

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

SCOPE

1 **Guideline title**

Blood transfusion

1.1 **Short title**

Transfusion

2 **The remit**

The Department of Health has asked NICE: 'to develop a cross cutting clinical guideline on the assessment for and management of transfusion'.

3 **Clinical need for the guideline**

3.1 **Epidemiology**

- a) Blood transfusions are commonly used in clinical practice. In 2011 NHS Blood and Transplant issued 1,829,951 units of red blood cells, 260,278 units of platelets, 248,163 units of fresh frozen plasma and 122,516 units of cryoprecipitate to hospitals in England and North Wales.
- b) In 2002 an estimated 430,000 patients received a red blood cell transfusion.
- c) Blood transfusion is an essential part of modern healthcare. However, it is also associated with clinical risks. The risk of transfusion-related death was 2.7 per million blood components issued and the risk of transfusion-related major morbidity was 39.9 per million blood components issued. The proportion of adverse incident reports resulting in death or major morbidity has reduced from 34% in 1996/97 to 6.9% in 2011.

- d) Transfusion of blood to the wrong patient is an avoidable serious hazard of transfusion. It can result from errors made anywhere in the transfusion process, including patient identification, blood sample collection, laboratory testing and handling of samples, retrieval from blood transfusion refrigerators and the bedside check immediately before transfusion. Transfused patients require careful monitoring for any adverse effects.
- e) Appropriate decision-making about the use of blood based on clinical findings and laboratory parameters and avoidance of over-transfusion are essential parts of good transfusion practice.
- f) Haemovigilance data from the Serious Hazards of Transfusion scheme in the UK indicate that 'incorrect blood component transfused' accounts for the largest proportion of all adverse events, and is the second most frequent cause of mortality and morbidity associated with transfusion.

3.2 *Current practice*

- a) There has been a considerable decline in the use of red blood cell transfusion. A study in the north of England showed a decline in the transfusion rate from 45.5 to 36 units per 100,000 population between 1999 and 2009. In contrast, the use of platelets and fresh frozen plasma has been increasing. However, the use of red blood cells in England remains higher than in some countries such as Canada.
- b) The ageing population and new therapies in cancer, transplantation and many other fields of medicine may increase blood use in the future.
- c) Between 1999 and 2009 the proportion of red blood cells used in surgical patients declined from 41% to 29%. Over the same period the proportion of red blood cells used in medical patients increased

from 52% to 64%; use in obstetrics and gynaecology remained stable at 6%.

- d) Blood transfusion in the UK is safer now than it has ever been but it is not risk-free. Numerous initiatives over the past 15 years in the UK, primarily involving the education and training of the many staff involved in the transfusion process, have had a considerable effect on improving transfusion safety.
- e) A current concern is the high level of inappropriate use of blood components, which is wasting a scarce and costly resource, and putting patients at unnecessary risk. There remains considerable variation between hospitals. Inappropriate use of all blood components is estimated to be 20% or higher from the results of national and large regional audits in the UK.
- f) Efforts are needed to promote evidence-based strategies and measures to reduce the inappropriate use of blood components, and increase the use of alternatives to transfusion. These will both improve patient care and reduce hospital costs. New technologies have the potential to improve the safety of the transfusion process, such as using electronic systems for patient identification and to check that the right blood will be transfused. They also have the potential to support the appropriate use of blood by linkage to the electronic patient record to provide 'decision support'. However, as yet, they have not been widely adopted in the NHS.

4 The guideline

The guideline development process is described in detail on the NICE website (see section 6, 'Further information').

This scope defines what the guideline will (and will not) examine, and what the guideline developers will consider. The scope is based on the referral from the Department of Health.

The areas that will be addressed by the guideline are described in the following sections.

4.1 *Population*

4.1.1 Groups that will be covered

- a) Adults.
- b) Children and young people.
- c) Specific consideration will be given to the needs of:
 - Elderly population
 - Religious groups

4.1.2 Groups that will not be covered

- a) Neonates and infants up to 1 year of age (except for patient safety issues listed in section 4.5.5).
- b) Foetuses.

4.2 *Healthcare setting*

- a) All healthcare settings.

4.3 *Clinical management*

4.3.1 Key clinical issues that will be covered

- a) Appropriate use of red blood cell transfusion:
 - indications for starting transfusion, based on clinical considerations, medical comorbidities such as myocardial infarction and haemoglobin (Hb) concentration thresholds
 - dose of red blood cells (number of units of red blood cells)
 - target Hb levels.

- b) Appropriate use of platelet transfusion:
- indications for starting transfusion, based on clinical considerations including the presence or absence of bleeding and platelet count thresholds
 - dose of platelets
 - target platelet counts.
- c) Appropriate use of fresh frozen plasma (FFP), cryoprecipitate and prothrombin complex concentrate (PCC) transfusion:
- indications for starting transfusion, based on clinical considerations including the presence or absence of bleeding and abnormalities of tests of haemostasis
 - dose of FFP, cryoprecipitate and PCC
 - target results of haemostasis tests.
- d) Alternative treatments to blood transfusion in surgical patients:
- oral iron
 - intravenous (IV) iron
 - recombinant erythropoietin
 - tranexamic acid as an adjunct to minimise transfusion. Note that guideline recommendations will normally fall within licensed indications; exceptionally, and only if clearly supported by evidence, use outside a licensed indication may be recommended. The guideline will assume that prescribers will use a drug's summary of product characteristics to inform decisions made with individual patients
 - cell salvage therapy.

- e) Patient safety:
 - monitoring of signs and symptoms of acute transfusion reaction
 - electronic patient identification systems to ensure patient safety during blood transfusions.
- f) Electronic decision support at the time of blood ordering for the appropriate use of blood
- g) Patient information and support specific to blood transfusion.

4.3.2 Clinical issues that will not be covered

- a) Investigations and treatment of anaemia in medical patients
- b) Use and administration of blood products, including:
 - immunoglobulin.
- c) Coagulation factor concentrates
- d) Recombinant activated factor VII
- e) Albumin
- f) Fibrinogen
- g) Identification and testing for anaemia
- h) Treatment of anaemia in medical patients
- i) Laboratory procedures relating to the quality and safety of blood products (content, characteristics, storage and residual risks of infection) including:
 - handling of samples
 - documentation
 - ABO and RhD blood grouping

- antibody screening and identification
 - selection and issue of red blood cells
 - procedures after blood components have been issued.
- j) Near patient testing of haemoglobin and haemostasis
- k) Human leucocyte antigen (HLA) sensitisation with transplantation.
- l) This is a cross cutting guideline focussing on the general principles of transfusion and the appropriate use of blood. No specific clinical condition will be excluded, but the detailed management of specific clinical conditions (such as haemoglobinopathy, minor coagulopathy, obstetrics) will not be considered. The following specialist areas will not be included in the guidance as they are covered by other related NICE guidance:
- anaemia in chronic kidney disease
 - upper gastrointestinal bleeding
 - trauma or massive haemorrhage.

4.4 Main outcomes

- a) Mortality
- b) Quality of life
- c) Length of stay (hospitalisation)
- d) Infections (for example, pneumonia)
- e) Number of patients needing transfusions
- f) Number of units transfused
- g) Bleeding
- h) Serious adverse events.

4.5 *Review questions*

4.5.1 **Red blood cell transfusion**

- a) What is the clinical and cost effectiveness of red blood cell transfusion at different haemoglobin concentrations?

- b) What is the clinical and cost effectiveness of red blood cell transfusion based on clinical considerations including medical comorbidities?

- c) What is the clinical and cost effectiveness of different doses of red blood cell transfusion?

- d) What is the clinical and cost effectiveness of different target levels of post-transfusion haemoglobin concentrations for red blood cell transfusion?

4.5.2 **Platelet transfusion**

- a) What is the clinical and cost effectiveness of platelet transfusion at different platelet count thresholds?

- b) What is the clinical and cost effectiveness of platelet transfusion based on clinical considerations including the presence of or absence of bleeding?

- c) What is the clinical and cost effectiveness of different doses of platelet transfusion?

- d) What is the clinical and cost effectiveness of different target levels of post-transfusion platelet counts?

4.5.3 **Fresh frozen plasma (FFP), cryoprecipitate and prothrombin complex concentrate (PCC) transfusion**

- a) What is the clinical and cost effectiveness of FFP, cryoprecipitate and PCC transfusion at different levels of abnormal haemostasis?

- b) What is the clinical and cost effectiveness of FFP, cryoprecipitate and PCC transfusion based on clinical considerations including the presence or absence of bleeding?
- c) What is the clinical and cost effectiveness of different doses of FFP, cryoprecipitate and PCC?
- d) What is the clinical and cost effectiveness of different target levels of post-transfusion haemostasis tests?

4.5.4 Alternative treatments to blood transfusion in surgical patients

- a) What is the clinical and cost effectiveness of oral iron and IV iron in reducing blood transfusion requirements in surgical patients?
- b) What is the clinical and cost effectiveness of recombinant erythropoietin in reducing blood transfusion requirements in surgical patients?
- c) What is the clinical and cost effectiveness of tranexamic acid in reducing blood transfusion requirements in surgical patients?
- d) What is the clinical and cost effectiveness of cell salvage therapy in reducing blood transfusion requirements in surgical patients?

4.5.5 Patient safety

- a) What is the clinical and cost effectiveness of monitoring for acute reactions at different times in relation to the transfusion?
- b) What are the clinical and cost effectiveness of electronic patient identification systems such as patient identification bands, bar codes or radiofrequency identification to ensure patient safety during blood transfusions?

4.5.6 Electronic decision support blood order systems

- a) What are the clinical and cost effectiveness of electronic decision support blood order systems to reduce inappropriate blood transfusions?

4.5.7 Patient information and support specific to blood transfusion

- a) What is the clinical and cost effectiveness of providing information to people receiving blood transfusion and their family members or carers?

4.6 *Economic aspects*

Developers will take into account both clinical and cost effectiveness when making recommendations involving a choice between alternative interventions. A review of the economic evidence will be conducted and analyses will be carried out as appropriate. The preferred unit of effectiveness is the quality-adjusted life year (QALY), and the costs considered will usually be only from an NHS and personal social services (PSS) perspective. Further detail on the methods can be found in 'The guidelines manual' (see 'Further information').

4.7 *Status*

4.7.1 *Scope*

This is the final scope.

4.7.2 *Timing*

The development of the guideline recommendations will begin in June 2013.

5 Related NICE guidance

5.1 *Published guidance*

- [Acute upper gastrointestinal bleeding](#). NICE clinical guideline 141 (2012).
- [Caesarean section](#). NICE clinical guideline 132 (2011).

- [Anaemia management in people with chronic kidney disease](#). NICE clinical guideline 114 (2011).
- [Neonatal jaundice](#). NICE clinical guideline 98 (2010).
- [Intraoperative blood cell salvage during radical prostatectomy or radical cystectomy](#). NICE interventional procedure guidance 258 (2008).
- [Intraoperative blood cell salvage in obstetrics](#). NICE interventional procedure guidance 144 (2005).
- [Preoperative tests](#). NICE clinical guideline 3 (2003).

5.2 Guidance under development

NICE is currently developing the following related guidance (details available from the NICE [website](#)):

- Intravenous fluid therapy in adults. NICE clinical guideline. Publication expected November 2013.
- Intravenous fluids therapy in children. NICE clinical guideline. Publication expected November 2015.
- Ulcerative colitis. NICE clinical guideline. Publication expected June 2013.
- Erythropoiesis-stimulating agents (epoetin and darbepoetin) for the treatment of cancer-treatment induced anaemia (including review of TA142). NICE technology appraisal. Publication expected August 2014.
- Intrapartum care. NICE clinical guideline. Publication expected October 2014.
- Major trauma. NICE clinical guideline. Publication expected June 2015.
- Trauma services. NICE clinical guideline. Publication expected October 2015.
- Intrapartum care for high risk women. NICE clinical guideline. Publication date to be confirmed.
- Anaemia management in chronic kidney disease (update). NICE clinical guideline. Publication date to be confirmed.

6 Further information

Information on the guideline development process is provided in the following documents, available from the NICE website:

- [How NICE clinical guidelines are developed: an overview for stakeholders the public and the NHS](#)
- [The guidelines manual](#).

Information on the progress of the guideline will also be available from the [NICE website](#).