Complete Summary

GUIDELINE TITLE

(1) Perioperative blood transfusion for elective surgery. A national clinical guideline. (2) Perioperative blood transfusion for elective surgery. Update to printed guideline.

BIBLIOGRAPHIC SOURCE(S)

Scottish Intercollegiate Guidelines Network (SIGN). Perioperative blood transfusion for elective surgery. Edinburgh (Scotland): Scottish Intercollegiate Guidelines Network (SIGN); 2001 Oct. 34 p. (SIGN publication; no. 54). [173 references]

Scottish Intercollegiate Guidelines Network (SIGN). Perioperative blood transfusion for elective surgery. Update to printed guideline. Edinburgh (Scotland): Scottish Intercollegiate Guidelines Network (SIGN); 2004 Aug 31. 1 p. [2 references]

GUIDELINE STATUS

This is the current release of the guideline.

Any amendments to the guideline will be noted on the Scottish Intercollegiate Guidelines Network (SIGN) Web site.

**** REGULATORY ALERT ****

FDA WARNING/REGULATORY ALERT

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory and/or warning information has been released.

Drug Withdrawal

- May 14, 2008, Trasylol (aprotinin injection): Following publication of the Blood conservation using antifibrinolytics: A randomized trial in a cardiac surgery population (BART) study in the May 14, 2008 online issue of The New England Journal of Medicine, Bayer Pharmaceuticals notified the U.S. Food and Drug Administration (FDA) of their intent to remove all remaining supplies of Trasylol from hospital pharmacies and warehouses. Because Trasylol has been shown to decrease the need for red blood cell transfusions in patients undergoing coronary artery bypass surgery, future supplies of

Trasylol will continue to be available through the company as an investigational drug under a special treatment protocol.

Additional Notices

- July 31, 2008, Erythropoiesis Stimulating Agents (ESAs): Amgen and the U.S. Food and Drug Administration (FDA) informed healthcare professionals of modifications to certain sections of the Boxed Warnings, Indications and Usage, and Dosage and Administration sections of prescribing information for Erythropoiesis Stimulating Agents (ESAs). The changes clarify the FDA-approved conditions for use of ESAs in patients with cancer and revise directions for dosing to state the hemoglobin level at which treatment with an ESA should be initiated.
- November 8, 2007 and January 3, 2008 Update, Erythropoiesis Stimulating Agents (ESAs): The U.S. Food and Drug Administration (FDA) notified healthcare professionals of revised boxed warnings and other safety-related product labeling changes for erythropoiesis-stimulating agents (ESAs) stating serious adverse events, such as tumor growth and shortened survival in patients with advanced cancer and chronic kidney failure.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Conditions or diseases where elective surgery is an option

GUIDELINE CATEGORY

Management
Prevention
Risk Assessment

CLINICAL SPECIALTY

Hematology
Orthopedic Surgery

Pathology
Surgery

INTENDED USERS

Physicians

GUIDELINE OBJECTIVE(S)

- To provide a rational and practical framework on which to base transfusion decisions and practice
- To maximise patient safety by:
    - Helping clinicians to decide when allogeneic red cell transfusion is appropriate
    - Minimising the avoidable risks of transfusion
    - Helping clinicians to provide appropriate advice on options for treatment, in particular where patients are anxious about the risks of transfusion
- To provide more detailed information for cardiac and orthopaedic surgery teams, as the major users of red cells

Note: This guideline and its recommendations do not address the emergency management of acute blood loss, but could affect the decision to transfuse once the patient has been stabilised. Neither does the guideline address perioperative blood transfusion in paediatric surgery.

TARGET POPULATION

Adult patients undergoing elective surgical procedures

INTERVENTIONS AND PRACTICES CONSIDERED

1. Allogeneic blood transfusions:
    - Assessment of risk/predicting need for allogeneic transfusions
    - Use of equations to order blood (for example Mercuriali's formula)
    - Preoperative management of patients on anticoagulant therapy
    - Preoperative correction of anaemia, when possible
    - Haemoglobin transfusion thresholds (preoperative, intraoperative, postoperative)
    - Transfusion protocols
2. Blood sparing strategies:
    - Preoperative autologous blood donation (PABD)
    - Erythropoietin
    - Combination of preoperative autologous blood donation and erythropoietin
    - Acute normovolemic haemodilution
    - Anti-fibrinolytic drugs (aprotinin*, tranexamic acid) Note: Epsilon-aminocaproic acid was considered but not recommended
    - Cell salvage

***Note**: On May 14, 2008, Bayer Pharmaceuticals notified the U.S. Food and Drug Administration (FDA) of their intent to remove all remaining supplies of Trasylol from hospital pharmacies and warehouses. Because Trasylol has been shown to

decrease the need for red blood cell transfusions in patients undergoing coronary artery bypass surgery, future supplies of Trasylol will continue to be available through the company as an investigational drug under a special treatment protocol. See the U.S. Food and Drug Administration (FDA) Web site for more information.

MAJOR OUTCOMES CONSIDERED

- Rates of transfusions of blood and blood products and the variables that affect those rates
- Risks, complications, morbidity, and mortality associated with transfusion of blood or blood products and/or blood sparing strategies

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Searches were restricted to systematic reviews, meta-analyses, and randomised controlled trials. Material relating to children; blood plasma, leukocyte, or platelet transfusions; emergency surgery; surgical techniques; and national strategies for transfusion services was specifically excluded from the searches. Internet searches were carried out on the Web sites of the Canadian Practice Guidelines Infobase, the New Zealand Guidelines Programme, and United States National Guidelines Clearinghouse. Searches were also carried out on the search engines Northern Light and OMNI, and all suitable links followed up. Database searches were carried out on Cochrane Library, Embase, Healthstar, and Medline from 1985 - May 1999. A number of ancillary searches were carried out on specific subtopics during the guideline development process. The Medline version of the main search strategy and notes on the coverage of ancillary searches can be found on the Scottish Intercollegiate Guidelines Network (SIGN) Web site, in the section covering supplementary guideline material. The main searches were supplemented by material identified by individual members of the development group.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Levels of Evidence

1++: High quality meta-analyses, systematic reviews of randomized clinical trials, or randomized clinical trials with a very low risk of bias

1+: Well-conducted meta-analyses, systematic reviews, or randomized clinical trials with a low risk of bias

1-: Meta-analyses, systematic reviews, or randomized clinical trials with a high risk of bias

2++: High quality systematic reviews of case control or cohort or studies

High quality case control or cohort studies with a very low risk of confounding or bias and a high probability that the relationship is causal

2+: Well-conducted case control or cohort studies with a low risk of confounding or bias and a moderate probability that the relationship is causal

2-: Case control or cohort studies with a high risk of confounding or bias and a significant risk that the relationship is not causal

3: Non-analytic studies, e.g. case reports, case series

4: Expert opinion

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses
Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

The Scottish Intercollegiate Guidelines Network (SIGN) carries out comprehensive systematic reviews of the literature using customized search strategies applied to a number of electronic databases and the Internet. This is often an iterative process whereby the guideline development group will carry out a search for existing guidelines and systematic reviews in the first instance and, after the results of this search have been evaluated, the questions driving the search may be redefined and focused before proceeding to identify lower levels of evidence.

Once papers have been selected as potential sources of evidence, the methodology used in each study is assessed to ensure its validity. Scottish Intercollegiate Guidelines Network has developed checklists to aid guideline developers to critically evaluate the methodology of different types of study design. The result of this assessment will affect the level of evidence allocated to the paper, which in turn will influence the grade of recommendation it supports.

Additional details can be found in the companion document titled "SIGN 50: A Guideline Developers' Handbook." (Edinburgh [UK]: Scottish Intercollegiate

Guidelines Network. [SIGN publication; no. 50]). Available from the SIGN Web site.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The process for synthesizing the evidence base to form graded guideline recommendations is illustrated in the companion document titled "SIGN 50: A Guideline Developer's Handbook." (Edinburgh [UK]: Scottish Intercollegiate Guidelines Network. [SIGN publication; no. 50], available from the SIGN website.

Evidence tables should be compiled, summarizing all the validated studies identified from the systematic literature review relating to each key question. These evidence tables form an important part of the guideline development record and ensure that the basis of the guideline development group's recommendations is transparent.

In order to address how the guideline developer was able to arrive at their recommendations given the evidence they had to base them on, SIGN has introduced the concept of considered judgement.

Under the heading of considered judgement, guideline development groups are expected to summarise their view of the total body of evidence covered by each evidence table. This summary view is expected to cover the following aspects:

- Quantity, quality, and consistency of evidence
- Generalisability of study findings
- Applicability to the target population of the guideline
- Clinical impact (i.e., the extent of the impact on the target patient population, and the resources need to treat them.)

Guideline development groups are provided with a pro forma in which to record the main points from their considered judgement. Once they have considered these issues, the groups are asked to summarise their view of the evidence and assign a level of evidence to it, before going on to derive a graded recommendation.

The assignment of a level of evidence should involve all those on a particular guideline development group or subgroup involved with reviewing the evidence in relation to each specific question. The allocation of the associated grade of recommendation should involve participation of all members of the guideline development group. Where the guideline development group is unable to agree a unanimous recommendation, the difference of opinion should be formally recorded and the reason for dissent noted.

The recommendation grading system is intended to place greater weight on the quality of the evidence supporting each recommendation, and to emphasise that

the body of evidence should be considered as a whole, and not rely on a single study to support each recommendation. It is also intended to allow more weight to be given to recommendations supported by good quality observational studies where randomised controlled trials (RCTs) are not available for practical or ethical reasons. Through the considered judgement process guideline developers are also able to downgrade a recommendation where they think the evidence is not generalisable, not directly applicable to the target population, or for other reasons is perceived as being weaker than a simple evaluation of the methodology would suggest.

On occasion, there is an important practical point that the guideline developer may wish to emphasise but for which there is not, nor is their likely to be, any research evidence. This will typically be where some aspect of treatment is regarded as such sound clinical practice that nobody is likely to question it. These are marked in the guideline as "good practice points." It must be emphasized that these are not an alternative to evidence-based recommendations, and should only be used where there is no alternative means of highlighting the issue.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

The grade of recommendation relates to the strength of the evidence on which the recommendation is based. It does not reflect the clinical importance of the recommendation.

Grade A: At least one meta-analysis, systematic review of randomized controlled trials (RCTs), or randomized controlled trial rated as 1++ and directly applicable to the target population; *or*

A body of evidence consisting principally of studies rated as 1+, directly applicable to the target population, and demonstrating overall consistency of results

Grade B: A body of evidence including studies rated as 2++, directly applicable to the target population, and demonstrating overall consistency of results; *or*

Extrapolated evidence from studies rated as 1++ or 1+

Grade C: A body of evidence including studies rated as 2+, directly applicable to the target population and demonstrating overall consistency of results; *or*

Extrapolated evidence from studies rate as 2++

Grade D: Evidence level 3 or 4; *or*

Extrapolated evidence from studies rated as 2+

Good Practice Points: Recommended best practice based on the clinical experience of the guideline development group.

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

External Peer Review
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

A national open meeting is the main consultative phase of Scottish Intercollegiate Guidelines Network (SIGN) guideline development, at which the guideline development group presents their draft recommendations for the first time. The national open meeting for this guideline was held at the Royal College of Physicians of Edinburgh on 30th May 2000. The draft guideline was also available on the Scottish Intercollegiate Guidelines Network Web site for a limited period at this stage to allow those unable to attend the meeting to contribute to the development of the guideline.

The guideline was reviewed in draft form by a panel of independent expert referees, who were asked to comment primarily on the comprehensiveness and accuracy of interpretation of the evidence base supporting the recommendations in the guideline.

As a final quality control check, the guideline is reviewed by an Editorial Group comprising the relevant specialty representatives on Scottish Intercollegiate Guidelines Network Council to ensure that the peer reviewers' comments have been addressed adequately and that any risk of bias in the guideline development process as a whole has been minimised.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Note from the National Guideline Clearinghouse (NGC): In August 2004 the Scottish Intercollegiate Guidelines Network (SIGN) released an update to this guideline, available on the SIGN Web site. None of the following recommendations were affected by the update.

Note from SIGN and NGC: In addition to these evidence-based recommendations, the guideline development group also identifies points of best clinical practice in the original guideline document.

The strength of recommendation grading (A-D) and level of evidence (I++-4) are defined at the end of the "Major Recommendations" field.

Risks of Allogeneic Blood Transfusion

Immunomodulation

B: Transfusion of leucodepleted allogeneic blood should not be limited by concerns over increased cancer recurrence or perioperative infection.

Procedural Error

D: The British Committee for Standards in Haematology (BCSH) collaborative guideline for the administration of blood and blood components and management of transfused patients (Transfus Med 1999;9:227-38) should be implemented in all Scottish hospitals where transfusion takes place.

All Risks

D: Given the potential risks, however small, each allogeneic transfusion must have a valid, defined and justifiable indication.

Preoperative Anticoagulant Therapy

D: All surgical and anaesthetic units should have protocols: to prepare anticoagulated patients for all types of surgery; for deep vein thrombosis prophylaxis in the preoperative period

Haemoglobin Transfusion Thresholds

Preoperative

C: Where possible, anaemia should be corrected prior to major surgery to reduce exposure to allogeneic transfusion.

Postoperative

D: Transfusion is unjustified at haemoglobin levels >100 g/l.

D: Transfusion is required at haemoglobin levels <70 g/l.

C: Patients with cardiovascular disease, or those expected to have covert cardiovascular disease (e.g., elderly patients or those with peripheral vascular disease) are likely to benefit from transfusion when their haemoglobin level falls below 90 g/l.

Aids to Effective Blood Ordering

Predictors of Allogeneic Transfusion

C: When ordering blood, all nine factors (listed below) determining the risk and degree of transfusion should be taken into account, for example by using Mercuriali's formula.

The factors determining risk of allogeneic transfusion are:

- Low preoperative haemoglobin/hematocrit, either before intervention or on day of surgery
- Low weight
- Small height
- Female sex
- Age over 65 years
- Availability of preoperative autologous blood donation
- Estimated surgical blood loss
- Type of surgery
- Primary or revision surgery

Blood Ordering Equations

C: All hospitals should use a maximum surgical blood ordering schedule to provide concentrated red cells.

Transfusion Protocols

D: Transfusion guidelines should be combined with audit and/or educational initiatives to reduce the number of allogeneic transfusions.

Blood Sparing Strategies

Preoperative Autologous Blood Donation

D: Preoperative autologous blood donation should be offered only when it is possible to guarantee admission and operative dates.

B: Preoperative autologous blood donation can be used to reduce allogeneic blood exposure, although it does increase the total number of transfusion episodes.

C: Preoperative autologous blood donation can be used safely in elderly populations with diverse comorbidities.

C: Preoperative autologous blood donation should be targeted to men who present with haemoglobin 110 to 145 g/l and women who present with haemoglobin 130 to 145 g/l.

Erythropoietin

B: Erythropoietin use should be targeted to patients aged under 70 years who are scheduled for major blood losing surgery and who have a presenting haemoglobin <130 g/l.

D: Erythropoietin can be used to prepare patients with objections to allogeneic transfusion for surgery that involves major blood loss.

Combination of Preoperative Autologous Blood Donation and Erythropoietin

B: In fit patients undergoing major surgery, erythropoietin can be used in combination with autologous blood collection to reduce allogeneic transfusion.

B: In fit patients undergoing major surgery, erythropoietin can be used to obtain multiple autologous red cell donations while maintaining an adequate day of surgery haemoglobin.

Acute Normovolemic Haemodilution

D: Acute normovolemic haemodilution should be limited to patients with a haemoglobin level sufficiently high to allow 1,000 ml of blood to be removed, and in whom a relatively low target haemoglobin is deemed appropriate.

Cardiac Surgery

Aprotinin* and Antifibrinolytic Drugs

B: The use of aprotinin or tranexamic acid is recommended for patients undergoing cardiac surgery which carries a high risk of transfusion (e.g. repeat cardiac operations, multiple valve replacements, thoracic aortic operations, patients on preoperative aspirin therapy and procedures with anticipated long bypass times).

***Note**: On May 14, 2008, Bayer Pharmaceuticals notified the U.S. Food and Drug Administration (FDA) of their intent to remove all remaining supplies of Trasylol from hospital pharmacies and warehouses. Because Trasylol has been shown to decrease the need for red blood cell transfusions in patients undergoing coronary artery bypass surgery, future supplies of Trasylol will continue to be available through the company as an investigational drug under a special treatment protocol. See the U.S. Food and Drug Administration (FDA) Web site for more information.

Cell Salvage

C: Reinfusion of washed shed mediastinal blood may be used to reduce allogeneic transfusion in cardiac surgery.

Orthopaedic Surgery

Aprotinin*

B: Aprotinin may be considered to reduce blood loss in hip and knee arthroplasties but its use should be restricted to procedures with an increased risk of high blood loss (e.g., bilateral and revision) and to circumstances when other blood conservation techniques are not appropriate (e.g., treatment of Jehovah's Witnesses).

***Note**: On May 14, 2008, Bayer Pharmaceuticals notified the U.S. Food and Drug Administration (FDA) of their intent to remove all remaining supplies of Trasylol from hospital pharmacies and warehouses. Because Trasylol has been shown to decrease the need for red blood cell transfusions in patients undergoing coronary

artery bypass surgery, future supplies of Trasylol will continue to be available through the company as an investigational drug under a special treatment protocol. See the U.S. Food and Drug Administration (FDA) Web site for more information.

Tranexamic Acid

B: Tranexamic acid can be used to reduce blood loss and transfusion requirements in patients undergoing knee replacement surgery, when other blood conservation techniques are inappropriate and where major blood loss is anticipated.

Cell Salvage

D: Unwashed postoperative salvage using drains should be considered in patients in whom a postoperative blood loss of between 750 ml and 1,500 ml is anticipated (e.g., bilateral joint replacement).

B: Washed intraoperative salvage should be considered in patients in whom an intraoperative blood loss of more than 1,500 ml is anticipated (e.g., major pelvic, spinal or non-infected revision surgery).

B: In orthopaedic surgery, cell salvage using either unwashed or washed red blood cells may be considered as a means of significantly reducing the risk of exposure to allogeneic blood.

Definitions:

Grades of Recommendation

A: At least one meta-analysis, systematic review, or randomized clinical trials rated as 1++, and directly applicable to the target population; *or*

A body of evidence consisting principally of studies rated as 1+, directly applicable to the target population, and demonstrating overall consistency of results

B: A body of evidence including studies rated as 2++, directly applicable to the target population, and demonstrating overall consistency of results; *or*

Extrapolated evidence from studies rated as 1++ or 1+

C: A body of evidence including studies rated as 2+, directly applicable to the target population and demonstrating overall consistency of results; *or*

Extrapolated evidence from studies rated as 2++

D: Evidence level 3 or 4; *or*

Extrapolated evidence from studies rated as 2+

Good Practice Points: Recommended best practice based on the clinical experience of the guideline development group.

Levels of Evidence:

1++: High quality meta-analyses, systematic reviews of randomized clinical trials, or randomized clinical trials with a very low risk of bias

1+: Well-conducted meta-analyses, systematic reviews, or randomized clinical trials with a low risk of bias

1-: Meta-analyses, systematic reviews, or randomized clinical trials with a high risk of bias

2++: High quality systematic reviews of case control or cohort or studies

High quality case control or cohort studies with a very low risk of confounding or bias and a high probability that the relationship is causal

2+: Well-conducted case control or cohort studies with a low risk of confounding or bias and a moderate probability that the relationship is causal

2-: Case control or cohort studies with a high risk of confounding or bias and a significant risk that the relationship is not causal

3: Non-analytic studies, e.g. case reports, case series

4: Expert opinion

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The specific type of supporting evidence is explicitly identified in each section of the original guideline document.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Guideline utilization will help physicians make appropriate decisions about transfusion practice in order to maximize the safety of patients who are undergoing elective surgery.

Subgroups Most Likely to Benefit:

Although blood sparing strategies should be considered for all patients who may require a transfusion and who have consented to transfusion, there are also specific circumstances where blood sparing strategies should be given a high priority, for example for patients who are Jehovah´s Witnesses, have multiple antibodies, or have serious anxieties about the transfusion of allogeneic blood.

POTENTIAL HARMS

Risks of Blood Transfusion

All risks

Overall, the total risk from blood transfusion in Scotland is low, at approximately one incident per 12,000 transfusions (derived from Serious Hazards of Transfusion reports). Serious complications, such as intravascular haemolysis, transfusion-induced coagulopathy, renal impairment and failure, admission to intensive care, persistent viral infection, and death, occur at a rate of 1 in 67,000 transfusions. Since the Serious Hazards of Transfusion scheme started in 1996, 47 deaths have been reported that were associated with transfusions. Over the same period more than 12 million blood components were issued in the United Kingdom.

Transfusion transmitted infections

Nowadays, the risk of contracting hepatitis B virus, hepatitis C virus, and human immunodeficiency virus (HIV) from blood transfusion is minimal and probably falling (See Table 2 titled "Transfusion Transmitted Infections Reported to SHOT" and Section 2.1 in the original guideline document for a detailed discussion of transfusion transmitted infections.) Other viruses still need to have their transmissibility assessed and their prevalence in the donor population established, although none has yet been relevant to transfusion practice.

Direct immune injury

There were five major transfusion reactions (acute and delayed) in 1999, three of which were fatal. Other syndromes, such as post-transfusion purpura, transfusion-related lung injury and transfusion-associated graft versus host disease, were collectively responsible for eight deaths amongst 20 serious transfusion incidents. These complications could not have been predicted, although early recognition and appropriate therapy might help to reduce the associated morbidity.

Procedural error

It has been suggested that in the United States, human error occurs in approximately 1:24,000 transfusions. Serious Hazards of Transfusion (SHOT) estimates that in the United Kingdom, human error affects around 1:25,000 transfusions.

Risks of Not being Transfused

There are risks of not transfusing blood, such as the risk of perioperative anaemia. The rate of fatal complications due to anaemia in 16 reports of the

surgical management in Jehovah's Witnesses ranges between 0.5% and 1.5%. A more recent retrospective survey of a similar patient population indicates that, if confounding factors are taken into consideration, mortality does not increase as the haemoglobin (Hb) falls to 80 g/l.

Note: The guideline developers caution that the decision to transfuse any patient for a given indication must balance the risks of not transfusing, influenced for example by disease prognosis, against the risks of transfusion, influenced for example by the probable duration of patient survival and the incubation time of known infective agents.

Risks Associated with Blood Sparing Strategies

Erythropoietin

Concerns exist about thrombotic risk and hypertension; however, studies suggest that there is no increase in thrombotic complications or uncontrolled hypertension.

Combination of erythropoietin and preoperative autologous blood donation

Mild side effects include vasovagal episodes.

Aprotinin*

Aprotinin* is associated with a transient deterioration in renal function, indicated by an elevation of serum creatinine above baseline, which returns to normal post-surgery. The overall incidence of renal failure in cardiac surgery is not affected. Up to 6% of patients exposed to aprotinin* for the second time develop significant allergic reactions. This incidence falls as the interval between aprotinin* exposures increases. A possible increase in thrombosis may occur.

***Note**: On May 14, 2008, Bayer Pharmaceuticals notified the U.S. Food and Drug Administration (FDA) of their intent to remove all remaining supplies of Trasylol from hospital pharmacies and warehouses. Because Trasylol has been shown to decrease the need for red blood cell transfusions in patients undergoing coronary artery bypass surgery, future supplies of Trasylol will continue to be available through the company as an investigational drug under a special treatment protocol. See the U.S. Food and Drug Administration (FDA) Web site for more information.

Tranexamic acid

The major risk with tranexamic acid is the potential risk of thrombosis.

Subgroups Most Likely to be Harmed:

Evidence from observational studies suggests that the elderly and those patients suffering from cardiovascular and peripheral vascular disease are less tolerant of perioperative anaemia and should therefore be transfused at a higher haemoglobin level (i.e., a lower threshold for transfusion).

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- The decision to transfuse any patient for a given indication must balance the risks of not transfusing, influenced for example by disease prognosis, against the risks of transfusion, influenced for example by the probable duration of patient survival and the incubation time of known infective agents.
- The Scottish Intercollegiate Guidelines Network (SIGN) guidelines are intended as an *aid* to clinical judgment not to replace it. Guidelines do not provide the answers to every clinical question, nor guarantee a successful outcome in every case. The ultimate decision about a particular clinical procedure or treatment will always depend on each individual patient´s condition, circumstances and wishes, and the clinical judgment of the health care team.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

Implementation of national clinical guidelines is the responsibility of each National Health Service Trust (UK) and is an essential part of clinical governance. It is acknowledged that every Trust cannot implement every guideline immediately on publication, but mechanisms should be in place to ensure that the care provided is reviewed against the guideline recommendations and the reasons for any differences assessed and, where appropriate, addressed. These discussions should involve both clinical staff and management. Local arrangements may then be made to implement the national guideline in individual hospitals, units and practices, and to monitor compliance. This may be done by a variety of means including patient-specific reminders, continuing education and training, and clinical audit.

Implementation of the guideline and compliance with the Scottish Executive MEL (1999) Better Blood Transfusion depends not only on the commitment of clinicians but also the support of Trust and hospital managements to provide organisational resource to enable:

- Preadmission assessments 3 to 6 weeks before operation
- Patients to be given fixed admission dates if pre-donation or preoperative erythropoietin therapy has been agreed
- Availability of erythropoietin for the limited number of patients in whom it is clearly indicated
- Availability of blood salvage equipment where caseload is shown to justify its use
- Availability of suitable anaesthetic support if acute normovolemic haemodilution is being used
- Adequate audit of transfusion practice locally through the hospital Blood Transfusion Committee
- Adequate audit of transfusion practice nationally training of all staff involved in the transfusion process

Key points for audit are identified in the original guideline document.

Key messages for patients and the public are provided in the original guideline document for possible use by clinicians in discussing treatment options with patients who are at risk of requiring transfusion. They may be incorporated into local patient information materials.

The guideline developer refers users to the section of the original guideline document titled Implementation and Audit for additional information.

IMPLEMENTATION TOOLS

Patient Resources
Quick Reference Guides/Physician Guides

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better
Staying Healthy

IOM DOMAIN

Effectiveness
Patient-centeredness
Safety

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Scottish Intercollegiate Guidelines Network (SIGN). Perioperative blood transfusion for elective surgery. Edinburgh (Scotland): Scottish Intercollegiate Guidelines Network (SIGN); 2001 Oct. 34 p. (SIGN publication; no. 54). [173 references]

Scottish Intercollegiate Guidelines Network (SIGN). Perioperative blood transfusion for elective surgery. Update to printed guideline. Edinburgh (Scotland): Scottish Intercollegiate Guidelines Network (SIGN); 2004 Aug 31. 1 p. [2 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2001 Oct (addendum released 2004 Aug 31)

GUIDELINE DEVELOPER(S)

Scottish Intercollegiate Guidelines Network - National Government Agency [Non-U.S.]

SOURCE(S) OF FUNDING

Scottish Executive Health Department

GUIDELINE COMMITTEE

Not stated

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Guideline Development Group: Dr Pat Tansey (*Chairman*); Dr Brian McClelland (*Methodologist*); Mrs Pauline Cumming; Mrs Sandra Gray; Dr Rachel Green; Mr William Hadden; Mr Robin Harbour; Dr Cameron Howie; Mr Robert Jeffrey; Dr Martin Lees; Dr Allan Merry; Mr Robert Murdoch; Dr Dianne Plews; Dr Safia Qureshi; Dr Steve Rogers; Dr Colin Sinclair; Mr John Taylor; Mr George Welch

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

All members of the Scottish Intercollegiate Guidelines Network (SIGN) guideline development groups are required to complete a declaration of interests, both personal and non-personal. A personal interest involves payment to the individual concerned, e.g., consultancies or other fee-paid work commissioned by or shareholdings in the pharmaceutical industry; a non-personal interest involves payment which benefits any group, unit or department for which the individual is responsible, e.g., endowed fellowships or other pharmaceutical industry support. SIGN guideline group members should be able to act as independently of external commercial influences as possible, therefore, individuals who declare considerable personal interests may be asked to withdraw from the group. Details of the declarations of interest of any guideline development group member(s) are available from the SIGN executive.

GUIDELINE STATUS

This is the current release of the guideline.

Any amendments to the guideline will be noted on the Scottish Intercollegiate Guidelines Network (SIGN) Web site.

GUIDELINE AVAILABILITY

Electronic copies: Available from the Scottish Intercollegiate Guidelines Network (SIGN) Web site:

- HTML format
- Portable Document Format (PDF)

Electronic copies of Addendum: Available from the SIGN Web site.

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- Quick reference guide: Perioperative blood transfusion for elective surgery. Edinburgh (Scotland): Scottish Intercollegiate Guidelines Network, 2001. 2 p. Available in Portable Document Format (PDF) from the Scottish Intercollegiate Guidelines Network (SIGN) Web site.
- Guideline 54: perioperative blood transfusion for elective surgery. Supporting material [online]. Edinburgh (Scotland): Scottish Intercollegiate Guidelines Network, 2001. Available from the SIGN Web site.
- SIGN 50: A guideline developer's handbook. Edinburgh (Scotland): Scottish Intercollegiate Guidelines Network, 2001 Feb. (SIGN publication; no. 50). Electronic copies available from the SIGN Web site.
- Appraising the quality of clinical guidelines. The SIGN guide to the AGREE (Appraisal of Guidelines Research and Evaluation) guideline appraisal instrument. Edinburgh (Scotland): Scottish Intercollegiate Guidelines Network, 2001. Available from SIGN Web site.

PATIENT RESOURCES

The following is available:

- Key messages for patients. In: Perioperative blood transfusion for elective surgery. Edinburgh (Scotland): Scottish Intercollegiate Guidelines Network, 2001 Oct. pp. 25. (SIGN publication; no. 54).

Electronic copies: Available from the Scottish Intercollegiate Guidelines Network (SIGN) Web site:

- HTML format
- Portable Document Format (PDF)

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC STATUS

This NGC summary was completed by ECRI on April 17, 2002. The information was verified by the guideline developer on July 11, 2002. This NGC summary was updated by ECRI on September 28, 2004. The information was verified by the guideline developer on January 26, 2005. This summary was updated by ECRI on February 14, 2006 following the U.S. Food and Drug Administration (FDA) advisory on Trasylol (aprotinin). This summary was updated by ECRI on October 4, 2006 following the updated FDA advisory on Trasylol (aprotinin). This summary was updated by ECRI on January 5, 2007 following the updated FDA advisory on Trasylol (aprotinin). This summary was updated by ECRI on January 29, 2007, following the U.S. Food and Drug Administration advisory on erythropoiesis stimulating agents. This summary was updated by ECRI Institute on July 9, 2007, following the FDA advisory on erythropoiesis stimulating agents. This summary was updated by ECRI Institute on November 12, 2007, following the U.S. market withdrawal of Trasylol (aprotinin). This summary was updated by ECRI Institute on March 21, 2008 following the FDA advisory on Erythropoiesis Stimulating Agents. This summary was updated by ECRI Institute on August 15, 2008 following the U.S. Food and Drug Administration advisory on Erythropoiesis Stimulating Agents (ESAs).

COPYRIGHT STATEMENT

DISCLAIMER

NGC DISCLAIMER

developers or authors of guidelines represented on this site do not necessarily state or reflect those of NGC, AHRQ, or its contractor ECRI Institute, and inclusion or hosting of guidelines in NGC may not be used for advertising or commercial endorsement purposes.

Readers with questions regarding guideline content are directed to contact the guideline developer.

Date Modified: 11/3/2008