Framework for the Provision of Blood Transfusion Out of the Acute Hospital Setting

Jan Green and Liz Pirie

Third edition November 2012
(amended October 2013)
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First edition 2005
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Executive Summary

This document was produced in collaboration between the Scottish National Blood Transfusion Service and NHS Blood and Transplant. It is intended to provide clearly defined guidance to assist organisations develop policies and procedures for delivering blood transfusion outside the hospital setting. The framework has been developed in response to the desire to minimise the intrusion of hospital care for patients requiring intermediate or long term transfusion support whilst maintaining a safe, high quality and efficient blood transfusion service.

Out of the acute hospital setting refers to:
- The patient’s own home
- Residential and nursing homes
- Hospices
- Renal satellite units
- Local treatment centres
- All other areas where blood components are administered that are not covered by local acute hospital protocols.

This framework sets out guidance around:
- Legislation and guidance documents; to ensure compliance with relevant local and national guidelines and regulations
- Personnel; to ensure co-ordination of the many personnel involved in performing different tasks required
- Training; which is fundamental to every aspects of blood transfusion safety
- Equipment; to ensure safety, suitability, availability, validation and documentation
- Transport; which includes personnel, to ensure compliance with equipment and cold chain requirements
- Patient selection; to ensure that suitability has been assessed on an individual patient basis
- Clinical responsibilities; to ensure that there are clearly stated responsibilities and boundaries for all staff
- Communication; to ensure effective exchange between all stakeholders
- Adverse events; to ensure that patients receive prompt and appropriate care
- System follow up and review of service; to identify if any improvements are required.

Overall this document seeks to support developments to improve the quality of life of blood transfusion dependent patients. It aims to ensure that the safety and quality of the transfusion process is maintained by providing guidance to the essential aspects organisations need to consider.
1. Introduction
For many patients with certain disorders blood transfusion support is essential to maintain life and relieve symptoms. Transfusion support may be required on an intermediate or long term basis and as a number of these patients may have a reduced life expectancy, it is essential that hospital services intervene no more than necessary (Bates 1994). There is a desire to minimise the intrusion of hospital care for this patient group however, organising a safe, efficient blood transfusion service out of the acute hospital setting involves the co-ordination of many personnel performing different tasks.

National Health Service (NHS) organisations had a statutory duty of quality placed on them through the 1990 NHS Act 2. Clinical governance was introduced to ensure that organisations have a structure to support continuous improvement in the quality of care, this includes having policies and procedures to safeguard patient care.

The aim of this document is to assist organisations develop their local policies and procedures for delivering blood transfusion out of the acute hospital setting. The Framework sets out guidance around; policy and service level agreements (SLAs) required, and addresses issues such as personnel, training, transport and equipment to ensure that transfusion practice, in the out of acute hospital setting, is conducted safely and meets statutory requirements and national guidance.
2. Providing Blood Transfusion Out of the Acute Hospital Setting

The out of acute hospital setting refers to:
- The patient's own home
- Residential and nursing homes
- Hospices
- Renal satellite units
- Local treatment centres
- All other areas where blood components are administered that are not covered by local acute hospital protocols.

Current legislation and guidance documents must be adhered to when developing a service in the out of the acute hospital setting. The following points should be considered:
- There must be clear and concise Service Level Agreements (SLAs), between providers and users of blood components, which cover all aspects of the service in place.
- There should be documented evidence of relevant risk assessments.
- Written safety and hygiene instructions should be in place.
- There must be clear lines of responsibility and accountability between providers and users of the service.
- Systems to cover adverse event reporting, traceability and recall of all units issued, to the out of acute hospital setting.
- There should be identified key workers known to both providers and users of the service for the purposes of liaison, problem solving, training and competency assessment.
- A local policy for the transfusion of blood components should be drawn up reflecting national recommendations (BCSH 2009).
- A unique patient identification number must be used throughout the process, including sample collection and the administration of blood components.
- Patients receiving blood components must have an identification band or risk assessed equivalent.
- There must be a clear plan of action to be followed in case of an emergency or transfusion reaction.
- Training and competency assessment must be provided to all staff involved in out of acute hospital transfusion.

A steering group or working party with the appropriate expertise should be established to formally agree the remit, identify the geographical scope and the annual budget required. When planning the service it is advised that the maximum number of units to be transfused per episode should be decided as this will impact on how the service will be delivered.

The local policy and service level agreements between provider and users should reflect the need for an assessment of the facilities where blood transfusion is to take place to determine environmental suitability. This should include a predetermined list of basic requirements and must include:
- The availability of hand-washing facilities
- A landline telephone
- Post transfusion patient support/supervision.

Each service provider should implement a confidential system for recording patient demographic and transfusion details. All transfusion documentation that is used should take account of the local hospital and transfusion laboratory documentation. A review of the service including all transfusion practices and patient satisfaction levels should be audited on a regular basis to allow the steering group to undertake a periodic review of the feasibility of the service. This will also provide evidence for providers and users that service level agreements are being met.

2.1 Personnel
The staff groups that are required to deliver the service should be identified. Transfusion should only take place if there is sufficient and appropriate staff to cover the agreed operational hours (SHOT 2010).

The findings of a collaborative project between the Better Blood Transfusion teams in the Scottish National Blood Transfusion Service (SNBTS) and NHS Blood and Transplant (NHSBT) identified that there were no legal barriers to an appropriately trained and competent nurse undertaking the role of 'prescribing' blood components (Pirie and Green 2007). It is for each individual organisation however, to determine where these roles are established in light of service needs. Each organisation is responsible for ensuring that there are governance structures in place to support any role development.

To support nurses who wish to undertake this role a Governance Framework document outlining guidance is available at: http://www.transfusionguidelines.org.uk/Index.aspx?Publication=BBT&Section=22&pageid=1298

2.2 Training
Education and training is fundamental to every aspect of blood transfusion safety. The EU Directive 2005/62/EC requires that all staff must be trained and competent to perform their tasks.

In Scotland the NHS Quality Improvement (NHSQIS) Clinical Standards for Blood Transfusion (2006) state that no staff member should participate in blood transfusion unless they have evidence that they have been trained to Module 1 Safe Transfusion Practice level or equivalent. Module 1 Safe Transfusion Practice can be accessed at: www.learnbloodtransfusion.org.uk

The National Patient Safety Agency Safer Practice Notice 14 (2006); Right Patient, Right blood has determined that all staff involved in the blood transfusion must undergo a competency based assessment every 3 years.

Local policy and service level agreements between providers and users of the service must determine who is responsible for delivering the training, assessing competence and maintaining individual and departmental training records.

The following personnel should be included, where applicable to the setting:
- Doctors
- Nurses
- Phlebotomy staff
- Biomedical Scientists and Healthcare Scientists
- Trainee Assistant Practitioners and Medical Laboratory Assistants
- Porters
- All persons involved in handling/transfer of the blood components from the hospital transfusion laboratory to the patient, which could include a taxi driver or a volunteer
- Relatives and carers.

All individuals should be trained appropriate to their role. Essential knowledge and skills for the transfusion process are:
- Making the decision to transfuse
- Blood sampling and labelling for pre-transfusion testing
- Ordering blood components
- Collection and delivery of blood components
- Storage of blood components
- Administration of blood components
- Monitoring the transfused patient
- Management and reporting of adverse events, including anaphylaxis and critical events
- Basic life support
- Recall and traceability of blood components.

Other areas where knowledge and skills are required:
- Cannulation
- Central line management (e.g. Hickman lines)
- Intravenous bolus drug administration
- Local policies and protocols.

The training records should reflect:
- Name of trainee
- Trainee unique identification number
- Place of work
- Date of training session
- Type of training session
- Duration of training session
- Training method
- Name of the trainer(s)
- Evaluation method
- Attainment achieved
- Record of competency
- The date the next update is planned.

2.3 Equipment
The local policy must identify all equipment that will be required to provide the service, and consideration should be given as to how the equipment will be transported (e.g. closed and locked container).
- The equipment should be readily available and accessible
- Emergency equipment such as oxygen and drugs for the treatment of anaphylaxis must be available
- A named person must be responsible for re-stocking and checking that all the equipment is in working order
- There should be documented evidence that equipment, which is required to be tested annually, has met the required standard.

2.4 Transport personnel
There must be competency based training in the safe handling of blood components for all personnel involved in the transportation of blood components, including spillage and cold chain requirements. Service level agreements between users and providers must stipulate transport arrangements. If taxi or volunteer drivers are employed, their training needs must also be addressed and a record of the training given should be recorded.

Each service provider should determine the mode of transport to be used, and consider the following:
- Business insurance will be required for car drivers
- Identify car mileage rate allowance
- Identify if car parking charges will be incurred
- Determine who is responsible for any costs incurred when using taxi transportation.

2.5 Transportation of blood components
There must be local policy and service level agreements between providers and users.

There must be Standard Operating Procedures (SOP’s) outlining the transportation of blood components between the provider and user. These SOPs are available from the local hospital transfusion laboratory or Blood Transfusion Centre. All SOP’s should be in line with the Guidelines for the UK Blood Transfusion Services (2005).

If operating an offsite clinic where multiple transfusion episodes are to take place for different patients, then consideration should be given to the use of an authorised satellite fridge. The responsibility for the care and maintenance of all satellite fridges must be clearly defined in a SLA. Standard Operating Procedures (SOP’s) outlining the stocking, de-reserving and monitoring measures required are available from the local hospital transfusion laboratory or Blood Transfusion Centre.

The following should be considered:
- Blood components should only be released from the hospital transfusion laboratory for one patient at a time (unless for an off-site clinic)
- The individual/s who will take responsibility for contacting the hospital transfusion laboratory to notify them of imminent collection of the blood component
- The type of box for transporting the different blood components should be validated to meet current quality standards
- The individual/s who are responsible for monitoring the suitability of the transport box
- The individual/s who will take responsibility for packing the blood component/s for transfer
- Packing the blood component/s according to current guidelines
- The appropriate transfusion documentation required
- The maximum number of blood components that can be transferred and transfused at one time
- The number of units of red cells that can safely stay in the transport box/s while the initial unit is being transfused
- If there is no prospect of imminent transfusion, within the validated storage time of the transport box, the unit must returned to the hospital transfusion laboratory
- If a unit of red cells has been out of temperature controlled storage for more than 30 minutes they should not be put back into storage for re-issue
- Cold chain requirements
- Traceability and recall procedures.

2.6 Return of transport boxes
Local policy and service level agreements between providers and users should include how the transport boxes and relevant documentation are returned to the hospital transfusion laboratory in a timely manner.

2.7 Traceability
The Blood Safety and Quality Regulations (BSQR) (SI 2005/50), as regulated by, the Medicines and Healthcare products Regulatory Agency (MHRA) state that it is a legal requirement that the hospital transfusion laboratory records the final fate of all blood components, and that the transfusion record must be kept and be accessible for 30 years. Therefore there must be a validated procedure in place to ensure that staff administering blood components provide documented evidence of transfusion and verify that each blood component the hospital transfusion laboratory issues is accounted for, and the final fate recorded.

2.8 Recall
The BSQR require that a procedure is established for the efficient withdrawal from distribution of blood components associated with any adverse notification including a description of the responsibilities and actions to be taken and the requirement to inform the competent authority.
3. Delivering the Service to the Patient

It is the responsibility of the clinician in charge of the patient's treatment and care, to decide if transfusion out of the acute setting is appropriate. However transfusion should only take place if there is sufficient and appropriately trained staff to cover the agreed operational hours (SHOT 2010). Blood transfusion should only be performed where there are the staff and facilities to recognise and treat anaphylaxis.

It is the responsibility of the requesting hospital to ensure that there is a local policy, which complies with current BCSH guidance (2009) in place. The local policy should consider the following issues:

3.1 Patient selection

Each service provider should identify the patient groups and define the medical conditions that are considered appropriate for the transfusion of blood components in the out of acute hospital setting. All patients should have a clinical assessment as to their suitability and the following points should be considered:

Is the patient:
- Medically stable
- Receiving treatment that necessitates routine transfusion e.g. chemotherapy.
- Receiving palliative care
- Risk assessed for “Transfusion Associated Circulatory Overload” (TACO) and other potential complications/reactions in relation to concomitant medical conditions
- Competent to confirm their identity, or have an agreed responsible adult present?

The patient should have had:
- At least one transfusion in an acute setting with no severe reactions
- Two previous group and antibody screen tests.

Patients and/or their carers should be made aware of the risk of late adverse reactions occurring up to 24hrs after transfusion.

*Contact cards for immediate medical advice (including out of hours) should be provided to all patients.*

3.2 Clinical responsibilities

The local policy and any service level agreements should address the following:
- There must be an identified medical consultant/practitioner who has overarching responsibility for the out of acute hospital blood transfusion service
- There must be an identified medical consultant/practitioner who has responsibility for the overall care and treatment of the patient
- Clearly stated responsibilities and boundaries for all staff e.g. Nurse Authorisers
- Establish who is responsible for the following:
  - Reviewing haemoglobin results
  - Requesting the pre transfusion test
- Assessing the patient's fitness for transfusion
- Informing the patient of the risks and benefits and confirming the patient's consent on each transfusion episode
- Ordering the blood components (specifying any special requirements)
- Providing the written instruction for transfusion
- Documenting the date, time and duration/rate of the transfusion
- (Note: No pharmaceutical agent with the exception of desferioximine, should be infused through a lumen that is used for the transfusion of blood components).

- All patients should receive an information leaflet about blood transfusion, which is available from all the UK Blood Transfusion Services.
- Patients should be made aware of their need for any special transfusion requirements and be provided with clear written information (BCSH 2010).
- The following should be documented in the patient's notes/transfusion record:
  - Indication for transfusion
  - Discussion with the patient
  - Administration of the transfusion and any adverse events
  - Clinical outcome
- There should be an agreed period between medical reviews, for each patient
- Who can prescribe concomitant drugs if required.
- Ensuring a formalised ‘handover’ process for communicating transfusion decisions is in place and adhered to (e.g. use of a clinical handover template). The Royal College of Physicians have produced a toolkit to aid this process; it can be accessed at: [http://www.rcplondon.ac.uk/resources/acute-care-toolkit-1-handover](http://www.rcplondon.ac.uk/resources/acute-care-toolkit-1-handover)

### 3.3 Consent for transfusion

The Advisory Committee on the safety of Blood, Tissues and Organs (SaBTO) has issued recommendations on consent for blood transfusion (2011). These include:

- Valid consent should be obtained and documented in the patient's clinical records
- The consent standard developed by Health Improvement Scotland (formerly NHS Quality Improvement Scotland) should be adopted throughout the UK
- There should be a modified form of consent for long term multi-transfused patients; details of which should be explicit in an organisations consent policy. Consideration of the time limit or number of transfusion episodes the consent is valid for is recommended. [http://www.transfusionguidelines.org.uk/index.asp?Publication=BBT&Section=22&pageid=7691](http://www.transfusionguidelines.org.uk/index.asp?Publication=BBT&Section=22&pageid=7691)

The patient may not see a medical practitioner during the transfusion episode therefore it is recommended that nursing staff pay particular attention to Nursing Midwifery Council (NMC) guidance on consent (NMC 2008).
3.4 Checking the patient's identity
All patients having a blood transfusion must wear a patient identification band (or risk assessed equivalent (BCSH 2009). The minimum patient identifiers are:
- Last Name
- First Name
- Date of Birth
- Unique patient identification number (ideally the NHS number, Community Health Index (CHI) number in Scotland or Health and Social Care (HSC) number in Northern Ireland)

Patients in the out of acute hospital setting however, may not be wearing a patient identification band at the time the pre-transfusion sample is taken. SHOT have consistently identified that incorrect or inadequate patient identification, leading to a sample for blood grouping being taken from, or labelled for, the wrong patient may result in at best delays in processing, or at worst a fatal ABO-incompatible transfusion. One approach to address this issue is to supply the patient with an alternative method of verifying their identity e.g. the use of a photo identity card or identification band produced by the person who took the pre-transfusion sample, which would be presented again at the time of transfusion.

Local guidelines and service level agreements between providers and users must reflect best practice, and rationale must be given if it deviates from the current guidance. There is guidance on identity issues from the National Patient Safety Agency Safer Practice notice 11 (2005); Safer Patient Identification; Wristbands for hospital inpatients improves safety and Safer Practice notice 14 (2006); Right patient Right Blood.

3.5 Blood sampling for transfusion
Local policy and service level agreements between providers and users should determine who is permitted to take blood from the patient for pre-transfusion testing. This may include a trained relative or carer. The policy should also establish who is permitted to complete the pre-transfusion request form. The following should be highlighted in the policy and service level agreement:
- The laboratory has the right to refuse forms or samples, which are incomplete, illegible or incorrectly labelled. The details on the request form are to enable the laboratory to perform the correct tests and avoid mistakes or delays in providing the correct blood type and component.
- Addressograph labels are only acceptable on the request form (BCSH 2009).
- Forms must be completed clearly and correctly. Details must include:
  - Full name including First Name and Last Name
  - Date of Birth
  - Gender
  - Unique patient identification number such as NHS, e.g. CHI or HSC number
  - Location of where the transfusion is to take place
  - Date and time required
  - Date of request
- Signature of requester
- Reason for transfusion
- Diagnosis
- Component required
- Number of units required
- Special requirements
- Previous transfusion history.

When a pre-transfusion blood sample is taken, it is important to bleed only one patient at a time in order to reduce the risks of a patient identification error occurring (SHOT 2003). The following criteria should be included in the local policy:
- Before drawing the sample, ask the patient to state their
  - First Name
  - Last Name
  - Date of Birth
  - Check these details against the patients identity band
- The sample tube label must be hand-written at the time the patient is bled, in the presence of the patient
- The sample tube label must be signed by the person performing the venepuncture
- It is imperative that all the details on the sample tube match those on the request form
- Timing of the blood sample for cross-match in relation to previous transfusions.

3.6 Communicating with the hospital transfusion laboratory
Local policy and service level agreements between providers and users should be in place:
- For the delivery of the sample to the laboratory, taking into account;
  - the laboratory working hours
  - the time required to undertake full pre-transfusion testing
- For the reporting of haemoglobin results
- As to how the appropriate clinicians review the test results
- As to how to order blood components if they are required
- For communicating the need for specialist components. It is the responsibility of the prescribing practitioner to identify any special transfusion requirements and clearly communicate the request to the transfusion laboratory.

3.7 Administration of blood components
Local policy and service level agreements between providers and users should determine who is permitted to undertake the checking, administration and monitoring of the transfused patient in the out of acute hospital setting. There should be a suitably trained nurse with the patient during the transfusion (or a trained carer / individual with parental responsibility). A responsible person should stay with the patient for at least two hours after the completion of the transfusion to monitor for any untoward events.
The local policy and service level agreements between providers and users should include information regarding:

- If a compatibility report form is issued it should not form part of the final bedside patient identification check (NPSA SPN 14 (2006))
- The issue of blood components of a different but suitable blood group; there should be a method for notifying staff and recording this variance
- The disposal of completed blood component bags in accordance with local infection control policies
- The disposal of uncompleted blood component bags in accordance with local hospital transfusion laboratory policies.

Written protocols and service level agreements between providers and users should emphasize that the practitioner should ensure that:

- The blood component has been prescribed and any special transfusion requirements identified
- The patient has been correctly identified
- Baseline observation of temperature, pulse, blood pressure and respirations are undertaken (no more than 60 minutes before the start of the component transfusion)
- The expiry date of the component has been checked
- Visual inspection of the component for any signs of discoloration, clumping or leaks has been undertaken
- The blood group and the donation number on the tie on tag label are identical to the blood group and donation number on the blood component
- Any discrepancies noted at this point should be reported and the transfusion suspended until the issue has been resolved
- The checking process **must** be repeated for each blood component administered
- The patient must be monitored as per local policy and observations recorded, as a minimum, after 15 minutes of commencing the component transfusion and within 60 minutes of completion.
- The maximum recommended transfusion time for red cells is 4 hours from the time of removal from controlled temperature storage.

Records must be maintained for each transfusion episode, this should include:

- Observations recorded at the start, during and on completion of each unit
- Signatures of those involved in the checking process
- Start and completion time of each unit
- Volume transfused
- Any adverse events and outcomes.

There must also be a procedure in place for reporting to other members of the team the outcome of the transfusion episode.
3.7 Adverse events
SHOT data on acute transfusion reactions from 2009 show that the median time of presentation is 45 minutes although more severe reactions such as anaphylaxis or hypotension present more rapidly, (median time 15 and 20 minutes respectively). Regular observation of the patient throughout the transfusion with additional observations as required must take place.

Patients should be informed of possible adverse effects, the associated symptoms and the time scales in which they can occur. They should be encouraged to report the onset of any new symptoms irrespective of how unrelated they appear. Local policies must ensure that procedures are in place to deal with any adverse event or incident. All staff should know the procedure to follow with regard to:

- The importance of stopping the transfusion as soon as a reaction is suspected
- Clinical management e.g. in anaphylaxis
- The next of kin or identified person
- Contacting the medical team responsible for the patient
- Arranging urgent admission to hospital
- Type and number of blood samples required
- Informing the issuing hospital transfusion laboratory
- Returning the partially used blood component to the issuing hospital transfusion laboratory for investigation
- Documentation of the event in the patient's medical and nursing notes, and through the organisation's incident reporting mechanism
- The reporting of an adverse event to the issuing laboratory, so that they can report to the MHRA via Serious Adverse Blood Reactions & Events (SABRE) and/or Serious Hazards of Transfusion (SHOT).

In the situation where it is a carer who remains with the patient after the transfusion is complete, they should be informed about what action to take if an adverse event occurs and be provided with contact details for how to receive advice and gain assistance. It may be that the patient will have to be admitted to hospital and the policy should take account of this situation.

3.9 Patient follow up
There must be procedure in place to ensure that all patients receive regular medical review of their blood transfusion care.

3.10 System follow up and service quality review
Local policy and service level agreements between providers and users must demonstrate service monitoring to identify if any improvements are required. This should include

- Training of staff and support personnel
- Regular traceability audit/
- Cold chain monitoring
- Sample rejection rate
- Appropriateness of transfusion requests
- Adverse event management
- Testing of the recall system
- Patient satisfaction.
4. References
Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO) (2011) Patient consent for blood transfusion
Blood Safety and Quality Regulations (2005) No. 50 (as amended No.2) Regulations 2005 No. 2898
HSC 2007/001: Better blood transfusion - safe and appropriate use of blood
HSC 2002/009 - Better blood transfusion: appropriate use of blood
HSC 1998/224: Better blood transfusion
National Patient Safety Agency NPSA SPN14 (2006); Right patient, right blood: advice for safer blood transfusions
National Patient Safety Agency NPSA SPN 24 (2007); Standardising wristbands improves patient safety
NHS Quality Improvement Scotland (2006) Blood Transfusion Clinical Standards
Nursing & Midwifery Council (2008) The code: Standards of conduct, performance and ethics for nurses and midwives
Serious Hazards of Transfusion Annual Reports 1999- 2010 London: SHO
5. Resources

British Blood Transfusion Society
http://www.bbts.org.uk

British Committee for Standards in Haematology (BCSH) Guidelines
http://www.bcshguidelines.com

Department of Health
http://www.doh.gov.uk/publications/coinh.html

General Medical Council
http://www.gmc-uk.org

Learn Blood Transfusion Education Programme
http://www.learnbloodtransfusion.org.uk/

Medicines and Healthcare products Regulatory Authority (MHRA)

National Patient Safety Agency (NPSA)
(From 1 June 2012 the key functions and expertise of NPSA have been transferred to the NHS Commissioning Board Special Health Authority
http://www.commissioningboard.nhs.uk/

NHS Litigation Authority (NHS LA) Clinical Risk Management Standards
http://www.nhsla.com

NHS Blood and Transplant
http://www.blood.co.uk

NHSBT Hospitals & Science Website
http://hospital.blood.co.uk/

Nursing and Midwifery Council
http://www.nmc-uk.org

Professional Guidelines, best practice and clinical information
http://www.transfusionguidelines.org/

Royal College of Nursing
http://www.rcn.org.uk

Scottish National Blood Transfusion Service
http://www.scotblood.co.uk

Serious Hazards of Transfusion (SHOT) Annual Report
http://www.shotuk.org