Key Messages and Recommendations 4

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Key SHOT messages

- **Ensuring transfusion teams are well resourced:** Clinical and laboratory teams can function optimally only if adequately staffed and well resourced. Healthcare leaders and management must ensure that staff have access to the correct information technology (IT) equipment and financial resources for safe and effective functioning
- **Addressing knowledge gaps, cognitive biases, and holistic training:** Transfusion training with a thorough and relevant knowledge base in transfusion to all clinical and laboratory staff along with training in patient safety principles, understanding human factors and quality improvement approaches are essential. It is important that staff understand how cognitive biases contribute to poor decision making so that they can be mitigated appropriately
- **Patient safety culture:** Fostering a strong and effective safety culture that is 'just and learning' is vital to ensure reduction in transfusion incidents and errors, thus directly improving patient safety
- **Standard operating procedures (SOP):** SOP need to be simple, clear, easy to follow and explain the rationale for each step. This will then ensure staff are engaged and more likely to be compliant and follow the SOP
- **Learning from near misses:** Reporting and investigating near misses helps identify and control risks before actual harm results, thus providing valuable opportunities to improve transfusion safety
- **Learning from the pandemic:** The learning from the pandemic experiences should be captured in every organisation, by everyone in healthcare and used to improve patient safety

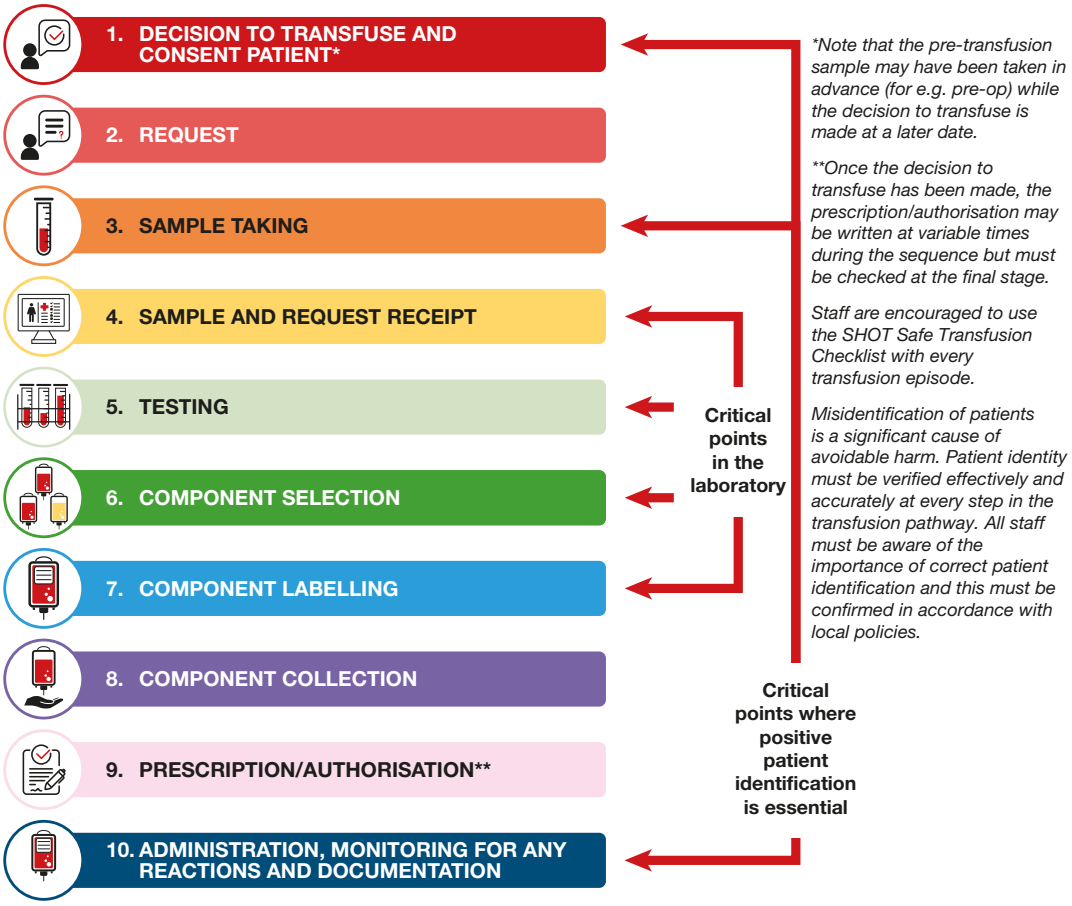
Abbreviations used in this chapter

CAPA	Corrective and preventive action
CQC	Care Quality Commission
EBMS	Electronic blood management system
GI	Gastrointestinal
Hb	Haemoglobin
HFIT	Human factors investigation tool
ICH	Intracranial haemorrhage
IT	Information technology
LIMS	Laboratory information management system
MHP	Major haemorrhage protocol
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
NPSA	National Patient Safety Agency
OGD	Oesophago-gastro-duodenoscopy
RCA	Root cause analysis
SaBTO	Advisory Committee on the Safety of Blood, Tissues and Organs
SCRIPT	SHOT UK Collaborative Reviewing and Reforming IT Processes in Transfusion
SOP	Standard operating procedure
UK	United Kingdom
UKAS	United Kingdom Accreditation Service
WCT	Wrong component transfused

Blood transfusion is a critical element of medical and surgical therapies. Transfusions are very safe and effective when used appropriately. The risk of death from transfusions in UK is very low despite the steady increase in the number of reports submitted to SHOT year on year (see Chapter 3, Headline Data: Deaths, Major Morbidity and ABO-Incompatible Transfusions). Changes in transfusion practices have resulted in a reduction in pathological transfusion reactions and deaths from infections. The main risks however are related to human factors. Pulmonary complications and delays in transfusions are now the main causes of transfusion-related deaths. Ensuring transfusion process safety is as important as blood component safety and quality. Potential for serious problems exists at each step in the process of transfusion and learning from incidents reported should drive improvements in healthcare. Figure 4.1 covers the steps in the transfusion process at the recipient end from making the decision to transfuse to administration of blood and monitoring for any reactions. The nine steps referenced in previous SHOT reports have been updated following feedback from transfusion colleagues to include the decision to transfuse and patient consent.

Use of checklists, embedding the use of electronic identification systems and incorporation of human factors and ergonomics principles in transfusion practices will help to improve decision making in transfusion. The key messages and recommendations from the previous Annual SHOT Reports remain relevant and all healthcare organisations involved in transfusion are encouraged to continue implementing these and ensuring measures have been effective.

Figure 4.1: Ten steps in transfusion



All staff involved in blood transfusions need to have basic knowledge of blood components, indications for use, alternative options available, risks and benefits and possible reactions and their management. SaBTO released an updated set of recommendations to NHS Trusts/Health Boards on patient consent for a blood transfusion. These guidelines were approved and released by SaBTO in December 2020 (SaBTO 2020) and supersede the previous SaBTO 'Patient consent for blood transfusion guidelines from 2011'. Table 4.1 highlights the key aspects that need to be covered when consenting patients for transfusions.

	Key aspects to be covered when consenting patients for transfusion
1	Patient and/or family/carer have been provided with relevant information about blood transfusions that would help in their decision-making process
2	The reason for the transfusion has been discussed
3	The benefits of the transfusion have been explained
4	Transfusion risks, both short and long-term risks have been discussed with the patient and/or family/carer (including any additional risks pertinent to long term multi-transfused patients)
5	The risks, benefits, and consequences of NOT accepting blood transfusion have been elaborated
6	Transfusion issues specific to the patient have been highlighted
7	Relevant alternative options have been discussed including how they might reduce the need for a transfusion
9	The transfusion process has been explained
10	The need for any specific requirements for blood components and rationale, including need for anti-D Ig post transfusion as appropriate has been elaborated and relevant patient information leaflet has been provided
11	Patient and/or family/carer has also been informed that once transfused, they are no longer eligible to donate blood
12	Patients and carers/family have been given the opportunity and been encouraged to ask questions
13	Patient and/or family/carer is aware that if they change their mind at any point before the transfusion, they are entitled to withdraw their consent, and this should be documented and managed appropriately
14	Synopsis of discussions and decisions taken documented in patient's clinical notes

Table 4.1: Consenting patients prior to transfusions (based on the SaBTO guidance and NICE guidance NG24)

The Safe Transfusion Checklist that is available to download from the SHOT website covers most aspects of the transfusion process at the bedside (https://www.shotuk.org/resources/current-resources/). The ABCDE approach to transfusions shown below helps in the transfusion decision-making process.

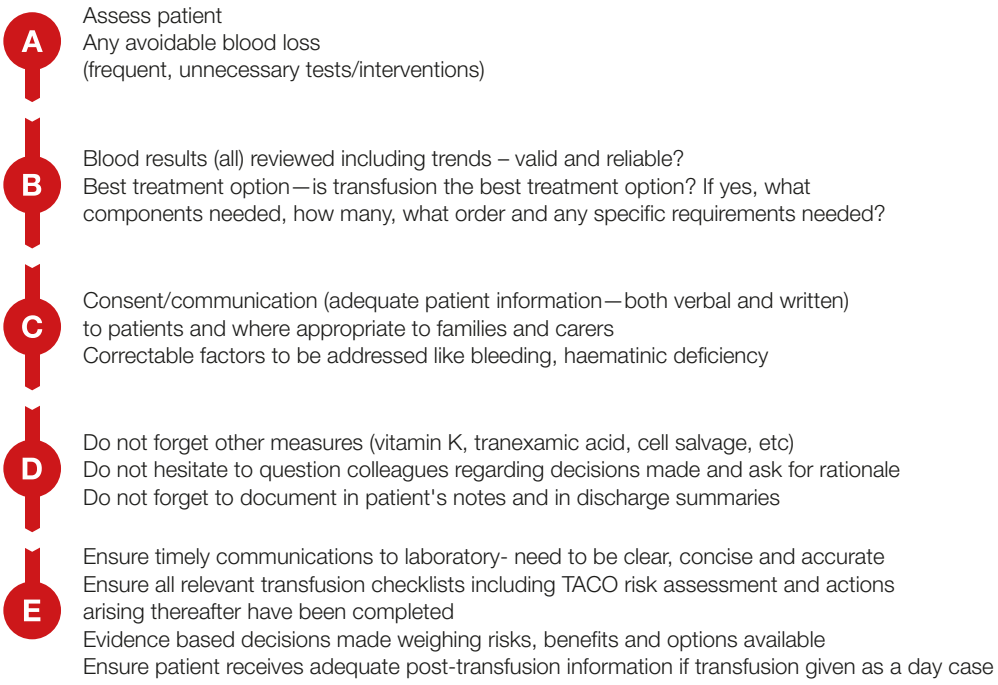


Figure 4.2: The A-E Decision Tree to facilitate decision making in transfusion

Key SHOT recommendations for 2020

The main SHOT recommendations from the preceding years remain pertinent as improvements still need to be made to address gaps previously identified. The first NHS-wide Patient Safety Syllabus (AoMRC, 2020) supports a transformation in patient safety education and training in the NHS for all healthcare professionals. It highlights the importance of human factors principles and promotes a systems approach to patient safety. The following are the key recommendations based on the emerging themes from the 2020 Annual SHOT Report. For the first time a gap analysis tool has been developed by the SHOT team to help local organisations to identify key areas for improvement (link provided in the recommended resources at the end of the chapter).

Addressing transfusion delays

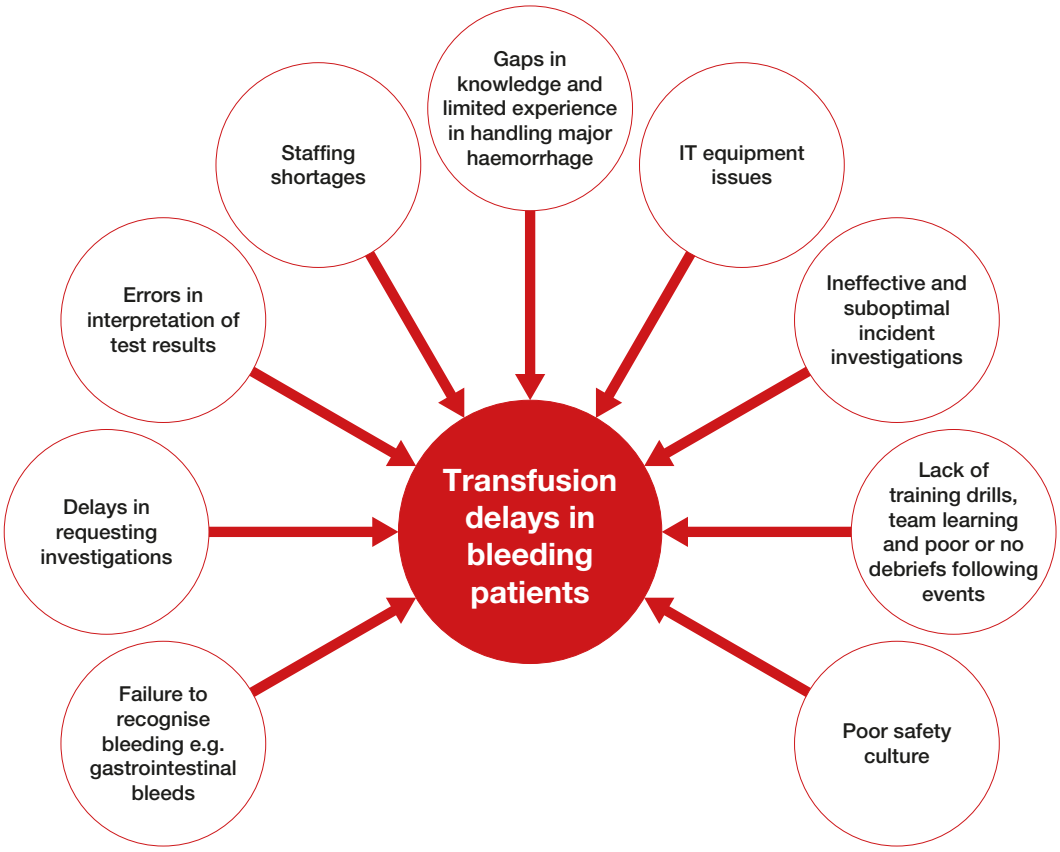
The number of cases of transfusion delays reported to SHOT are increasing year on year and contribute significantly to transfusion-related patient deaths. These delays are largely avoidable, and serial Annual SHOT Reports have highlighted that measures need to be taken by clinical and laboratory transfusion teams to address delays and improve safety. Transfusion delays have been reported in adults and children. Instances where laboratory test results have not been interpreted correctly resulting in delays in accessing specialist help have also been reported.

It is concerning that delays have been reported in relation to MHP activation including delays in anticoagulant reversal where every minute counts. A published review of 680 trauma patients noted that every minute of delay from activation of the MHP to delivery of components increased the odds of death by 5% (Meyer et al. 2017).

It is now more than 10 years since the NPSA published their Rapid Response Report (NPSA 2010). This alert was issued in relation to 11 deaths and 83 incidents of harm due to delays reported over a 4-year period. The number of reports submitted to SHOT as 'delayed transfusions' are increasing year on year and 133 cases were reported in 2020 with 12 cases resulting in patient death. The increase in both total number of reported delays and deaths is of concern. The most important factor contributing to delay is poor communication. Guidelines published in 2015 recommend that all staff 'involved in frontline care must be trained to recognise major blood loss early, know when to activate/trigger the local major haemorrhage protocol and take prompt and appropriate action' (BSH Hunt et al. 2015) and good communication is essential. The key components of a MHP are listed in recent review (Booth and Allard 2018) and include scope, activation method, choice of components, communication, stand-down, and regular review including training and drills. The evidence from SHOT reporting suggests that there is room for improvement.

Factors contributing to transfusion delays in bleeding patients is shown in Figure 4.3. Serial delays at different transfusion steps are cumulative and can result in patient harm or death. Details about the cases reported to SHOT can be found in Chapter 12a, Delayed Transfusions.

Figure 4.3: Factors contributing to transfusion delays in bleeding patients



Gastrointestinal bleeding can be deceptive, the severity is often masked, diagnosis may be delayed; hypotension and tachycardia are important clinical signals. NICE guidelines recommend that patients with an upper gastrointestinal bleed should have an OGD within 24 hours (of admission) (NICE 2012). Patients with upper GI bleeding should have a Blatchford score recorded to assess the bleeding risk (Banister et al. 2018; Chatten et al. 2018). Patients with evidence of GI haemorrhage require close monitoring, timely investigation, and appropriate transfusion; this may be incremental to keep up with bleeding, keeping a close watch on the Hb and clinical signs of bleeding.

Obstetric haemorrhage can be rapid and massive; it is vital that major haemorrhage protocols work smoothly and quickly. Improving staff knowledge and training drills and learning to work together as teams are essential. In MH scenarios there must be a process for safe concessionary release of red cells for patients with antibodies. In complex cases transfusion experts should be contacted for advice to ensure appropriate and timely management.

Systemic shortcomings should be identified and urgently addressed to reduce the time between decision to transfuse to actual transfusion. These include review of the porter services and emergency back-up arrangements. Where the use of refrigerators has to be suspended there must be clear communication of alternative procedures for emergencies. The management of major haemorrhage continues to require improvement in many hospitals with attention to streamlining communication, training, and drills. Communication between hospitals during patient transfer must be comprehensive and include all laboratory information. Clinicians must provide laboratory staff with relevant clinical information so that they provide appropriate interpretation of results and be open to challenge by laboratory staff. A holistic systems approach to incident investigation, reviewing timelines and mapping events throughout the patient journey would help to identify missed learning opportunities. Seeking urgent specialist input especially in cases with haemolysis, and/or a positive antibody screen will help prevent unnecessary delays. No patient should die from want of blood.

Main recommendation 1

- Transfusion delays, particularly in major haemorrhage and major trauma situations, must be prevented. Delays in provision and administration of blood components including delays in anticoagulant reversal, particularly in patients with intracranial haemorrhage (ICH), can result in death, or serious sequelae. Every minute counts in these situations

Actions required:

Multidisciplinary hospital transfusion committees should:

- Ensure that procedures are in place detailing identification, escalation and blood provision in major haemorrhage and trauma cases
- Ensure procedures are agreed by relevant clinical and laboratory groups, are accessible, and incorporated in regular training and simulation exercises
- Ensure that procedures are in place detailing appropriate use of anticoagulant reversal agents without requirement for approval by a consultant haematologist
- Ensure appropriate use and access to anticoagulant reversal agents is incorporated into regular training for clinical and laboratory staff
- Consider implementation of a fixed dose regime for prothrombin complex concentrates, with rapid access for ICH cases

Pathology laboratory management should:

- Ensure that procedures are in place enabling rapid provision of blood components in complex situations, using concessionary release pathways
- Ensure major haemorrhage, trauma and concessionary release procedures are incorporated into regular training and competency-assessment for all staff working in transfusion laboratories

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Reliable and robust IT systems to support transfusion practices

IT systems are integral to the safety and efficiency of the transfusion chain vein-to-vein, right from donor management to donation management and processing to issue to hospitals and transfusions to patients. Electronic bedside identification systems using hand-held computers and portable printers will minimise the risk of wrong transfusions caused by blood sampling error for compatibility testing and patient identification error before blood administration. Fully automated hospital transfusion laboratory immunohaematology testing systems together with LIMS help reduce hospital transfusion laboratory errors. Remote electronic blood release systems, an extension of the hospital transfusion laboratory LIMS to refrigerators in the clinical arena may aid the safe release of computer crossmatch-compatible blood. Computer transfusion requests would guide clinicians in making appropriate requests, and connectivity with electronic patient records and hospital transfusion laboratory LIMS would provide clinical decision support and thus help prevent human errors. EBMS are invaluable in the collection and administration of blood components as a second check to prevent errors, and provide detailed audit trails, helping improve transfusion safety.

SHOT has highlighted the importance of IT in preventing human errors and the need for effective implementation of appropriate IT solutions in safe transfusions for the last 2 decades. The use of computerised identification systems to avoid patient identification errors was first mentioned in the Annual SHOT Report for 1999-2000 (Love et al. 2001). This was a key SHOT recommendation in the 2017 Annual SHOT Report, 'All available information technology (IT) systems to support transfusion practice should be considered and these systems implemented to their full functionality. Electronic blood management systems should be considered in all clinical settings where transfusion takes place. This is no longer an innovative approach to safe transfusion practice; it is the standard that all should aim for' (Bolton-Maggs et al. 2018). SHOT has strongly supported the use of IT to reduce human errors in transfusion medicine. This has also been supported by NICE (NICE NG24, 2015). The NICE guidance states 'consider using a system that electronically identifies patients to improve the safety and efficiency of the blood transfusion process'.

The adoption and widespread use of IT in transfusion still lags behind its knowledge and awareness of impact on safety. The key to closing this gap is for healthcare leaders to make this a key priority and invest in safety.

The 2018 SHOT recommendations survey highlighted that there are significant gaps in IT adoption and use across the NHS and competing priorities, stretched resources and finance were commonly cited as barriers (https://www.shotuk.org/resources/shot-surveys/). Responses were received from SHOT reporters. Of concern there were several comments stating senior leaders and managers failed to recognise the importance of IT in improving transfusion safety.

A multicentre study, the first of its kind, demonstrated a lower incidence of IBCT-WCT and near-miss IBCT-WCT with electronic patient identification systems compared to manual processes, thus demonstrating the application of information technology in minimising wrong transfusions through the reduction of human steps that are prone to errors (Murphy et al. 2019).

A 3-year retrospective review (2016 to 2018) of near miss SHOT reports identified with an IT element highlighted the importance of electronic systems in the detection and reporting of errors, but also show where design and implementation flaws introduce errors (Davies et al. 2020). Greater reliance

on IT makes thorough system validation critical. Robust systems are needed to ensure patient specific requirement flags are added to LIMS. Drop down lists are ergonomically dangerous, if present LIMS should include a validation function for confirmation of the entered reaction pattern against the selected blood group during any manual entry of blood groups.

The Department of Health and Social Care of the United Kingdom released 'The future of healthcare: our vision for digital, data and technology in health and care' in 2018 (DHSC 2018). This sets out plans for a truly joined-up health and care, designed around the needs of patients and their care networks, with good integration of physical and digital services. The vision is to have a safe and secure data infrastructure that protects the health and care system. Patients and local organisations would be able to make the right technology choices for their own area, while also maintaining high quality systems than can communicate across the entire NHS, achieving better, safer, more targeted care.

NHS Digital has published a draft of a new framework that will set out the core standards on technology and data by which all IT systems and digital services in the NHS must abide. Greater standardisation of data, the right infrastructure and platforms, secure systems and interoperability will ensure that patient care is more joined-up, safer and more efficient. All these elements are critical to the safe and successful use of technology, ensuring that systems talk to each other and that the right data get to the right place at the right time. Interoperability or the lack of it has been a major impediment in transfusions. Connected systems ensure that clinicians have immediate access to relevant and appropriate patient data, both clinical and laboratory, from care providers and settings. Data can be communicated between systems with absolute fidelity, eliminating misinformation and misunderstandings (NHS Digital 2020).

IT systems support staff to administer blood components safely and appropriately. Electronic systems are vital in the detection and reporting of errors, but for IT systems to be effective and reliable, they should be designed and implemented appropriately with a robust validation process. Staff must be trained and should have access to subject matter experts. IT system design and implementation flaws introduce errors. Reliance on IT does not equate to complacency. Greater reliance on IT makes thorough system validation critical. Robust systems are needed to ensure patient-specific requirement flags are added to LIMS. Recognising the urgent need for improvements in this area, SHOT is aiming to bring together transfusion experts to work with IT experts and the manufacturers of these systems to ensure we have the best possible outcomes for our patients. The SHOT UK Collaborative Reviewing and reforming IT Processes in Transfusion (SCRIPT) group was initiated by the SHOT IT and laboratory working expert group members in 2020. The SCRIPT work will include the specification and implementation of IT systems as well as promoting interoperability, raising the profile of transfusion requirements within IT systems, and could also include training transfusion experts in IT and IT experts in transfusion.

SCRIPT work plans include:

1. A survey completed by SHOT reporters giving a UK-wide picture of IT systems that support transfusion – this has been completed and is undergoing analysis
2. To engage with software providers and with healthcare IT strategy groups and individuals
3. To run a SCRIPT workshop in collaboration with key stakeholders with both transfusion personnel and IT providers to inform and educate about transfusion IT and identify areas for improvement
4. To support and maintain a community of practice within transfusion IT

Further information about the SCRIPT work can be accessed on the SHOT website (https://www.shotuk.org/resources/current-resources/script/)

Main recommendation 2

- Effective and reliable transfusion information technology (IT) systems should be implemented to reduce the risk of errors at all steps in the transfusion pathway, provided they are configured and used correctly

Actions required:

Hospital senior management should:

- Ensure transfusion IT systems that support good practice and safe patient care, as recommended by the hospital transfusion committee or equivalent, are implemented across the organisation

Transfusion IT providers should:

- Ensure systems are compliant with the relevant current national legislation, guidelines, and recommendations
- Ensure systems support safe practice using appropriate alerts with consideration to reduce risk of alert fatigue

Pathology laboratory management should:

- Ensure that all transfusion IT systems are used to their full potential, are compliant with relevant national legislation, guidelines, and recommendations and are regularly validated
- Ensure that use and understanding of the transfusion IT systems is incorporated into staff training and regular competency-assessment

Hospital IT management should:

- Consider the impact of changes to, or implementation of, any clinical IT system on the delivery of the transfusion service, including planned downtime events
- Review opportunities to improve transfusion safety, from the decision to transfuse through to the administration and monitoring of the transfusion, by harnessing interoperability between clinical IT systems and transfusion IT systems

Investigating incidents

Investigating incidents is integral to providing a safe transfusion service and preventing patient harm. The quality and safety risk in the context of the patient should be central to all investigations. Effective incident investigation processes can reduce error, improve practice and lead to safer systems. Learning from experiences can prevent harmful incidents from recurring- safety is enhanced by learning from all incidents.

Incident investigations often are inadequate and fail to identify causes of failure or improvement actions to reduce recurrence. Introduced into SHOT reporting in 2016, the HFIT results have shown that investigations disproportionately blame individuals while system failures are overlooked (see Chapter 8, Human Factors in SHOT Error Incidents). Re-training or supervising one individual will not fix the system or prevent recurrence of errors. To truly improve practice, provide safe processes and reduce risk a systems-based approach to investigating incidents is required. A systems-based approach to the investigation of incidents and moving to a just and learning culture is essential. Incorporating a just and learning culture in all NHS organisations and moving away from a blame culture was a key SHOT recommendation in 2018 (Narayan et al. 2019) – this is fundamental for a good safety culture in any organisation.

Regulatory guidelines and standards require that incidents, or non-conformances, are identified, investigated and that actions are taken to reduce the risk of recurrence:

- Good Practice Guidelines 2018 (9.4) include the requirement for an appropriate level of RCA and identification of CAPA (Council of Europe 2018)

- UKAS ISO15189:2012 includes identification of the root causes, implementation of CAPA and review of the effectiveness of the actions (UKAS 2019)
- NHS England and NHS Improvement provide standardised tools and templates for patient safety incident investigations, guides to duty of candour and supporting a just culture (NHS England n.d.)
- CQC regulation 12: safe care and treatment require that incidents are reviewed, thoroughly investigated by competent staff and monitored to make sure that action is taken to remedy the situation, prevent further occurrences and make sure that improvements are made as a result (CQC 2014)

Incident analysis is part of the incident management continuum in every organisation and needs to be reviewed regularly. Thorough incident investigations using human factors principles will help identify the causal and contributory factors; and will inform the corrective and preventive actions to improve patient safety. This year one of the ABOi cases has been worked through using the new SHOT HFIT framework (incorporating the Yorkshire Contributory Factors Framework) and the Systems Engineering Initiative for Patient Safety (SEIPS) model to illustrate the benefits of applying human factors principles and systems thinking to incident investigations- both these re-worked investigation reports can be accessed online (https://www.shotuk.org/shot-reports/report-summary-and-supplement-2020/).

Main recommendation 3

- Effective investigation of all incidents and near miss events, application of effective corrective and preventive actions, and closing the loop by measuring the effectiveness of interventions should be carried out to optimise learning from incidents

Actions required:

Risk management departments should:

- Provide support and training for all staff involved in transfusion-related incident investigation
- Ensure procedures and templates are available that include consideration of human factors and a system-based approach to investigation, include plans for corrective and preventive actions and a process for reviewing the effectiveness of the actions
- Provide a platform to share learning from transfusion errors and near miss events across the whole organisation

Pathology laboratory management should:

- Ensure capacity plans include provision of adequate staffing to support robust investigation of all transfusion-related incidents and near miss events
- Ensure that staff involved in incident investigation have received adequate training, including human factors and a system-based approach to investigation
- Provide support with implementation of effective corrective and preventive actions, ensuring that these are forcing functions* wherever possible

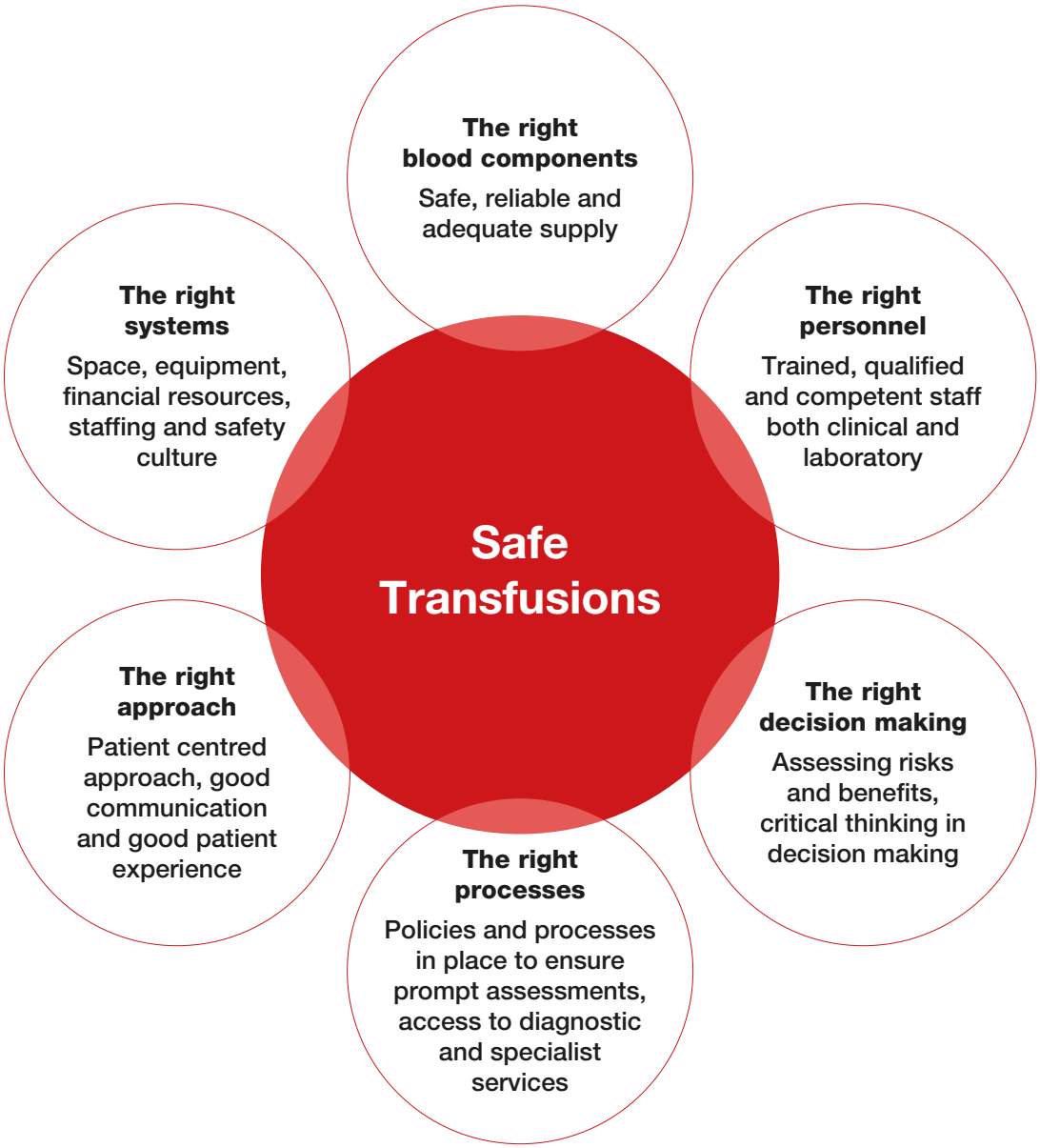
A **forcing function is an aspect of a design that prevents the user from taking an action without consciously considering information relevant to that action (e.g. rule in LIMS that does not allow issue of ABOi red cell units).*

Framework for safe transfusions in the NHS

The 10 'Rs' framework discussed in the 2019 Annual SHOT Report based on the 10' R's safe prescribing and safe administration of medications acknowledges that the responsibility for managing the environment where transfusions take place and the responsibility for safe transfusions is a multi-disciplinary concern (Narayan et al. 2020). It is therefore clear that the actions needed to address transfusion errors should be multifaceted. Transfusion errors are often the result of faulty systems, processes, and conditions that lead people to make mistakes. The key to eradicating transfusion errors and advancing patient safety is to create systems for healthcare delivery that doctors, nurses, and others providing patient care can rely on.

At a macro-system level all the following aspects (Figure 4.4) are vital for safe transfusions in healthcare:

Figure 4.4: Framework for safe transfusions



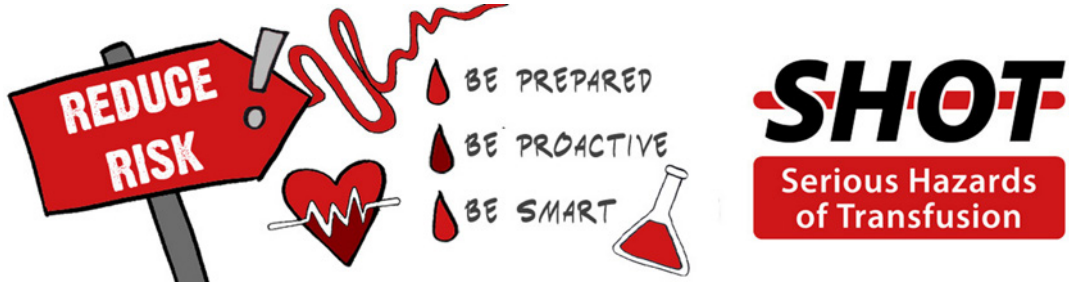
Systems-based strategies with a collaborative effort by everyone in healthcare comprising frontline staff, supporting workforce including those in management and executives, are needed urgently to bring about sustainable and tangible improvements in patient safety.

Recommended resources

SHOT Bite No. 1a and 1b: Incident Investigation
SHOT Bite No. 8: Massive Haemorrhage – Delays
SHOT Bite No. 13: Information Technology in Transfusion – Highlights and Lessons
SHOT Bite No. 16: Errors with Prothrombin Complex Concentrate
SHOT Bite No. 17: Near Miss
https://www.shotuk.org/resources/current-resources/shot-bites/

2020 Annual SHOT Report gap analysis tool for all recommendations
https://www.shotuk.org/shot-reports/report-summary-and-supplement-2020/

SHOT educational video about transfusion delays in major haemorrhage can be accessed at the link
https://www.shotuk.org/resources/current-resources/videos/



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