Complete Summary

GUIDELINE TITLE

Guidelines for policies on alternatives to allogeneic blood transfusion. 1. Predeposit autologous blood donation and transfusion.

BIBLIOGRAPHIC SOURCE(S)

British Committee for Standards in Haematology, Transfusion Task Force, Boulton FE, James V. Guidelines for policies on alternatives to allogeneic blood transfusion. 1. Predeposit autologous blood donation and transfusion. Transfus Med 2007 Oct;17(5):354-65. [54 references] PubMed

GUIDELINE STATUS

This is the current release of the guideline.

** 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.

- 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)

Any condition (including orthopedic or cardiac conditions and scoliosis) for which elective surgery is undertaken with the potential need for blood or blood component transfusion

GUIDELINE CATEGORY

Assessment of Therapeutic Effectiveness

CLINICAL SPECIALTY

Cardiology
Hematology
Orthopedic Surgery
Pediatrics
Surgery
Thoracic Surgery

INTENDED USERS

Clinical Laboratory Personnel
Hospitals
Patients
Physicians

GUIDELINE OBJECTIVE(S)

- To comment on and update the policies for predeposit autologous blood donation and subsequent transfusion of the stored component described in the previous British Committee for Standards in Haematology (BCSH) Guideline (1993)
- To give an update on the legal regulatory circumstances pertaining to the United Kingdom following recent European Directives

TARGET POPULATION

Adults and children in the United Kingdom in need of blood or blood product transfusion under the following circumstances:

- Patients with rare blood groups where allogeneic difficult to obtain
- Children with scoliosis
- Patients at serious psychiatric risk if blood transfusion is thought to be likely to cover their elective surgery
- Patients who refuse to consent to allogeneic transfusion but who would consent to predeposit autologous donation

INTERVENTIONS AND PRACTICES CONSIDERED

1. Predeposit autologous blood transfusion* versus allogeneic blood or blood product transfusion
2. Patient selection
3. Supportive care (iron supplementation, erythropoietin)
4. Apheresis for autologous red cells

*Note: Predeposit autologous blood transfusion is not recommended except in exceptional circumstances (see "Target Population" and "Major Recommendations" fields).

MAJOR OUTCOMES CONSIDERED

- Incidence of anaemia
- Incidence of need for additional allogeneic transfusion

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Searches were carried out on Medline and PubMed using the following terms: autologous, blood transfusion, pre-operative, pre-deposit, EPO, iron, cardiac surgery, elderly, children, orthopaedics, directive and regulations. The recent European and United Kingdom legislations were also scrutinized.

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

Statements of Evidence

Ia Evidence obtained from meta-analysis of randomized controlled trials.

Ib Evidence obtained from at least one randomized controlled trial.

IIa Evidence obtained from at least one well-designed controlled study without randomization.

IIb Evidence obtained from at least one other type of well-designed quasi-experimental study.

III Evidence obtained from well-designed non-experimental descriptive studies, such as comparative studies, correlation studies and case studies.

IV Evidence obtained from expert committee reports or opinions and/or clinical experiences of respected authorities.

METHODS USED TO ANALYZE THE EVIDENCE

Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Grades of Recommendations

Grade A Requires at least one randomized controlled trial as part of a body of literature of overall good quality and consistency addressing the specific recommendation (evidence levels Ia and Ib).

Grade B Requires the availability of well-conducted clinical studies, but no randomized clinical trials on the topic of recommendation (evidence levels IIa, IIb and III).

Grade C Requires evidence obtained from expert committee reports or opinions and/or clinical experiences of respected authorities. Indicates an absence of directly applicable clinical studies of good quality (evidence level IV).

COST ANALYSIS

Costs

In a study of autologous versus allogeneic transfusion in hip replacements, 34 (41%) of the 82 autologous units were wasted. At a charge of $379 per autologous unit, there was an additional cost of $758 for each patient in the donor group.

Cost Effectiveness

Many reports cast uncertainty as pre-operative autologous blood donation (PAD) can be associated with wastage rates of up to 55% of autologous blood units collected. In an as yet unpublished Health Technology Assessment, the authors describe six studies comparing economic evaluations of PAD with allogeneic blood use. Three indicated that PAD was not cost-effective. One showed that PAD in patients having a coronary artery bypass graft produced limited health benefits at high societal costs, although some of the Guidelines for policies on alternatives to allogeneic blood transfusion cost-inefficiency was "strongly dependent" on estimates of post-transfusion hepatitis incidence but less so on human immunodeficiency virus (HIV). They also observed that as blood gets safer, the relative costs of PAD increase and that even a small estimate of fatality risk associated with PAD in a cardiac patient negates all life expectancy benefits of PAD. One study also reported that the increased safety of PAD use was limited and may not justify the cost, and another study reported that PAD alone was not more cost-effective than a do-nothing strategy. In contrast, the other three of the six studies claimed that PAD was cost-effective. One reported net cost-savings compared with use of allogeneic blood over a wide range of complication rates, patients' ages and transfusion requirements; another group based their estimates on hospital charges in which the cost of autologous blood was approximately $50 per unit, whereas hospital cost increased by $1,000 to $1,500 per allogeneic unit used, and found unsurprisingly that patients needing allogeneic blood on top of autologous had significantly higher hospital costs, to which increased length of stay added. They also believed that increases in postoperative infection (to which they assumed such patients were more susceptible as a result of receiving allogeneic blood) also contributed to their findings. The last of the three studies "in favour," in a cost utility analysis, demonstrated that even if there were a modest increase in the risk of bacterial infection following allogeneic transfusion, PAD would result in improved outcomes at a cost-effectiveness that compares favourably with well-accepted health interventions. It has to be borne in mind that these analyses were undertaken in several countries in circumstances that may not prevail in the UK either at present or in the future.

The costs of erythropoietin therapy, even when perhaps ameliorated by concomitant iron therapy, add significantly to the costs of PAD. From these reports further doubt on PAD is cast by the significant wastage.

METHOD OF GUIDELINE VALIDATION

External Peer Review
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

These Guidelines were approved by

- Clinicians who may wish to undertake this form of therapy
- Senior representatives of blood establishments in the United Kingdom
- Hospital blood banks considering applying for valid appropriate authorization

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Recommendation grades (**A-C**) and levels of evidence (**Ia-IV**) are defined at the end of the "Major Recommendations" field.

Particular note needs to be taken of the specific developments in the UK, including:

- A developing consensus for conforming to the recommendations described in the UK Chief Medical Officers' recommendations described in 'Better Blood Transfusion 2'
- The increasing compliance with this as indicated by
    - Audit
    - The current decline in issues of allogeneic red cells to hospitals in England (from 2,243,000 in 1999/2000 to an estimated 1,900,000 for 2005/2006)
    - The fact that all blood donors are non-remunerated volunteers
    - The current estimates of risks of infection transmitted by transfusion of allogeneic blood components from UK donors indicated in the Position Statement of the UK Joint Professional Advisory Committee (see www.transfusionguidelines.org.uk), which are
        - 1 in 500,000 for hepatitis B virus (HBV)
        - 1 in 5 million for human immunodeficiency virus (HIV)
        - 1 in 30 million for hepatitis C virus (HCV)
- Continuing developments in surgical techniques resulting in reduced blood requirements
- Increased use of intraoperative autologous transfusion (for which further BCSH guidelines are being developed)
- Growing patient demand for alternatives to allogeneic blood transfusion

Specific Recommendations

Whole Blood

The use of pre-operative autologous blood donation (PAD) is not recommended unless the clinical circumstances are exceptional.

Exceptional circumstances may include

- Rare blood groups where allogeneic difficult to obtain
- Children with scoliosis (**Ib, A**)
- Patients at serious psychiatric risk if blood transfusion is thought to be likely to cover their elective surgery (**IV, C**)
- Patients who refuse to consent to allogeneic transfusion but who would consent to PAD

When PAD of whole blood is undertaken, the following criteria are required but do not of themselves justify it if they can be fulfilled.

- Patients considered for the procedure must be candidates for elective surgery, where blood transfusion is expected to be needed (**Ib, A**).
- The admission and operation days must be guaranteed (**IIb, B**).
- Sufficient time to enable optimal collection of the blood must be allowed prior to surgery but should not exceed the licensed time for storing the collected blood component. For red cells, this is in practice at least 5 weeks (**IIa, B**).
- Sufficient time should be given from the date and time of the ultimate PAD collection prior to surgery for the patient to make a full circulatory and volaemic recovery. The 15th edition of the Standards of the American Association of Blood Banks (1993) recommends a minimal interval of 72 hours (**IIb, B**).

Potential candidates

- Should be judged by a competent clinician to be able to tolerate the repeated loss of the predetermined volume of blood at each collection; this should normally be no more than 10% of their estimated blood volume (**IV, C**)
- Should be provided with adequate information concerning the eligibility criteria for PAD and the reasons behind such criteria by the physicians providing the PAD service
- Should be considered for supplementation with erythropoietin (**Ib, A**)
- Should present with the following haemoglobin (Hb) before embarking on PAD (**III, B**)
    - Men, 110 to 145 grams per liter (g/L^{-1})
    - Women, 130 to 145 g/L^{-1}
- For each individual case, there should be a clear reason for preferring PAD to allogeneic blood as PAD is not indicated for most patients fulfilling the above criteria. Indeed, the clinical indications for collecting and using PAD are limited: for the majority of patients undergoing elective surgery of a nature likely to require transfusion to treat surgical and postoperative blood loss, allogeneic blood is the preferred option.
- PAD is not recommended for children younger than 10 years, mainly because of technical difficulties (large bore needle in veins of limited size) and it can be difficult to gain sufficient co-operation (**Ib, A**).
- Wherever appropriate, supplemental means of reducing use of allogeneic blood should be used, such as cell salvage.

Candidates who meet the criteria for PAD but who are positive for relevant markers of transfusion-transmissible infection present safety issues for staff collecting and processing the donations and also potential for administrative and other errors. For these reasons, the Task Force does not recommend that PAD be offered to such patients unless they also fall into one of the exceptional categories.

Given the costs of erythropoietin, its economic value to supplement PAD must be regarded as doubtful. The Task Force therefore does not recommend that erythropoietin be used unless the clinical circumstances are exceptional.

Although iron therapy prior to PAD has little effect on subsequent transfusion needs in individuals who are iron replete, there are advocates of iron therapy during PAD on a priori grounds though there is no good clinical evidence on which to base such recommendations. Therefore, the Task Force does not recommend

prophylactic iron to iron-replete individuals undergoing PAD (**Ib, A**) and further recommends that PAD be denied to persons who are iron deficient and receiving iron therapy until they have been effectively treated and their iron deficiency reversed.

PAD of Red Cell Components Collected by Apheresis

As the collection of allogeneic red cell component donations by apheresis becomes more widespread, autologous red cell component collection by apheresis may also be suggested. Allogeneic donors selected for red cell component collection (i.e., by apheresis) may also be selected for greater volume and frequency of donation and therefore be heavier, have a higher blood Hb concentration than Hb concentration for standard allogeneic donation (e.g., 140 gL^{-1}) and have adequate iron status. However, there are no studies of such systems applying to PAD. The Task Force does not recommend that PAD be conducted by apheresis until and unless costs become comparable with those for standard donation collection and processing, and even then, only under the exceptional circumstances pertaining to PAD by standard collection already considered.

Definitions:

Statements of Evidence

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Grade C Requires evidence obtained from expert committee reports or opinions and/or clinical experiences of respected authorities. Indicates an absence of directly applicable clinical studies of good quality (evidence level IV).

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for selected recommendations (see "Major Recommendations").

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- Compatibility of blood or blood components
- Patient peace of mind

POTENTIAL HARMS

- Collection may need to be deferred because of comorbid conditions.
- The autologous blood and blood components might not suffice for the intended transfusion requirements.
- There is a 50% wastage rate.
- Approximately 50% of patients are anaemic on the day of surgery and are more likely to need infusion.
- Adverse reactions to transfusion.
- The current estimates of risks of infection transmitted by transfusion of allogeneic blood components from UK donors are: 1 in 500 000 for hepatitis B virus, 1 in 5 million for human immunodeficiency virus, and 1 in 30 million for hepatitis C virus.
- Candidates who meet the criteria for PAD but who are positive for relevant markers of transfusion-transmissible infection present safety issues for staff collecting and processing the donations and also potential for administrative and other errors.

CONTRAINDICATIONS

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Contraindications to predeposit autologous donation include patients predisposed to bacteraemia, for example those with

- An indwelling urinary catheter
- A device penetrating the skin

QUALIFYING STATEMENTS

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Although the advice and information in these guidelines are believed to be true and accurate at the time of going to press, neither the authors, the British Society for Haematology, nor the publishers accept any legal responsibility for the content of these guidelines.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better
Living with Illness
Staying Healthy

IOM DOMAIN

Effectiveness
Patient-centeredness
Safety

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

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ADAPTATION

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

DATE RELEASED

2007 Oct

GUIDELINE DEVELOPER(S)

British Committee for Standards in Haematology - Professional Association

SOURCE(S) OF FUNDING

British Committee for Standards in Haematology

GUIDELINE COMMITTEE

British Committee for Standards in Haematology, Transfusion Task Force

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Task Force Members: F. E. Boulton, National Blood Service, Southampton; V. James, National Blood service, Sheffield, UK

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available from the British Committee for Standards in Haematology Web site.

Print copies: Available from the British Committee for Standards in Haematology; Email: bcsh@b-s-h.org.uk.

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI Institute on May 23, 2008. The information was verified by the guideline developer on June 30, 2008. 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).

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