Blood Conservation and Alternatives to Allogeneic Blood Transfusion

National Blood Service, Ghana

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Blood Conservation and Alternatives to Allogeneic Blood Transfusion

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Foreword

The Health Services Rehabilitation Project III (HSRP III) of the Ministry of Health of Ghana aims at reducing inter-regional disparities in performance and quality of health care delivery by addressing priority areas identified in the MOH's Second Five Year Programme of Work (2002-2006).

One of the components of the HSRP III is the 'Support to the National Blood Transfusion Services'. This component aims to achieve well-organized, coordinated and improved blood services in Ghana through the modernization and restructuring of the National Blood Service. The overall objective is the institutionalizing of the collection of safe blood and blood components from regular voluntary non-remunerated blood donors, and ensuring adequate and appropriate processing by trained and competent professional staff at three Area Blood Centres, for distribution to hospitals in Ghana.

Under the Technical Assistance Services aspect of the HSRPIII, Component 2, a Technical Working Group on Safe Clinical Transfusion Practice (TWG 5) was constituted in July 2008. It was given the task to formulate a National Clinical Blood Policy based on WHO guidelines, develop policy and procedures for Autologous Blood Transfusion and develop a Strategy and System for Emergency Blood Supply as part of its Terms of Reference.

The Technical Working Group that comprised Blood Transfusion Specialists, Consultants in Haematology, Obstetrics and Gynaecology, Paediatrics and Anaesthesia completed the "Guidelines for Autologous Blood Transfusion in Health Institutions" in July 2009.

This document is a review and update of the 2009 guidelines in the light of the progress in blood conservation methods and up-to-date approaches to auto-transfusion, blood salvage and alternatives to the use of allogeneic donor blood. This review is based on the experience gained in other blood services, and on a number of international and expert references that are given at the end of the document.

Introduction

It is well recognised that most errors in blood transfusion practices are operational rather than technical. Thus, errors in obtaining and labelling blood samples, requesting, storage, collection and administration of blood or blood components can lead to significant risk to patients.

Many 'wrong blood' episodes involve multiple errors at various stages of blood transfusion process. It is believed that such errors can be prevented if appropriate steps are taken to ensure that transfusion practices are performed to high standards of safety and effectiveness.

The procedures set out in this document, which must be considered in its entirety, constitute the NBS Ghana Clinical policy for transfusion of blood and blood components. These have been based on and are in line with the National Guidelines for the Clinical use of Blood and Blood Products (revised in 2009) and the National Blood Policy (2006).

The contents of this policy are broadly based on the National Guidelines for the Clinical use of Blood and Blood Products and covers the administration of blood and blood components and the management of transfused patients published in 2002 and revised in 2009. The guidelines reflect current professional opinion.

Glossary

ABC	Area Blood Centre
Anti-HCV	Anti Hepatitis C Virus
Anti-HIV	Anti Human Immunodeficiency Virus
ANH	Acute Normovolaemic Haemodilution
CVA	Cerebrovascular Disease
EBV	Estimated Blood Volume
EPO	Erythropoietin
Fe^{2+}	Ferrous (ion tablets)
Hb	Haemoglobin level
HBsAg	Hepatitis B Surface Antigen
Hct	Haematocrit
Hct_o	Hct before haemodilution
Hct_1	desired Hct after haemodilution
Hct_{av}	average of the haemotocrit before and after haemodilution
NBTS	National Blood Transfusion Service
PABD	Pre operative Autologous Blood Donation
ICS	Intraoperative Cell Salvage
PCS	Postoperative Cell Salvage

1 General Introduction

The bulk of the nation's blood goes to women and children. Anaemia in this group and in the general population, as a whole, should be prevented at the primary, secondary and tertiary levels by: supporting good nutrition, food supplementation, prophylactic haematinics, and by strengthening of laboratories to give quick, reliable and accurate blood counts to aid diagnosis when indicated, linked with quick and adequate management of malaria, worm infestation and anaemia especially in pregnancy.

In the same time practitioners and managers are being asked to focus attention on quality of transfusion practice aiming at blood conservation and reduction in unnecessary transfusion through effective clinical use of blood. These revised guidelines will start with autologous transfusion and will be followed by guidance on the use of alternative measures to reduce the use and exposure to of allogeneic blood, its labile components and other plasma-derived products.

Most planned surgical procedures do not result in sufficient blood loss. Additionally many patients can tolerate low levels of haemoglobin without transfusion. Autologous transfusion should only be considered where sufficient blood loss to require transfusion has occurred or is anticipated to occur although, in emergency, the autologous alternative may provide the only readily available source of blood for transfusion.

Whenever possible, interventions to reduce the need for transfusion should be employed. These include meticulous attention to haemostasis including the use of diathermy during surgery, active management of the third stage of labour to reduce haemorrhage along with increased and judicious use of crystalloid and/or colloid solutions to maintain a normal circulating blood volume.

These aims can also be achieved by establishing a "comprehensive blood management policy and plans" for patients requiring transfusion. This approach may include the various procedures for blood conservation

including autologous transfusion and the use of any other suitable alternatives for blood and blood products.

Approaches to autologous transfusion

It is the responsibility of the National Blood Service to facilitate the development of local programmes for autologous transfusions and blood conservation as part of the overall national policy for good clinical blood transfusion practice.

Autologous transfusion is the collection and subsequent re-infusion of the patient's own blood or blood components. Interest in autologous transfusion arose because of concerns regarding transfusion-transmitted disease from exposure to allogeneic blood collected from donors other than the patient. It gained special relevance in countries where the prevalence of markers for human immunodeficiency and hepatitis viruses (hepatitis B and C) may be high in blood donor populations, and where reliable screening techniques may not be generally available.

Autologous transfusion not only prevents transmission of disease but also avoids immunological complications of homologous transfusion such as alloimmunisation and transfusion reactions. Autologous transfusion permits greater access to donor blood in situations where blood supply, may be limited. Different methods of autologous transfusion can be used alone or in combination to reduce or eliminate the need for allogeneic blood.

These guidelines are intended to assist the national blood service and encourage health care facilities, physicians and other health care professionals to establish and make use of conservation and blood salvage systems for autologous transfusion according to established quality and safety standards, while taking into account local circumstances.

Preoperative blood collection of blood (PABD) for autologous transfusion should conform to the standards applied for voluntary donor blood. The selection of patients should take into consideration the risks

of the procedure against the risks of pre-operative anaemia and the availability of and access to safe donor blood. Improvements in blood safety and advances in surgical and anaesthetic techniques may have decreased international interest in PABD. It remains, however, a potential source of blood for elective surgery where there is shortage of supply, in patients with red cell antibodies and in general to reduce exposure to allogeneic blood and protect the community blood stock reserves.

Responsibility for the development and management of an autologous blood initiative should be with a physician who is familiar with these techniques. The physicians responsible for blood transfusion centres or transfusion facilities in hospitals would normally be able to implement a preoperative donation programme. A surgeon or anaesthetist would normally manage intraoperative and postoperative blood salvage and acute normovolaemic haemodilution.

Acute normovolaemic haemodilution (ANH) has the added benefit of ensuring that fresh autologous blood is available with optimal platelet and clotting activity. It should be explored as one of the measures to reduce the use of allogeneic blood within the overall strategy of blood conservation.

Intra-operative cell salvage should only be considered when the anticipated blood volume loss is 20% or more. It should be considered as one of the blood conservation measures in cardiovascular surgery, selected procedures involving the liver, some orthopaedic procedures and traumatic penetrating injuries.

Post-operative cell salvage is recommended whenever the anticipated post-operative blood loss is sufficient to cause anaemia or haemodynamic instability. Blood may be salvaged from body cavities, wound drains and joint spaces, and re-infused with or without cell washing (unwashed cells will require filtration). This autologous procedure can be considered for cardiac and chest surgery, as well as for certain orthopaedic operations.

Resources and training should be made available to establish facilities for intra and post-operative blood salvage in units where these

procedures would be required, since the devices used are costly and require to be run by specially trained operators. Equipment, especially for blood salvage should be subjected to medical device validation.

The national blood transfusion service should facilitate the training of health professionals involved in autologous blood donation and salvage procedures. Regional training workshops, audio-visual learning aids and relevant technical literature are all useful training techniques.

A well-organized blood transfusion service will be in a position to facilitate the introduction of an autologous transfusion programme. These programmes should be designed with appropriate and realistic targets and basic quality assurance indicators. The programmes should be periodically reviewed to determine the degree to which these targets are being achieved.

A programme for autologous transfusion should be incorporated into a comprehensive plan for good transfusion practice. Autologous blood transfusion should complement and extend efforts to recruit safe voluntary blood donors and should not, in any way, be considered as a replacement strategy to curtail efforts for supporting the voluntary blood donation system and efforts.

2 Guidelines and Standard Procedure for Preoperative Autologous Blood Donation

Preoperative autologous blood donation (PABD) is an effective procedure for patients undergoing elective surgery. The patient's blood is collected prior to elective surgery so that at operation there are one or more units of blood available if operative blood loss necessitates transfusion. Patients should not be encouraged to donate autologous blood if transfusion is unlikely during surgery. It has been previously reported that many patients (up to 50%) do not require transfusion and therefore the collection testing and storage of PABD would not be cost effective.

PABD is limited by patient suitability. It can be effective in covering elective procedures. It is important to recognise that PABD for autologous use carry the same risks of bacterial contamination at collection. The risks of clerical errors during processing of the unit, and incorrect identification at transfusion are the same as for ordinary donations. These are some of the reasons that made PABD less popular in many well-developed transfusion services. Nevertheless it is reasonable to maintain PABD services in situations of chronic shortages and until the national blood supply becomes adequate to cover the needs of the community.

The procedural details for PABD vary according to how the autologous service is delivered at the various health care facilities where blood collection, storage and reinfusion is conducted. It requires precise record keeping and labelling, and adequate facilities for collection and storage. A properly organised blood transfusion service is therefore essential.

Costs of PABD have been shown to be higher than those of allogeneic blood transfusion. These costs must be weighed against those of long-term morbidity and mortality of transfusion-transmitted disease, especially in places with limited health resources.

The benefits to the blood transfusion service include the ability to provide blood for surgical procedures in areas where the blood supply and availability may be unpredictable. In addition unused autologous units could be used for other patients. Although this is not allowed in many countries, it is reasonable to adopt the crossover policy in situations of chronic shortages provided transfer of pre-deposit donations collected for autologous use meet all the standards for ordinary blood donation, including screening for transfusion transmissible agents.

Most patients who are healthy enough to undergo elective surgery are eligible to PABD. Patients are usually suitable as autologous donors if the haemoglobin exceeds 100g/l, or the packed red cell volume (PCV) exceeds 0.30l/l.

Underweight adults (less than 50 kg) should donate no more than 9-10 ml/kg body weight. This procedure is equally applicable for men and women. There are no age restrictions. However, in paediatric patients over 8 years old, no more than 10% of the patient's blood volume may be taken at each phlebotomy. They should also be willing, co-operative and require parental consent.

It is particularly important to ensure that:

- Date for surgery is fixed, so that blood does not become out dated.
- Attendance for blood collection is possible.
- There is sufficient time before surgery to donate the number of units required.

Patients with bacteraemia, serious cardiac disease (e.g. angina, aortic stenosis) and sickle cell disease should be excluded as autologous blood donors. Information on the suitability of patients with other haemoglobin disorders for autologous donation is insufficient. Controlled mild to moderate hypertension on medication, diabetics controlled on oral agents and asthmatic in remission should not exclude patients from PABD.

PABD should be considered for all surgical procedures where blood

replacement is anticipated. Examples include urological and prostate surgery, orthopaedic surgery and joint replacement, cardiovascular aneurysms, major abdominal surgery as for splenectomy.

The risks and benefits of the procedure should be discussed with the patient and consent obtained prior to PABD. The patient should be informed that donating autologous units does not eliminate the possibility that transfusion with allogeneic blood may become necessary. The patient must meet the minimum criteria for autologous donation at the time of each donation. Every donation must be in accordance with the standard operation procedures.

Donations are recommended to be 7 days apart but may be scheduled as frequently as three days. The minimum interval between the final donation and surgery is 72 hours. Oral iron supplementation is necessary. This schedule allows up to five units of blood to be collected in citrate-phosphate-dextrose-adenine (CPD-A1) or a similar anticoagulant solution. This blood can be stored for up to five (5) weeks using standard hospital blood bank conditions.

If surgery is delayed or postponed, the oldest autologous units can be serially re-transfused to the donor and fresh units drawn ("leapfrog" technique). Alternatively, the units can be released to the blood stocks only if all standard donor criteria have been met, otherwise the units may be discarded.

If the donor is found to have a marker for transfusion transmissible disease, it is recommended that the collected unit be discarded and that no further donations be made.

Autologous units should be stored in a section of the blood bank refrigerator that is separate from other blood donations ready for issue or in a separate refrigerating unit. Autologous units should be clearly labelled with the patients name and with an indication that the unit is for "autologous use only". This information should be removed if the unit is entered into the banked blood inventory.

On admission to hospital for surgery, the patient with stored autologous units should have a fresh venous blood sample taken to confirm ABO, RH

and to perform the routine compatibility testing as well as haemoglobin level before re-transfusion.

Most practitioners agree that the autologous pre transfusion laboratory procedures should be the same as for ordinary donor units. They do not support a more liberal approach to standard procedures. National and local transfusion policies and the physician's clinical assessment should guide such decisions

Standard operating procedure for PABD

The following example of information is required to develop a standard operating procedure for PABD, to be adapted according to the local working conditions, and to be followed at the autologous transfusion unit, whether it is by the blood centre or in a teaching, regional, district hospitals, or any other health delivery facility licensed to administer blood transfusion

Step 1: Pre-donation

- Initiate request for PABD after educating patient (patient's surgeon/ anaesthetist/ doctor at blood centre)
- Obtain informed consent from patient.
- Complete PABD request form specifying type, date of surgery and number of units needed (patient's surgeon)
- Send completed PABD request form to Medical Doctor at the blood centre.
- Established liaison between Medical Doctor at blood centre and surgeon or anaesthetist.
- Assess patient/donor for suitability to enter PABD programme (Medical Doctor at blood centre).
- Put eligible patient/donor on oral iron supplements (ferrous sulphate 200mg i.e. 65mg elemental iron t.i.d., for 2-4weeks) 1-2 weeks before starting the procedure. The addition of erythropoeitin may also be recommended.

- Schedule blood collections at weekly intervals with a week between last collection and date of surgery.
- Check Hb level before each collection.
- Defer Patient with Hb below 11 g/dL.
- Take patients with acceptable Hb levels through pre-donation counselling, medical assessment and complete donor clinical record form.

Step 2: Donation/blood collection

- Carefully label Blood bag as 'autologous' and with a special donation number. e.g. JKA1/0021/04 (initials of donor and no. of autologous donation(s) by
- Donor/PABD donation in register/year of donation)
- Collect blood under the supervision of a doctor using same procedure as for collection of allogeneic blood.
- Issue completed autologous blood donation slip (NBTS/D.33) to patient/donor when collection(s) are complete.

Step 3: Post-donation (Blood Centre)

Processing and storage

- Perform ABO, Rh 'D' grouping and all available microbiological screening tests on all samples. Record results on respective blood bags.
- Label carefully all units confirmed reactive for HBsAg, anti HCV or VDRL as biohazard "restricted only to autologous patients use".
- Discard all units confirmed reactive for anti-HIV.
- Store autologous blood units in a dedicated compartment in the blood bank refrigerator.

Step 4: Collection of blood from the bank:

- Complete standard blood request form

- Send completed blood request, together with autologous blood collection slip (NBTS/D.33) and 5mls of patients blood sample to the blood bank laboratory 48hours prior to the surgery.
- Perform compatibility testing on each unit.
- Issue out autologous blood units on the day of the surgery.

Step 5: Returns from clinicians on day of discharge

- Complete autologous blood transfusion record form on day of discharge of patient (Patient's surgeon)
- Send completed form to the Doctor at the blood centre.

Step 6: Following confirmation that patient would not require transfusion

- Discard all units of autologous blood labelled as biohazard.
- Cross over units negative for all microbiological markers into the regular bank pool for allogeneic use.

3 Guidelines and Standard Procedure for Acute Normovolaemic Haemodilution

Acute normovolaemic haemodilution (ANH) is accomplished by the removal of a predetermined volume of the patient's own blood either immediately before or shortly after induction of anaesthesia, and prior to the commencement of surgery. The volume removed is simultaneously replaced with sufficient crystalloid or colloid solution to maintain normovolaemia during surgery and also reduces the red blood cells in any given volume of blood lost during surgery. The recent concerns about colloid preparations restricts the safety of ANH as excessive dilution may cause microcirculation collapse and weaker clot structure that may lead to silent myocardial ischaemia. A recent meta-analysis suggested limited benefits. This technique is not currently recommended in the UK and some other centres.

ANH ensures that fresh autologous blood is immediately available for transfusion. This procedure is particularly valuable when the expected blood loss is no less than one litre or 20% of the estimated blood volume.

The fresh autologous units collected by this procedure are available for transfusion without delay and have the added value to provide optimum levels of platelets and coagulation factors. ANH should be explored as one of the measures to reduce the use of allogeneic blood within the overall strategy of blood conservation. Its value has been demonstrated to be of special benefit in cardiac surgery.

The transmission of disease is avoided and blood compatibility testing is not required. ANH reduces the need for allogeneic blood transfusion, which is of special importance in areas where access to blood banking facilities are limited or absent and where the seroprevalence of markers for infectious disease is elevated.

The autologous blood collected is subsequently re-infused, preferably when the bleeding has been controlled or at the conclusion of surgery.

The fresh units of autologous whole blood maintain the patient's haemoglobin concentration and blood volume. This technique has the added benefit that it does not require specialized equipment other than standard blood bags and transfusion sets. It can be used in conjunction with other methods of autologous transfusion.

A specialist physician should be consulted before ANH is performed on patients with coronary artery disease, aortic stenosis, significant cardiac arrhythmias, severe hypertension, severe respiratory disease, severe renal impairment, coagulation disorders, severe liver disease or sepsis.

Caution should be used when regional anaesthesia is used because of possible hypotension. Blood collection should be from one venous line while simultaneous infusion of replacement fluids is carried through a second venous line. If there is only one intravenous line available, then blood collection and replacement must alternate.

The patient's haemoglobin or PCV must be determined and must be adequate to perform ANH. Venesection should be carried out immediately prior to the start of surgery and blood must be collected aseptically.

ANH is suitable in patients who can tolerate rapid withdrawal of one or several units of blood (not exceeding 20 ml/kg) before the period of blood loss. The amount of blood removed must be at least 2 units and the total volume of blood collected should not exceed 40% of the patient's estimated blood volume.

Replacement should be with crystalloid (3.0 ml for every 1.0 ml blood collected) and/or colloid (1.0 ml for every 1.0 ml blood collected). The physician in charge determines the PCV, after haemodilution. The haemoglobin and PCV may be allowed to fall to 9 g/dL or to a PCV of 0.27-0.3l/l. This should not cause adverse effects, provided that circulating volume is maintained at all times.

The volume of blood to be collected for a given haematocrit can be determined by the following formula:

$$\text{Volume of blood removed} = \frac{\text{Estimated Blood Volume x Initial PCV}}{\text{Mean of the Initial and Desired PCVs}}$$

Estimated blood volume = body weight (kg) x 70 (adults)
= body weight (kg) x 80 (children)

Blood should be collected into standard plastic blood packs containing citrate phosphate-dextrose (CPD) or similar anticoagulant with adequate mixing. Weighing the blood packs as they are filled should monitor the volume of blood collected. The procedure should be completed within 10 to 30minutes.

The blood packs should be clearly labelled with the patient's name and the date and time of collection. They should be numbered in the order of collection. They should remain with the patient until transfused. If the interval from collection to use is expected to exceed six hours, the blood should be stored in a refrigerator at 4°C.

Reinfusion should take place when major bleeding has been controlled, but may be given earlier if excessive bleeding is encountered. The last unit collected should be the first unit to be transfused. A blood administration set with a standard filter should be used.

It is essential to monitor carefully the surgical blood loss and to avoid risk of poor tissue oxygenation/perfusion. Standard haemodynamic monitoring (pulse, blood pressure and urine output and, when available, central venous pressure) must be followed during blood collection and continued during surgery to ensure that normovolaemia is maintained. Records of the collection and reinfusion should be entered on the anaesthesia record and fluid balance charts.

Equipment requirements are minimal but include an instrument to determine PCV and haemoglobin, an apparatus for measuring blood volume by weight (e.g. spring balance) and standard intravenous cannulas, tubing and blood bags. ANH is simpler and less expensive than

PABD and available to patients undergoing surgery at short notice. Further patient management to build-up of the starting haemoglobin may be considered using haematinics, increased protein diet, antimalarial therapy and if required, erythropoietin.

Standard operating procedure for ANH

The following example of information is required to develop a standard operating procedure for ANH, to be adapted according to the local working followed by the autologous transfusion unit, whether it is in in a teaching, regional, district hospitals, or any other health delivery facility licensed to administer blood transfusion

Eligibility Criteria

The patient should have

- Initial haemoglobin (Hb) 10-11 g/dL
- No age restriction or weight restriction
- Controlled mild or moderate hypertension
- No severe respiratory disease, e.g. controlled asthmatic
- No renal, liver impairment
- No cerebrovascular disease or previous CVA
- Controlled diabetics
- No evidence of ischaemic heart disease, critical stenotic heart valve disease or heart failure
- Normal coagulation
- No evidence of active or potential bacterial infection
- Normovolaemia
- Patient should not be hepatitis A, B, C or HIV positive if possible

Step 1: Pre-operative

- Patient should give valid informed consent.
- Explain the procedure, its associated merits, risks and the possibility of homologous transfusion.

- Assess for eligibility
- Estimate the amount of blood to be removed; 10-20ml/kg depending on age and amount of expected blood loss.

Volume withdrawn = EBV x (Hct_0 - Hct_1)/Hct_{av}

EBV = estimated blood volume
Hct_0 = Hct before haemodilution
Hct_1 = desired Hct after haemodilution
Hct_{av} = average of the Hct before and after haemodilution

For example:

EBV = 4000ml
Hct_0 = 42%
Hct_1 = 30%
Hct_{av} = 36%

Volume to be removed = $4000 \times \frac{42-30}{36} = 1{,}333ml$

Step 2: Volume replacement

- One(1) large cannula in one arm.
- Start IV fluids 3ml per ml of blood or Colloids, 1ml / 1ml blood
- Fluids include crystalloids, normal saline, ringers lactate, or colloids- gelatins, hydroxyl ethyl starch (The use of colloids may be restricted in view of the recent concerns about the safety of colloid preparations)
- Crystalloid and/or colloid should be given simultaneously as blood is withdrawn

Step 3: Blood collection

- Collect blood under strict aseptic technique to provide maximum assurance of a sterile product.

- Blood collection should be in the opposite arm to the arm with the IV fluids
- Blood should be withdrawn through an arterial or venous catheter into the blood bag(s).
- The attending anaesthetist should directly supervise the collection of blood.

Step 4: Monitoring

- Monitor level of consciousness if the procedure is by regional anaesthesia
- Monitoring of ECG continuously if available or by hand on the pulse
- Measure non-invasive blood pressure every 5 minutes in venous collection or every 2 minutes if donation is from an arterial line.

Step 5: Labelling and Storage

- The label should have a suitable adhesive for refrigerated storage.
- Autologous blood must bear an easily recognisable label with the message "For Autologous Use Only"
- Label should bear the patient's name, identification number, date and time of collection,
- Sequential number of units must be written (if more than one unit is removed)
- Name and signature of the phlebotomist should be included.
- Keep the blood in the same operating room as the patient and maintain at room temperature to preserve platelet function.
- If it is anticipated that more than 6 hours will elapse before transfusion will take place, the blood should be refrigerated, ideally in a blood bank type refrigerator at 4°C ± 2°C.

Step 6: Blood Administration and Disposal

- The anaesthetist shall be responsible for determining transfusion need.

- It is recommended to return the blood in reverse order so that the first unit with the highest haematocrit and platelets is administered last.
- Blood kept at room temperature must be reinfused within 6 hours of collection.
- All unused blood after 24 hours must be properly discarded and documented

Step 7: Documentation on the anaesthetic chart

- The amount of blood withdrawn
- The amount and type of fluid infused,
- The amount of blood returned or discarded
- The vital signs

4 Guidelines and Standard Procedure for Intraoperative Blood Salvage (ICS)

Intraoperative cell salvage (ICS) is by far the most widely used and accepted method of autologous transfusion. ICS services proved to be very valuable particularly in many tertiary surgical and obstetric health care facilities with busy emergency and trauma units.

Blood lost during surgery or shed from a wound or in a body cavity is recovered; the red blood cells are separated from the other components, and re-infused with or without washing to the patient. Blood is recovered in proportion to blood loss and reduces allogeneic blood usage. Oxygen transport is preserved as 2,3 DPG levels are high. ICS has additional advantages, as it may be easier to organise since all resources are contained within the theatre environment, which limits the risk of clerical and handling errors. It is not affected by the cancellation of surgery. It is applicable to both elective and emergency procedures and provides fresh red cells that would otherwise be lost.

ICS should be considered when the anticipated blood loss is 20% or more of the patient's estimated blood volume or when the usual transfusion requirement exceeds one unit. This procedure is useful in cardiovascular surgery, ruptured ectopic pregnancy, ruptured spleen, selected orthopaedic procedures, and traumatic penetrating injuries. Maximum benefit of this system can be gained by capture of emergency cases, which often require large volume blood component support.

The salvage of blood contaminated with bowel contents, bacteria, malignant cells, amniotic fluid or topical bactericidal irrigants is not recommended. If bacterial contamination of the re-infused blood is suspected, broad-spectrum antibiotics may be necessary. The contraindications for this procedure and the risk must be balanced against the benefit for each patient.

There are four common methods for intraoperative blood salvage available to the clinician, which are appropriate for differing levels of health care:

- Gauze filtration
- Reusable or suction collection devices
- Disposable suction collection devices
- Semi-continuous flow centrifugation cell-washing systems

Traditional gauze filtration is inexpensive and is suitable for blood salvage from body cavities. The method requires sterile stoppered glass bottles or similar sterile plastic container with a suitable anticoagulant. At operation the surgeon collects blood from the body cavity using a ladle or small bowl and transfers it into a larger bowl or kidney dish containing the anticoagulant solution from the bottle. The blood is then filtered back into the sterile container through four to six layers of sterile gauze placed in a funnel, then sealed with a stopper and re infused through a blood infusion set with a standard filter.

Alternatively a convenient reusable suction collection system can be used for suction of blood via a wide-bore tube with several large terminal collection openings. This tube should not be unduly long and should be attached to one of two ports in a stoppered glass bottle containing a suitable anticoagulant solution. Suction is applied to a tube attached to the second port in the bottle. To avoid excessive haemolysis, suction pressure should be as low as possible (maximum 100 mmHg). The salvaged blood is re-infused to the patient through a blood infusion set with a standard filter. Blood salvage may continue by using additional replacement bottles.

There are several specifically designed, commercially available disposable suction collection systems, some of which use a rigid reservoir containing a disposable liner and others a single use, self-contained reservoir. Cardiotomy reservoirs can also be used for this purpose.

Semi-continuous flow centrifugation cell-washing devices use disposable components to collect and wash red cells prior to their reinfusion. These devices are useful in large-volume blood loss surgery. Washing removes unwanted debris and tissue fluid, which may contain activated coagulation factors that could affect haemostasis. In trauma

cases washed cell salvage can be used to re-cycle the drainage from chest drains. The conventional chest drainage system is primed with heparinised isotonic (0.9%) saline instead of water, the cell washing system is used to process the heparinised blood, which is washed and immediately re-infused. Manufacturers' instructions should be followed at all times.

ICS service using these devices is effective although costly to set up, however it can nearly be cost neutral when used appropriately. It requires a trained, dedicated operator. A practical management requirement is to appoint a member of staff from among the theatre orderlies, perfusionists or anaesthetic nurses to be trained to carry the responsibility to coordinate operations requiring ICS. Ideally the coordinator will oversee the training of other members of staff in theatre and/or wards; maintain competency levels of trained staff and for keeping training records. The coordinator will also be responsible for arranging for cell salvage to be available at a clinician's request and when appropriate, for cell salvage services to be available 24/7 as cover for emergency procedures. In addition the coordinator's task will be to keep records of all procedures undertaken as well as providing statistics for the Hospital Transfusion Committee (HTC). The ICS coordinator should be technically responsible for machine maintenance and quality control of re-infused cells as well as writing organisational policies and protocols for the use of machines and share with the blood transfusion laboratory in auditing the use of cell salvage

Choosing the ICS machine/system

There are several options to choose from. In helping to decide on the most appropriate machine for your organization a number of factors should be considered. These mainly include the cost, the maintenance, training, and post-sales support package. It is also important to consider the degree of flexibility for different types of surgery where blood loss will be at different rates as well as the ability to separate collection and processing disposables

Cell washing devices

These operate either as a centrifugal bowl system, a continuous rotary system or a dynamic disc system.

The fixed volume centrifugal bowl system allows red cells to be separated through centrifugation and washed using saline. The quality of the red cells depends on the volume of the wash solution. Larger volumes are recommended when tissue contaminants are likely as in orthopaedic surgery. In these systems it is possible to set up the collection reservoir and only process should bleeding be excessive and if enough blood is collected to make transfusion worthwhile.

The continuous rotary system works by continuous elution of the supernatant anticoagulant and contaminants, and washing of the red cells with saline. This system requires very little priming and is ideal for paediatric use.

The Dynamic disc system allows for a variable volume of red cells to be processed and is not normally used for high or rapid blood loss cases.

Standard operating procedure for Intraoperative Cell Salvage:

Information is required to develop a standard operating procedure for intraoperative blood salvage, to be adapted according to the local working conditions and to be followed by the blood conservation unit in any facility licensed to administer blood transfusion

5 Guidelines and Standard Procedure for Postoperative Cell Salvage

Postoperative blood salvage should be considered whenever the anticipated postoperative blood loss is sufficient to cause anaemia or haemodynamic instability that would require blood transfusion. Blood may be salvaged from body cavities and joint spaces and re-infused with or without cell washing.

Postoperative blood salvage is most useful after cardiac surgery. It is also suitable after selected orthopaedic procedures and surgery for penetrating wounds of the chest.

Postoperative salvage and reinfusion is unlikely to be necessary if the volume of blood collected over a six-hour period is less than 200 ml (50ml of red cells) or is less than 5% of the patient's estimated blood volume.

The risks of this procedure must be balanced against the benefit for each patient. The salvage of blood contaminated with bacteria is contraindicated. The salvage of blood contaminated with malignant cells or fat is not recommended.

Postoperative blood salvage must conform to the following safety requirements:

a. Salvage should be performed in accordance with written standard procedures.

b. Salvaged blood must be clearly labelled with a specific patient identifier and with the date and time of the initiation of blood collection. The time from initiation of collection to reinfusion should not normally exceed six hours.

c. A qualified physician should be responsible for the safe conduct of this procedure. This responsibility can be delegated to properly trained health workers. Special attention should be given to less experienced ward personnel who may be manipulating the blood prior to reinfusion.

d. The equipment used in these procedures must conform to accepted standards of sterility.

Gravity or minimal suction (less than 40 mm Hg for thoracic drainage and less than 100 mm Hg for other closed wounds) may be used. The salvaged blood is collected in stoppered glass bottles or a similar sterile plastic container containing a suitable anticoagulant solution. Although anticoagulation is ordinarily not required for blood salvaged from the mediastinum because this blood is usually defibrinated prior to collection except when bleeding is brisk. Blood should be re-infused through a standard blood filter with strict adherence to sterile protocols.

Several commercial devices are available. They are specifically designed for postoperative blood salvage. Cell washing machines were discussed in the previous chapter.

Standard operating procedure for Postoperative Cell Salvage:

Information is required to develop a standard operating procedure for postoperative blood salvage, to be adapted according to the local working conditions and to be followed by the blood conservation unit in any facility licensed to administer blood transfusion

6 Guidance on alternatives to blood, labile components, plasma-derived products and approaches for blood conservation in surgery.

Patient blood management and alternatives

Patient Blood Management (PBM) is an evidence-based, multidisciplinary team approach, which crosses health care boundaries. The aim of PBM is to establish patient care pathways to increase the use of alternatives to transfusion and introduce strategies to reduce the inappropriate use of red cells, fresh components and plasma-derived products. Point of care testing according to blood management algorithms can be helpful and is able to detect in vivo coagulopathic changes in order to introduce targeted alternative therapeutic interventions and improve the outcome in severe trauma.

The challenge for the use of alternatives is driven by risks of transfusion, patient outcomes and also by cost. The inherent risks of blood and blood products along with the severe shortage and compromised access in many communities are likely to favour approaches that reduce reliance on allogeneic therapeutic interventions. The risk-benefit of using autologous blood, erythropoeietic stimulants, haematinics and a variety of other pharmacologic agents becomes worthwhile exploring.

The detection, assessment and treatment of perioperative anaemia is an important and essential component in the planning of PBM strategies to minimize exposure to allogeneic sources and to help maintain adequate blood stocks. Successful management of preoperative anaemia is known to have decreased blood transfusion in patients undergoing orthopaedic and cardiac surgery. Meticulous surgical procedures and developments in anaesthetic technology have also contributed to reduce blood transfusion.

Reducing operative blood loss

General tips for surgeons

Blood loss, however minimal during surgery, is inevitable.

This section deals with minimizing loss in order to reduce transfusion requirements. It is particularly intended to provide information for practitioners working in remote areas and where support services and facilities are limited.

Every practitioner who engages in procedures that put patients at risk of blood loss and subsequent transfusion owes the patient all the caution at his/her disposal to reduce the risk of transfusion.

It is imperative that transfusion is not taken lightly and the safety precautions concerning transfusion be carefully thought through and implemented in view of the biohazard and immunologic risks of transfusion, In general attention to detail and proper planning should reduce significantly perioperative risks of bleeding.

Additionally reduced blood loss helps the surgeon see clearly the surgical field and also earns the trust of other practitioners especially the anaesthetist.

The approaches that can be used to reduce the amount of blood loss and reduce the risk of transfusion can be divided into phases

a. Pre-operative phase
b. Intra-operative phase
c. Post-operative phase

The pre-operative phase

Preoperative planning and a preadmission protocol include thorough clinical assessment for the causes of anaemia. A comprehensive history taking, for drugs and family or haemostatic problems in previous dental or surgical procedures, is recommended.

Haemostatic problems

A history of excessive bleeding in prior surgical procedures or traumatic events needs to be assessed for haemostatic disorders such as hemophilia and other hereditary coagulopathies. Steps can then be taken in consultation with the hematologist to counteract the problem. Patients with obstructive jaundice must have their clotting profiles corrected with the use of parenteral vitamin K

Sepsis

In the event of severe sepsis, the risk of coagulopathy must not be forgotten and platelet concentrates, fresh frozen plasma as well as coagulation factors may be administered before or during procedures. The help of the hematologist may be sought and the anaesthetist should be made fully aware of the patient's condition

Anticoagulant therapy and drugs

The use of anticoagulants by patients for venous disease should be assessed. Patients on warfarin should be switched to heparin that has a shorter half-life and whose effects can be more easily reversed 2-3days prior to surgery for elective purposes. In emergencies, fresh frozen plasma and vitamin K may used to reduce the risk

Aspirin and or platelet inhibitors for primary prevention should be stopped 7 days prior to surgical intervention. However in secondary prevention of thrombotic events it is advisable to consult the treating physician and always inform the anaesthetist. There is also evidence to suggest that the bleeding in this setting may not be significant

General safety measures

Prior to the induction of anaesthesia, the use of the WHO safety checklist

reduces a lot of anguish that may occur with the failure of equipment intra operatively. Issues like adequate lighting and reliable functioning of equipment should be dealt with prior to the operation

Intra operative care

"The only weapon with which the unconscious patient can immediately retaliate upon the incompetent surgeon is haemorrhage."
WS Halsted

Autotransfusion

The various methods for blood salvage and auto transfusion should be planned ahead of the surgical procedures and in trauma and should be implemented according to the expected volume of blood loss (see main document above).

Anaesthesia

The use of hypotensive anaesthesia can be very useful to minimise blood loss especially in prolonged procedures.

Local infiltration of incision site with adrenalin containing solutions can cause vasoconstriction and reduce incision site bleeding. This can be very useful in haemorrhoidectomy and other procedures

Once the procedure is underway, blood loss can be controlled by local or systemic methods.

Local Control of Bleeding

Mechanical

Packing and direct pressure is considered the simplest but most effective mechanical means of reducing blood loss. This should be enough as an interim measure until more specific methods are implemented.

Other mechanical methods using clamps (including artery forceps and other vascular clamps) are also reliable everyday tools. Efforts should be made to identify vessels before they are damaged and clamping should

as much as possible be of the actual vessels and not blind mass clamping of tissues.

Sutures are an adjunct to clamping and give added security. Vascular clips are a more expensive alternative to sutures. They are particularly useful in inaccessible areas prior to cutting vessels (e.g. in radical prostatectomy).

Stapling of tissues with linear cutting or circular stapling devices should reduce operating time and by inference bleeding as well. There have however been reports of suture line bleeding that can be troublesome but not with life threatening consequences.

Pressure bandaging of operation site especially for extremity surgery should help. One should remember to inspect the toes for ischemia. Reversal of intra operative anticoagulants is also essential

Thermal and electro cautery devices

These are very useful devices that are in common use

These devices although expensive, they reduce bleeding significantly and save operating time as well, thus reducing overall costs and risks.

Mono polar electro cautery devices utilizing a patient pad have two settings for cutting and coagulation. A blend of both methods is offered by some manufactures allowing surgeons to cut with minimal bleeding.

Bipolar devices do not use a patient pad and allow more precise coagulation with minimal collateral tissue damage. The devices are particularly useful in fine micro vascular and neurosurgery.

Improvements in bipolar technology have developed devices that can seal larger vessels of up to 7mm in diameter with little collateral damage (Ethicon®, Covidien®)

The Harmonic Scalpel by Ethicon® utilizes ultrasound technology with an active blade moving up to 55,000 times per second and able to seal vessels of up to 5mm in diameter.

Occasionally there is a raw surface that continues to ooze with no identifiable vessel. This can be controlled using topical agents that

promote local clotting providing it is not caused by a spurting vessel. These include cellulose, gelatin sponges and collagen. Autologous fibrin glue made from the patient's plasma and thrombin, can be useful in cardiac and ENT surgery. Bone wax can be useful in orthopaedic surgery. It is useful in sealing off bone marrow and reducing bleeding

Post-operative care

Maintenance of normothermia through the procedure and post operatively should create an ideal environment for optimum enzymatic action and thus improve clotting and haemostasis. Maintenance of correct electrolyte balance should also help with homeostasis

The use of intravenous calcium for every 3-4 units of blood administered was thought to also reduce bleeding but there is no evidence to support this particularly with the use of the current anticoagulant and preservative solutions.

Management of preoperative blood loss

The amount of blood lost and the patient's clinical condition will determine the urgency of treatment, the choice of product and the volume to be replaced. A loss of 20% blood volume in a healthy adult is generally tolerable and requires no replacement. More than 30% volume loss may lead to shock. This requires urgent volume replacement and may require blood. Volume replacement is more urgent than red cell replacement in acute blood loss.

The initial critical decision involves use of plasma volume expanders instead of blood. They are immediately available, relatively inexpensive and do not have most of the dangers associated with the use of whole blood. In addition blood is rarely necessary in the initial stages of treatment of hypovolaemia.

The judicious use of plasma volume expanders can result in adequate restoration of blood volume at an economic cost. Although in the past albumin solutions have been used in first line therapy this practice is seldom justified, as much less expensive synthetic products are readily

available and equally effective. The non-blood volume expanders are of two classes; crystalloids and colloids.

Systemic haemostatic agents

Systemic pharmacologic agents are resorted to in the event of failure of local methods or where a generalized coagulopathy is encountered. Agents for systemic use include vitamin K for anticoagulant reversal, protamine sulphate to neutralise the effect of heparin, blood products like plasma, cryoprecipitate and recombinant factor VII a. Other drugs like tranexamic acid, epsilon amino caproic acid as well as aprotinin and etamsylate. They are described in some detail later in this document.

Crystalloids

It is recommended that initial resuscitation should be with 1-3 litres of non-calcium containing crystalloid solution or normal saline. Adequate crystalloid resuscitation may often avert the need for other plasma expanders. Colloid products can then be used in the recommended doses, if prolonged volume expansion is required such as in a severely ill trauma patient. Ringer's lactate and dextrose solution must not be used in conjunction with a red cell infusion, as the solutions are not compatible.

Gelatin Solutions

This is a 3-4% solution prepared from heat degraded cattle bone gelatin. Half of the infused volume remains in the circulation for 4-5 hours. It does not to interfere with laboratory blood matching procedures but must not be used in in the same giving set with a red cell transfusion. It is known to cause severe reactions, which can be acute and anaphylactic in nature. At least 3-5 litres can be used at a time. It has a marginal effect upon bleeding time.

Dextran Solutions (Dextran 40, Dextran 70)

These preparations consist of long chains of glucose units modified to make preparations of a desired molecular weight. The smaller molecular weight product Dextran 40 has an immediate effect in expanding the

plasma volume but its effect is maintained only a few hours since it is rapidly excreted in the kidney. Dextran 40 is absolutely contraindicated in the treatment of shock since it will obstruct the renal tubules. Dextrans will cause rouleaux formation of the red cells, impair coagulation and platelet function and may precipitate renal failure in patients who already have compromised renal function.

Hydroxyethyl Starch (HES)

A wide variety of HES solutions are available for use in plasma volume expansion especially with critically ill patients who suffer from excessive capillary permeability. HES solutions are prepared from chemically modified amylopectin. Generally this product has similar properties to those of albumin as far as plasma volume expansion is concerned. HES has the advantage that it is completely metabolised and excreted. The 6% solution in saline is commonly used, and 50% of the infused volume remains for 24 hours in the circulation.

No more than 1 litre is recommended per day as it can also interfere with haemostasis. Although side effects were thought to be rare, it has recently been reported to cause acute kidney damage and coagulopathy in critically ill patients with sepsis. The debate on the effectiveness and safety of HES solutions for use in intensive care units is still raging and the use of human albumin is currently under renewed consideration as the colloid of choice.

Haemopoietic Growth Factors

Recombinant human erythropoietin

Genetically engineered haemopoietic growth factors are expected to have an increasing impact on the use of allogeneic blood components in place of the original human erythropoietin preparations.

Therapy with erythropoietin is now well established in certain forms of chronic anaemia such as in chronic renal failure. Although of little value in acute bleeding, it has been used successfully in the pre- and post-operative period to reduce patient exposure to allogeneic transfusion. Iron stores must be adequate and accessible for a successful response.

The administration of recombinant human erythropoietin can increase the rate of red cell production in patients with chronic renal failure with significant reduction in the requirement for repeated transfusion of red cells.

Chronic anaemia patients with rheumatoid arthritis, chemotherapy, and with myelodysplastic syndromes, who are treated with erythropoietin may require fewer red cell transfusions.

The role and safety in cardiac surgery has recently been questioned. Its use in Canada and the EU has been restricted to the management of preoperative anaemia in orthopaedic patients.

Granulocyte Stimulating Factor (G-CSF)

This is accepted therapy in place of granulocyte transfusion in the management of patients with severe neutropenia associated with chemotherapy and bone marrow failure.

Thrombopoietin (TPO)

Two recombinant forms of thrombopoietin have undergone extensive clinical investigation however they have not been shown to replace the use of platelet transfusions in patents with bleeding and low platelet counts. Etamsylate is believed to stimulate thrombopoeisis and platelet release. It also increases capillary endothelial resistance and promotes platelet adhesion.

Alternative approaches to the use of plasma derived products

Recombinant Coagulation Factors

Recombinant Factor VIII It has considerably reduced the use of plasma-derived factor VIII and cryoprecipitate in the management of Haemophilia A, particularly in the home therapy programmes. Recombinant Factor IX has similar efficacy to plasma-derived factor IX in the management of bleeding, in haemophilia B patients

Recombinant Factor VIIa is licensed for the treatment of bleeding episodes in patients with haemophilia A or B who have inhibitors to

factors VIII and IX respectively. This product is also increasingly being used to reduce blood loss and/or allogeneic blood transfusion in patients with uncontrolled bleeding. Recombinant factor VIIa which was considered a miracle drug has now been found to increase the risk of thrombotic events in patients. Thus this extremely expensive drug has very limited use for only in severe life threatening trauma and war casualties.

Non-transfusion pharmacological therapy

Desmopressin (DDAVP) is a synthetic analogue of the antidiuretic hormone vasopressin. It shortens the bleeding time and is an established non-transfusion form of therapy that can release factor VIIIc and von Willebrand factor from endothelial storage sites. Its effect on factor VIII parameters lasts for 6-8 hours and on the bleeding time for 1-3 hours.

Patients may become progressively unresponsive to DDAVP with repeated daily or twice daily doses over 2-3 days. Responsiveness will return when the drug has been discontinued for 2 days. Administration is either by IV or subcutaneous injection. Intranasal presentations of desmopressin are available, and although considered unreliable because of variable absorption. It can safely be given subcutaneously 1.5-2 hours preoperatively. The routine use of DDAVP to control bleeding in cardiac surgery is presently not recommended

Aprotinin is a protease inhibitor that interferes with coagulation and fibrinolytic activated factors. Its administration may cause fatal anaphylactic or anaphylactoid reactions. The risk for reactions is increased among patients with prior aprotinin exposure within the previous 12 months. It was removed from market in 2007 but is coming back to be approved in Canada and the EU in cardiac surgery.

Tranexamic acid and **epsilonaminocaproic Acid** (EACA)

These agents act as inhibitors of fibrinolysis. Initially these compounds were used primarily to reduce mucosal bleeding in haemophilia and von Willebrand disease patients. Currently they are also used to decrease blood loss in cardiopulmonary bypass surgery, Glanzmann's

thrombasthenia, menorrhagia and variety of other disorders of haemostasis. Tranexamic acid has also been used in thrombocytopenic patients with malignancy to reduce mucosal blood loss. Use of either tranexamic acid or EACA carries the risk of clot formation that is resistant to fibrinolytic therapy and is generally contraindicated in DIC and thromboembolic disease. The use of tranexamic acid has been been proven in large-scale trials to reduce transfusion requirements in trauma and in surgery.

Autotransfusion: Therapeutic Principles, Efficacy and Risks

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http://www.transfusionguidelines.org/

WHO surgical safety checklist implementation manual

Appendix 1:

Sample PABD Form

National Blood Transfusion Service
P. O. Box KB 78
Korle-Bu
..... 20.....

Dear Dr. .....

Re .....

The above named patient is being attended to by you at the ..... for ....., and is to have surgery.

He/She would want to have a preoperative autologous blood donation if all conditions are satisfactory since he/she would want to be transfused with his/her own blood during surgery.

We will be grateful if you can give us the exact date for the scheduled operation to enable the Blood centre programme the dates for the blood collection(s).

Counting on your co-operation.
Thank you

.....
Name and signature of Doctor

Appendix 2:

Sample Request for Autologous Transfusion to the Doctor, Blood Centre

Name _____

Age _____ Sex _____

Diagnosis/Type of Surgery _____

Hb _____ g/dL No of Units required _____

Proposed Date of Surgery _____

Relevant Medical History

- ☐ High BP
- ☐ Diabetes Mellitus
- ☐ Cardiovascular Disease
- ☐ Others (State) _____

Name of Referring Doctor _____

Date _____

Appendix 3:

Sample Autologous Blood Collection Form

Name _____

Hospital _____

Surgeon _____

Type of Surgery _____

Collection Date	Donation Number	Expiry Date
1	.....	.....
2	.....	.....
3	.....	.....
4	.....	.....

.....	.....
Signature	Stamp

Appendix 4:

Sample Autologous Blood Transfusion Record

Complete on day of discharge and return to the blood bank laboratory within 24 hours.

Patient's name _____

Hospital/Ward _____

Donation Number (s) :

_____ _____ _____

Date of Surgery _____

Was patient transfused with the blood during/after surgery?

Yes _____ No _____

Patient will/will not require blood transfusion.

Doctor's Signature _____

Date _____


NATIONAL BLOOD SERVICE GHANA