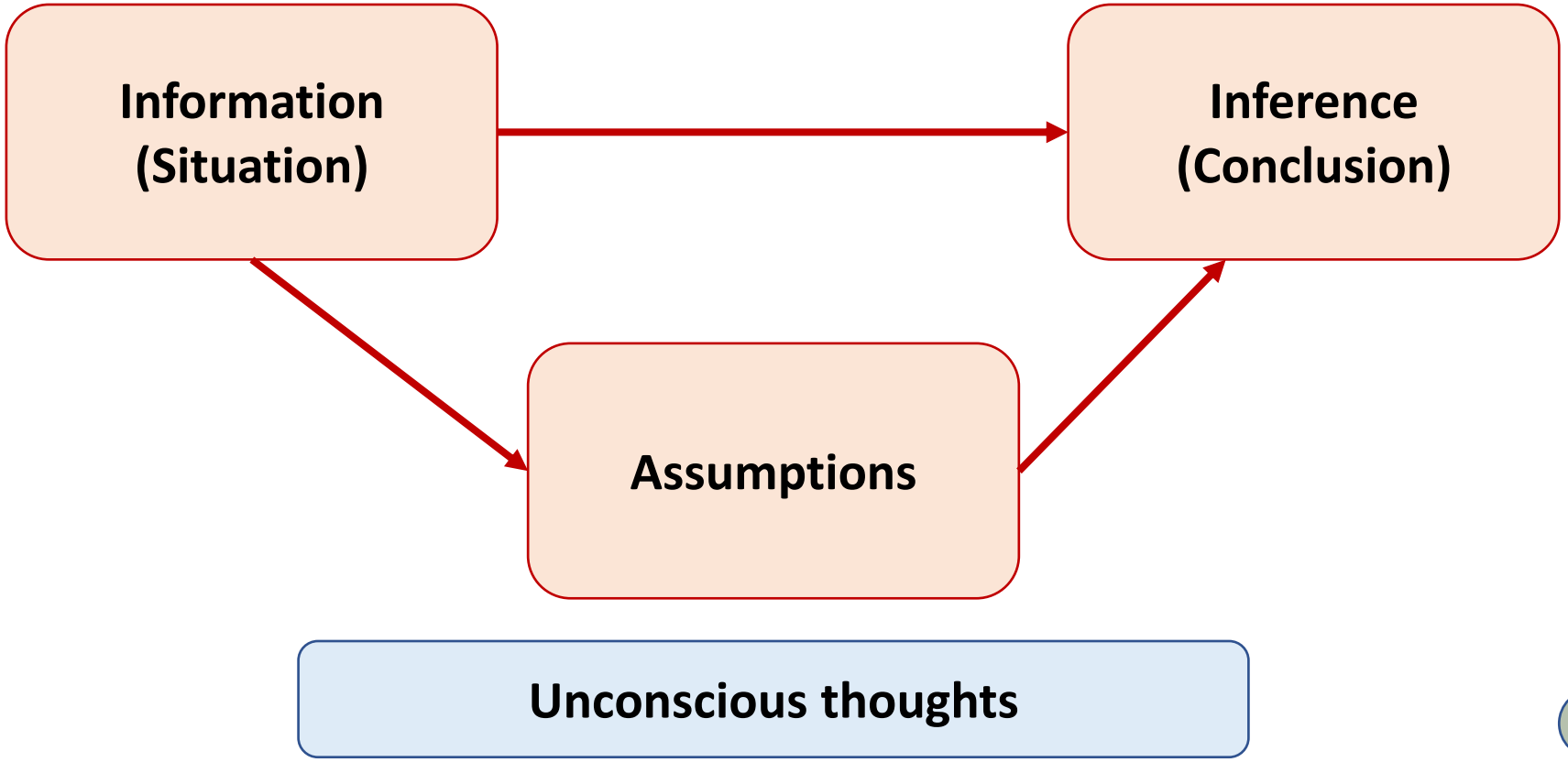
1. A man in his 50s was transferred from hospital A, then to hospital B and eventually to a third hospital C for management of a subdural haemorrhage. His admission blood tests at Hospital C, taken in the ED out-of-hours, were significantly different compared to those taken before or afterwards
2. The patient received three units of platelets as a result of the apparent low platelet count. This inconsistency in results was identified 5 days later when blood results before and after showed the discrepancy
3. The blood group results were consistent with previous ones, but the haematology and biochemistry results suggested they were from a different patient
4. This incident of ‘wrong blood in tube’ was investigated thoroughly

https://www.shotuk.org/wp-content/uploads/myimages/Chapter-11-Avoidable-Delayed-or-Under-Overtransfusion-ADU-2021.pdf

Case 3:



Cognitive biases as sources of errors



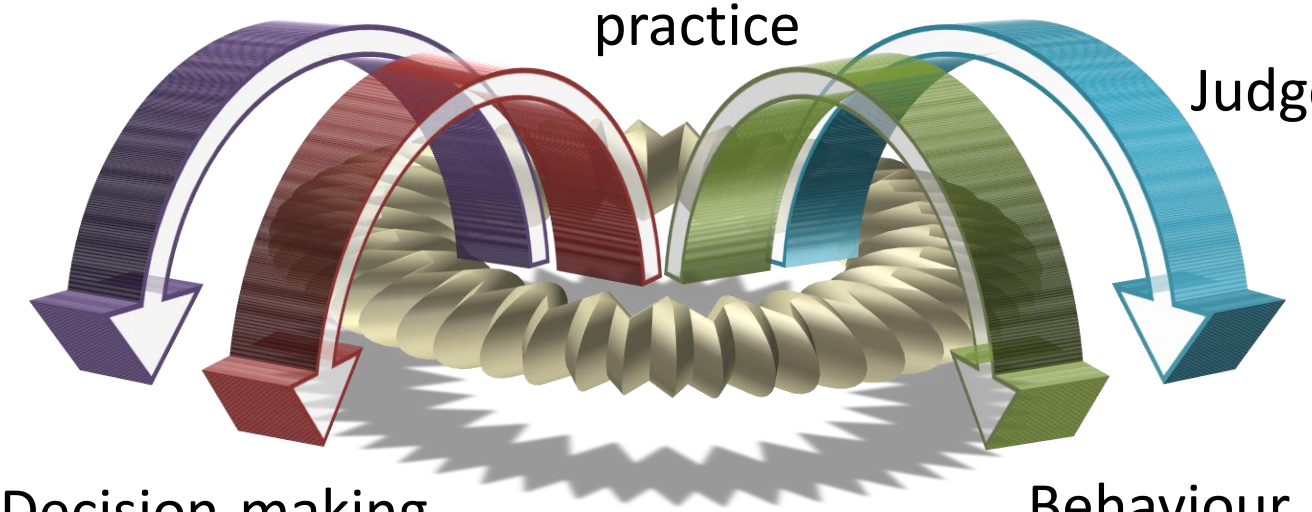
Cognitive biases are cognitive short-cuts used to aid our decision-making and can contribute to errors in healthcare but can be mitigated through various measures.
Find out more here: https://www.shotuk.org/wp-content/uploads/myimages/SHOT-Bite-12-Cognitive-Bias-1.pdf

Cognitive bias can affect:

Be aware,
recognise,
minimise impact of
cognitive bias in
practice

Memory

Judgement



Decision-making

Behaviour

Case 4: Cognitive bias contribute to errors in decisions

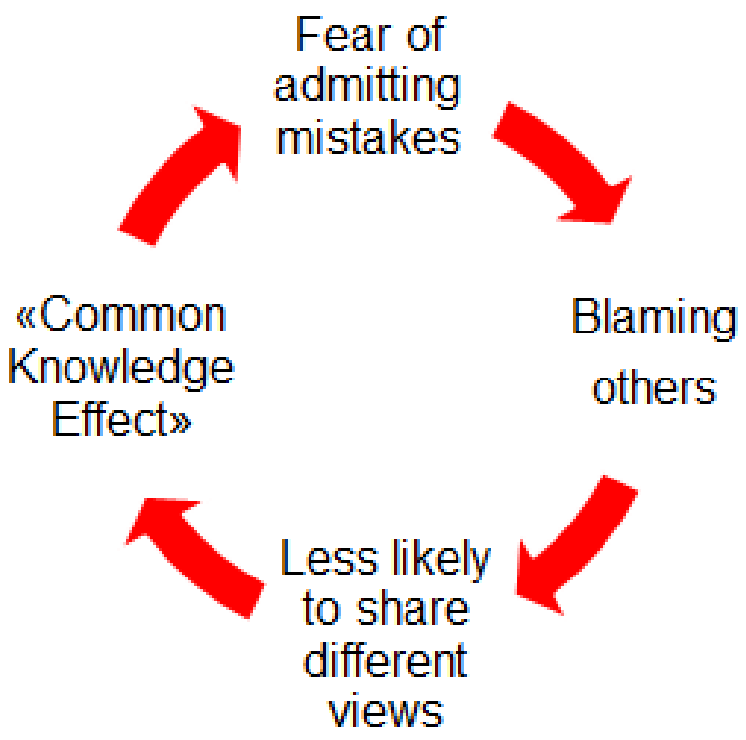
A young patient in mid-20's received 2 units of fresh frozen plasma(FFP) and 2 units of cryoprecipitate out of hours in error instead of 4 units of FFP prior to computerised tomography guided biopsy for a mediastinal mass

The cryoprecipitate was stored in the wrong location in the freezer and staff failed to check the components prior to thawing and issue, assuming all four to be FFP. Staff collecting the component and administering also failed to identify the error and this was only noticed by laboratory staff the next day

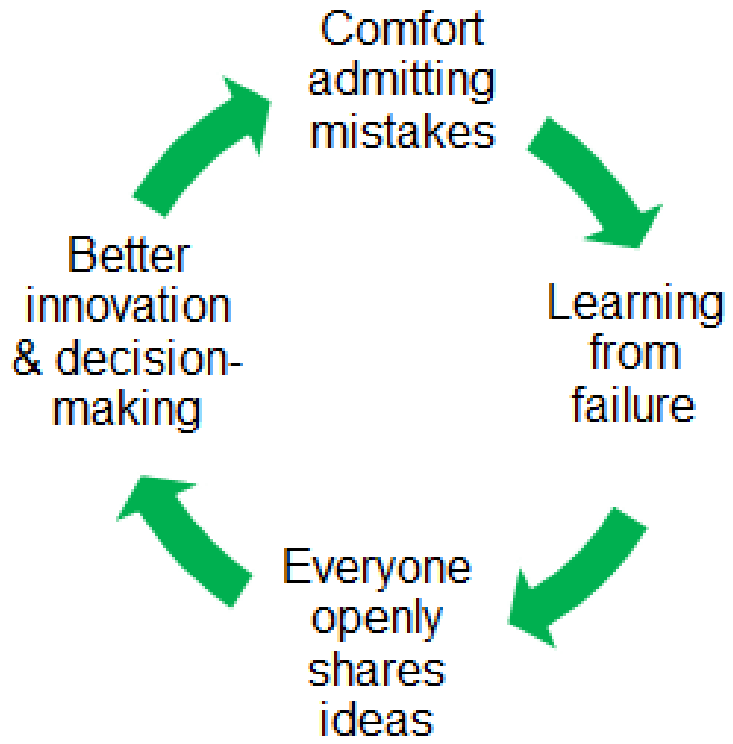
Safety culture

Civility, leadership and compassionate governance

Psychological Danger



Psychological Safety



https://www.weforum.org/agenda/2016/04/team-psychological-danger-work-performance/

Prevention is better than cure

INVESTIGATE NEAR MISS EVENTS

ROBUST PROCESS-BASED RISK ASSESSMENT

SAFETY CULTURE

LISTENING LEADERSHIP

UK Transfusion Laboratory Collaborative

https://www.shotuk.org/resources/current-resources/uktlc/

Kerry Dowling – UKTLC Chair

Jeni Davies – UKTLC Deputy Chair

UK TRANSFUSION LABORATORY COLLABORATIVE

Minimum standards for staff qualifications, training, competency and the use of information technology in hospital transfusion laboratories 2023

Purpose

The UKTLC standards have been revised for 2023, replacing the previous version (Chaffe *et al.*, 2014) and a full report will be published in Transfusion Medicine. An abridged version of the standards is provided here for laboratories to begin the compliance and gap analysis process. To support this process a gap analysis template is also provided, along with other resources that can be used to aid compliance.

For further information please contact:

Kerry Dowling, UKTLC Chair Kerry.Dowling@uhs.nhs.uk

Jennifer Davies, UKTLC Deputy Chair Jennifer.davies56@nhs.net

UKTLC collaborators

The UK Transfusion Laboratory Collaborative membership is: Institute of Biomedical Science (IBMS), British Blood Transfusion Society (BBTS), the Medicines and Healthcare products Regulatory Agency (MHRA), the Ministry of Defence (MoD), the Royal College of Pathologists (RCPath), Serous Hazards of Transfusion (SHOT), United Kingdom Accreditation Service (UKAS), United Kingdom National External Quality Assessment Service (UKNEQAS) and the NHS England National Blood Transfusion Committee (NHSE NBTC) and their equivalents in Scotland, Wales and Northern Ireland. The standards have been revised, agreed and approved by these professional bodies.

Standard 1: Staffing

UK Transfusion Laboratory Collaborative

Staffing levels

Skill Mix

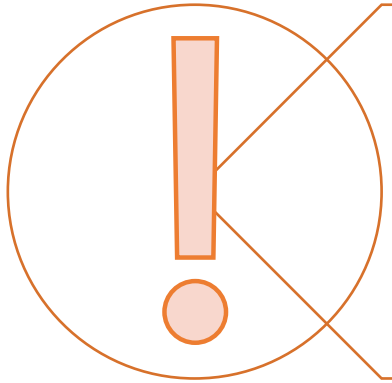
Capacity plan

Quality management system

Transfusion advanced specialist staff

Survey results – capacity planning

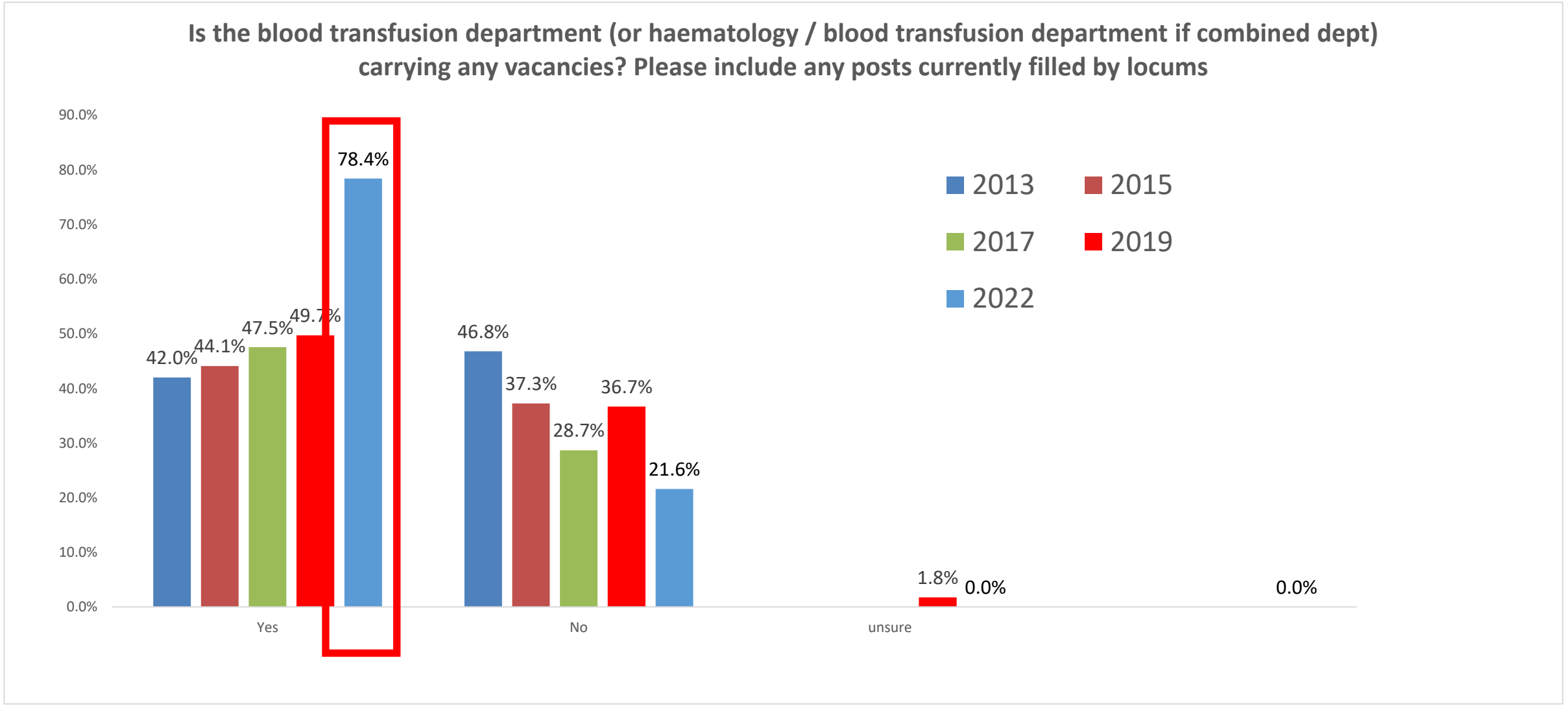
The number of laboratories with capacity plans had increased from 62% in the 2019 survey to 86.5% in 2022 survey



However, respondents noted lack of compliance with the capacity plan and deficiencies in both staffing numbers and skill mix

Survey results - vacancies

UK Transfusion Laboratory Collaborative



UK Transfusion Laboratory Collaborative

Standard 2: Qualifications, knowledge and skill

Staff training

Resources

Competency assessment

Protected time

Survey results - qualifications

UK Transfusion Laboratory Collaborative

Staff who work unsupervised have the appropriate qualifications/experience as stipulated in the UKTLC standards for their grading

Where standards are not met, please give further details why

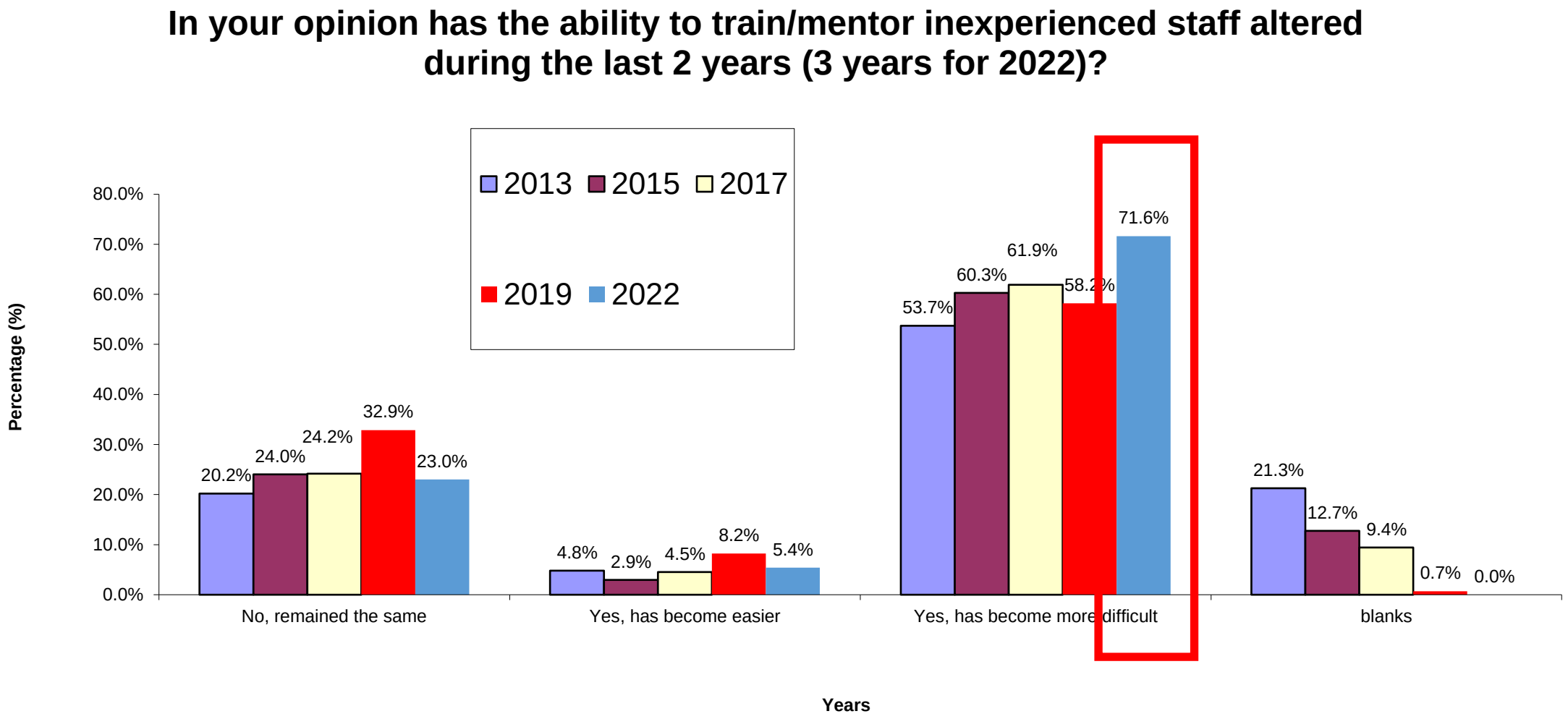
51 responses

Working towards meeting this standard

Multidisciplinary working

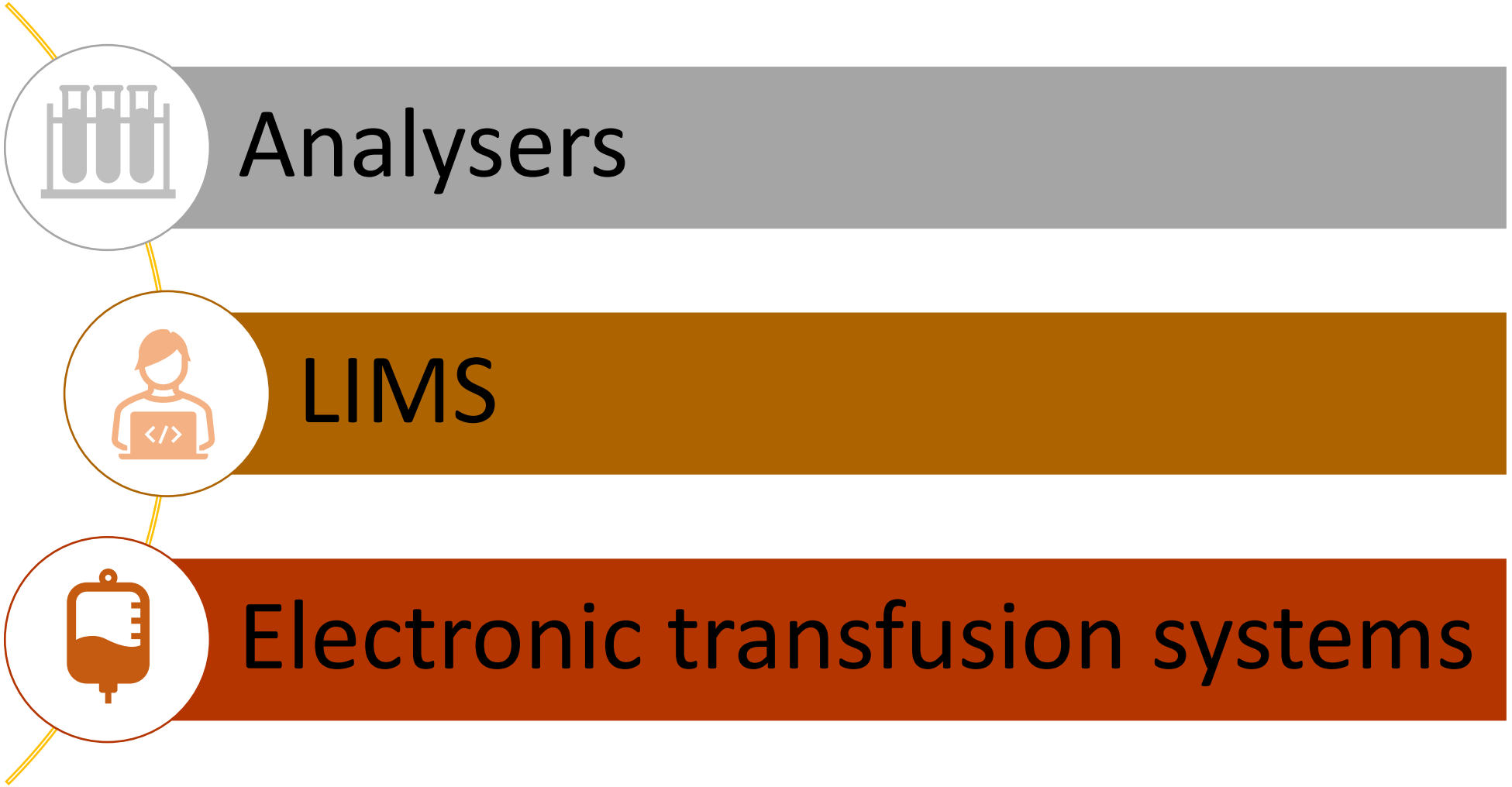
Local training

Survey results - training

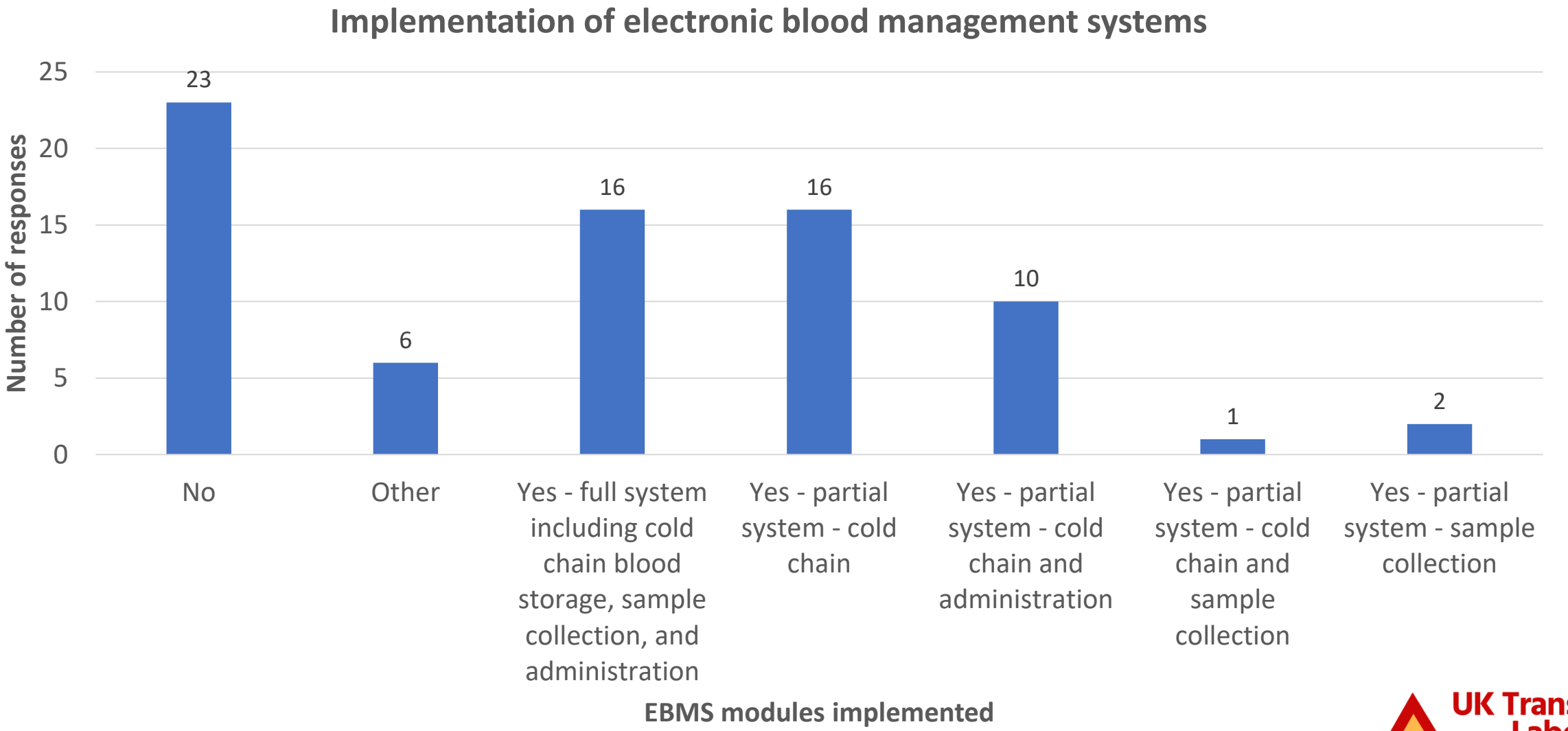


Standard 3: Information technology

UK Transfusion Laboratory Collaborative



Survey results – Electronic blood management systems

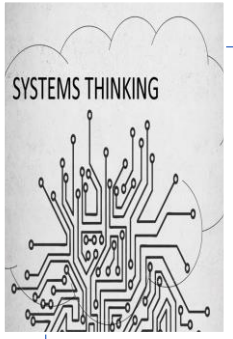


UK Transfusion Laboratory Collaborative

Standard 4: A just culture

Led by management

Learning from good and bad events

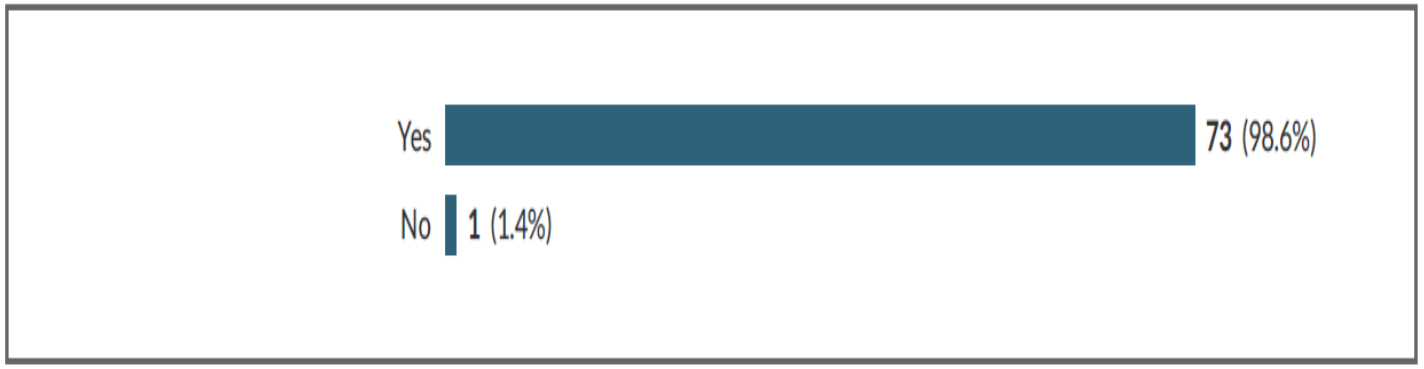


Human factors and systems thinking

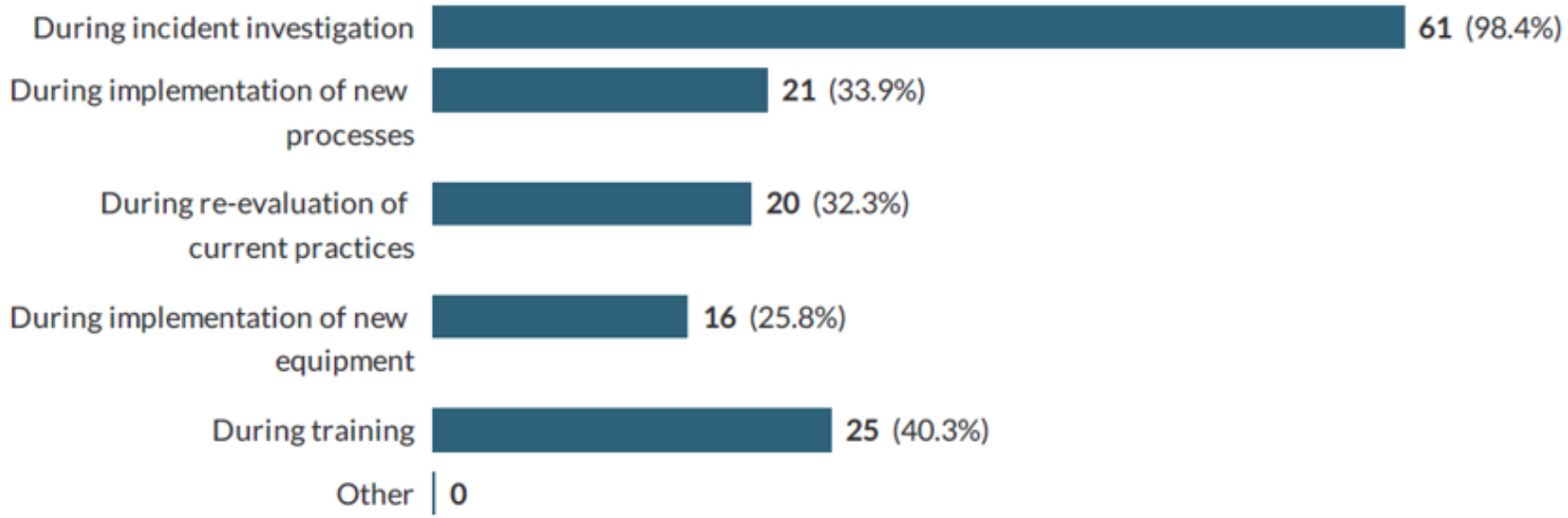
Survey results – A just culture

UK Transfusion Laboratory Collaborative

Do you feel there is a just culture within your transfusion laboratory where issues are freely raised and concerns openly discussed?

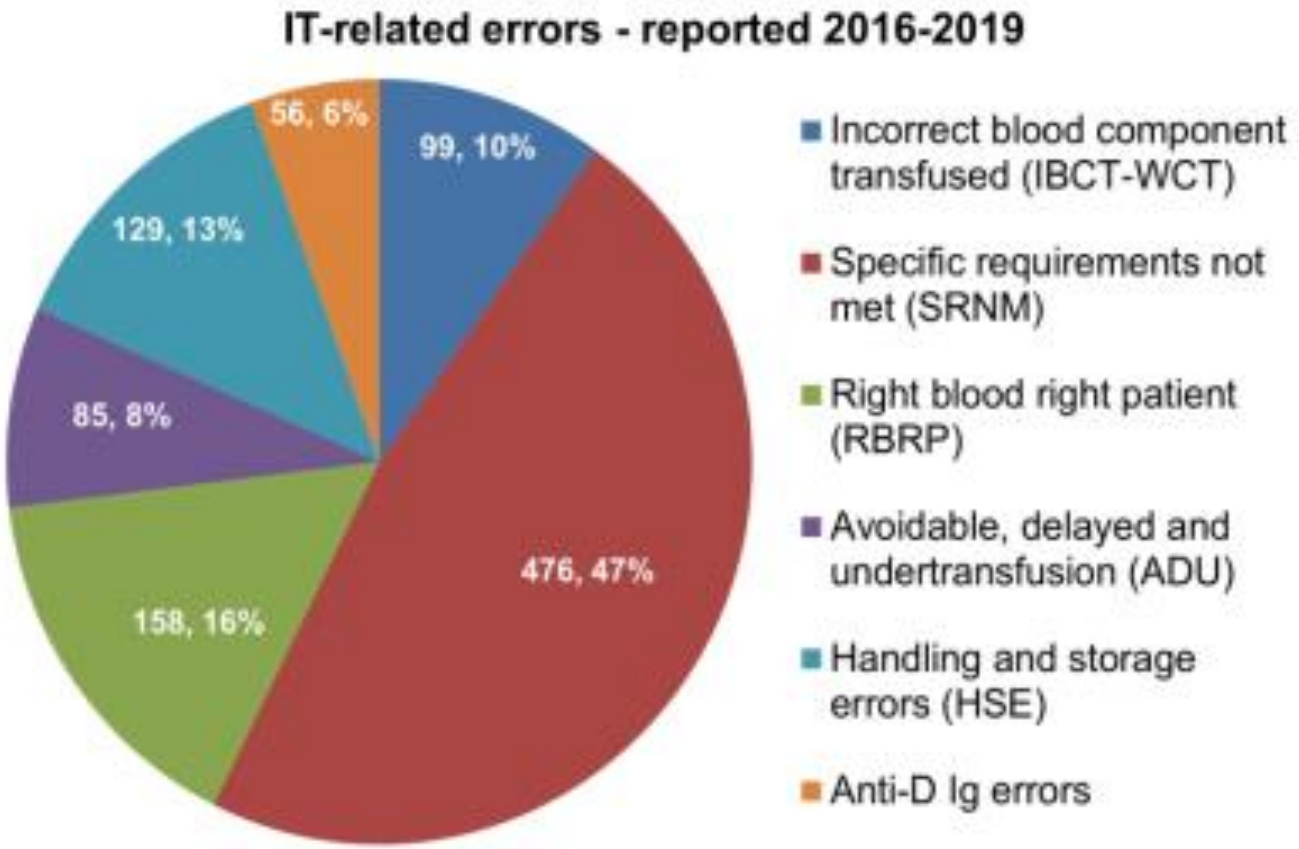


Where Human Factors principles are incorporated?



IT and transfusion

Looking at IT errors over time



https://www.shotuk.org/wp-content/uploads/myimages/SHOT-Bite-No.-13-IT.pdf

IT-related error	Number of errors
Failure to use flags and/or logic rules	217
Warning flag not updated	119
Warning flag in place but not heeded	109
Equipment failure	93
Failure to consult or identify historical record	84
Errors related to electronic blood management systems	72
Incorrect result/data entered/accessed manually	67
Anti-D related	56
Computer or other IT systems failure	49
Failure to link, merge or reconcile computer records	36
Discrepancy between LIMS and PAS	36
Blood issued against wrong patient ID (sample or request form)	36
Miscellaneous	29
Total	**1003**

IT Solutions

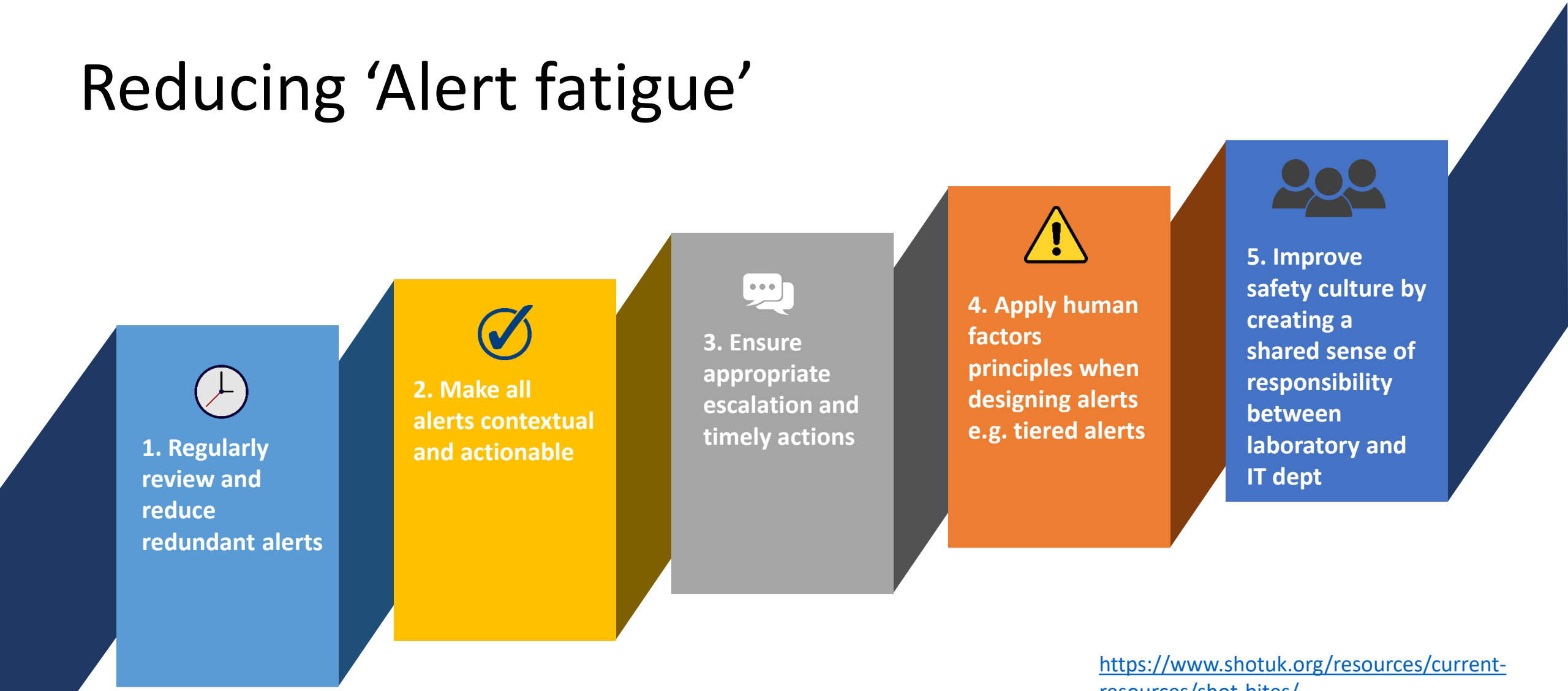
Simple and easy to use - must not increase cognitive load

Intuitive - little or no training if possible

Compatible with current equipment and does not disrupt workflow

Works with every procedure - systems change across hospital, nationally , internationally

Reducing ‘Alert fatigue’



https://www.shotuk.org/resources/current-resources/shot-bites/

OPTIMISE INTEROPERABILITY TO HELP IMPROVE PATIENT SAFETY

GOOD INTEROPERABILITY = BETTER ACCESS TO INFORMATION
= SAFER TRANSFUSION DECISIONS

SHOT
Serious Hazards of Transfusion

Case 5: Tracker downtime

- Patient A transfused with RBC intended for Patient B
- Nurse collected unit correctly, but bedside tracker lost power during bedside checking stage
- Nurse did not follow downtime procedures and continued to check unit without second checker
- Next shift nurse noticed wrong patient's details on unit and transfusion stopped
- Fortuitously both patients were O D-positive with no red cell antibodies

Case 6: Antigen-negative requirements missed due to cognitive bias

The biomedical scientist (BMS) received a request for two red cell units for patient with multiorgan failure with known anti-e and anti-C.

Upon seeing the patient's date of birth (DOB) and assumed that, as the patient was of childbearing potential, they should receive R_1R_1 (c-E-) red cells in accordance with local policy, rather than identifying that patient required R_2R_2 (C-e-) red cells due to presence of anti-C and anti-e red cell antibodies

Laboratory information management system (LIMS) warning flags were in place but were not heeded as these do not appear visually at the point of reserving/issuing units

C and e-positive red cell units were serologically crossmatched and issued

No harm was detected in the patient

SHOT Serious Hazards of Transfusion

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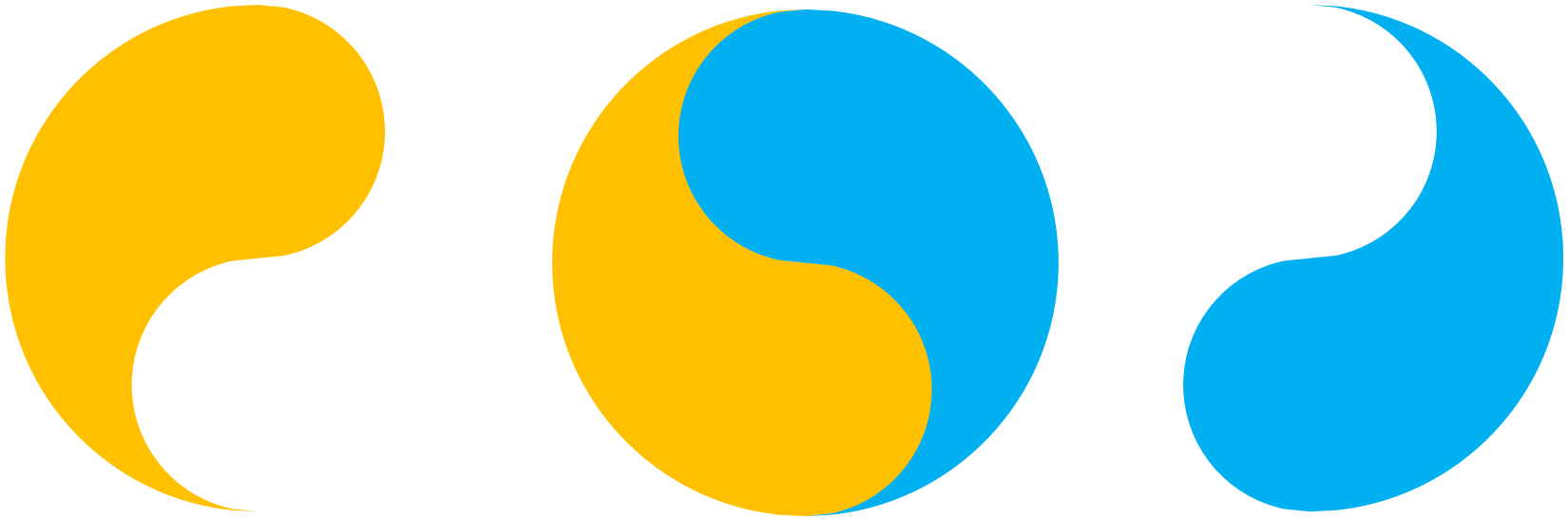
SHOT Serious Hazards of Transfusion

Safety synergy

A holistic approach to safety



Safety-I

Reactive

Safety

Need both approaches to improve patient safety

Safety-II

Proactive

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

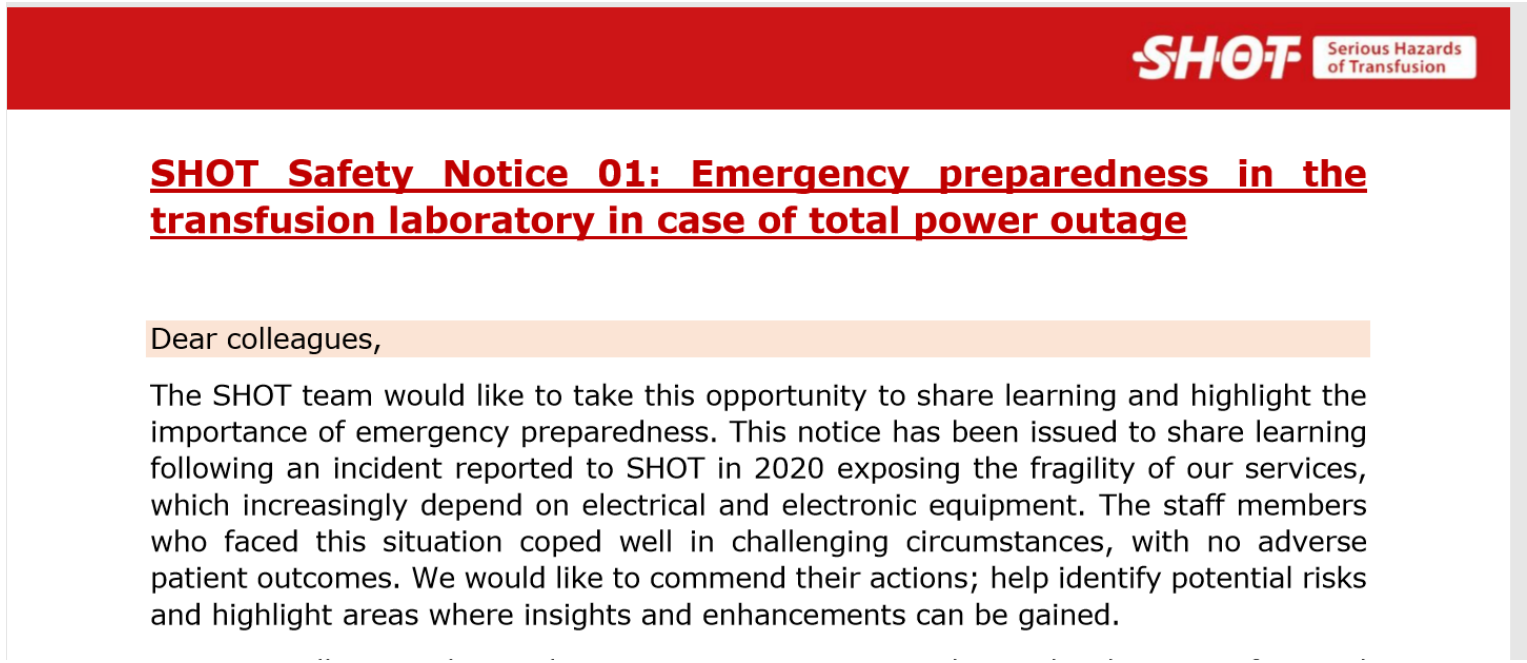
- Learning from all events and experiences including excellence
- Appreciative enquiry
- Making visible the hidden work people do to successfully navigate problems
- Build resilient teams and systems

Example ACE

- Full power outage in UK hospital
- Disconnected analysers
- Blood component storage devices failed
- Computer systems down
- No telephone system

Outcome

- National safety notice
- Shared learning across the UK
- Review of contingency plans



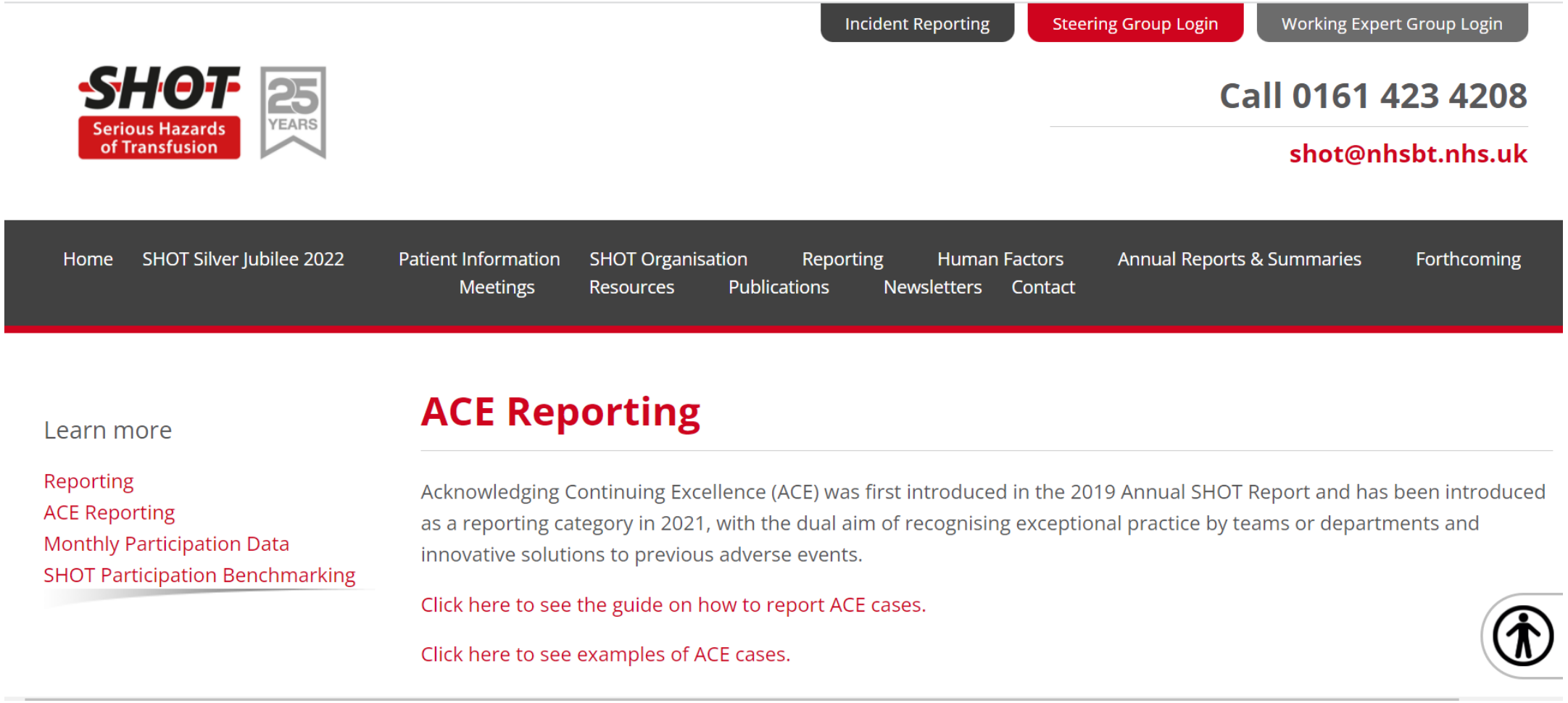
SHOT Serious Hazards of Transfusion

SHOT Safety Notice 01: Emergency preparedness in the transfusion laboratory in case of total power outage

Dear colleagues,

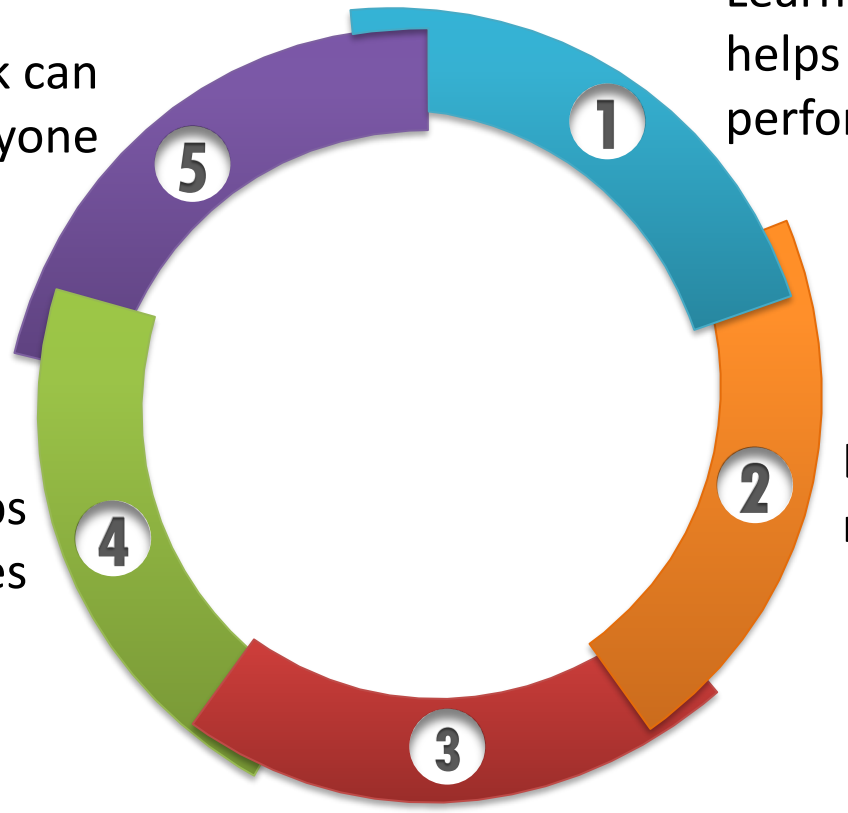
The SHOT team would like to take this opportunity to share learning and highlight the importance of emergency preparedness. This notice has been issued to share learning following an incident reported to SHOT in 2020 exposing the fragility of our services, which increasingly depend on electrical and electronic equipment. The staff members who faced this situation coped well in challenging circumstances, with no adverse patient outcomes. We would like to commend their actions; help identify potential risks and highlight areas where insights and enhancements can be gained.

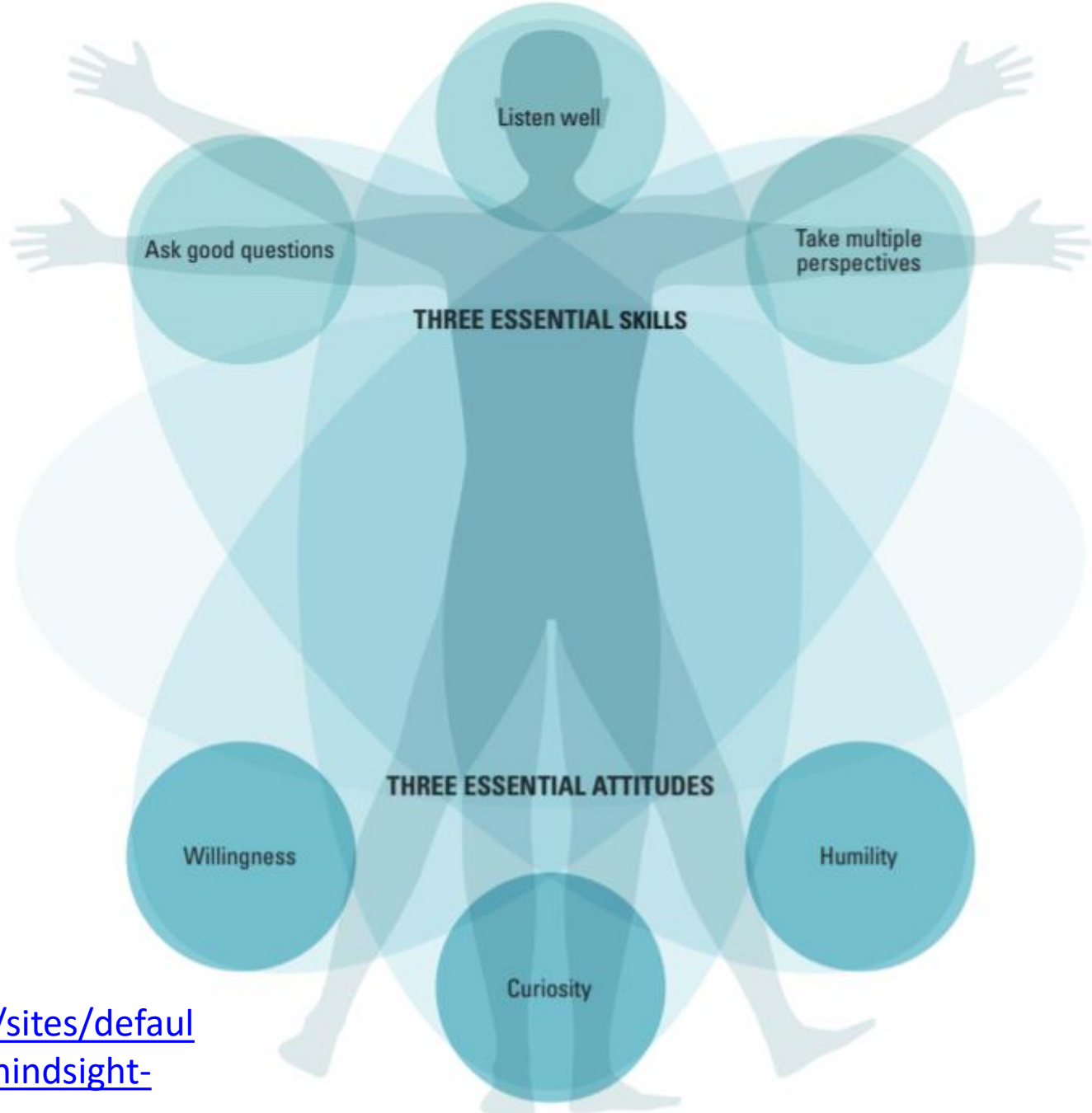
Links to SHOT ACE reporting guidance, chapters and examples:



Why learn from everyday work?

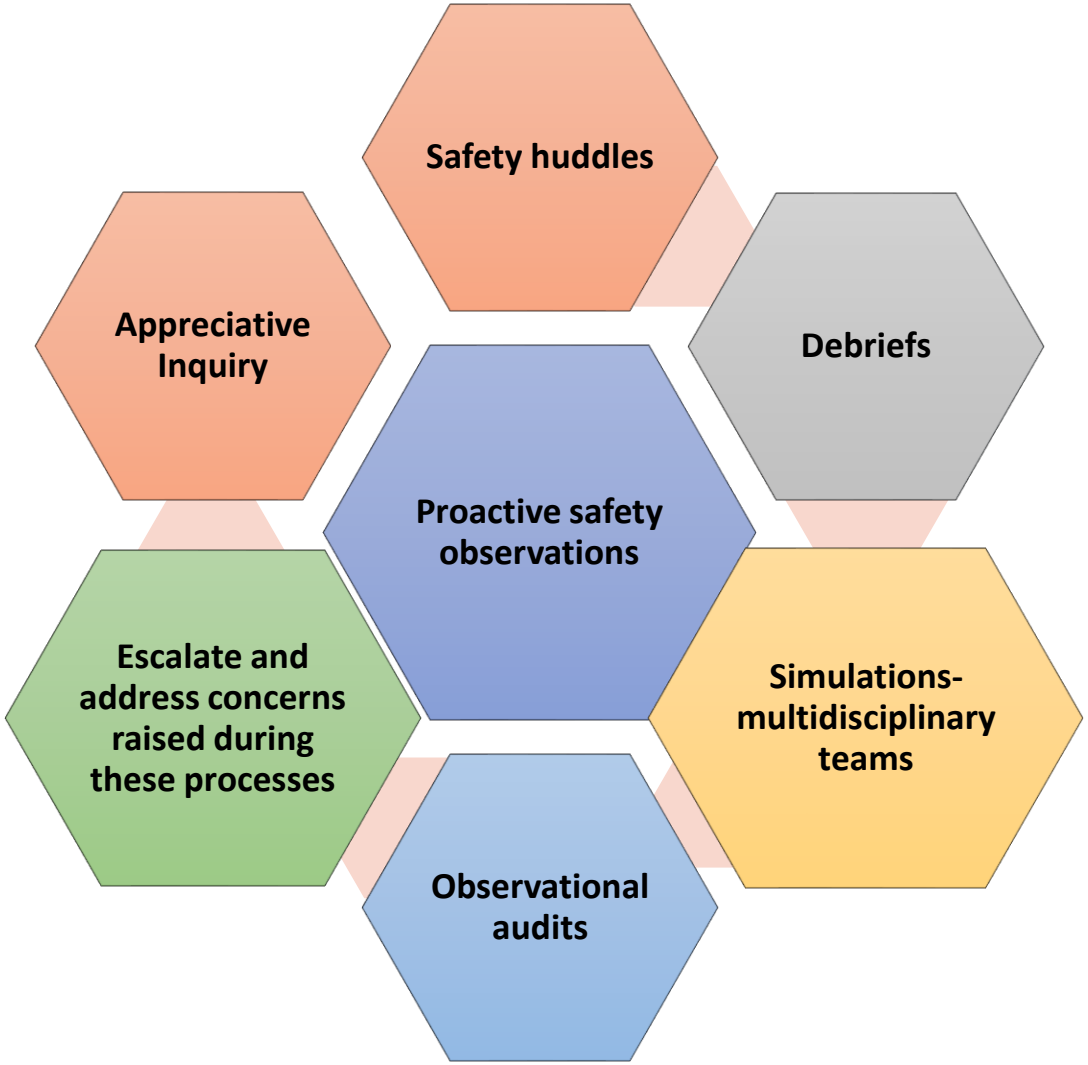
1. Learning from everyday work helps to improve all aspects of performance and wellbeing
2. Learning from everyday work does not require unwanted events
3. Learning from everyday work helps to see and build on what's strong
4. Learning from everyday work helps to see slow changes
5. Learning from everyday work can involve everyone

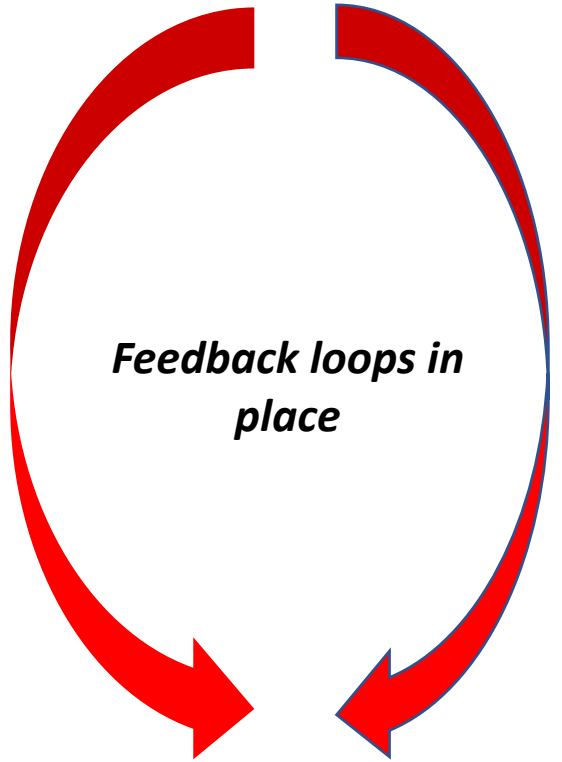




https://www.eurocontrol.int/sites/default/files/2022-05/eurocontrol-hindsight-magazine-31.pdf

Operationalising Safety-II- safety tools that can be used






Involving Patients
Partnering with patients to improve transfusion safety

Patient webpage on the SHOT website

Aide memoire for patients receiving blood transfusions - Tips to help enhance transfusion safety

What can you do to stay safe?

Transfusions

1. **Correct identification**

   Staff must check your identification (first name, surname, date of birth and unique identification number; in Wales, you will be asked your home address as well) before blood sampling and before transfusion. Accurate identification prevents transfusion errors and wrong components from being transfused. You should challenge any healthcare worker who does not ask and check your name and date of birth.

2. **Bring any red cell antibody cards you may have been given in the past.**
   It can help your treating team keep your records up to date and help you get blood that is appropriate for you.

3. **Make sure your clinician knows about any allergic reactions or any adverse reactions you have had to transfusions in the past. Also make sure that the clinician knows about any special transfusion requirements you may have (e.g., need for irradiated blood components).**
   This can help you to avoid getting a transfusion that could harm you.

4. **Make sure your treating team are aware of your medications, especially blood thinners and aspirin/related medications.**

   Some of these medications may impact transfusion decisions.

5. **Labelling of blood samples must be done accurately, in your presence and must be legible. They must contain your identification details.**

   Labelling errors can result in the sample being rejected by the transfusion laboratory and you may need to attend for another blood test. There is also a risk of wrong transfusion if samples aren't labelled correctly. You should challenge any healthcare worker who takes a sample but doesn't label it by your side.

6. **Ask for information about your planned transfusions in terms you can understand—both when blood components for your transfusion are prescribed and when you get them:**
   - What is the transfusion for?
   - What blood component/s is/are being transfused?
   - How is it going to be given and how long will it take for the transfusion?
   - What side effects are likely? What do I do if they occur especially when I am back home?
   - Are there any alternatives to transfusion?
   - Are there any precautions that I need to be aware of?

7. **Ask for written information about the transfusion which provides information about risks, benefits, and alternatives. If you have any questions about the transfusion, ask.**

If you know what might happen, you will be better prepared if it does or if something unexpected happens.

Several patient information leaflets about blood transfusions are available and can be accessed using this link: https://hospital.blood.co.uk/patient-services/patient-blood-management/patient-information-leaflets/

8. **Understand that "more" is not always better.**

   It is a good idea to find out why a test or treatment including transfusion is needed and how it can help you. Not all tests or transfusions are essential.

9. **When the blood component is being connected prior to administration, ask is this what has been prescribed/authorised for me.**

   You should challenge any healthcare professional who has not checked your name and date of birth, as stated by you, against the unit and the prescription.

10. **You will be monitored regularly during your transfusion. Unless essential, routine transfusions will be carried out during "normal working" hours.** Ask for help if you feel unwell during a transfusion and speak up if you have any concerns regarding your transfusion and/or monitoring.

11. **When you are being discharged from the hospital, ask your clinician to explain the treatment and follow up plan after discharge.**
    This includes information about any delayed complications, making sure you know when to schedule follow-up appointments. Make sure a transfusion summary including any special requirements and reactions you may have had are recorded in the discharge summary and ask about it if it isn't there.

12. **If you have had a blood test, do not assume that no news is good news.**
    Ask how and when you will get the results.

13. **Learn about your condition and treatments by asking your doctor and nurse and by using other reliable sources such as NHS fact sheets/websites.**

    Please do not hesitate to speak up if you have any questions or concerns.

*The term "clinician" is used in this leaflet to refer to the person who helps you manage your health care which could be a doctor, a nurse, midwife, or other trained healthcare worker.

Based on 'Tips To Help Prevent Medical Errors: Patient Fact Sheet'. Content last reviewed November 2020. Agency for Healthcare Research and Quality, Rockville, MD.

https://www.ahrq.gov/questions/resources/20-tips.html

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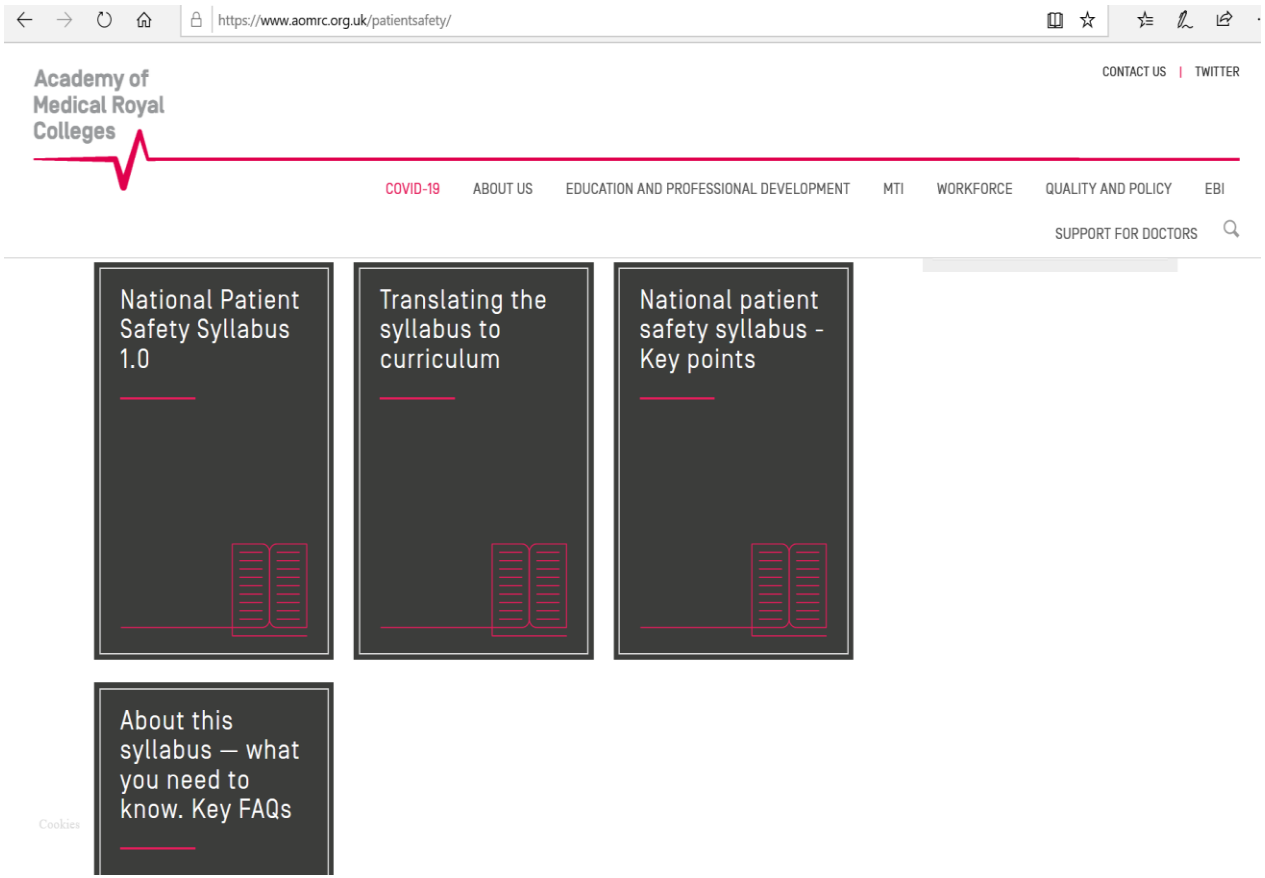
Serious Hazards of Transfusion

What else is happening in the wider NHS?

National Patient Safety Syllabus Jan 2020

https://www.aomrc.org.uk/patientsafety/



This is

- the first NHS-wide patient safety syllabus
- a multi-professional syllabus
- covers all the patient safety training and educational needs of people currently working in the NHS or in training to work in the NHS. This includes both clinical and non-clinical staff and covers the voluntary sector and social care
- The syllabus is based on a systems approach to human factors. It is holistic in its use of human factors, both system- and person-based

Patient Safety Syllabus Training

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Programme information

Title:

Patient Safety Syllabus Training

Description:

The first level, Essentials for patient safety, is the starting point for all NHS staff, and includes sections on:

- Listening to patients and raising concerns

- The systems approach to safety, where instead of focusing on the performance of individual members of staff, we try to improve the way we work

- Avoiding inappropriate blame when things don't go well

- Creating a just culture that prioritises safety and is open to learning about risk and safety

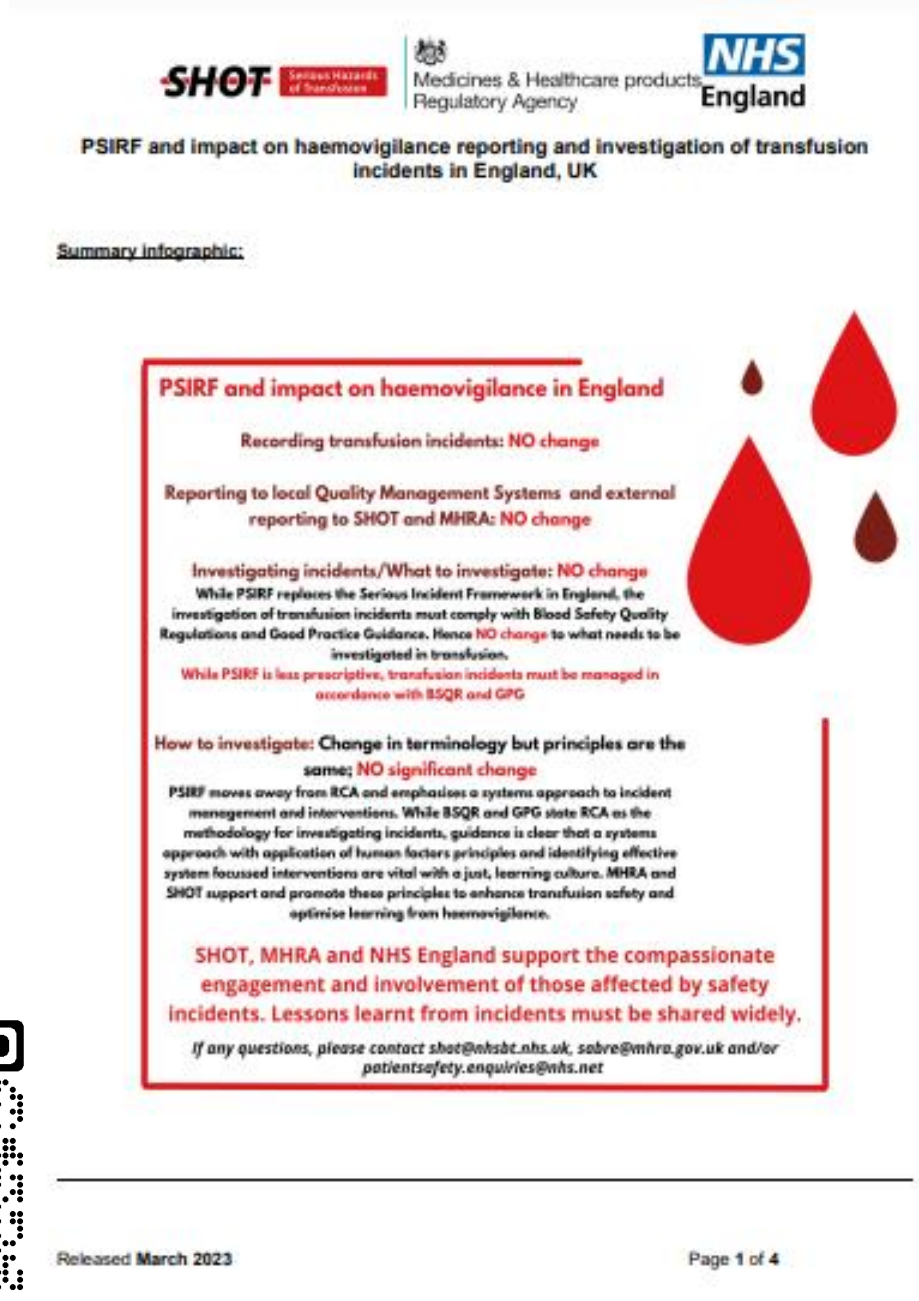
- Level two, Access to practice is intended for those who have an interest in understanding more about patient safety or who want to go on to access the higher levels of training. There are two sessions. The first introduces systems thinking (how the way we work can be used to reduce error and improve safety) and risk expertise (how we can identify and manage risk to keep patients safe). The second session looks at human factors (the science of work and of working together in safely designed systems) and safety culture (the significance of a true learning culture, free of inappropriate blame).

PSIRF and haemovigilance

NHS England published the Patient Safety Incident Response Framework (PSIRF) in August 2022 as a core element of the NHS Patient Safety Strategy in England.

The Framework sets out the NHS's approach to developing and maintaining effective systems and processes for responding to patient safety incidents for the purpose of learning and improving patient safety.

All NHS trusts in England began implementing PSIRF in September 2022 with an expectation for transition to PSIRF by Autumn 2023.



SHOT Serious Hazards of Transfusion | Medicines & Healthcare products Regulatory Agency | NHS England

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, sabre@mhra.gov.uk and/or patientsafety.enquiries@nhs.net

Released March 2023

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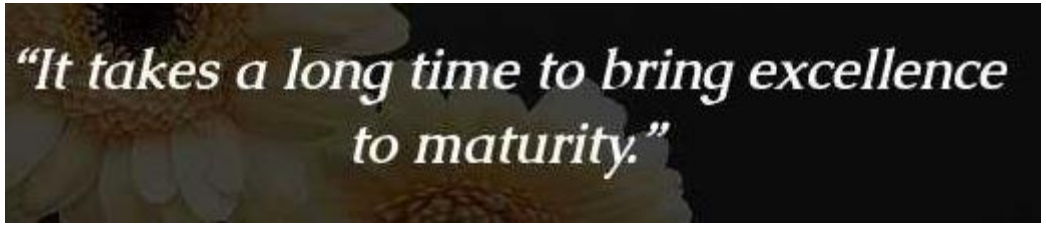


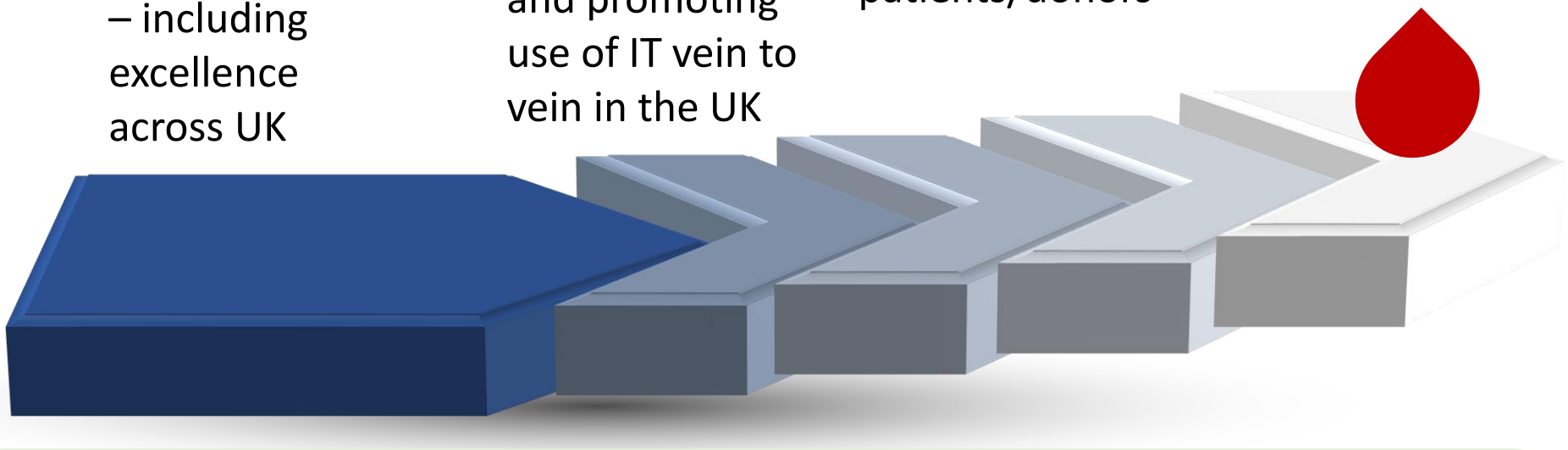
What next?

Embed learning from all events – including excellence across UK

Safety culture and promoting use of IT vein to vein in the UK

Partnering with patients/donors

Refining data collection- interventions



Widen awareness, use and impact of incorporating human factors principles in patient care

Promote use of available transfusion resources among health care professionals

Learning objectives

- Understand the importance of effective incident investigation
- Identify how optimising learning from incidents contributes to transfusion safety
- Explore contributory factors and effective corrective and preventative actions
- Explore some illustrative case studies

Resources

- Many more resources, including the 2021 Annual SHOT Report are available on the SHOT website www.shotuk.org

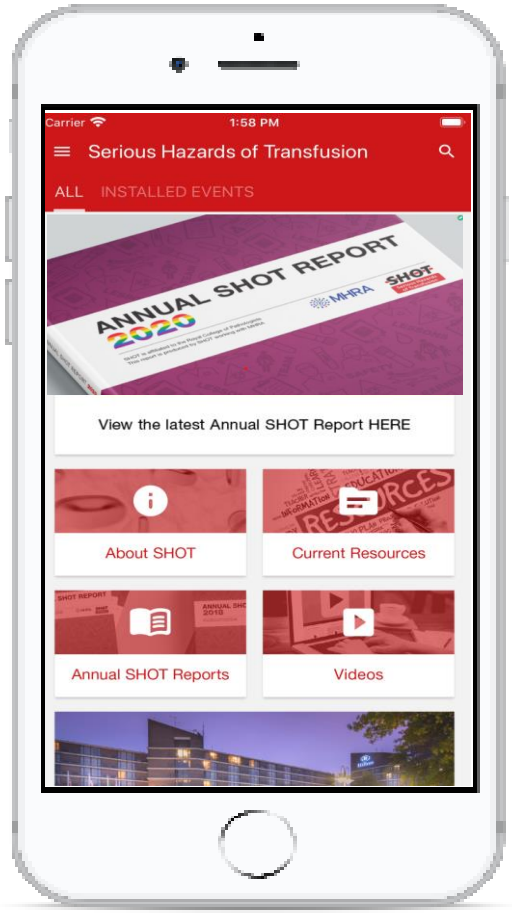
- In particular our educational resources
  - SHOT Bites
  - SHOTcasts
  - Webinars
  - Videos (Laboratory errors)
  - Email signatures

UK Transfusion Laboratory Collaborative

SCAN ME

SHOT
Serious Hazards of Transfusion

SHOT App



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Serious Hazards of Transfusion

Annual SHOT Symposium 2023

Save the date!

Tuesday 04 July 2023

Etihad Stadium, Manchester, M11 3FF

Acknowledgements

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

For further information visit: www.shotuk.org