**SHOT Transfusion Safety Standards**

**Contents**

[**Standard 1 :** Transfusion safety 1](#_Toc202798187)

[**Standard 2 :** Transfusion information technology (IT) and equipment 4](#_Toc202798188)

[**Standard 3 :** Supporting staff to work safely 6](#_Toc202798189)

[**Standard 4 :** Staff education and training 7](#_Toc202798190)

[**Standard 5 :** Safety culture 8](#_Toc202798191)

[**Standard 6 :** Patients as safety partners 10](#_Toc202798192)

[**Standard 7 :** Haemovigilance and risk management 11](#_Toc202798193)

[**Standard 8 :** Governance 13](#_Toc202798194)

# **Standard 1 : Transfusion safety**

**All blood transfusions will prioritise patient safety and comply with clinical guidance and regulatory requirements.**

**Intention for this standard:** To safeguard every transfusion by standardising best practices, minimising risks, and ensuring the right blood is received by the right patient, every time.

**1.1 Transfusion policies and procedures**

Policies, procedures, and processes must support safe transfusion practices at every step, from the decision to transfuse to administration, including the recognition and management of transfusion reactions. These must be aligned with current evidence-based national guidelines, regulatory standards and best practice recommendations.

**1.2 Traceability of blood components**

All blood components must be fully traceable from donor to recipient and *vice versa*. This requires accurate and timely documentation of every stage in the transfusion chain, including acceptance from Blood Service, storage, selection, labelling, issue, collection, administration, and final outcome. Regular traceability audits across the regulatory timeframe (to ensure legacy systems are included) must be conducted to ensure compliance, identify gaps, and enable corrective actions.

**1.3 Patient blood management**

Effective patient blood management must ensure the appropriate use of blood components, including single-unit transfusions or weight-based transfusions when relevant (for neonates and children as well as underweight adults), the use of cell salvage, tranexamic acid and other alternatives including haematinics, and the prevention of unnecessary wastage and/or unnecessary transfusion.

**1.4 Effective anaemia management**

Effective anaemia management must include timely evaluation of cause/s of anaemia and relevant treatment including haematinic replacement when appropriate.

**1.5 Risk controls and safety measures**

Controls must be in place to identify and minimise adverse events in critical aspects of the transfusion pathway. At a minimum, this includes:

* **1.5.1** Ensuring sample labelling is performed at the patient’s side and adherence to sample acceptance policies.
* **1.5.2** Using a pre-administration checklist as part of the pre-transfusion safety checks.
* **1.5.3** Performing a formal pre-administration transfusion-associated circulatory overload (TACO) risk assessment for adults (note: no paediatric or neonatal TACO risk assessment tool is currently available, also **see 4.3** for paediatric and neonatal transfusions).
* **1.5.4** Ensuring timely provision of blood components and optimising transfusion support for patients with major haemorrhage or severe, symptomatic anaemia according to national guidelines.
* **1.5.5** Ensuring a massive haemorrhage protocol is in place, which should be regularly reviewed and practiced. Staff must receive appropriate training to follow this protocol.
* **1.5.6** Establishing clearly documented procedures for concessionary release especially in urgent clinical situations where transfusion specific requirements cannot be met. This ensures timely provision of the most suitable ABO-compatible blood components, particularly for patients with clinically significant red cell alloantibodies or other specific requirements. Laboratory staff are trained and competency-assessed in these procedures.
* **1.5.7** Ensure policies and procedures are in place and staff adequately trained for timely provision of prothrombin complex concentrate (PCC) (or equivalent), which is critical for rapid anticoagulant reversal in life-, limb-, or sight-threatening bleeds.
* **1.5.8** Using laboratory information management systems (LIMS) to prevent ABO-incompatible blood components from being assigned or issued, particularly in emergencies where the patient’s blood group is unknown or in case of grouping anomalies.
* **1.5.9** Meeting specific transfusion requirements for patients by:
	+ Ensuring timely communication of transfusion-specific requirements to the laboratory and maintaining accurate laboratory records for correct blood component provision.
	+ Updating clinical electronic or paper records promptly with specific transfusion requirements to ensure this information is accessible to all staff overseeing patient care.
* **1.5.10** Establishing effective communication pathways when patient care is shared across different organisations including input from Blood Services and/or specialist reference laboratories, ensuring the safe exchange of transfusion requirements (e.g., for patients with sickle cell anaemia, thalassaemia, or haemopoietic stem cell transplants). Standardised handover and communication templates are used for co-ordinated shared care.

**1.6 Monitoring transfusion outcomes**

Transfusion outcomes, including changes in blood counts and patient-reported changes in clinical status, are recorded in the clinical notes and monitored as part of transfusion governance processes.

**1.7 Management of transfusion reactions**

Transfusion reactions must be promptly identified and appropriately managed:

* **1.7.1** Suspected transfusion reactions are managed by qualified personnel. Treatment and medications are appropriate for the reaction type. Relevant investigations are conducted including evaluation for any preventable causes (e.g., an ABO-incompatible transfusion or an incorrect blood component transfused) and guidance for future transfusions is provided.
* **1.7.2** Patient notes and discharge communications (electronic or paper-based) must include a summary of transfusions received, any reactions, adverse events, specific transfusion requirements, investigation results, and plans for future transfusions.

**1.8 Patient awareness upon discharge**

Discharge communications must inform patients of any transfusion/s received during their admission and noted in records. This includes transfusions given with informed consent under anaesthesia and unexpected transfusions during an emergency. Information about any reactions, and specific transfusion requirements must also be included. Additionally, patients who have received transfusions must be informed that they will no longer be eligible to donate blood in the UK.

# **Standard 2 : Transfusion information technology (IT) and equipment**

**All IT systems and equipment to support safe vein-to-vein transfusion practice are configured, validated, implemented and utilised correctly to their full functionality.**

**Intention for this standard:**To ensure reliable, secure, and smart transfusion systems by leveraging technology and equipment that enhance safety, efficiency, and traceability.

**2.1 IT systems for safe transfusions**

IT systems must be in place to support both clinical and laboratory transfusion practices, ensuring safe transfusion processes.

**2.2 System validation and approval**

All transfusion IT systems must be validated and approved for use by designated personnel within the organisation.

**2.3 System functionality and interoperability**

IT systems are utilised to support safe transfusion practices. Any deficiencies including issues with interoperability must be escalated, with progress monitored by the organisation and supplier, ensuring clear timelines for resolution.

**2.4 Electronic data transfer**

Where systems are interfaced, the transfer of information must be electronic, eliminating the need for manual data entry.

**2.5 Alerts and notifications**

Alerts within IT systems must be clear, relevant, and meaningful to users. They must be regularly reviewed and rationalised to prevent unnecessary interruptions or confusion.

**2.6 Compliance with regulatory and safety standards**

All transfusion IT systems, equipment, and devices in clinical and laboratory settings must comply with regulatory and safety requirements. This includes user requirement specifications for procurement, installation, validation, maintenance, user access protocols, quality checks, and routine reviews. Any safety or performance concerns must be promptly addressed.

**2.7 Staff training**

Healthcare personnel must receive appropriate training to ensure effective use of transfusion IT systems and equipment.

**2.8 Consideration of human factors and ergonomics**

Human factors and ergonomics principles must be integrated into the design, implementation, and updates of transfusion IT systems and equipment to optimise safety and usability.

**2.9 Expert involvement in IT management**

Transfusion subject matter experts must be actively involved in the selection, procurement, and ongoing management of IT systems to ensure they meet operational and clinical requirements.

**2.10 Business continuity and downtime management**

Robust business continuity plans must be in place and practiced for planned and unplanned IT system downtime, both short-term and long-term. These contingency plans must provide clear, accessible instructions for all staff, undergo regular reviews, and be subjected to assurance testing to confirm effectiveness.

# **Standard 3 : Supporting staff to work safely**

**Adequate numbers of appropriately trained and supported staff are available to deliver safe transfusions, prioritising staff wellbeing and professional development.**

**Intention for this standard:**To create a supportive environment where staff feel empowered, equipped, and valued in delivering safe, high-quality care.

**3.1 Staffing assessment and provision**

A structured process must be in place to assess and determine the necessary staffing levels for transfusion activities. This should account for all aspects of transfusion, including training and education, quality management, governance, participation in oversight meetings, and IT support. Staffing provisions should consider skill mix and ensure that appropriately trained personnel are assigned to relevant transfusion tasks.

**3.2 Professional standards and compliance**

Professionally regulated staff must maintain up-to-date registrations, appraisals, revalidation as appropriate, personal development, and performance reviews as required. They must adhere to professional standards and comply with relevant codes of conduct, such as those set by the General Medical Council, Nursing and Midwifery Council, and Health and Care Professions Council.

**3.3 Workforce planning and recruitment**

Effective succession and workforce planning must be implemented, ensuring the timely recruitment of staff; especially for roles that are historically difficult to fill.

**3.4 Contingency planning for staffing shortages**

Organisations must establish contingency plans outlining specific actions to be taken when staffing levels fall below required thresholds. These plans must include both short-term tactical responses and long-term strategic measures to maintain safe service provision in the absence of adequate staffing.

**3.5 Risk escalation and management**

Risks associated with inadequate staffing must be promptly escalated to appropriate governance groups and documented in organisational risk registers. Steps must be taken to address staffing gaps effectively.

**3.6 Wellbeing and fatigue management**

Policies and processes must ensure that all staff have access to timely wellbeing support. Additionally, risks related to fatigue must be identified, assessed, and mitigated to maintain staff safety and performance.

# **Standard 4 : Staff education and training**

**Healthcare organisations ensure that all staff are trained, competent and have access to appropriate development opportunities to support a systems-approach to safe transfusion practice.**

**Intention for this standard:**To build confident, competent teams by making safety education and continuous training a cornerstone of everyday practice.

**4.1 Qualifications and knowledge**

All staff involved in transfusion activities must have the relevant education, qualifications, and transfusion knowledge required for their role to ensure evidence-based decision-making.

**4.2 Induction and ongoing training**

Induction and ongoing training must be provided, regularly reviewed, and aligned with current national recommendations. Training must cover both technical and non-technical skills (See 4.7 about requirement for continuing professional development)

**4.3 Paediatric and neonatal transfusion training**

Induction and refresher training for staff working in paediatric and neonatal care must include weight-based prescribing to ensure appropriate blood transfusion volume calculations to minimise risk of TACO, along with additional specific transfusion requirements for these patients.

**4.4 Training in human factors and patient safety**

Training for clinical and laboratory staff must include basic awareness of human factors and ergonomics principles, and patient safety concepts to improve decision-making and reduce errors.

**4.5 Competency assessments**

A structured programme for knowledge-based and practical skills-based competency assessments must be in place, relevant to staff roles and responsibilities, and reviewed regularly.

**4.6 Incident investigation training**

All staff responsible for investigating incidents must receive appropriate training in incident investigation techniques, including the use of human factors frameworks to optimise learning and improve safety outcomes.

**4.7 Continuing professional development (CPD)**

Adequate protected time must be allocated for staff to attend educational events relevant to their role and fulfil CPD requirements within their scope of practice.

# **Standard 5 : Safety culture**

**A just, restorative, learning safety culture is promoted, supported, and embedded across all levels of healthcare organisations to ensure safe transfusions and learning from all events.**

**Intention for this standard:**To embed a culture of continuous learning and openness that turns every safety insight into an opportunity for improvement.

**5.1 Promoting a learning culture**

A just, restorative, learning safety culture must be fostered, ensuring staff feel psychologically safe to speak up and learn from both successes and errors. Policies and processes must be in place to support this environment. Such a culture embraces balanced accountability, where learning, openness, and psychological safety replace blame.

**5.2 Listening to staff concerns**

Organisations must implement clear and effective strategies to ensure staff concerns are heard, considered, and managed appropriately in a timely and fair manner.

**5.3 Leaders as role models**

Staff in leadership positions must model expected workplace behaviours. Leadership skills and behaviours should be assessed annually as part of performance appraisals, using appropriate key performance indicators.

**5.4 Organisational safety assessment**

Hospital senior management must regularly assess the organisation’s safety culture using tools such as safety assessment surveys, staff interviews, and key indicators (e.g., reported safety concerns, participation in safety training, and frequency of safety audits). Identified concerns must be addressed promptly.

**5.5 Patient and family engagement**

Policies and processes must allow patients and families to raise concerns, participate in incident investigations when appropriate, and provide feedback on actions taken.

**5.6 Transparency in incident reporting**

Clinical and laboratory transfusion leads must demonstrate to their teams how the organisation ensures fair handling of reports. Staff clearly understand how reported incidents lead to learning and action to enhance safety.

**5.7 Supporting staff who raise concerns**

Organisations must establish mechanisms to support staff who raise concerns. This includes maintaining an open and transparent feedback loop and ensuring protection for employees who speak up about unsafe practices.

**5.8 Holistic approach to safety**

Systems and processes must be in place to embed a culture of proactive learning, capturing insights from adverse events, near misses, potential risks, routine practices and excellence to continuously enhance safety, quality, and resilience.

# **Standard 6 : Patients as safety partners**

**Patients are informed, supported and involved as ‘partners’ in their own care to facilitate shared decision-making and safe transfusions.**

**Intention for this standard:**To work with patients as active safety partners by fostering open communication, shared responsibility, and a culture of trust in healthcare decisions.

**6.1 Encouraging patient and carer involvement**

Patients and carers should be actively encouraged to participate in their transfusion care and be given opportunities to contribute to organisational safety initiatives. Key aspects include:

* **6.1.1 Informed consent and patient rights**

Informed consent processes must align with current legal requirements, national guidelines, and best practices. This includes ensuring evidence of consent, shared decision-making, and providing clear patient information on the right to refuse transfusion and available alternatives. Verbal and written information must be accessible, easy to understand, and tailored to the needs of patients, carers, and families. Additionally, potential transfusion recipients must be informed that they will no longer be eligible to donate blood in the UK once they receive a transfusion.

* **6.1.2 Clear and timely communication**

Communication with patients and families must be clear, timely, and comprehensive. This must include details of transfusions received, any reactions, and specific transfusion requirements upon discharge.

* **6.1.3 Participation in adverse event reviews**

Patients and families should be invited to participate in adverse event reviews to support learning and identify areas for improvement. Staff must maintain transparency and honesty when errors occur, adhering to professional and statutory duty of candour principles.

* **6.1.4 Support and education for patient partners**

Policies and processes must ensure patients who collaborate with hospital staff in governance, design, measurement, and evaluation activities receive appropriate support and education.

# **Standard 7 : Haemovigilance and risk management**

**Healthcare organisations have systems in place to identify, trend and learn from transfusion-related safety events including near misses, and implement effective improvement actions.**

**Intention for this standard:**To protect patients and donors by driving safer transfusion practices through vigilant monitoring, timely response, and continuous learning.

**7.1** **Reporting adverse reactions and events**

Adverse transfusion reactions and events must be submitted to Medicines and Healthcare products Regulatory Agency and SHOT as per reporting requirements in addition to internal quality management systems.

**7.2 Duty of candour**

All staff involved in transfusion-related incidents must uphold professional and statutory duty of candour, ensuring openness and transparency in accordance with national policies and organisational procedures.

**7.3 Investigating and learning from transfusion safety events**

Investigations into transfusion safety events must take into account human factors and all contributory elements, using validated structured investigation frameworks. Systems must be in place to share the learning from these events widely and effectively.

**7.4 Review and approval of reports**

Investigation reports must be reviewed and approved by the appropriate personnel or governance groups.

**7.5 Implementing system-focused improvements**

Corrective actions aimed at achieving sustained safety improvements must be identified and implemented through a change control process.

**7.6 Effective improvement actions**

Improvement actions are aligned with the SMART criteria (specific, measurable, achievable, relevant, and time-bound) and must prioritise system-level changes over individual actions.  Their effectiveness must be reviewed at appropriate intervals. Long-term system improvements, such as IT enhancements, should also be documented, monitored and regularly reviewed, especially when essential for safety advancements.

**7.7 Risk assessments and monitoring**

Risk assessments must cover critical steps in the transfusion pathway, be visible at the organisational level, reflect actual and potential risks, and be regularly reviewed by trained personnel. Progress in addressing risks must be monitored and escalated where necessary.

**7.8 Annual review and audits**

A structured process must be in place to review and improve the appropriate use of blood components, trending of transfusion errors reported including near misses, management of transfusion reactions, and treatments based on reaction type. This should occur at least once every two years and include participation in local and national audits.

**7.9 Safety monitoring and continuous improvement**

Organisations must continuously assess, monitor, and drive improvements in transfusion service quality and safety, including enhancing patient experience.

**7.10 Emergency preparedness and response**

Hospital transfusion teams must have a comprehensive emergency preparedness, resilience, and response (EPRR) plan based on local and national guidelines to ensure continuity of transfusion support and service provision during major incidents. Emergency preparedness must include post-incident debriefing to support staff and facilitate future service improvements.

# **Standard 8 : Governance**

**Effective transfusion governance systems are in place with adequate oversight to enable organisations to actively manage and improve the safety and quality of transfusion care.**

**Intention for this standard:** To facilitate effective transfusion governance within healthcare organisations that ensures patients receive safe and high-quality care.

**8.1 Accountability and compliance**

Clearly defined terms of reference must be available for hospital transfusion teams (HTT) and hospital transfusion committees (HTC) (or equivalent), detailing accountability structures. Regular meetings must be documented, demonstrating compliance with the terms of reference.

**8.2 Escalation of outputs**

Key outputs from HTT and HTC (or equivalent) must be escalated to relevant executive-level governance forums through appropriate channels, including risk registers.

**8.3 Executive oversight**

There must be clear accountability and documented evidence of executive-level oversight of transfusion activities.

**8.4 Governance representation**

There must be representation from patient safety/governance teams at HTC (or equivalent) meetings, ensuring strategic alignment and decision-making support.

**8.5 Regulatory and professional standards compliance**

Policies and processes must be in place to facilitate the timely implementation, monitoring, and resolution of gaps related to recommendations and standards from regulatory and professional transfusion bodies. These include the British Society for Haematology, National Institute for Health and Care Excellence, UK Transfusion Laboratory Collaborative, SHOT, and national patient safety alerts.

**8.6 Integration with patient safety governance**

Governance processes within hospitals must fully align with the recommended national transfusion governance framework and be integrated into the organisation’s broader patient safety governance structures.