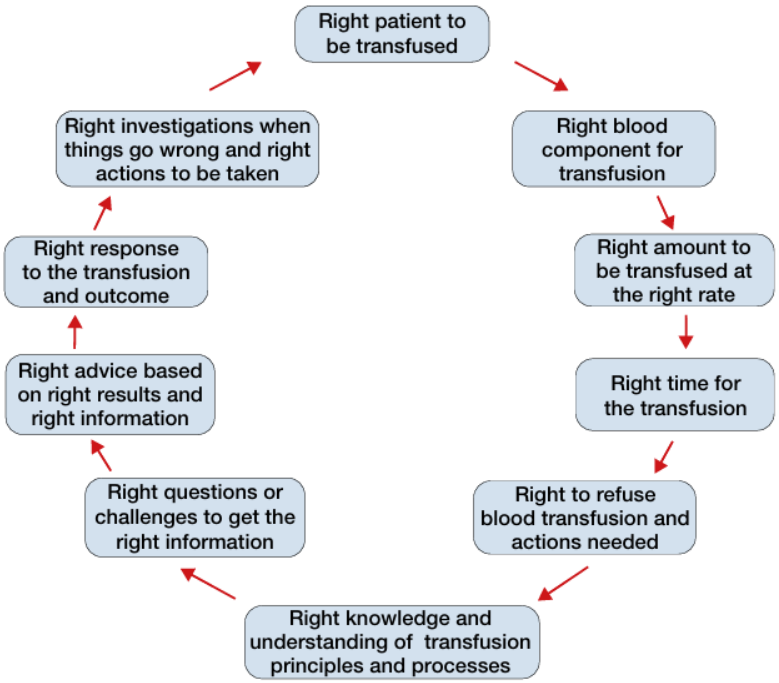
Framework for safe transfusions

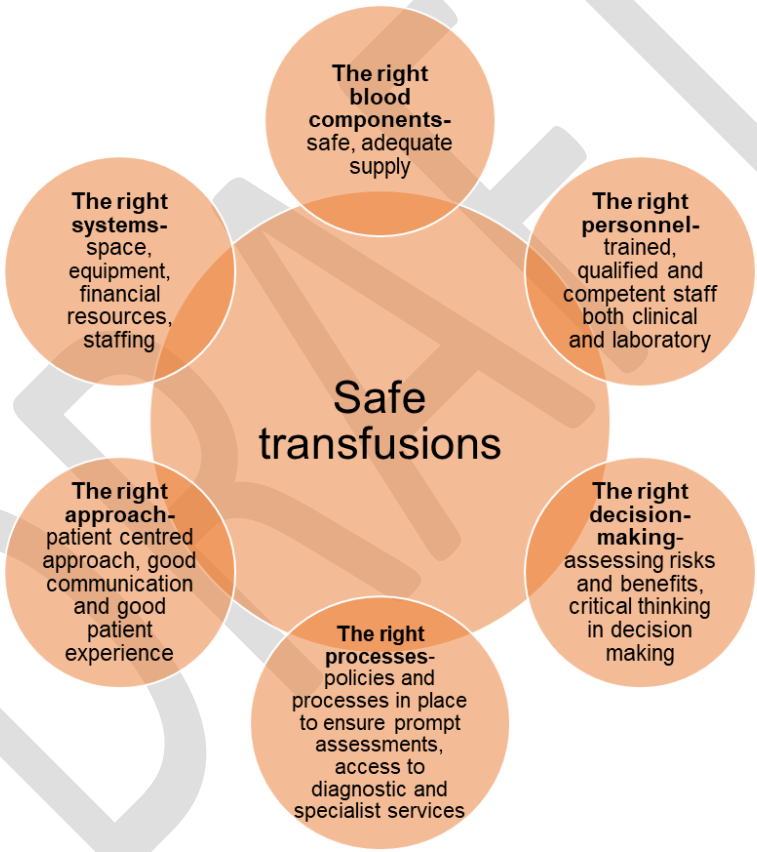
Transfusion is a complex multistep process and involves members of several different professional groups working together in a coordinated manner to ensure timely provision of blood components to save and improve lives. The 10 'Rights' (10 'Rs') for safe transfusions as discussed in the 2019 Annual SHOT Report includes considerations to follow before, during and after transfusions by both clinical and laboratory transfusion staff. This highlights key actions needed from healthcare staff to support safe transfusions. These considerations encompass the need for critical thinking when making transfusion decisions, which can be complex to ensure safe practices. All staff involved in blood transfusions must have essential knowledge of the blood components, indications for use, alternate options available, risks and benefits and possible reactions and their management.

Figure 1.0: Ten 'Rights' for safe transfusions



The 10 ‘Rs’ framework 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). At a macro-system level all the following (Table 2) need to be considered for safe transfusions in healthcare.

Figure 2: Framework for safe transfusions



SHOT Transfusion Safety Standards

Transfusions can save and improve lives but there are also risks associated with their administration and use. Adverse outcomes can vary in frequency and severity, and include allergic and immunological complications, infections, and process-based errors such as incorrect blood transfusions. Serial Annual SHOT Reports have shown that avoidable errors contribute to >80% cases analysed annually, and these are potentially preventable. Errors are evident both in clinical and laboratory areas and while these are usually multifactorial, they can adversely impact transfusion outcomes and patient experiences. Transfusion reactions can range from clinically mild to life-threatening and can be acute or delayed. The nature of the reaction may not be immediately apparent, as many reactions begin with nonspecific symptoms such as fever or chills. In addition, patients receiving transfusions often have complex underlying clinical conditions, the symptoms of which may mimic a transfusion reaction. It is often challenging to attribute imputability of the patient's reaction/complication to transfusion when there are multiple ongoing medical and surgical issues in the patient.

Additional drivers for developing these safety standards include recommendations from the Infected Blood Inquiry report, Lord Darzi's report from an independent investigation of the NHS in England and the Health Services Safety Investigations Body report released in September 2024 'Recommendations but no action: improving the effectiveness of quality and safety recommendations in healthcare'. Transfusion safety standards will help drive improvement actions to minimise risks, maintain reliability, ensure effectiveness of transfusions and optimise safety for all.

To optimise safety of transfusions, every healthcare organisation must have policies, procedures, and processes for safe transfusion practice in laboratory and clinical settings. ***Healthcare leaders within organisations should ensure that there is evidence that these are effective and embedded in practice.*** These standards cover all aspects of the SHOT 10 steps for allogeneic and autologous blood component handling and use (https://www.shotuk.org/wp-content/uploads/myimages/Ten-steps-in-transfusion.pdf).

These SHOT Transfusion Safety Standards do not replace but complement other regulatory or best practice recommendations such as the Blood Safety and Quality Regulations, British Society for Haematology guidelines, UK Transfusion Laboratory Collaborative (UKTLC) Standards and National Institute for Health and Care Excellence (NICE) Transfusion Quality Standards. These standards provide a framework for peer review/self-assessment, compliance check by regulatory organisations and/or national oversight. Where inspection against the SHOT Safety Standards show deficiencies, organisations may be requested to demonstrate compliance with these other transfusion requirements.

Intention of these standards:

The SHOT transfusion safety standards have been drafted to promote and ensure safe and effective transfusions by identifying risks, implementing strategies that create a safer environment for everyone involved, contributing to better patient outcomes, staff wellbeing and overall system safety. It is important to recognise that local improvement plans must be identified and implemented to address any non-compliance with any of these standards to ensure optimal transfusion safety.

It is expected that compliance level against each of these standards can be recorded locally as either fully compliant/partially compliant or non-compliant with an action plan to address gaps when not fully compliant.

Explanatory notes and background information:

SHOT is the UK's independent, professionally led haemovigilance scheme analysing transfusion errors and reactions submitted annually since 1996 to identify areas for improvement to optimise safety. Haemovigilance reporting and learning from reports submitted contribute to improving patient safety. These reports provide a mechanism to identify risks so that all healthcare organisations can implement interventions to reduce these risks. Data from SHOT provide valuable information to identify hazards and worthwhile learning opportunities. SHOT collaborate and work closely with MHRA as the regulators and other key transfusion stakeholders to enhance transfusion safety.

The SHOT haemovigilance data from 2023 show worrying trends which reflect the increasing challenges in healthcare. From the 2023 Annual SHOT Report, the risk of death related to transfusion in the UK is approximately 1 in 58,000 components issued, and the risk of serious harm is approximately 1 in 11,000 components issued. Avoidable errors continue to account for most of the reports 3184/3833 (83.1%). This figure includes errors with no harm to patients but had the potential to do so such as near misses and right blood right patient errors.

Recurring themes in analysed incidents include:

- Staffing issues, with shortages and mismatched with workload, inadequate skill mix, staff retention and recruitment challenges;
- Gaps in staff knowledge with no protected training time, accelerated/abbreviated training programmes, poor awareness of importance and application of human factors;

- Inadequately resourced systems – lack of equipment or not fit for purpose;
- IT issues: poor implementation, suboptimal staff training, no access to subject matter experts, overreliance on IT, complacency with alert fatigue/warning flags not heeded;
- Poor communication within and between teams, especially during handovers;
- Failure to listen to patients and families with missed opportunities for engagement;
- Poor leadership and safety culture

To address risks and problems identified, SHOT produces recommendations to improve patient safety which are put into its annual report. Prioritisation and implementation of recommendations are left to individual healthcare organisations, both NHS and independent ones. With limited resources and ongoing challenges, while some recommendations relating to immediate patient safety risks may be implemented, it remains patchy with a lack of sustained long-term change and similar themes continuing to be evident in reports analysed year on year. Haemovigilance is an ongoing exercise, and while SHOT monitor the impact and extent of implementation of these recommendations, there is no effector arm for SHOT. Lack of effective implementation of these recommendations, clashing priorities and worsening healthcare challenges post pandemic means that the gaps identified and the recommendations to address them continue to be the same year on year.

The main recommendations from SHOT in the recent years have been relating to:

- Ensuring well resourced systems with safe staffing levels and staff having appropriate knowledge and technical and non-technical skills
- Making safe transfusion decisions, assessing risks and benefits; addressing transfusion delays and TACO; timely, effective and appropriate management of anaemia
- Accurate and complete patient identification and appropriate use of IT for the same
- Patient engagement/involvement and shared decision making
- Effective timely communications to ensure safe transfusions
- Effective, reliable IT systems vein to vein
- Just, learning safety culture; optimising learning from incidents; effective sustainable systemic actions
- Holistic approach to safety- combining Safety-I and II; learning from NM, excellence and day-to day events

These are fundamental principles to ensure safe transfusions for all, and incorporating these into safety standards provides a structured and consistent approach to maintaining safety and will help crate lasting changes by embedding safe practices into daily operations making them part of organisational culture. Standards will also help establish clear benchmarks, support regulatory checks, facilitate tangible improvements, and foster accountability among healthcare providers. These will also help focus proactively addressing known risks systematically and help organisations allocate resources effectively by prioritising essential safety measures.

Explanation of terms used:

Transfusion activities – includes direct patient care activities, laboratory, quality, regulatory, training, education, advice, IT support.

Blood components (red cells, platelets, FFP, cryoprecipitate, granulocytes) and autologous (intraoperative cell salvage, pre- or post-operative using patients own blood) transfusion covered by this safety standard unless otherwise specifically stated for particular blood/plasma derived medicinal products (such as anti-D immunoglobulin and prothrombin complex concentrates).

Shared care – where a patient is treated/managed by different organisations or laboratory testing is performed by different organisations.

Scope of these standards:

The SHOT transfusion safety standards cover the key elements evident from serial Annual SHOT Reports relating to the clinical and laboratory aspects in healthcare systems that help ensure safe transfusions.

Effective implementation and use of these transfusion safety standards require:

- Healthcare leaders and managers to implement policies, processes, and practices to ensure the safe, appropriate, efficient, and effective use of blood components.
- Clinicians and laboratory staff ensure effective and appropriate use of blood components and participate in quality improvement activities, blood safety and quality systems.
- Patients (and carers) are engaged in decisions about their management and, if they receive blood components, they do so appropriately and safely.

The following key areas are covered in the transfusion safety standards:

1. Governance, oversight and reporting structures
2. Staffing levels
3. Education and training
4. Transfusion information technology
5. Transfusion safety
6. Haemovigilance and risk management

Standards:

1. Governance

1.1. Terms of reference for Hospital Transfusion Teams (HTT) and Hospital Transfusion Committees (HTC) (or equivalent) are available that detail accountability. There is evidence of regular meetings and compliance with terms of reference.

1.2. Outputs from Hospital Transfusion Teams and Hospital Transfusion Committees are escalated to relevant executive level governance forums.

1.3. There is accountability and evidence at executive level providing oversight of transfusion activities.

1.4. There is governance representation at HTC or equivalent meeting.

1.5. Policies and processes in place to facilitate implementation, monitor progress and address gaps related to recommendations and standards from regulatory and professional transfusion bodies (such as British Society for Haematology, NICE, SHOT) and national patient safety alerts

2. Staffing

2.1. Staffing numbers are adequate for transfusion activities. This includes all activities related to transfusion, including training, quality, governance, attendance at governance and oversight meetings. Adequate staffing provision includes consideration of skill mix.

2.2. Succession planning/workforce planning is in place. Delays in recruitment are minimised, particularly where posts are considered hard to fill.

2.3. Contingency plans detail actions when adequate staffing levels cannot be met. Escalation of inadequate staffing levels are reviewed by appropriate personnel and effective actions are taken.

3. Education and training

3.1. All staff involved in transfusion activities have the relevant education, qualifications and transfusion knowledge for their role to o be able to make evidence-based decisions
3.2. There is induction and regular training provided that is reviewed and reflects current national recommendations. Training includes technical and non-technical skills.
3.3. There is a programme for competency assessment relevant to the role.
3.4. There are opportunities for all staff to access educational events relevant to their role.

4. Transfusion Information Technology (IT)

4.1. IT systems are in place that support safe practice for all steps in the transfusion pathway.
4.2. IT systems have been validated and approved for use by appropriate personnel.
4.3. IT system functionality and interoperability are used to their full potential. Deficiencies are escalated and progress for resolution monitored by the organisation and supplier, with clear timelines for resolution.
4.4. Where systems are interfaced there is full electronic transfer of information, with no requirement for manual entry.
4.5. Where alerts are used, these are appropriate, clear, and meaningful to the user.
4.6. Staff are provided with training to use the IT systems.
4.7. Evidence that Human factors and ergonomics principles have been considered, and are regularly reviewed, for all IT systems.
4.8. Transfusion subject matter experts are involved in the selection, procurement, and management of IT systems.
4.9. Contingency plans for downtimes are accessible, include adequate instructions, are regularly reviewed and subject to assurance testing.

5. Transfusion safety

5.1. Policies, procedures, and processes support safe practice for all steps in the transfusion pathway, from sample taking and labelling to administration of the blood component, recognition and management of transfusion reactions.
5.2. Failsafes are in place to identify and minimise adverse events for critical aspects. At a minimum this includes:
  5.2.1. Assurance that sample labelling is performed at the side of the patient, and adherence to sample acceptance policies.
  5.2.2. A checklist is used as part of the pre-administration transfusion process.
  5.2.3. A pre-transfusion TACO risk assessment is performed.
  5.2.4. Delays in provision of blood components are avoided for patients with major haemorrhage or severe anaemia.

5.2.5. Delays in provision of Prothrombin Complex Concentrate (PCC) (or equivalent) are avoided where this product is clinically indicated for rapid reversal of anticoagulants in life, limb or sight threatening bleeds.

5.2.6. Transfusion specific requirements are communicated to the laboratory and patient records (laboratory and clinical) updated in a timely manner that ensures provision and transfusion of correct components.

5.2.7. Where patient care is shared between different organisations, communication pathways are effective in providing current transfusion requirements (including but not limited to patients with sickle cell anaemia, thalassaemia, haemopoietic stem cell transplants)

5.3. Patients and carers are encouraged to be active participants in their transfusion care and offered opportunities to contribute to organisational safety initiatives. Key aspects include:

5.3.1. Informed consent processes comply with legislation, national guidelines and best practice with evidence of consent, shared decision making, and availability of patient information including right to refuse transfusion. Information, both verbal and written, is provided in a way that meets the needs of patients, carers and families and is easy to understand and use.

5.3.2. Timely and clear communications to patients and families including information at discharge; being open and honest with patients and carers, when things go wrong.

5.3.3. Involving patients and families in adverse event reviews to enhance learning and improvement actions needed.

5.3.4. Polices and processes are in place to orientation, support and education to patients who are partnering in the governance, design, measurement and evaluation of organisation.

5.4. Transfusion outcomes are recorded in patients notes and monitored as part of transfusion governance processes.

5.5. Transfusion reactions are identified in a timely manner and managed appropriately. This means:

5.5.1. Suspected transfusion reactions are managed by appropriate personnel. Treatment and medication given to the patient is appropriate for the reaction type. Relevant investigations are performed, and advice provided for subsequent transfusions.

5.5.2. Patient notes (electronic or paper-based) and discharge communications must include a summary of reactions, adverse events, specific transfusion requirements, results of investigations and plans for future transfusions.

6. Haemovigilance and risk management

6.1. Adverse reactions and events are reported to MHRA and SHOT as appropriate.

6.2. Personnel involved in investigating adverse events and reactions have appropriate training.

6.3. Investigation of adverse events includes consideration of human factors and all contributory factors.

6.4. Investigation reports are reviewed and approved by appropriate personnel and/or groups.
6.5. Improvement actions are SMART (Specific, Measurable, Achievable, Relevant and Time-bound), and effectiveness of the actions is reviewed at an appropriate interval.
6.6. Risk assessments cover the whole transfusion pathway, are visible at an organisational level, reflect actual and potential risks and are regularly reviewed by appropriately trained personnel.
6.7. Risks are managed at an appropriate level within the organisation. Progress with improvements actions is monitored and escalated where required.
6.8. There should be a process in place to regularly review and improve appropriate use of blood components, management of transfusion reactions and appropriate treatment according to reaction type.
6.9. Assess, monitor and drive improvement in the quality and safety of the transfusion services provided on a regular basis, including the quality of the experience for people using the service.

Stakeholder engagement

Feedback will be obtained from the following key stakeholders for these standards:

- MHRA haemovigilance team
- SHOT Steering Group and Working Expert Group Members
- UK Forum comprising of the 4 UK Blood Services
- Transfusion Specialty Advisory Committee of the Royal College of Pathologists
- UK and Ireland Blood Transfusion Network with representatives from all UK nations
- UK Transfusion Laboratory Collaborative group
- National Transfusion Laboratory Managers group
- National Transfusion Practitioners Group
- National Blood Transfusion Committees for England, Scotland, Wales, and Northern Ireland including working groups such as the NBTC education, patient involvement and emergency planning working groups
- National Comparative Audit team for Blood Transfusion

- British Society for Haematology Transfusion Task Force
- NHS England and representatives from Scottish and Welsh Governments and the Department of Health Northern Ireland
- Members of the Infected Blood Inquiry 7c, d, e, f subgroups (these include representatives from a wide range of stakeholders including some of the professional organisations mentioned above, Integrated Care Boards and Pathology Networks in England)

Additional work planned

As part of agreed deliverables under the Infected Blood Inquiry report recommendations related to SHOT, we are hoping to:

- Work with Implementation science experts to address barriers that inhibit implementation of SHOT transfusion safety standards and report recommendations and to enable evidence-based practice
- Undertake health economic analysis to drive improvements identified as requiring action to meet safety standards with the progress monitored through benchmarking