

Clinical Standards ~ *September 2006*

Blood Transfusion

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www.nhshealthquality.org

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1 Background on NHS Quality Improvement Scotland

NHS Quality Improvement Scotland (NHS QIS) was set up by the Scottish Parliament in 2003 to take the lead in improving the quality of care and treatment delivered by NHSScotland.

We achieve our objectives through four key functions that link together:

- setting standards
- reviewing and monitoring performance
- providing advice and guidance on effective practice, and
- supporting staff to improve services.

We deliver our commitments to the public and to NHSScotland by following an approach that is:

- independent - we reach our own conclusions and report on what we find
- open and transparent - we explain what we do, how and why we do it, and what we find, using language and formats that are easy to understand and to access
- sensitive and professional - we recognise needs, beliefs and opinions and respect and encourage diversity.

Our work is:

- partnership-focused - we work with patients and the public, NHSScotland and many organisations to improve the quality of care and avoid duplication
- evidence-based - we base our conclusions and recommendations on the best evidence available
- quality-driven - we make sure our own work is monitored and evaluated, internally and externally.

2 Development of NHS Quality Improvement Scotland Standards

Basic principles

A major part of our remit is to develop and run a national system of quality assurance of clinical services. Working in partnership with healthcare professionals and members of the public, we set standards for clinical services, assess performance throughout NHSScotland against these standards, and publish the findings. The standards are based on the patient's journey as he or she moves through different parts of the health service. A wide range of diseases and services have already been addressed, including the provision of safe and effective primary medical services out-of-hours, maternity services and anaesthesia services.

In fulfilling our responsibility to develop and run a system of quality assurance, we take account of the principles set out in Fair for All and Partnership for Care, to ensure that 'our health services recognise and respond sensitively to the individual needs, background and circumstances of people's lives'.

We will ensure that consideration of equality and diversity issues feature prominently in the design, development and delivery of all our functions and policies.

The standards are developed in accordance with the commitments of the National Health Service Reform (Scotland) Act (2004) which state that 'individual patients receive the service they need in the way most appropriate to their personal circumstances and all policy and service developments are shown not to disadvantage any of the people they serve.'

The standards set by NHS QIS are clear and measurable, based on appropriate evidence, and written to take into account other recognised standards and clinical guidelines. The standards are:

- written in simple language and available in a variety of formats
- focused on clinical issues and include non-clinical factors that impact on the quality of care
- developed by healthcare professionals and members of the public, and consulted on widely
- regularly reviewed and revised to make sure they remain relevant and up to date, and
- achievable but stretching.

Clinical governance and risk management standards

Every patient using healthcare services should expect these to be safe and effective. The NHS QIS standards for clinical governance and risk management will ensure NHS boards can provide assurance that clinical governance and risk management arrangements are in place, and are supporting the delivery of safe, effective, patient-focused care and services.

The clinical governance and risk management standards underpin all care and services delivered by NHSScotland and provide the context within which NHS QIS service and condition-specific standards apply. They should be read in conjunction with all our standards.

The clinical governance and risk management standards are effective from November 2005 and are available on request from NHS QIS or can be downloaded from the website (www.nhshealthquality.org).

Process

We have an annual work programme and for each project in the work programme, a group is established comprising clinical and non-clinical membership drawn from a range of backgrounds and representatives of the public to:

- oversee the development of, and consultation on, the standards and self-assessment framework, and
- recommend an external peer review process.


The way in which standards are developed is a key element of the quality assurance process. Project groups working on behalf of NHS QIS are expected to:

- adopt an open and inclusive process involving members of the public, voluntary organisations and healthcare professionals
- work within NHS QIS policies and procedures, and
- test the measurability of draft standards by undertaking pilot reviews.

Format of standards and definition of terminology

All standards set by NHS QIS follow the same format.

- Each standard has a title, which summarises the area on which that standard focuses.
- This is followed by the standard statement, which explains the level of performance to be achieved.
- The rationale section provides the reasons why the standard is considered to be important.
- The standard statement is expanded in the section headed criteria, which states exactly what must be achieved for the standard to be reached. Most criteria are essential, in that it is expected that they will be met wherever a service is provided. Other criteria are desirable, in that they are being met in some parts of the service and demonstrate levels of quality which other providers of a similar service should strive to achieve. Each project group is responsible for determining which criteria are essential and which are desirable. The criteria are numbered for the sole reason of making the document easier to work with, particularly for the assessment process. The numbering of the criteria is not a reflection of priority. The distinction between 'essential' and 'desirable' is the only way in which criteria have been prioritised.



Assessment of performance against the standards

The framework for the NHS QIS review process is as follows.

- Once the standards have been finalised, each relevant NHS board/service is asked to undertake a self-assessment of its service against the standards.
- A review team visits the NHS board/service on behalf of NHS QIS to follow up this self-assessment exercise with an external peer review of performance in relation to the standards.
- NHS QIS reports the findings for the NHS board/service, based on the self-assessment exercise and on the external peer review.

Our processes are subject to internal and external evaluation, to help improve the quality assurance system.

3 Development of clinical standards for blood transfusion

An introduction to blood transfusion

Over 3 million units of blood component are used in the UK each year - 300,000 of these in Scotland alone. Blood is given regularly and routinely for chronic disorders, before and after surgery, as well as in emergency situations and the service is dependent on freely given donations to meet this need. In Scotland, over 240,000 donations are given each year.

The Scottish National Blood Transfusion Service (SNBTS) is responsible for collecting, processing, storing and supplying all blood and blood components in Scotland and NHS boards are responsible for ordering and managing their supplies in a safe and effective manner. Both SNBTS and NHSScotland are aware of the risks involved in all aspects of blood management and two important pieces of work have been carried out, which identified a number of areas where processes and practice could be improved. As a result of this the Scottish Executive Health Department (SEHD) introduced an extensive programme of work to improve and support transfusion practice in Scotland (the Better Blood Transfusion Programme, see Appendix 5) and asked NHS QIS to consider how it could address the identified quality improvement issues.

NHS QIS set up a steering group to take this work forward and a report (available on www.nhshealthquality.org) was produced in July 2004 with recommendations which focus on tackling key blood transfusion issues. One of the main recommendations within the report is that clinical standards for transfusion practice be developed and disseminated throughout NHSScotland.

Development of clinical standards for blood transfusion

In April 2005, NHS QIS appointed two advisors to identify key areas for possible standards development: Ms Sandra Gray, Programme Manager for the Effective Use of Blood Group (EUB); and Dr Fiona Cutler, Consultant Haematologist, NHS Ayrshire and Arran. Sandra and Fiona undertook a detailed scoping exercise over a 3-month period and this work formed the evidence base for the development of the standards.

To take forward the development of the standards, NHS QIS appointed a project group chaired by Dr Robert Heading. The group first met in July 2005 and its full membership can be found in Appendix 1. The group considered a number of topics surrounding the patient transfusion process (see Appendix 4) and from this starting point, four critical areas for clinical standards were identified:

- core principles
- clinical management - pre-transfusion
- clinical management - hospital transfusion laboratory, and
- clinical management - blood and blood component collection, administration and monitoring.

These standards cover transfusion of blood and blood components in all adult and paediatric settings, eg primary care, acute care and in all hospice and home care settings.

Evidence base

During the development of the clinical standards for blood transfusion, the project group considered a wide range of documents from a variety of sources and these are fully referenced in Appendix 2. The following documents formed the core evidence reviewed by the project group.

- British Committee for Standards in Haematology Blood Transfusion Guidelines

The British Committee for Standards in Haematology (BCSH) is a subcommittee of the British Society for Haematology (BSH), which oversees the whole process of guideline development; individual blood transfusion guidelines are developed by a task force.

'Guidelines for the administration of blood and blood components and the management of transfused patients' (1999) sets out the principles on which to base local guidelines and protocols for requesting blood, collecting a blood sample, laboratory practices, collection and administration of blood components, monitoring the transfused patient, managing an adverse event and documenting the transfusion event.

'Guidelines on the use of red blood cells' (2001), 'Guidelines for the use of platelet transfusions' (2003), and 'Guidelines for the use of fresh-frozen plasma, cryoprecipitate and cryosupernatant' (2004) set out pragmatic guidelines to aid clinical decision-making when using blood components.

Other BCSH guidelines cover aspects of clinical and laboratory practice from ensuring the right blood is assigned to the right patient, to providing guidance on how to minimise wastage. These include 'Guidelines for compatibility procedures in blood transfusion laboratories' (2004), 'Guidelines for blood bank computing' (2000), 'The specification and use of Information Technology (IT) systems in Blood Transfusion Practice' (2006), 'Guidelines for gamma irradiation of blood components for the prevention of transfusion-associated graft-versus-host disease' (1996), and 'Guidelines for implementation of a maximum surgical blood order schedule' (1990).

The BCSH guidelines target all staff involved in the blood transfusion process.

Relevance to standards development: These documents present the best available evidence and, in the absence of data from systematic reviews, randomised controlled trials or cohort studies, the authors provide expert opinion. The guidelines provide principles on which hospitals can base their local protocols, which influence local practices for blood transfusion. A number of the guidelines also provide algorithms, quick reference guides and audit tools.

- Scottish Intercollegiate Guidelines Network (SIGN) (54) (2001): Edinburgh. Perioperative Blood Transfusion for Elective Surgery

The Scottish Intercollegiate Guidelines Network (SIGN) guideline for perioperative blood transfusion for elective surgery was published in 2001. The aim of the guideline is to 'provide a rational and practical framework on which to base transfusion decisions and practice'. The guideline covers:

- the risks of allogeneic transfusion
- haemoglobin transfusion thresholds
- aids to effective blood ordering
- blood sparing strategies
- cardiac surgery, and
- orthopaedic surgery.

Each section includes key recommendations and good practice points, which reflect the strength of evidence available in 2001. The guideline also includes an example of a blood ordering algorithm, a quick reference guide and advice for implementation and audit, and recommendations for further research.

Relevance to standards development: This is a detailed and clinically focused guideline, with over 25 recommendations and 12 good practice points. It provides an excellent basis for hospitals to develop their locally-based protocols and guidelines.

- Scottish Executive Health Department Letters (HDLs): Management Executive Letter (MEL) (1999)9; HDL(2003)19; HDL(2005)25 and HDL(2006)34

The first Better Blood Transfusion Management Executive Letter, MEL(1999)9, set out a list of actions which aimed to improve transfusion practice. The MEL actioned trusts to: set up a hospital transfusion committee (HTC); participate in the Serious Hazards of Transfusion (SHOT) reporting scheme; implement agreed local protocols for transfusion (based on national guidelines) supported by in-house education; and explore the feasibility of autologous transfusion (including cell salvage). HTCs are charged with promoting education and training for all staff involved in the transfusion process as well as promoting best practice (via clinical governance) and leading multi-professional audit.

HDL(2003)19 detailed the plans for an NHSScotland programme, the Better Blood Transfusion Programme (BBTP), which aimed to ensure that blood was used in a clinically appropriate way. This HDL aimed to ensure that blood components were used following consideration of the risks and benefits to the patient, and that blood components were administered correctly and safely. These targets were to be met by providing each trust with Transfusion Practitioners (as part of the hospital transfusion team) who would implement an education programme aimed at increasing the knowledge of staff and changing the culture surrounding the prescribing of blood. The BBTP would also develop a tailored information system designed to provide feedback to clinicians on their blood use.

HDL(2005)25 set out details of: the SNBTS blood stocks management scheme; the NHS Implementation Group for the UK Blood Safety and Quality Regulations (2005); and emergency planning for the management of blood shortages (outlined in Annexe C of this HDL) .

HDL(2006)34 is a good practice guide on consent for health professionals and has guided the project group on consent issues.

Relevance to standards development: These documents guide operating divisions and clinicians to implement measures necessary to improve transfusion practice. The aims of MEL(1999)9 and HDL(2003)19 are to ensure safe, effective and appropriate transfusion for all patients.

HDL(2005)25 deals with reducing wastage via a blood stocks management scheme. It also provides guidance for hospitals regarding compliance with the UK Blood Safety and Quality Regulations (2005), in particular dealing with traceability of blood and blood components, serious adverse event and reaction reporting, and quality management systems.

- UK Blood Safety and Quality Regulations (2005)

In February 2005, two EU Directives - 2002/98/EC and 2004/33/EC were transposed into UK law through the Blood Safety and Quality Regulations 2005 (Statutory Instrument 2005/50 and Statutory Instrument 2005/1098). These regulations set the standards for quality and safety for the collection, testing, processing, storage and distribution of human blood components. There are two aspects of the regulations, which directly impact on staff involved in the transfusion process. Traceability stipulates that unambiguous evidence of the final fate of every blood component issued from the transfusion service is kept for thirty years. Haemovigilance reporting requires that any serious adverse event or serious adverse reaction, which might lead to death or life-threatening, disabling or incapacitating conditions for patients or which results in, or prolongs, hospitalisation or morbidity must be reported to the UK interim competent authority, the Medicines and Healthcare products Regulatory Authority (MHRA). MHRA has developed an online reporting system, Serious Adverse Blood Reactions and Events (SABRE), to facilitate reporting of serious adverse events and reactions (www.mhra.gov.uk).

Relevance to standards development: The UK Operational Impact Group (OIG), has recommended that training is undertaken for clinical staff and all involved in the transfusion process, otherwise it is unlikely that compliance will be achieved. (<http://www.transfusionguidelines.org.uk/index.asp?Publication=REGS&Section=23&pageid=437>).

- Serious Hazards of Transfusion Annual Reports (1996-2003)

Serious Hazards of Transfusion (SHOT) has accumulated 7 years of data on serious hazards of transfusion and, based on these, has made firm recommendations to improve transfusion safety. Year on year there has been an increase in reporting (45% since 1996), with the largest increase consistently in the incorrect blood component transfused (IBCT) category, ie 'wrong blood to patient episodes' (66.7% of reports). In the IBCT category, 16 patients have died and 85 patients have suffered major morbidity related to the transfusion process. SHOT has stated that wrong blood incidents are, without exception, avoidable errors and that the formal identity check at the bedside is the final opportunity to prevent a mis-transfusion.

Relevance to standards development: SHOT is currently a voluntary, anonymised system which aims to collect data on serious adverse events of transfusion of blood components, and to make recommendations to improve transfusion safety.

Through the participating Royal Colleges and professional bodies, SHOT findings can be used to:

- inform policy within transfusion services
- improve standards of hospital transfusion practice
- aid production of clinical guidelines for the use of blood components, and
- educate users on transfusion hazards and their prevention.

SHOT has recommended that education and training are key elements in promoting safe and effective transfusion practice, and that protocols and guidelines should be in place for all aspects of the transfusion process.

- Handbook of Transfusion Medicine (3rd edition / 4th edition in press)

The 'Handbook of Transfusion Medicine' provides staff with guidance to ensure that the right patient gets the right blood at the right time. Many aspects of blood transfusion practice have not been rigorously proved by clinical trials so it is impossible to give a completely evidence-based account. The authors of the Handbook and the reviewers have tried to use the best available evidence regarding effective treatment, and where evidence is not available, to give a balanced view of current opinion about good clinical practice.

Relevance to standards development: The Handbook first published basic standards in 2003, which apply to all users of blood components. The authors have recommended that these standards be adopted for any aspect of care where transfusion is involved, or when patients may require transfusion.

These standards will apply to clinical aspects of blood transfusion only and are in no way applicable to blood donation, processing or testing. Associated issues, such as individual compensation or legal redress for transfusion associated infection, are not covered by the remit of these standards.

4 Clinical standards for blood transfusion

Standard 1 - Core principles

Standard 2 - Clinical management – pre-transfusion

Standard 3 - Clinical management – hospital transfusion
laboratory

Standard 4 - Clinical management – blood and blood
component collection, administration and
monitoring

Standard 1: Core principles

Standard Statement 1a:

There are systems in place supporting clinical governance to ensure safe, effective and appropriate blood transfusion.

Rationale

MEL(1999)9 requires the establishment of an adequately resourced multidisciplinary hospital transfusion committee (HTC) and specifies its role as an integral part of clinical governance in respect of blood transfusion.

Less transfusions are required if carried out by qualified practitioners who transfuse according to agreed guidelines and protocols.

Regulation 9(1)(a) of the UK Blood Safety and Quality Regulations (2005) requires hospitals to ensure the provision of specific regularly updated training for hospital transfusion laboratory staff involved in the testing, storage and distribution of blood and blood components. It is also a requirement that a training record be maintained for all staff. The NHS Operational Impact Group (NHS OIG) recommends that relevant training is provided for all staff involved in the transfusion process. The Better Blood Transfusion Programme (BBTP) has been specifically developed to improve transfusion practice and currently represents the best means of implementing these requirements and recommendations.

References: 1, 2, 4, 5, 6, 7, 8, 9, 11, 12, 14, 18, 24, 25, 26, 27, 29, 30, 31, 32, 33, 35, 36

Essential Criteria

- 1a.1 There is an established, active, multidisciplinary hospital transfusion committee (HTC) that has defined responsibilities and accountability to the chief executive/NHS board via the clinical governance structure.
- 1a.2 The HTC has roles and responsibilities as outlined in MEL(1999)9 and HDL(2003)19. These include involvement in multi-professional audit, education and training, development and modification of guidelines and protocols, and involvement of stakeholders.
- 1a.3 The HTC, in collaboration with the clinical governance committee, implements the NHSScotland Better Blood Transfusion Programme (BBTP).
- 1a.4 The HTC reviews all reports of adverse events and near miss incidents relating to blood transfusion and, in response, implements changes in practice where necessary.



Standard Statement 1b:

The NHS board has a system in place to ensure that every unit of blood component received into the hospital transfusion laboratory can be unmistakably traced to its recipient, or to its final fate if not transfused.

Rationale

UK Blood Safety and Quality Regulations (2005) and HDL(2005)25 require hospitals to have systems in place which ensure that every unit of blood and blood component received into the hospital transfusion laboratory (HTL) can be traced to the individual recipient or to its final fate if not transfused.

Recording of transfusion events is essential for traceability and informs audit.

References: 1, 2, 4, 5, 6, 7, 8, 9, 11, 12, 14, 18, 24, 25, 26, 27, 29, 30, 31, 32, 33, 35, 36

Essential Criterion

1b.1 There is a validated system to ensure that evidence of unmistakable traceability is generated, stored and accessible for 30 years.

Standard Statement 1c:

There is a robust system in place to establish patient identification details and maintain this at every stage of the clinical transfusion process.

Rationale

Incorrect patient identification increases the risk of patients receiving the wrong blood.

Patients who cannot confirm their identity are at particular risk; attention to correct identification of the patient at all stages of the transfusion process is essential.

References: 1, 2, 4, 5, 6, 7, 8, 9, 11, 12, 14, 18, 24, 25, 26, 27, 29, 30, 31, 32, 33, 35, 36, 39

Essential Criteria

- 1c.1 The minimum identification data set (surname, forename, sex, date of birth and unique identification number, eg Community Health Index [CHI]) is used at every stage of the clinical transfusion process to positively identify the patient.
- 1c.2 All patients must be identifiable at all times. Inpatients and day patients must wear an identification wristband. If the wristband becomes inaccessible for any reason, an alternative, risk-assessed form of identification is adopted immediately.
- 1c.3 There is a system (eg distinctive wristbands) to alert qualified practitioners to patients who have specific transfusion requirements, including the wish to not be transfused.
- 1c.4 For patients whose identity cannot be confirmed (eg unconscious patients or patients with communication difficulties), a minimum of gender and one unique identifier (eg accident and emergency number or CHI number) is essential for positive patient identification.



Standard Statement 1d:

The NHS board has a strategy for management of blood shortages.

Rationale

A plan of action to be adopted in the event of blood shortage represents sensible contingency planning.

References: 1, 2, 4, 5, 6, 7, 8, 9, 11, 12, 14, 18, 24, 25, 26, 27, 29, 30, 31, 32, 33, 35, 36, 41

Essential Criterion

1d.1 Emergency blood management arrangements (EBMA) are established as defined in HDL(2005)25.

Standard 2: Clinical management – pre-transfusion

Standard Statement 2a:

The decision to transfuse is made following consideration of the potential risks and benefits of, and the alternatives to, transfusion. Where possible this is discussed between the clinician and patient (or their legal guardian) in advance of transfusion.

Rationale

Treatment options (including valid alternatives to transfusion) should be discussed with the patient.

Valid consent to treatment is an absolute requirement in all forms of healthcare.

The principles governing the requirement for explanation and discussion, obtaining the patient's consent and documenting this information in the case record are the same for transfusion of blood and blood components as for any other therapeutic intervention.

References: 1, 2, 3, 4, 5, 6, 9, 11, 12, 15, 16, 17, 18, 25, 27, 29, 30, 31, 32, 33, 35, 41

Essential Criteria

- 2a.1 The patient's records contain evidence that the reason for transfusion of blood or blood components has been explained and discussed with the patient. This includes discussion of valid alternatives to transfusion and the option to refuse.
- 2a.2 Leaflets explaining the risks and benefits of, and alternatives to, transfusion are readily available for patients who may require to be, or have been transfused.
- 2a.3 Where pre-transfusion discussion is not possible (eg in an emergency) there is a system, compatible with the patient's clinical needs, to investigate and act in accordance with the patient's treatment preferences. This includes compliance with an advance decision document.
- 2a.4 When pre-transfusion discussion has not taken place, the reasons for transfusion (based on risks and benefits) are discussed with the patient and written information offered retrospectively.



Standard Statement 2b:

Positive patient identification at the time of sampling and the use of a minimum identification data set on samples and request forms is essential for pre-transfusion testing and blood component requests.

Rationale

Most transfusion errors reported to Serious Hazards of Transfusion (SHOT) relate to failure to correctly identify patients.

Correct identification is essential for patient safety.

References: 1, 2, 3, 4, 5, 6, 9, 11, 12, 15, 16, 17, 18, 25, 27, 29, 30, 31, 32, 33, 35

Essential Criterion

2b.1 Blood samples for transfusion purposes are obtained and labelled in accordance with local protocols which are based on national guidelines.

Standard Statement 2c:

Blood and blood component prescribing is the responsibility of a qualified practitioner.

Rationale

Prescription by a medical practitioner is a requirement for clinical transfusion.

References: 1, 2, 3, 4, 5, 6, 9, 11, 12, 15, 16, 17, 18, 25, 27, 29, 30, 31, 32, 33, 35

Essential Criteria

2c.1 All prescriptions for blood and blood components are signed by a qualified practitioner.

2c.2 Blood and blood component prescriptions specify:

- blood component to be administered
- number of units (millilitres in paediatric patients) to be transfused
- duration of transfusion
- any special requirements, and
- any special instructions.

Standard 3: Clinical management – hospital transfusion laboratory

Standard Statement 3a:

Laboratory operations comply with current regulatory requirements.

Rationale

Regulatory compliance ensures good practice, consistency of service and enhances staff responsibility to patients. See the UK Blood Safety and Quality Regulations 2005.

References: 2, 5, 7, 8, 26, 33, 35, 37, 38

Essential Criteria

- 3a.1 All transfusion laboratories within the NHS board are accredited by Clinical Pathology Accreditation (UK) Ltd (CPA) or equivalent and are compliant with the Medicines and Healthcare products Regulatory Agency (MHRA) requirements.
- 3a.2 Competency-based training and assessment systems are in place and training records are maintained.

Standard Statement 3b:

Procedures are in place to optimise blood use and minimise wastage.

Rationale

Optimising use of blood and minimising wastage is part of good practice. See the UK Blood Safety and Quality Regulations 2005.

References: 2, 5, 7, 8, 26, 33, 35, 37, 38,

Essential Criteria

3b.1 Protocols endorsed by the HTC are in place, including but not limited to:

- the maximum surgical blood ordering schedule (MSBOS)
- massive blood loss
- major incidents, and
- emergency blood management arrangements.

3b.2 There is a stock management system to eliminate excess inventory and reduce waste, supported by an information technology (IT) system.

3b.3 In collaboration with clinical specialties, laboratory staff participate in audit of transfusion issues.

Standard 4: Clinical management – blood and blood component collection, administration and monitoring

Standard Statement 4a:

Positive patient identification is performed against the blood component and any accompanying documentation at every stage of the clinical transfusion process.

Rationale

Failure to correctly identify the patient is still the most common problem leading to transfusion error.

The formal patient identity check, in accordance with local guidelines immediately before clinical transfusion is the final opportunity to prevent this occurrence.

References: 2, 18, 19, 22, 29, 30, 31, 33, 35, 37, 38

Essential Criteria

- 4a.1 Only staff who have completed the BBTP continuing education programme (or equivalent) appropriate to their role can participate in the clinical transfusion process.
- 4a.2 The minimum identification data set is recorded on all transfusion documentation (see standard criterion 1c.1).

Standard Statement 4b:

Patients are monitored for any adverse events or reactions during and after the transfusion process as clinically indicated.

Rationale

Patient monitoring ensures that transfusion reactions can be detected swiftly and remedial action taken promptly.

Monitoring and reporting of adverse events or reactions helps identify problems, informs the quality improvement strategy and complies with the UK Blood Safety and Quality Regulations (2005).

References: 2, 18, 19, 22, 29, 30, 31, 33, 35, 37, 38

Essential Criteria

- 4b.1 Patients are monitored according to hospital transfusion policy and any untoward events (including suspected adverse reactions) are immediately clinically managed and promptly reported to the HTL.
- 4b.2 Serious adverse events and near miss incidents are reported on the clinical incident reporting system in accordance with local protocols.
- 4b.3 Reports of serious adverse events or reactions and near miss incidents are submitted to Serious Adverse Blood Reactions and Events (SABRE) and the Serious Hazards of Transfusion (SHOT) initiative by the relevant staff.

5 Appendices

Appendix 1	Membership of the clinical standards for blood transfusion project group
Appendix 2	Evidence base
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Appendix 5	The role of the Better Blood Transfusion Programme
Appendix 6	List of useful websites

Appendix 1: Membership of the clinical standards for blood transfusion project group

Name	Title	NHS board area/organisation
Dr Robert Heading (Chair)	Consultant Gastroenterologist (retired)	Lothian
Mr Gus Campbell*	Member	Hospital Liaison Committee of Jehovah's Witnesses
Mr Neil Campbell*	Member	Hospital Liaison Committee of Jehovah's Witnesses
Dr Tara Cooper	Consultant Obstetrician & Gynaecologist	Lothian
Ms Diane Creighton	Transfusion Practitioner	Greater Glasgow & Clyde
Dr Fiona Cutler	Consultant Haematologist	Ayrshire and Arran
Ms Sandra Gray	Effective Use of Blood Manager	Scottish National Blood Transfusion Service
Mrs Elizabeth Higgins	Ward Manager	Highland
Mrs Catherine Howell	Transfusion Liaison Nurse Manager	National Blood Transfusion Service
Ms Tina King	Transfusion Practitioner	Greater Glasgow & Clyde
Mrs Betty Kyle	Senior Chief Biomedical Scientist	Lanarkshire
Ms Kate Lambie	Practice Development Nurse	Lothian
Dr Nigel Leary	Head of Clinical Service, Anaesthesia and Critical Care	Borders
Mrs Gillian McPhillips	Senior Information Analyst	National Services Scotland
Mr Mike Maginnis	Laboratory Manager for SNBTS Clinical Directorate	Scottish National Blood Transfusion Service
Mr Ron Marsh	Public Partner	Grampian
Mrs Elaine Moore	Clinical Risk Co-ordinator	Ayrshire & Arran
Dr Fiona Scott	Consultant Haematologist	Tayside
Mr Ian Stephenson	National Pathology Manager	BUPA Hospitals
Ms Anna Thomson	Public Partner	Forth Valley
Dr Henry Watson	Consultant Haematologist	Grampian

* Mr Neil Campbell and Mr Gus Campbell contributed to the development of standards 1c and 2a only, by providing input from an ethical perspective.

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NHS QIS would like to thank the following for their input and support during the development of the clinical standards for blood transfusion:

- Mr David Finlayson, Consultant Orthopaedic Surgeon, NHS Highland.
- Mr James Steers, Consultant Neurosurgeon, NHS Lothian.

Appendix 2: Evidence base

- 1 Association of Anaesthetists of Great Britain and Ireland - Working Party. 2001. Blood Transfusion and the Anaesthetist: *Red Cell Transfusion*. London: The Association of Anaesthetists of Great Britain and Ireland. www.aagbi.org/pdf/blood_tran.pdf Url cited 02/08/06.
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Appendix 3: Glossary

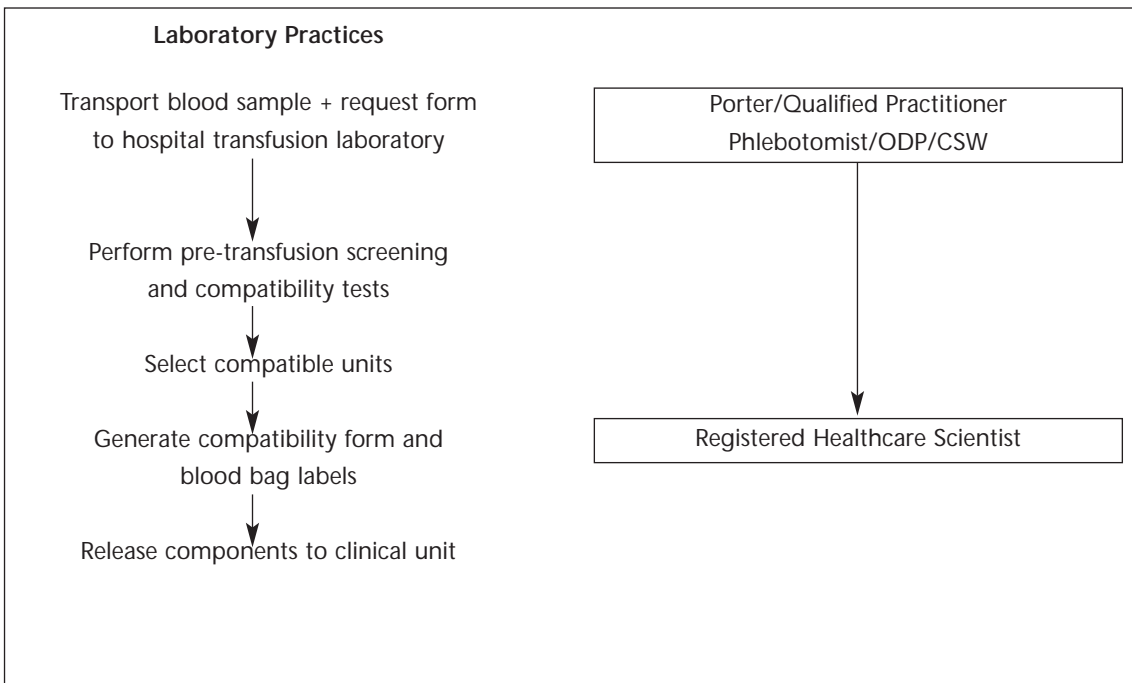
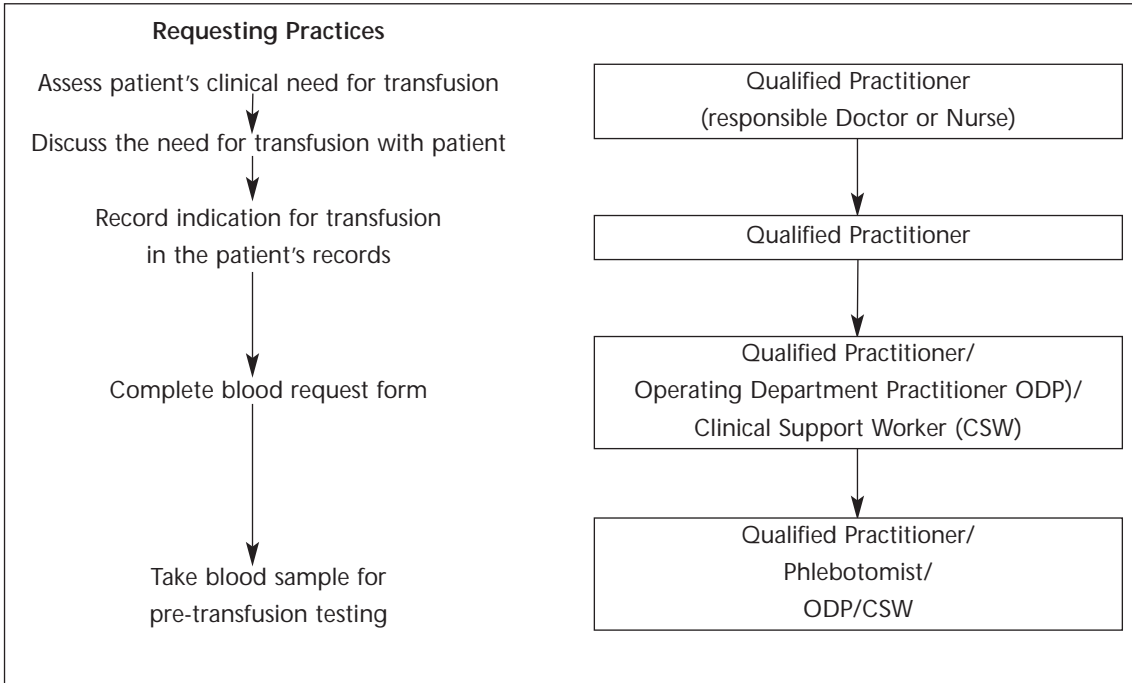
advance decision	A written, witnessed document made when the patient is well, setting out how he or she would prefer to be treated (or not treated) if they were to become ill in the future.
allogeneic transfusion	Blood and blood components collected from an individual and intended for transfusion to another individual.
audit	The measuring and evaluation of care against agreed standards with a view to improving practice and care delivery.
autologous transfusion	Transfusion to an individual of blood collected from him or herself. Includes salvage from operation site.
Better Blood Transfusion Programme (BBTP)	A programme developed for the conservation and improved management of blood as outlined in HDL(2003)19. One of its major aims is to deliver an enhanced service and quality of care to patients who need transfusion as part of their treatment.
blood bank	See 'Hospital Transfusion Laboratory'.
blood component	A therapeutic constituent of human blood (redcells, platelets, plasma, or cryoprecipitate).
British Committee for Standards in Haematology (BCSH)	A committee within the British Society of Haematology publishing national guidelines in the field of blood transfusion and haematology.
clinical effectiveness	The extent to which specific clinical interventions do what they are intended to do, ie maintain and improve health, securing the greatest possible health gain from the available resources.
clinical governance	The system through which NHS organisations are accountable for continuously monitoring and improving the quality of their care and services, and safeguarding high standards of care and services.
Clinical Pathology Accreditation (UK) Ltd (CPA)	The company which assesses the ability of a pathology laboratory to provide a high quality service.
compatibility test	A laboratory test between donor and recipient blood carried out prior to transfusion to avoid, where possible, serious adverse reactions.
core competency	Fundamental knowledge, ability or expertise in a specific area or skill set.
criterion(sing)/criteria(pl)	Provide the more detailed and practical information on how to achieve the standard.
cryoprecipitate	A component of human blood that forms when plasma is frozen and then thawed. This can be used to treat patients who are deficient in the blood agents necessary for clotting.
emergency blood management arrangements (EBMA)	An integrated plan for the management of blood shortages as outlined in HDL(2005)25.

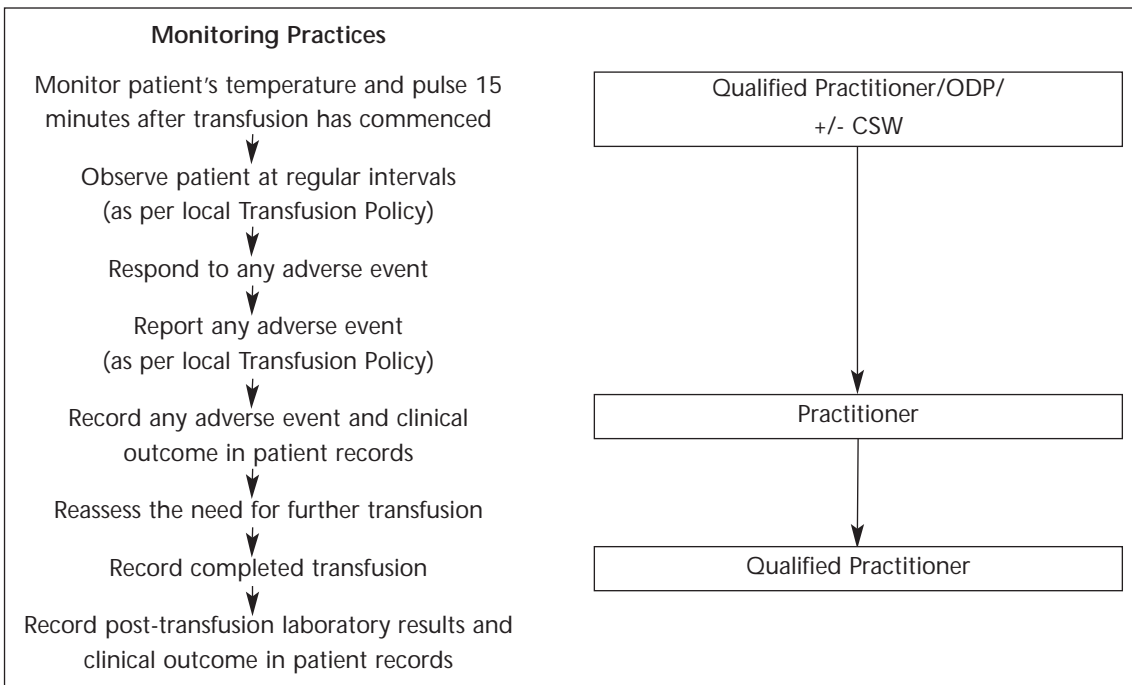
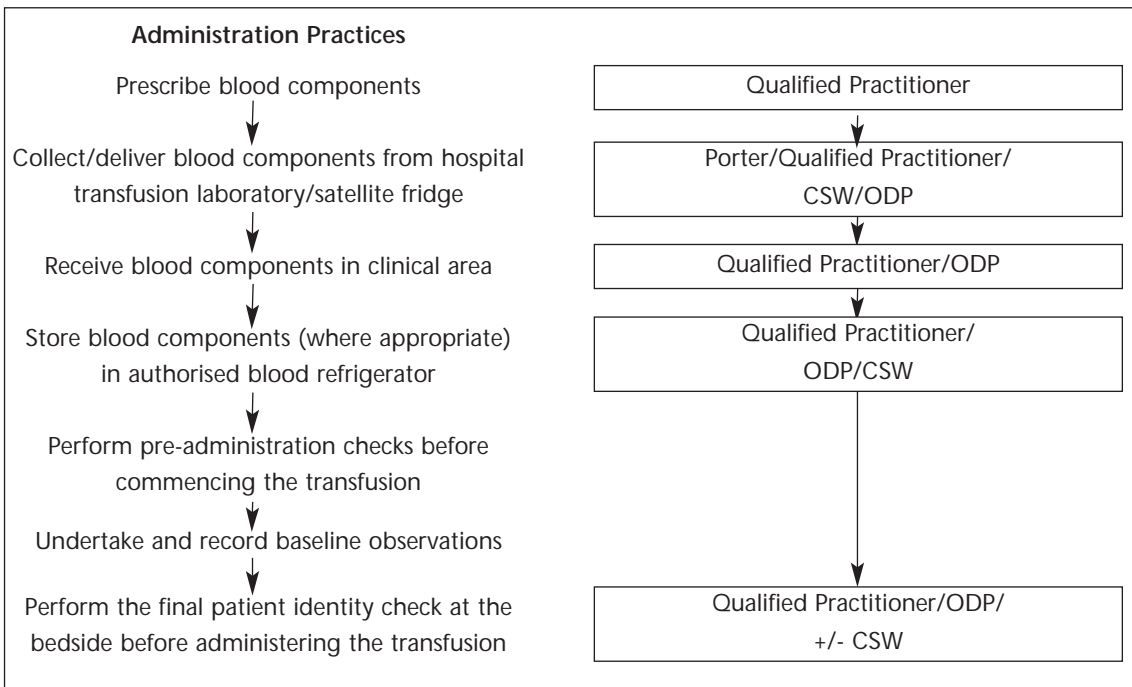
evidence-based practice	An approach to decision-making in which the clinician uses the best evidence available to decide on the clinical option which best suits the patient.
fresh-frozen plasma	Plasma which is frozen within eight hours of separation from blood, in order to preserve its therapeutic benefits.
Health Department Letter (HDL)	Formal communications from the Scottish Executive Health Department (SEHD) to NHSScotland.
hospital transfusion laboratory (HTL)	Any unit within a hospital which stores and distributes blood and may perform compatibility tests on blood and blood components exclusively for use within hospital facilities.
Medicines and Healthcare products Regulatory Agency (MHRA)	The UK body responsible for the licensing of pharmaceuticals and blood service activities. The MHRA is the interim competent authority for the Blood Safety and Quality Regulations, 2005.
minimum identification data set	The patient's forename, surname, sex, date of birth and unique hospital/accident and emergency number. See also 'positive patient identification'.
multidisciplinary	An approach combining the knowledge, skills and expertise of a range of organisations and professionals.
NHS board	NHS boards are responsible for the strategic planning, service delivery, performance management and governance of each of Scotland's 14 local health systems. There are 22 NHS boards in Scotland. 14 are territorial boards, responsible for care and services in their areas and 8 are special health boards, which provide national clinical and non-clinical care and services.
NHS Operational Impact Group (NHS OIG)	A group formed to consider the requirements of the UK Blood Safety and Quality Regulations (2005) to make recommendations to the UK Departments of Health regarding measures necessary to comply with these regulations.
NHS Quality Improvement Scotland (NHS QIS)	NHS QIS has been established (January 2003) to lead in improving the quality of care and treatment delivered by NHSScotland. To do this it sets standards and monitors performance, and provides NHSScotland with advice, guidance and support on effective clinical practice and service improvements. Website: www.nhshealthquality.org
peer review	Review of a service by those with expertise and experience in that service, either as a provider, user or carer, but who are not involved in its provision in the area under review. In the NHS QIS approach, all members of a review team are equal.

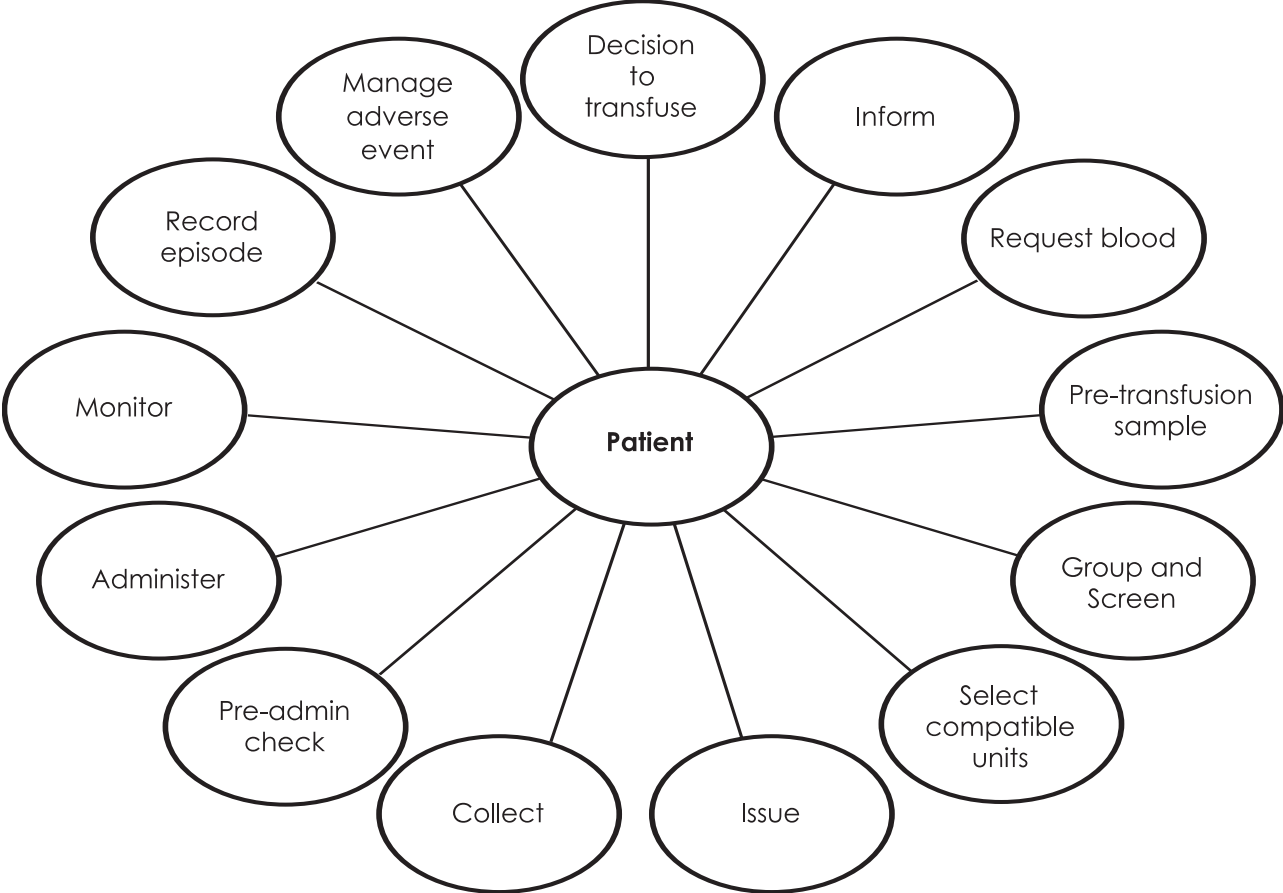
plasma	The liquid portion of the blood in which cells are suspended. Plasma may be separated from the cellular portion of a whole blood collection for therapeutic use as fresh-frozen plasma, or further processed to cryoprecipitate and cryoprecipitate-depleted plasma for transfusion. See also fresh frozen plasma (FFP).
positive patient identification	Verification of a patient's identity through a check of identification wristband details and, where possible, verbal confirmation with the patient.
protocol	A documented plan for the delivery of a particular aspect of care.
qualified practitioner	An appropriately trained individual who has responsibility for prescribing and administering blood transfusions.
quality assurance	Improving performance and preventing problems through planned and systematic activities including documentation, training and review.
rationale	Scientific/objective reason for taking specific action.
Scottish Executive Health Department (SEHD)	The Scottish Executive Health Department is responsible for the central management of NHSScotland, and the development and implementation of health and community care policy across Scotland.
Scottish Intercollegiate Guidelines Network (SIGN)	Umbrella organisation of healthcare professional bodies. SIGN is part of NHS QIS and develops clinical guidelines for effective practice.
Scottish National Blood Transfusion Service (SNBTS)	A major division within NHS National Services Scotland. SNBTS supply chain directorate is responsible for the collection, testing and distribution of donor blood, while the clinical directorate supports a significant proportion of pre-transfusion testing and investigation of compatibility complications.
self-assessment	Assessment of performance against standards by individual/team/board providing the service to which the standards are related.
Serious Adverse Blood Reactions and Events (SABRE)	An electronic reporting system for reporting serious adverse reactions and events to MHRA and SHOT (Blood Safety and Quality Regulations 2005).
serious adverse event (SABRE definition)	Any untoward occurrence associated with the collection, testing, processing, storage and distribution, of blood or blood components that might lead to death or life-threatening, disabling or incapacitating conditions for patients or which results in, or prolongs, hospitalisation or morbidity.

serious adverse reaction (SABRE definition)	An unintended response in a donor or in a patient associated with the collection or transfusion of blood or blood components that is fatal, life-threatening, disabling or which results in or prolongs hospitalisation or morbidity.
Serious Hazards of Transfusion (SHOT)	The UK reporting system for adverse transfusion events and 'near misses'.
traceability	Ability to trace each individual unit of blood or blood component to its final destination.
transfusion	The introduction of blood and blood components directly into the bloodstream.
Transfusion Practitioner	Specialist practitioner with a role in implementing staff training, developing local transfusion guidelines and reporting systems for blood ordering, administration and prescribing, including monitoring of wastage and error rates.
transfusion process	The series of events comprising the requesting of blood or blood components for transfusion, taking pre-transfusion blood samples, laboratory practices, collection and administration of blood or blood components, monitoring the transfused patient, managing an adverse event and documenting the transfusion events.
valid consent	Process by which a patient accepts a form of treatment. Central to the process is the importance of providing adequate information on the risks and benefits of a procedure to allow the patient (or patient's guardian) to come to an informed decision.

Appendix 4: The clinical transfusion process







Appendix 5: The role of the Better Blood Transfusion Programme

Role of the programme

The NHSScotland Better Blood Transfusion Programme (BBTP) was established in March 2003 in response to recommendations of the UK Chief Medical Officers for the development of programmes which would assure the delivery of safe and effective transfusion practice throughout Scotland.

The BBTP in Scotland is a key element of the overall strategy to reduce the residual unavoidable risks to patients from blood transfusion primarily through the avoidance of unnecessary transfusions and also through the continuous improvement of quality systems for all aspects of transfusion practice.

The programme is also a cornerstone of the NHSScotland response to the UK Blood Safety and Quality Regulations (2005), and to potential future pressures on the blood supply and possible severe blood shortages.

The key objectives of the programme are:

- safer transfusion evidenced by more recording of near misses, reduced incidents and delivered through:
 - a national education and training programme covering medical, nursing, laboratory and support staff, and focusing on safe, efficient and effective practice
 - implementation of protocols and guidelines to national standards, and
 - audit and review of transfusion practice.

- 10% reduction in the use of red cells delivered through:
 - the development of a sustainable and accessible NHSScotland database of clinical transfusion practice to facilitate review, and national and international benchmarking of individual/divisional practice
 - reducing avoidable blood wastage, and
 - reducing excessive blood ordering and local stockholding.

- to provide support for:
 - implementation of the UK Blood Safety and Quality Regulations, and
 - development of emergency plans for the management of severe blood shortages.

Programme structure

The programme is managed centrally and funded by NHSScotland. It is accountable to a national steering group for delivery of the above objectives. A network of local Transfusion Practitioners support and guide best transfusion practice across Scotland. The Transfusion Practitioner works co-operatively within the local setting supported by an identified lead person and a range of functional specialists in each local site. The practitioners obtain direction and support from a central programme office.

The programme works closely with the SNBTS effective use of blood team who provide expert professional support, mentoring and educational/training materials for the programme and its staff.

Appendix 6: List of useful websites

- 1 www.bcshguidelines.com
Committee for Standards in Haematology (BCSH) guidelines - an excellent resource, which allows you to download all the current UK transfusion guidelines.
- 2 www.betterblood.org.uk
The Better Blood Transfusion Programme (BBTP) is an NHS Scotland programme aimed at delivering an enhanced service and quality of care to patients who need transfusion as part of their treatment.
- 3 www.learnbloodtransfusion.org.uk
An online continuing education programme, which has been designed to assist practitioners involved in the transfusion process to provide consistently high standards of care.
- 4 www.shot-org.uk
Serious Hazards of Transfusion (SHOT) reporting scheme provides access to the most up-to-date haemovigilance data from the UK reporting scheme.
- 5 www.transfusionguidelines.org
A comprehensive online resource, covering all aspects of transfusion medicine, which includes systematic review initiatives.

You can read and download this document from our website.
We can also provide this information:

- by email
- in large print
- on audio tape or CD
- in Braille, and
- in community languages.

NHS Quality Improvement Scotland

Edinburgh Office
Elliott House
8-10 Hillside Crescent
Edinburgh EH7 5EA

Phone: 0131 623 4300
Textphone: 0131 623 4383

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