NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

SCOPE

1 Guideline title

Transfusion: the assessment for and management of transfusion

1.1 Short title

Transfusion

2 The remit

The Department of Health has asked NICE to develop a 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 significant 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) Good clinical practice contributes to safe and effective transfusion by avoiding errors leading to ‘wrong blood transfusion’, appropriate decision-making about the appropriate use of blood based on clinical findings and laboratory parameters, and monitoring patients for adverse effects of transfusion and managing them if they occur. There is published evidence of suboptimal clinical transfusion practice in all of these aspects of transfusion.

e) Accurate patient identification is a critical step. 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 blood sample collection, laboratory testing and handling of samples, retrieval from blood transfusion refrigerators and the bedside check immediately before transfusion.

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 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 cells in England remains higher than other countries, including Canada and Northern Ireland.

b) There has been a decline between 1999 and 2009 in the proportion of red cells used in surgical patients from 41 to 29% of all red cells transfused, and an increase in the proportion of red cells used in medical patients from 52 to 64% of all red cells transfused; usage in obstetrics and gynaecology has remained stable at 6%.

c) Blood transfusion in the UK is safer now than it has ever been but, it is not risk-free. There remains considerable variation between hospitals. Inappropriate use of all blood components is estimated to be 20% or higher.

d) Numerous initiatives over the past 15 years in the UK have had a considerable effect on improving transfusion safety. A current concern is the high level of inappropriate use of blood components, which is wasteful of a scarce and costly resource and puts patients at unnecessary risk.

e) The ageing population and new therapies in cancer, transplantation and many other fields of medicine may increase blood use in the future.

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 NHS costs.

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) No patient subgroups have been identified as needing specific consideration.

4.1.2 Groups that will not be covered

a) Neonates and infants up to 1 year of age and foetuses.

4.2 Healthcare setting

a) All healthcare settings.

4.3 Clinical management

4.3.1 Key clinical issues that will be covered

a) Detection of anaemia, in surgical and medical patients:

- when to test, for example time before surgery

b) Appropriate use of red blood cell transfusion before and during surgery, and in medical patients:

- indications for starting transfusion, such as clinical symptoms and signs, and haemoglobin(Hb) levels
- dose and frequency of administration of red cells
- target Hb levels.

c) Alternatives to red blood cell transfusion during and after surgery, including:

- tranexamic acid as an adjunct to minimise transfusion
- cell salvage therapy.

d) Avoidance of harm:

- monitoring for signs and symptoms of acute transfusion reaction

- patient identification; for example, patient identification band, barcode or radiofrequency identification (RFID).

e) What information to give patients about red blood cell transfusion.

4.3.2 Clinical issues that will not be covered

a) Use and administration of the blood products, including:

- platelets
- fresh frozen plasma
- immunoglobin
- factor VII
- albumin
- cryoprecipitate.

b) 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 D grouping
- antibody screening and identification
- selection and issue of red cells
- procedures after blood components have been issued.

c) Near patient testing of haemoglobin and haemostasis.

d) Human leucocyte antigen (HLA) sensitisation with transplantation.

e) Red cell transfusions in specific clinical conditions, such as:

- malignancy or haematology
- liver disease patients
- critical care
- minor coagulopathy
- sickle cell disease
- 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) Adverse events.

4.5 Review questions

4.5.1 Detection of anaemia in relation to transfusion

a) What is the clinical and cost effectiveness of testing for anaemia at different times before surgery?

4.5.2 Red blood cell transfusion in patients before or during surgery and in medical patients

a) What is the clinical and cost effectiveness of transfusing at different Hb levels?

b) What is the clinical and cost effectiveness of transfusing patients with differing signs and symptoms?

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

d) What is the clinical and cost effectiveness of different administration frequencies of red blood cells in transfusion?

e) What is the clinical and cost effectiveness of different Hb target levels in transfusion?

4.5.3 Alternatives to red blood cell transfusion

a) What is the clinical and cost effectiveness of blood transfusions during and after surgery compared with:

- tranexamic acid
- cell salvage therapy.

4.5.4 Avoiding harm in red blood cell transfusions

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 different methods for identifying patients and checking that the right unit of blood will be transfused to minimise blood transfusion errors?

4.5.5 Patient information

a) What information should be given to patients and carers?

b) When and in what format should it be provided?

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 consultation draft of the scope. The consultation dates are 7 February to 7 March 2013.

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):

- 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.