SHOT Transfusion Safety 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 HTT and HTC are escalated to relevant executive level governance forums through appropriate channels including risk registers.

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 are 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, National Institute for Health and Care Excellence, SHOT) and national patient safety alerts.

1.6. Governance processes must be aligned with the recommended transfusion governance framework and fully integrated into patient safety governance within the organisation.

2. Staff safety

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

2.2. Professionally regulated staff to be up to date with their registrations, appraisals/revalidation/personal development and performance reviews as appropriate; maintain professional standards and comply with codes of conduct appropriate to their role (e.g., General Medical Council, Nursing Medical Council, Health and Care Professions Council).

2.3. Effective succession planning/workforce planning is in place with timely recruitment of staff, particularly where posts are considered difficult to fill.

2.4. Contingency plans detail actions when adequate staffing levels cannot be met.

2.5. Risks related to inadequate staffing levels must be escalated to relevant governance groups and recorded on organisational risk registers. Effective actions should be taken to address these gaps.

2.6. Policies and processes must be in place to ensure clinical and laboratory staff have access to timely wellbeing support, and that fatigue risks are identified, assessed and mitigated.

3. Education and training

3.1. All staff involved in transfusion activities have the relevant education, qualifications and transfusion knowledge for their role to 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. Induction and refresher training for involved in paediatric and neonatal care should include weight-based prescribing to prevent errors in calculation of blood transfusion volumes and additional specific requirements for transfusion in these patients.

3.4. Training for clinical and laboratory staff should include basics of human factors principles and application, impact of cognitive biases and patient safety principles.

3.5. There is a programme for competency assessments relevant to the role that is reviewed regularly.

3.6. Staff involved in investigating incidents should have appropriate training about incident investigation techniques and human factors methods to optimise learning from incidents.

3.7. Adequate protected time should be provided for all staff to access and attend educational events relevant to their role.

4. Transfusion Information Technology (IT) and equipment

4.1. IT systems are in place that support clinical and laboratory transfusion practice for safe transfusions.

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. Alerts should be reviewed and rationalised regularly.

4.6. All transfusion equipment/devices in clinical and laboratory areas meet regulatory and safety requirements. This should include installation, validation, maintenance, quality checks and regular reviews. Any safety issues must be addressed promptly.

4.7. Staff are provided with training to use the IT systems and equipment for transfusion.

4.8. Human factors and ergonomics principles should be considered to ensure safe implementation and updates to transfusion IT systems and equipment.

4.9. Transfusion subject matter experts are involved in the selection, procurement, and management of IT systems.

4.10. Contingency plans for downtimes are accessible, include adequate instructions, are regularly reviewed and subject to assurance testing.

5. Safety culture

5.1. A just, restorative learning culture must be promoted where staff feel psychologically safe to speak up and learn from both excellence and error. Policies and processes must be in place to support this.

5.2. Organisations must have clear and effective strategies to ensure that staff concerns are listened to, considered, and managed appropriately in a timely and equitable manner.

5.3. Staff with leadership responsibilities must act as role models following expected behaviours within the workplace. These leadership skills and behaviours must be assessed as part of their annual appraisals with appropriate key performance indicators.

5.4. Hospital senior management should ensure that the organisation's safety culture is regularly assessed (e.g., using a safety assessment survey) and take appropriate actions to address any concerns identified.

5.5. Policies and processes must be in place to facilitate patients and families to raise concerns, participate in incident investigations as appropriate and provide feedback on actions taken.

5.6. Clinical and laboratory transfusion leads should demonstrate to their team the measures the organisation takes to ensure reports are dealt with fairly and that the appropriate learning and action takes place to improve safety.

5.7. Organisations must have a mechanism in place to support staff who raise concerns and ensure that there is an open and appropriate feedback loop including protection for staff who do speak up about unsafe practice.

6. Transfusion safety

6.1. Policies, procedures, and processes support safe practice for all steps in the transfusion pathway, from decision to transfuse to administration of the blood component including recognition and management of transfusion reactions.

6.2. Ensuring effective patient blood management with appropriate use of blood components including use of single unit transfusion/weight-based transfusion as appropriate and avoiding unnecessary wastage.

6.3. Effective anaemia management should include timely evaluation of cause/s of anaemia and appropriate treatment including haematinic replacement.

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

6.4.1. Assurance that sample labelling is performed at the side of the patient, and adherence to sample acceptance policies.

6.4.2. A checklist is used as part of the pre-administration transfusion process.

6.4.3. A pre-transfusion TACO risk assessment is performed for adults *(currently there is no paediatric or neonatal TACO risk assessment tool).*

6.4.4. Delays in provision of blood components are avoided for patients with major haemorrhage or severe anaemia.

6.4.5. In urgent clinical situations where suitable antigen-negative blood is not available, delays must be avoided by transfuse red cell units which may be positive for a confirmed antibody using concessionary release

6.4.6. 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.

6.4.7. Laboratory information Management Systems Laboratory information management systems (LIMS) should be used to their full functionality, preventing ABO-incompatible (ABOi) red cell units being assigned or issued to the patient record, especially in an emergency when the patient's blood group is unknown.

6.4.8. A. Transfusion specific requirements are communicated to the laboratory and laboratory records updated in a timely manner that ensures provision and transfusion of correct components.

B. The electronic or paper clinical records for patients to also be updated appropriately with transfusion specific requirements that are easily accessible to staff overseeing the patient's care

6.4.9. 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). Using standardised handover/communication templates will ensure a safe, coordinated shared care for patients.

6.5. Transfusion outcomes (changes in blood counts with increments and/or patient reported outcomes) are recorded in patients notes and monitored as part of transfusion governance processes.

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

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

6.6.2. 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.

6.6.3. Discharge letters should explain that, after a transfusion, the patient can no longer donate blood in the UK.

7. Patients as safety partners

7.1. 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:

7.1.1. 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.

7.1.2. Communications to patients and families should be timely and clear. This should include information about transfusions received, reactions if any and specific requirements at discharge.

7.1.3. Patients and families should be invited to participate in adverse event reviews to enhance learning and improvement actions needed. Staff should be open and honest with patients and carers when things go wrong.

7.1.4. Policies and processes should be in place to provide support and education to patients who are partnering with hospital staff in the governance, design, measurement and evaluation of organisational activities.

8. Haemovigilance and risk management

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

8.2. Investigation of adverse events must include consideration of human factors and all contributory factors using validated structured investigation framework/s.

8.3. Investigation reports are reviewed and approved by appropriate personnel and/or groups.

8.4. System-focused actions that provide effective and sustained system improvement must be identified and implemented.

8.5. Improvement actions are SMART (Specific, Measurable, Achievable, Relevant and Time-bound), and effectiveness of the actions is reviewed at an appropriate interval. System improvements such as IT changes should also be recorded- these may be longer term but identified as essential to improve safety.

8.6. 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. Progress with improvement actions is monitored and escalated where required.

8.7. 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.

8.8. 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.