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Guidelines for autologous transfusion. I. Pre-operative autologous donation

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These guidelines were last published in 1988 (British Committee for Standards in Haematology, 1988). Since then, experience with autologous transfusion has grown and this has encouraged a revision of the guidelines. The term 'autologous transfusion' has tended, in the past, to be linked particularly with autologous pre-deposit but is now generally used in a wider context to include pre-deposit, acute normovolaemic haemodilution (ANH) and red cell salvage. Because these procedures complement each other, the revised guidelines for autologous transfusion will deal with all procedures. The guidelines will be in two parts, the first dealing with pre-deposit and the second with ANH and red cell salvage.

While these guidelines seek to deal with situations likely to be met in current clinical practice, it is recognized that exceptional circumstances may arise and that the final decision regarding the use of autologous pre-deposit rests with the doctor who undertakes the procedure.

GENERAL CONSIDERATIONS

1 Pre-operative autologous donation can provide an alternative to blood from volunteer donors for transfusion to some patients during elective surgical procedures; it avoids the possibilities of alloimmunization and immunosuppression and of acquiring transfusion-transmitted infection.

2 These guidelines relate to blood which is stored at 4°C in CPD Al for up to 35 days or in an optimal additive solution for up to 42 days. A pre-deposit of blood to be stored frozen for longer periods is not considered in detail.

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3 Autologous pre-deposit is only appropriate for a minority of patients requiring transfusion. Apart from eligibility on medical grounds, other factors, such as reliable dates for elective surgery and adequate venous access, are essential considerations.

4 Directed blood donation, that is donations from relatives or motivated friends of the patient, is not considered and should be actively discouraged because there is no evidence that directed donations are safer than blood provided by the Transfusion Services.

A relative who is in a risk group and under pressure to donate may find it difficult or impossible to avoid doing so. An exception may be made for the use of maternal blood for a neonate under special circumstances; indeed, maternal platelets may be the only suitable platelets for the management of neonatal alloimmune thrombocytopenia. However, the increased risk of graft-versus-host disease should be seriously considered in view of the shared HLA haplotypes. Maternal blood or blood components should therefore be irradiated if given to her new-born child.

5 The risks of viral transmission by allogeneic transfusion in the U.K. are very small. Whilst the avoidance of these risks undoubtedly adds to the patient's safety, it should be remembered that other hazards of blood transfusion remain, particularly those associated with documentation. These may be more likely to occur during an unfamiliar pre-deposit procedure. It is also the case that one or more venesections over a period of weeks may result in morbidity which needs to be balanced against the potential risks of receiving blood from volunteer donors, given the local prevalence of transfusion-transmitted viruses in the donor population.

6 Careful selection of appropriate patients is an important part of a safe and successful autologous pre-deposit programme. No less important is a clear understanding by all those involved of their responsi-

bilities at the various stages of the procedure, from the first consideration of eligibility through to the final checks before transfusion. A Standard Operating Procedure, incorporating details of local arrangements and specifying these responsibilities, is essential.

7 Pre-deposited blood should be transfused using similar clinical indications to those for allogeneic transfusion; it should not be transfused simply because it is available.

8 Autologous pre-deposit may reduce or avoid the need for transfusion of allogeneic blood. Attention is drawn to other factors which assist with this aim, particularly the use of haematinics rather than transfusion to raise the haemoglobin, where appropriate, and use of aprotinin to reduce blood loss during cardiac surgery. Other forms of autologous transfusion should also be considered.

SELECTION OF PATIENTS

1 Pre-operative autologous donation should only be considered for those elective surgical procedures with a reasonable expectation that blood will be transfused. Hospitals should have a Maximum Surgical Blood Ordering Schedule (MSBOS) before they embark on a programme of pre-deposit (British Committee for Standards in Haematology, 1990). Autologous pre-deposit should only be available for those patients who would normally have blood available for the procedure to be undertaken. Patients who would normally have a 'group and screen' should not be considered.

2 The selection of patients and consideration of their fitness for the procedure, and of the other criteria in this section, should be undertaken by the doctor with clinical responsibility for the patient. They should discuss with the patient the relative merits of autologous and allogeneic transfusion, together with the possibility that even if an autologous transfusion programme is undertaken it may be necessary to transfuse allogeneic blood. The referral of suitable patients who wish to pre-deposit should be made in a standard format signed by the clinician who has discussed pre-deposit with the patient (Appendix 1).

3 The final responsibility for ensuring that the patient's health is satisfactory to allow donation of the required number of units rests with the doctor who undertakes the pre-deposit procedure. This doctor should also obtain written consent to the procedure (Appendix 2).

4 Patients with virological markers which indicate infectivity for HBV, HIV or HCV, should not be considered for autologous pre-deposit.

5 Active bacterial infection is a clear contraindication to pre-deposit because of the possibility of bacteraemia and subsequent bacterial proliferation during the storage of blood.

6 The patient's haemoglobin should normally be greater than 11 g/dl in both men and women and never less than 10 g/dl. In pregnancy the haemoglobin should exceed 10 g/dl. The place of epoetin erythropoietin to encourage haemopoiesis in patients donating several units remains unclear and its general use is not recommended. It may be justified in patients with rheumatoid arthritis awaiting orthopaedic surgery or for patients with multiple or difficult alloantibodies where surgery is urgent. Note that, currently, recombinant erythropoietin is not licenced for this application.

7 It is now recognized that most elderly patients can pre-deposit safely provided that a careful assessment of their general health is made with particular reference to cardiovascular and cerebrovascular fitness.

8 Pre-deposit in children under 25 kg is technically difficult and rarely justified. Children between the ages of 8 and 16 years, with no unstable cardiovascular or pulmonary problems, can be considered for pre-deposit. The major indications are orthopaedic surgery (e.g. spinal fusion) and extensive plastic surgery. Pre-deposit is also indicated for paediatric bone marrow donors, a situation in which it has been used successfully for some years. An important requirement is that the child is able to comprehend and willing to co-operate with the procedure. Parental consent is mandatory. The donations should be collected in a hospital in close collaboration with a paediatrician.

9 Adult patients under 8 stone (50 kg) need special consideration and care should be taken that the volume drawn does not exceed 12% of the estimated blood volume. (See section on Practical Aspects of Collection, **5**.)

10 There are few indications for pre-deposit in pregnancy. Although the procedure appears to be without significant hazard for the mother, there is still insufficient information about possible harmful effects to the fetus. Where there is a specific indication for pre-deposit, e.g. multiple or difficult alloantibodies, it is preferable, where possible, to collect blood from the patient early in pregnancy and store it frozen. Autologous pre-deposit is contraindicated in pregnancies complicated by any condition associated with impaired placental blood flow and/or intrauterine growth retardation, including hypertension, pre-eclampsia, diabetes mellitus or any severe pre-existing medical condition. (See also Appendix 4.)

11 Subject to assessment by the referring cardiologist, some patients with cardiac disease can pre-deposit safely. Pre-deposit should not be offered to patients with significant aortic stenosis, prolonged and/or frequent angina, significant narrowing of the left main

coronary artery and cyanotic heart disease. The value of isovolaemic replacement with crystalloid has not been subjected to proper clinical trials but it seems reasonable to believe that maintenance of the blood volume will minimize the hazardous sequelae which may follow a reduction in blood volume. Volume replacement should be considered for patients on treatment with β-blockers and/or angiotensin converting enzyme (ACE) inhibitors because their ability to respond to a reduction in blood volume may be compromised by their treatment. The blood pressure should be monitored following donation to confirm a return to the baseline figure. Patients with uncontrolled hypertension should not be bled.

12 Patients with a history of epilepsy should not be considered as withdrawal of blood may precipitate a fit. Patients who have been blood donors and sustained a delayed faint, i.e. weakness or loss of consciousness several hours after donation should not be considered.

PRACTICAL ASPECTS OF COLLECTION, STORAGE AND TRANSFUSION

1 The collection and storage of pre-deposited blood should be under medical supervision. The doctor must obtain the patient's written informed consent to the procedure (Appendix 2) advising the patient about possible complications, particularly the possibility of needing allogeneic blood in addition to any blood prepared for autologous transfusion. The Medical Officer should be immediately available during donation.

2 Blood collection procedures may differ in detail between Regional Transfusion Centres and Hospitals. Important points of procedure can be found in Appendix 4. Consultation with the Regional Transfusion Centre may also be appropriate.

3 Blood should not be drawn more often that once a week with the last donation at least 4 days (preferably a week), before surgery; this will normally allow up to four or five units to be collected. Exceptionally, e.g. where surgery is postponed, it may be possible to use a 'leap-frog' technique, returning the oldest unit(s) to the patient to allow another (others) to be withdrawn.

4 The haemoglobin should be determined before each donation and blood should normally only be drawn where the haemoglobin is greater than 11 g/dl. Blood should never be taken from patients whose haemoglobin is 10 g/dl or lower.

5 For paediatric patients and for adults < 50 kg, blood should be drawn into packs for paediatric use which contain 35 ml of anticoagulant and are suitable for the collection of up to 250 ml of blood. For children < 30 kg, the volume collected should not exceed 12% of the estimated blood volume. Pedipacks with needles of appropriate gauge for phlebotomy in children should be used when available. Pre-operative ANH should be considered for paediatric patients, especially when phlebotomy would be difficult or pre-operative donation is contraindicated.

6 Oral iron should be prescribed for all patients who pre-deposit before the first donation and continued until surgery.

7 The label for the blood pack should include the formation listed in Appendix 3. The patient (or in the case of a child, the parent) should sign the label to validate this information and should do so immediately before donation, i.e. when the patient is on the couch. The label should be affixed during donation. The label should have a suitable adhesive for refrigerated storage.

8 Labelled blood bags or sample tubes should not be placed on a shared table or trolley between two adjacent donors. Any risk of transposition must be avoided.

9 Blood collected into CPD Al may be stored for up to 35 days. Red cells suspended in optimal additive solutions have an extended shelf-life of 42 days. Where several units are being pre-deposited, it may be advantageous to collect the first two into packs which will allow separation of the red cells and their resuspension in optimal additive solution.

10 Blood which has been pre-deposited for autologous transfusion should be stored securely segregated in a blood bank refrigerator at a controlled temperature of 4 ± 2 °C, which should be equipped with a recorder and an alarm.

11 The following tests should be carried out on the patient's blood.

(a) ABO and Rh D grouping: the results to be displayed on the pack label.

(b) At the first donation, serological screening for atypical red cell antibodies, in case allogeneic blood is required.

(c) On the first and last donation (as a minimum), tests for HBsAg, anti-HIV1 and 2, and anti-HCV, which conform to current Guidelines for the Blood Transfusion Services in the U.K.' (Department of Health, 1993). These are essential both to establish the patient's status for these markers and because current practices are such that donations which are positive for any of these tests would not be issued for use and the same criteria should apply for autologous transfusion. A test for syphilis should also be carried out. Advice for the patient about the significance

of a positive result in any of these tests should be available and must be in the case of HIV.

12 Where an autologous donor's blood is found to be reactive in screening test(s) for a virological marker(s) (see **11**) which, on confirmatory testing, does not indicate infectivity, i.e. 'false-positive' results, there is no contraindication to pre-deposit. However, practical problems arise. The planned pre-deposit programme is likely to be delayed while confirmatory tests are performed and reported; in many Regional Transfusion Centres, release procedures will not allow such donations to be issued.

13 Where the results of reference tests show that an autologous donor's blood has a virological marker indicating infectivity for HBV, HIV or HCV, any donation(s) which have been collected should be discarded with appropriate precautions and the autologous programme for the patient should be abandoned.

14 In those cases where the virological screening tests are repeatably reactive and the results of confirmatory tests are awaited from the Reference Laboratory, any donation(s) must be quarantined securely until the results of these tests indicate whether the donation is infectious.

PRE-TRANSFUSION TESTS

1 A blood sample should be obtained from the patient for compatibility testing when they are admitted for surgery.

2 Pre-transfusion testing should be carried out in accordance with the BCSH Guidelines for Compatibility Testing (British Committee for Standards in Haematology, 1987).

3 Each donation should carry the same type of compatibility label as that used routinely in the hospital to facilitate checking in theatre and at the bedside. The design of the autologous transfusion label should allow the compatibility label to be overstruck leaving the information about the blood group and expiry date readily visible.

DISPOSAL OF UNUSED BLOOD

Blood collected for autologous transfusion, which is not required for the donating patient, should not be transfused to another patient. It may be used for laboratory purposes, provided that tests for HBsAg, anti-HIV and anti-HCV have been performed and found negative. Otherwise unused blood must be discarded. Plasma from unused blood should not be included in pools for fractionation. The fate of autologous blood should be fully documented to ensure that each unit can be accounted for (Department of Health and Social Security, 1984).

RECORDS

Records of all pre-deposit procedures should be retained in a similar way to those for allogeneic blood.

QUALITY CONTROL AND AUDIT

Where autologous transfusion programmes are carried out in the form of pre-operative collection, storage and re-transfusion of donated blood, the procedures should be subjected to periodic medical and quality audits.

PRODUCT LIABILITY

Although such a situation has not yet been tested in the Courts, it appears inevitable that where an autologous donation becomes defective at any stage between collection and transfusion, there would be product liability under the Consumer Protection Act in the same way as with an allogeneic donation.

ACKNOWLEDGEMENTS

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DISCLAIMER

The advice contained in these guidelines is believed to represent the state-of-the-art at the time of going to press. It is policy to revise the guidelines as new developments occur. However, it may not be possible to do this at the time of such changes and the guidelines should always be used with due regard to current acceptable practice.

Comments are invited to assist the review process. All correspondence regarding the guidelines should be addressed to:

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APPENDIX 1

Referral letter for autologus pre-deposit (addressed to the doctor in charge of the pre-deposit programme)

Dear

This patient has requested autologous pre-deposit for his/her operation. I have discussed this with the patient, with appropriate reference to the *Guidelines for Pre-operative Autologous Donation* and am of the opinion that he/she is medically suitable for the procedure.

I would be grateful if you could see him/her with a view to making the necessary arrangements.

Patient's name (Mr/Mrs/Ms):.....
Patient's address:.....

Patient's date of birth:.....
Ward: .....
Hospital:.....
Hospital number:.....
Date of admission: .....
Date of operation:.....
Planned procedure:.....
Underlying pathology:.....
Requested number of donations (maximum is 5):.....
Haemoglobin (g/dl): .....
Additional comments: .....
.....
Signature of referring consultant clinician:.....
Name of referring consultant clinician (BLOCK LETTERS): .....
Date:.....

APPENDIX 2

Consent to autologous transfusion

This consent form is intended for adults and will need to be adapted in the case of children

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The purpose of autologous transfusion has been explained to me by Dr ..... who has also explained its possible complications and hazards.

I agree to my blood being withdrawn and stored for autologous transfusion.

I understand that it may not be possible for technical reasons to return to me all or any of the units which I donate.

I understand that it may be necessary to supplement my autologous transfusion with blood from volunteer donors from the Transfusion Services.

I agree to to my blood being tested for HBsAg (one of the viruses causing hepatitis), for anti-HCV (another virus causing hepatitis), for anti-HIV and for syphilis. In the event of a positive result in any of these tests, I agree to the clinician in charge of my case being informed.

Signed.....

Dated.....

Witnessed .....

APPENDIX 3

Blood pack label

Blood for autologous transfusion should be identified with an overstick label* which includes the following information:

Blood for autologous transfusion only
Surname.....
First names.....
Date of birth.....
Hospital number.....
Date of collection.....
Date of expiry.....
ABO and Rh(D) groups.....
Lab. ref. number.....
Patient's signature.....
(Parent or Guardian in the case of a child)

The patient signs the pack to confirm that the details on the label (apart from the ABO and (D) group which may not be entered when the first unit is drawn) are correct. The signature can also be compared as part of a pretransfusion checking procedure with the signature on the consent form which by then will be in the patient's notes.

*This label should not occlude the information given on the manufacturer's standard pack label

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APPENDIX 4

Blood collection

The advice in this Appendix may assist those other than Regional Transfusion Centres collecting autologous donations

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The followings points are of importance in collecting a blood donation.

1 Check the patient's blood pressure.
2 Blood may be collected into a single pack with CPD-Al anticoagulant giving a shelf life of 35 days. Where it is planned to take several units, the first two may be collected into a multiple pack system, allowing subsequent processing and resuspension of the red cells in Optimal Additive Solution, giving a shelf-life of 42 days.
3 Use a balance to measure the volume of blood drawn.
4 The skin should be cleaned thoroughly using chlorhexidine (in alcohol) or equivalent.
5 The use of a local anaesthetic is recommended.
6 The donor tubing should be clamped, for example with 'non-toothed' Spencer Wells forceps, before the guard is removed from the needle. This will prevent air entering the bag and possibly contaminating the donation. The clamp should remain in place until after the venepuncture.
7 A donation from an adult should normally be approximately 450 ml, but a smaller volume may be appropriate from small adults or children. Packs for the collection of 250 ml are available.
8 The pack should be agitated gently throughout collection to mix the blood with the anticoagulant.
9 Samples for laboratory tests can be taken at the end of the donation before the needle is withdrawn by clamping the donor tube in two places and cutting the tube between the clamps.
10 Attention to haemostasis after withdrawal of the needle will be particularly important if several donations need to be collected from the vein.
11 It is important to use a technique which will evacuate the blood from the donor tube and allow it to be replaced with anticoagulated blood from the pack.
12 The donor tube should be sealed, both at its cut end and close to the pack.

Note: pregnant patients

In the latter part of pregnancy, the weight of the uterus in the dorsal position impedes venous return. Because of this, these patients are more likely to react adversely to venesection and donations should therefore be collected with the patient lying in the lateral position.

APPENDIX 5

Fact sheet

This fact sheet provides information for patients. Additions or amendments, taking account of local practices, may be needed.

FACTS ABOUT AUTOLOGOUS BLOOD TRANSFUSION

What is autologous blood?

Autologous blood is blood from an individual to be given back to that individual should the need for transfusion arise. Blood can be stored for up to 42 days between collection and use.

What are the advantages of autologous blood?

Autologous blood has the advantage over blood from other individuals in that it is incapable of stimulating antibodies to red cells, white cells, platelets and plasma proteins. It also carries no risk of transmitting infections such as hepatitis or HIV. However, the very small risk of bacterial contamination at the time of collection is the same as for any blood donation.

What are the disadvantages of autologous blood?

In general, donation for autologous transfusion has the same minimal risk as any blood donation. Because of the need to collect several units of blood within a period of a few weeks, it will be necessary for the patient to take an iron supplement. There is also a minimal risk, as with any transfusion, that blood other than one's own may be transfused accidentally.

Who may donate for autologous transfusion?

Patients whose general health is good can be considered for autologous transfusion for some planned surgical procedures. Some children may also be able to take part in an autologous programme. The consultant in charge of your case will decide if you are suitable for autologous transfusion.

How many units of autologous blood may be donated?

The exact number would be determined by your consultant. As many as four or five units may be taken at approximately weekly intervals before the planned date for surgery.

Where is blood donated?

The donations will be taken at your local hospital or regional transfusion centre. The request is made by your consultant to the consultant haematologist who will arrange to collect and store your donations.

How long does the procedure take?

Collecting a donation takes about 30 min each time, after which you will be asked to rest for 15 min before leaving. You can drive a car afterwards if you feel perfectly well, but it may be advisable to have a friend who is willing to drive on the first visit. If you feel unwell or if you are in any doubt, you should inform the doctor. Some occupations involve some personal risks or include responsibility for the safety of others. If such hazards are a normal part of your work, ask the doctor how long you should wait before resuming your activities.

POINTS TO NOTE AFTER THE DONATION

1 Most people feel fine after donating; however, if you do feel light-headed it may mean that your system has not had enough time to adjust. You should restrict your activities and, if necessary, lie down and rest until you feel better.

2 Drinking extra fluid helps to replace some of the liquid portion of the blood you have donated. You will normally be offered a drink following donation.
3 If your arm starts to bleed, do not be alarmed. Simply raise the arm above your head and apply gentle continuous pressure immediately to the venepuncture for 10 or 15 min until bleeding stops.
4 Occasionally the area may appear bruised. This discoloration will disappear within a few days and should cause you no concern.
5 Usually the venepuncture heals without difficulty. However, if the site should become reddened and painful, you should contact the doctor who took your blood, or your general practitioner.