Policy for the provision of Intraoperative Cell Salvage

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Target Audience:

People who need to know about this document in detail	All Staff involved with or likely to be involved with delivering cell salvage or involved in the care of a patient receiving cell salvage. (eg Operating Department Practitioners, anaesthetists, Surgeons, midwives, nursing staff) All staff and departments involved with blood management services Hospital Transfusion committee
People who need to have a broad understanding of this document	Medical Director Nursing Director Consultant Lead for Transfusion Clinical Lead for ICS Theatre lead for ICS Theatre trainer for ICS Directorate Manager for Theatre Transfusion Practitioner Jehovah's Witness Hospital Liaison
People who need to know that this document exists	All staff involved in the development of Health Board Policies.

Integrated Impact Assessment:

Equality Impact Assessment Date & Outcome	**Date:** **Outcome:**
Welsh Language Standard	Choose an item.
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MAE EIN GWERTHOEDD YN EIN HELPU NI I FOD AR EIN GORAU
#CTMareingorau
RYDYN NI'N GWRANDO, YN DYSGU AC YN GWELLA
WE LISTEN, LEARN AND IMPROVE
RYDYN NI'N TRIN PAWB Á PHARCH
WE TREAT EVERYONE WITH RESPECT
RYDYN NI I GYD YN CYDWEITHIO FEL UN TÎM
WE ALL WORK TOGETHER AS ONE TEAM
OUR VALUES HELP US BE AT OUR BEST
#CTMatourbest

Guidance

This guidance has been adapted from the Joint United Kingdom (UK) Blood Transfusion and Tissue Transplantation Services Professional Advisory Committee (JPAC) guidance template 2016, whilst also referring to 2018 Association of Anaesthetists guidelines: cell salvage for perioperative blood conservation 2018.

All references to Cell Salvage (CS), Intraoperative Cell Salvage (ICS), Postoperative Cell Salvage (PCS) and combined systems (ICS/PCS) in this policy, relate to WASHED systems only (unless otherwise stated).

This policy does not relate to the use of unwashed cell salvage systems e.g. postoperative autologous wound drains or combined unwashed ICS/PCS devices.

This policy has been written to support the implementation and use of washed ICS. It may also be applicable when washed ICS devices are used in the pre and/or postoperative environment (e.g. Accident and Emergency, recovery, ward etc) and for devices specifically designed for combined washed ICS/PCS.

Contents

1 Introduction

Whilst allogeneic (donated) blood is an essential adjunct to health care, it is an expensive and limited resource (subject to the threat of future shortages) and can present a source of risk for patients, in particular the risk of “wrong blood” incidents as reported by the Serious Hazards of Transfusion (SHOT) scheme.

The Blood Health National Oversight Group (BHNOG) was established in 2017 to oversee the implementation of the Blood Health Plan for Wales.

The following is taken from the NHS Wales Blood Health Plan 2021. ‘Blood and blood component transfusions are essential, life saving treatments used everyday within NHS Wales. Transfusion however is not a risk free procedure and there is always a possibility of transfusion reactions or transmission of infection. It is therefore critical that blood and blood components are only given when needed and where no other suitable alternative exists.’

As part of BHNOGs implementation of the Blood Health Plan, Cell Salvage (CS) is seen as an integral part of delivering this through patient blood management.

Intraoperative cell salvage (ICS) is used routinely in some areas of surgical practice. The technique involves aspirating blood lost within the surgical field into a collection reservoir. Blood is mixed with an anticoagulant solution containing either heparin or citrate to prevent clotting. A modified aspiration line is used to deliver the anticoagulant to the tip of the suction. As blood enters the collection reservoir it is filtered to remove large particulate debris. The salvaged blood is then centrifuged and washed to produce red blood cells suspended in saline for reinfusion to the patient. The waste products (plasma, platelets, anticoagulant etc) are removed during processing and the washed red blood cells are transferred to a reinfusion bag. When used appropriately, by adequately trained staff, ICS is a simple, safe and cost-effective method of reducing allogeneic transfusion.

2 Policy Statement

Utilising appropriate alternatives to blood transfusion is cost-effective and complies with clinical governance requirements.

The collection and re-infusion of autologous red blood cells provides an important contribution to reducing the demand for allogeneic blood. However, it is only one aspect of a strategic approach to safe and appropriate transfusion practice.

3 Aims

The use of cell salvage will be based on an individual patients' risk/benefit and that clinical judgement by the clinicians involved in that persons care is exercised. Therefore, the aim of this policy is to provide information that will allow clinicians to utilise ICS in a safe and effective manner and to safely identify suitable patients undergoing elective and / or emergency surgical procedures where ICS could be used.

4 Objectives

The objectives of this policy are to provide a rational and practical framework on which to maximise patient safety during ICS by:

- Promoting safer transfusion as part of clinical governance responsibilities.
- Assisting clinical staff in the identification of patients and procedures considered suitable for ICS and outlining the indications and contraindications.
- Assisting clinical staff to provide appropriate advice on options for treatment, particularly where patients are anxious about risks associated with donor blood.
- Providing clear written information about the risks and benefits of autologous transfusions from blood salvaged intraoperatively.
- Assisting clinical staff to minimise avoidable/potential risks of autologous transfusions from blood salvaged intraoperatively.

5 Responsibilities

Overall responsibility for the provision of ICS is under the remit of the Hospital Transfusion Committee (HTC). A clinical lead for the trust must be identified who reports to the HTC. There must also be a coordinator for cell salvage at each site that CS is used (usually an ODP), who oversee a competence-based training programme for all involved staff. Data collection and audit is usually done via the transfusion practitioners.
Responsibilities associated with ICS include:

- Prescribing responsibilities.
- Labelling responsibilities.
- Individual responsibilities.
- Documentation responsibilities.

Prescribing Responsibilities
Salvaged blood reinfusion should be prescribed / authorised by the responsible clinician on the documentation approved by the Organisation.

Labelling Responsibilities
The reinfusion bag should be labelled as soon as is reasonably practical (i.e. when the patient is in theatre or as soon as the processing set is loaded if a "collect only" system has been used initially). If a "collect only" system has been set up, it is recommended as best practice that the collection reservoir is labelled, this label can then be transferred to the reinfusion bag when the processing set is loaded. The patient details should be handwritten on the label from the patient's identification band (attached to the patient) and include the following:

- Full name.
- Date of birth.
- Unique identification number.
- Expiry date and time of the salvaged blood.
- The statement "Untested Blood –"For Autologous Use Only"[11].

Addressograph labels should not be used because of the known associated risks[5].

Individual Responsibilities
Individual staff must ensure that they are adequately trained and competent in the use of the ICS system and their individual responsibilities according to their area of work i.e. operator, anaesthetic, scrub, recovery and ward staff. Individual staff should ensure they are adequately trained and competent in the use of ICS in each of the specialities they work in. Staff should not use equipment for which they have not been trained and competency assessed.

Documentation Responsibilities

Staff should ensure that documentation (including all appropriate labelling) accurately reflects the ICS process. The documentation record should include:

- The ICS audit form (Appendix I).
- The autologous transfusion label should be completed and attached to the reinfusion bag.
- At the time of reinfusion of the salvaged blood, the peel out section on the autologous transfusion label should be completed and attached in the appropriate place in the patient's clinical records on the 'All Wales Transfusion Record (AWTR)'.
- Appropriate labelling of heparin saline anticoagulant or citrate (ACD-A) at the start of the procedure.
- Bedside pre-transfusion checks and patient observations prior to and during ICS blood reinfusion should be performed and recorded in the same way as for the transfusion of allogeneic blood (Blood Transfusion Procedure for Prince Charles Hospital and Associated Sites – Merthyr & Cynon Locality & Blood Transfusion Procedure for Royal Glamorgan Hospital and Associated sites – Princess of Wales Bridgend policies)
- Additional observations are at the discretion of the clinical staff based on an individual patient assessment.
- Adverse incidents should be documented in the patient's clinical records and reported as in section 12.

6 Training

- Key personnel should be identified in each clinical area as a contact for communication and training. This person will usually be the ODP lead for ICS within each hospital, who will maintain training records of staff who have received training in the use of the ICS device (a copy of this record may be sent to the Clinical Lead for ICS for central collation).

- Theoretical and practical training must be undertaken, and staff must be competency assessed before they set up or operate ICS equipment without supervision. (See the ICS competency Assessment Workbook below)

- Individual staff should receive training in the indications, contraindications and technical differences specific to their speciality/specialities. If a member of staff moves from one speciality to another, it is good practice for training needs to be identified and addressed prior to the staff member using ICS in their new clinical environment.

- Staff carrying out ICS for Jehovah's Witness patients requesting continuous connectivity should have received training and have been competency assessed in preparing the equipment and blood for reinfusion in accordance with the patients' religious beliefs, prior to carrying out the procedure. See appendix IX and the Association of Anaesthetists 2018 guidance.

- An ICS Competency Assessment Workbook is available via the Transfusion Practice section of the JPAC website, at: www.transfusionguidelines.org.uk (see also Appendix II). It is strongly recommended that once assessed as competent, individuals keep an ongoing log (similar to that in the ICS Competency Assessment Workbook) of all the ICS procedures they carry out.

- Operators have a professional responsibility / accountability to ensure they are up to date and competent in relation to their practice. Where practical supervised training during real cases is ideal, however this might not be possible. As such regular training (such as using out of date blood form blood bank) is expected to be undertaken annually.

- Update training is recommended under the following circumstances:
  - Any reasonable length of time without practical use of the ICS device.
  - A learning need is identified by an individual member of staff or supervisor.
  - Changes in the product from the manufacturer or a change in the product due to the Organisation trialling/purchasing new products.
  - Changes to national and/or local guidelines relating to any aspect of autologous transfusion (including changes to the Organisation's Blood Transfusion Policy).
  - Following an incident or error.

Individual Responsibilities

Individual staff should ensure that they are adequately trained and competent in the use of the ICS system used and their individual responsibilities according to their area of work, i.e. operator, anaesthetic, scrub, recovery and ward staff.

7 Indications and Patient Selection

- Cell salvage is indicated in any surgical procedure, either planned or urgent, where the benefit results in the reduction or complete avoidance of allogeneic red cell transfusion.

  Procedure related factors:
  - Collection of blood for potential cell salvage ('collect only' mode) should be considered for surgical procedures where the blood loss may exceed 500ml (or > 10% of the calculated total blood volume in adults, or > 8ml/kg (>10% of the calculated total blood volume) in children weighing > 10kg.

  Patient related factors:
  - Refusal of allogeneic blood.
  - Difficulty in obtaining compatible allogeneic blood.
  - Patients with a low haemoglobin.
  - Increased risk of bleeding.

  Each patient presenting for surgery will have a greater or lesser risk of bleeding and consequently a varying threshold for requiring a transfusion. Any decision to use cell salvage should therefore be made on an individual patient basis.

- Patient selection for ICS is at the discretion of the surgeon and anaesthetist caring for the patient.

- If the surgical procedure to be carried out is associated with any of the contraindications as listed in section 8, the potential risks and hazards should be discussed with the patient and their agreement to undergo ICS documented in the patient's clinical records.

- **Indications for Cell Salvage in obstetrics**

  The association of anaesthetists guidelines recommend that Cell Salvage is not used routinely for caesarean section based on the current evidence, be it elective, urgent or emergency.

  However, Cell salvage should be considered in 'collect only' mode in patients who are anaemic before surgery or if there is unanticipated ongoing bleeding during surgery. If a decision is made to use it because a woman declines autologous transfusion or significant blood loss is anticipated, the risk and benefits should be discussed with the woman.'

  Also, the Association of Anaesthetists do not recommend routine use of double suction or Leucodepleted Filters (LDFs) in obstetric practice.

The NICE guidance "Intraoperative blood cell salvage in obstetrics" recommends that "whenever possible, the woman understands what is involved and the theoretical risks, and agrees (consents) to have the procedure". When obtaining formal consent for a caesarean section, the obstetrician or anaesthetist should discuss the advantages and risks of ICS with the woman and document clearly her agreement to undergo the procedure. Such detailed consent may not be practicable in an emergency, in which case the use of ICS should be fully discussed with the mother following the procedure.

Patient selection for ICS is at the discretion of the obstetrician and anaesthetist caring for the woman. The type of obstetric cases that could be considered for selection include:

- **Emergency situations**
  - Ruptured ectopic pregnancy
  - Placental abruption
  - Any emergency caesarean section where there is:
    - An anticipated blood loss of >1000mls

  Or where any of the following are present:
    - Risk factors for bleeding
    - Low pre-operative Haemoglobin
    - Rare blood group / multiple antibodies
    - The woman has objections to receiving allogeneic blood but has consented to receiving cell salvage blood
    - Surgical management of postpartum haemorrhage

- **Elective situations**
  - Women with an anticipated blood loss of >1000ml e.g. placenta accreta, placenta praevia, large uterine fibroids, coagulation disorders, multiple (three or more) repeat caesarean sections and/or other predictable causes of Major Obstetric Haemorrhage (MOH).
  - Women who for religious or other reasons refuse allogeneic blood and have consented to the use of Intraoperative Cell Salvage in elective or emergency bleeding situations or in significant anaemia[8]

- **RhD immunisation**
  The association of anaesthetists noted 'there is evidence of fetomaternal haemorrhage [with ICS], which supports the concerns regarding increased risk of haemolytic disease in future pregnancies' and 'emphasises the need for strict adherence to anti-D guide-lines in units using CS'

  This policy suggests following the trust's "Guideline for the use of Anti-D Immunoglobulin in Rhesus Negative Women' or the BCSH guideline for the use of anti-D immunoglobulin for the prevention of

haemolytic disease of the fetus and newborn can be found with the following link.
https://onlinelibrary.wiley.com/doi/full/10.1111/tme.12091

- **Cell Salvage after vaginal delivery**
  There is very little data on the use of cell salvage after vaginal delivery and the practicalities of its use in this situation may make it difficult. However one study suggests its potential, with red cell fetal contamination and bacterial contamination comparable to that of caesarean sections. Given this, prophylactic antibiotics should be given. The use of leucodepleted filters in this particular scenario is not covered by any guidelines. LDF's are generally encouraged in contaminated fields, however given the slow infusion rates their use in life threatening haemorrhage may not be practical.

  In summary, although there is little data recommending its use, there is also little data suggesting it unsafe, and when faced with a life threatening haemorrhage a pragmatic approach to its use is justifiable.

8 Contraindications, controversial areas and warnings

The risk/benefit ratio of ICS should be assessed for each individual patient by the surgeon and anaesthetist responsible for the patient's care.

Contraindications

ICS should not be used in the following situations:

- Patient refusal
- Heparin induced thrombocytopenia when heparin is the anticoagulant of choice (a citrate containing anticoagulant solution may be used instead).
- Lack of trained/competent staff

Controversial Areas

- **Infected and contaminated fields (Association of Anaesthetists: cell salvage for perioperative blood conservation 2018)**

  '**There is no absolute contraindication to ICS in this setting**. Its use is, however, controversial, because ICS might (theoretically) worsen sepsis by introducing infective agents and toxins recovered in the operative field. Conversely, CS reduces exposure to allogeneic blood, which may increase the incidence of postoperative infection through immunomodulation [Washing of collected blood and the use of LDFs removes most bacteria, but this effect is probably dependent on the level of contamination. There is no conclusive evidence that CS worsens sepsis, prognosis or the risk of other specific complications when used in contaminated fields, including major trauma surgery. We recommend that the use of cell salvage in cancer surgery and infected fields should be considered on a case by case basis. Whenever possible, patients in whom cell savage is used should be counselled and asked whether they consent to the procedure being used. Leucodepletion filters should be used for blood re-infusion.'

- **Cancer surgery (Association of Anaesthetists: cell salvage for perioperative blood conservation 2018)**

  Despite theoretical concern, **there is no absolute contraindication to CS in cancer surgery.** Its use is controversial because malignant cells are often present in the operative field, can be found in salvaged blood and may, theoretically, metastasise after re-infusion. Circulating malignant cells are often present in cancer patients undergoing surgery, regardless of CS use, and very few of these cells are thought capable of causing metastases. The number of malignant cells in salvaged blood can be reduced by the use of LDFs, with no apparent adverse effect on the quality of the product. The use of LDFs has not

been shown to be associated with either bradykinin or leukotriene generation in cell-salvaged blood. Cell salvage may reduce or eliminate exposure to allogeneic blood, which has been associated with immunosuppression and cancer recurrence. One major disadvantage of LDFs is that the rate of flow through them is considerably slower, and therefore clinicians may need to assess the benefit of quicker transfusion without a LDF vs. its use. In summary, despite theoretical risks and benefits, there is no conclusive evidence that CS can induce metastases or affect cancer prognosis. The theoretical risk of inducing metastatic spread (unproven) is offset by reduced allogeneic transfusion and immunomodulation, which is proven. As a result, many clinicians do offer cell salvage to patients undergoing major cancer surgery. The Working Party (Association of Anaesthetists) recommends that potential risks and benefits should be discussed with patients before cancer surgery, and specific consent obtained.'

Guidance on the use of ICS in radical prostatectomy and radical cystectomy is available from NICE.

The decision to use ICS in the presence of malignant disease should be made by the surgeon and anaesthetist in consultation with the patient.

- **Obstetrics (Association of Anaesthetists: cell salvage for perioperative blood conservation 2018)**

'Obstetric haemorrhage is a significant cause of maternal mortality and the leading cause of maternal morbidity in the UK. National surveys show that CS is a resource that is being used more frequently in UK obstetric units. Re-infusion rates and cost effectiveness are variable and directly associated with larger volumes of blood loss. Despite the growing availability of equipment and safety endorsements for its use, challenges remain in providing CS in an obstetric surgical setting. Haemorrhage associated with emergency operative delivery is often not predictable, rapid and occurs out of hours.
The SALVO trial (cell salvage during caesarean section: a randomised controlled trial) is the largest study to date (n = 3054) examining the role of CS in caesarean section. SALVO did not find a significant difference in donor transfusion rate in caesarean section or a cost benefit argument for routinely setting up a complete collection and re-transfusion system. However, institutional level costs are still dependent on case volume, expected levels of blood loss per case and initial investment costs. Use of strategies such as swab washing to improve collection rates should be considered to contribute to the complex analysis of cost effectiveness locally. Furthermore, although SALVO's exploratory analysis in cases of malplacentation did not demonstrate effectiveness, the trial cannot be used to justify or refute the use of CS in cases of anticipated torrential haemorrhage. As in previous studies, there is evidence of fetomaternal haemorrhage, which supports the concerns regarding increased risk of haemolytic disease in future pregnancies.
The group (Association of Anaesthetists) recommends further research on the long-term consequences of allo-immunisation to RhD and other red cell antigens following the use of CS and emphasises the need for strict adherence to anti-D guidelines in units using CS.

Use of leucocyte depletion filters and the requirement for separate suction for blood have now been questioned by some advocates of the technology A double suction technique – one waste sucker for amniotic fluid and another sucker attached to the cell salvage device for suctioning any blood lost – may reduce initial contamination, although in-vitro evidence consistently demonstrates that the cell salvage/filtration process can effectively remove plasma phase elements of amniotic fluid whatever the initial load.
Use of leucocyte depletion filters (LDF) should be considered but these slow re-infusion rates and evidence for their effectiveness in this setting is mixed. Because they are adhesion filters, blood cannot be forced through them and they may become saturated during use, requiring replacement, and have the potential to cause bradykinin-mediated hypotension.

The Working Party (of The Association of Anaesthetists) decided not to recommend routine use of double suction or LDFs in obstetric practice.

Therefore, the Working Party recommends that CS is not used routinely for caesarean section based on the current evidence, be it elective, urgent or emergency.

Cell salvage should be considered in 'collect only' mode in patients who are anaemic before surgery or if there is unanticipated ongoing bleeding during surgery. If a decision is made to use it because a woman declines autologous transfusion or significant blood loss is anticipated, the risk and benefits should be discussed with the woman.'

- **Trauma/Orthopaedics (Association of Anaesthetists: cell salvage for perioperative blood conservation 2018)**

'Intra-operative CS should be considered in all patients undergoing orthopaedic or trauma surgery when blood loss is expected to be > 500 ml. If bone cement is used, then CS should not be used while cement is being applied and can be resumed when the cement is fully set. For revision surgery, when metalwork may be in situ, such as previously instrumented spinal surgery, there is evidence that standard 40 micron filters do not eliminate the smallest fragments of titanium, so caution should be exercised. However, we (Association of Anaesthetists) still recommend that CS is considered in such cases, with the proviso that standard suction is used until the surgical field has been irrigated and all metal fragments removed. Also, CS should not be used while the surgical field is contaminated with antibiotics, iodine or topical clotting agents, but its use may be resumed once these have been washed away.'

- **Paediatrics (Association of Anaesthetists: cell salvage for perioperative blood conservation 2018)**

In many cases the volume of blood collected may not be of sufficient quantity to be processed. 'The Working Party (Association of Anaesthetists) recommends that CS should be considered at least in 'collect only' mode when

blood loss > 8 ml/kg (equivalent to approximately > 10% of total blood volume) is anticipated and the child's weight is > 10 kg.

- **Sickle Cell Disease** (see below)

Warnings

- ICS should be temporarily discontinued when substances not licensed for Intravenous (IV) use are used within the surgical field and could potentially be aspirated into the collection reservoir. The standard theatre suction should be used to aspirate the surgical field and the wound should be irrigated with copious IV normal saline (0.9% NaCl) before resuming ICS.

  Examples of non-IV materials that should not be aspirated into the ICS system include:
  - Antibiotics not licensed for IV use.
  - Iodine.
  - Topical Clotting Agents.
  - Orthopaedic Cement.

- **Gastric/pancreatic secretions** should not be aspirated into the system as they may cause enzymatic haemolysis and are not reliably removed by the washing procedure.

- **Pleural effusions** should not be aspirated and should be drained prior to cell salvage. However, blood which subsequently accumulates in the pleural space may be aspirated.

- **Sickle Cell disease (SCD)** - There are concerns relating to the use of ICS in patients with SCD (homozygous disease) and current national guidance does not cover these patients. The underlying concern is the possibility that cell salvage blood re-administered to the patient in question will sickle and further reduce oxygen-carrying capacity. Limited case reports describe no useable red blood cells recovered with a high percentage of cells showing characteristic sickle shape under light microscopy after processing. As such this document cannot support its use in those with homozygous sickle cell disease.

  Sickle cell trait (or carrier – heterozygous) is a relative contraindication - Several reports have been published describing successful cell salvage use in patients with sickle cell trait (or carrier – heterozygous), although one study has shown as much as 50% sickled cells after processing of sickle cell trait blood. Again current national guidance does not cover this situation.

  Therefore the decision to use cell salvage in the presence of sickle cell trait should be made on an individual patient basis and where possible appropriate informed consent should be taken before its use. It may be advisable to perform

a blood film of salvaged blood to assess the amount of sickling present and advice should be sought from Haematology.

Cautions

- The use of Hartmann's Solution will inhibit the action of citrate based anticoagulants (e.g. ACD) if used as an irrigant or wash solution. IV normal saline (0.9% NaCl) should be used as the wash solution

- Air will be present in the primary reinfusion bag when it is still connected to the cell salvage device or when it has been disconnected but air has not been evacuated. Where possible, all air should be evacuated from the primary reinfusion bag prior to reinfusion. Manufacturers advise NOT to use a pressure cuff as there is a risk of air embolus and some devices may also detect a back pressure if the reinfusion line is open.

- Manual mode – It is recommended that ICS devices are not run in manual mode as this may lead to reduced quality, insufficient washing of the final red blood cell product and the possible reinfusion of potentially harmful contaminants e.g. heparin. ICS devices should be run in automatic mode wherever possible. Manual mode should only be used when the benefits of doing so outweigh the risks e.g. emergency situations where the need to reinfuse the red cells quickly outweighs the risks associated with running the device in manual mode.

9 Patient Information

- Patients considered likely to have ICS during planned surgery should receive information about ICS before their operation. The process should be discussed with the patient pre-operatively whenever possible and the discussion documented in the patient's clinical records. Written information may be useful – for example the Patient Information Leaflet "Please Ask About Cell Salvage" (Appendix IV).

- For patients undergoing emergency surgery, the use of ICS is at the discretion of the surgeon and anaesthetist responsible for the patient's care when it cannot be discussed with the patient prior to surgery.

10 Conditions for Using ICS

Use of the ICS Equipment

- The ICS system should be used in accordance with the manufacturer's guidelines (Appendix V).
- All procedures should be carried out in accordance with the hospital's ICS policy and procedural documents.
- The ICS system should be routinely run in automatic mode (see Cautions - section 8).
- Contraindications should be considered as per this document.
- All staff that set up or operate ICS systems should receive theoretical and practical training and should have completed the ICS Competency Assessment Workbook (Appendix II).
- Staff should comply with hospital policies for infection control, management of sharps and blood transfusion.
- Clean / non-touch / aseptic technique should be used as appropriate, to reduce the risk of infection.

Anticoagulant

- The type of anticoagulant used should be documented in accordance with organisational policy.
- Anticoagulant prepared by the operator (e.g. heparin saline) should be labelled clearly to avoid error.

Wash Solution

- IV normal saline (0.9% NaCl) should be used as the wash solution.
- The minimum wash volume, as outlined in the manufacturers' guidelines (Appendix V) for the size of the centrifuge bowl in use and the type of surgical procedure, should be used in all but the most urgent situations.

Swab Washing

- Blood soaked swabs should be soaked in IV normal saline (0.9% NaCl).
- Gently compress the swabs to express any residual solution before discarding.

- Aspirate the swab wash solution into the cell salvage reservoir using the suction line.

- Consider evacuating the swab wash every 2 hours to avoid stagnation; it should not be left for more than 6 hours without processing.

Labelling

- All salvaged blood should be labelled.

- Labels should be handwritten. Pre-printed "addressograph" labels should not be used.

- Labelling information should include:
  - Full name.
  - Date of birth.
  - Unique identification number.
  - Expiry date and time of the salvaged blood.
  - The statement "Untested Blood – For Autologous Use Only"[11].

- To avoid errors in patient identification, an autologous transfusion label, such as that in appendix VI, should be completed at the patient's side when the patient has arrived in theatre i.e. the reinfusion bag should not be pre-labelled prior to the patient's arrival in theatre or labelled after the patient has left theatre. The patient's details must be taken from the identification band attached to the patient and not from any clinical records or charts that may be present in the operating theatre. All fields on the label should be completed in full.

- If the system has been set up as a "collect only" system (collection reservoir and aspiration and anticoagulant line only), the collection reservoir should be labelled in accordance with the above instructions for labelling a reinfusion bag. If a processing set is subsequently loaded into the machine, the autologous label on the collection reservoir should be transferred onto the reinfusion bag immediately or a new label completed (as above).

Re-infusion

- ICS may be set up as a "closed-circuit" system. Blood is aspirated from the surgical field, processed and transferred to a reinfusion bag. The reinfusion bag is simultaneously connected to the patients IV cannula via an appropriate filter. The person administering the reinfusion adjusts the rate at which the red cells are reinfused using a clamp on the administration set and by adjusting the height of the reinfusion bag. A pressure cuff should not be applied, to increase the flow rate, because of the risk of air embolism. The same reinfusion bag may fill and empty many times during an operation.

- Alternatively, ICS may be set up without simultaneous connection of the reinfusion bag to the patient (as above). In this case, the reinfusion bag is disconnected from the ICS device when it is full or at the end of the surgical

procedure and is subsequently connected and reinfused to the patient as in the "closed-circuit" system.

- A filter, appropriate to the type of surgery, should be used for reinfusion. A blood administration set containing a 200µm filter is suitable in most cases. Alternatively, a 40µm microaggregate blood filter can be used. A leukocyte depletion filter can be considered during reinfusion for cancer surgery and when blood is salvaged from an infected field. When ICS is proposed to be used in such cases, an explanation should be given to the patient of the potential risks and benefits and specific consent should be obtained. (Association of Anaesthetists 2018)

- Reinfusion of the salvaged blood should follow standard blood transfusion practice. The responsible clinician should authorise salvaged blood for reinfusion in the same manner as for allogeneic blood.

- The patient details on the reinfusion bag must be carefully checked against the details on the identification band attached to the patient before connecting the reinfusion bag to the patient. Positive Patient Identification must be confirmed prior to reinfusion commencing.

- The reinfusion of salvaged blood should be documented in the appropriate section of the patient's clinical record ('All Wales Transfusion Record (AWTR)'). The autologous transfusion label, as in Appendix VI, contains a peel out section which should be completed at the time of reinfusion and can be used for this purpose.

Storage

- ICS blood must not be stored.

- The reinfusion bag should be kept beside the patient at all times.

- The reinfusion bag must not be placed into a refrigerator.

Expiry

- The collection, processing and reinfusion of salvaged blood should be completed within the timeframes as recommended by the manufacturer. This should be in accordance with guidance from the American Association of Blood Banks (AABB) and the Organisation's Transfusion Policy.

The AABB Guidelines state the expiry times for cell salvaged blood as follows:

  - Intraoperative Cell Salvage: 4 hours from the completion of processing (applicable for both washed ICS and combined washed ICS / PCS devices during the intraoperative phase).
  - Postoperative Cell Salvage: 6 hours from the start of collection (applicable when intraoperative cell salvage devices are used to salvage blood postoperatively and for combined washed ICS / PCS devices during postoperative cell salvage).

- For ICS, processing should begin as soon as there is sufficient blood in the collection reservoir. The expiry time is calculated as 4 hours from the completion of processing.

- For combined washed ICS/PCS devices, two separate expiry times should be recorded using the guidance above. One for blood salvaged intraoperatively and one for blood salvage postoperatively.

- Any blood that has not been transfused within the timeframe specified in the guidelines should be disposed of in accordance with local policy for dealing with liquid bio hazardous waste.

- These time frames are in-use limits and not “shelf life” storage limits. ICS blood must not be stored away from the patient.

Documentation

- The collection and reinfusion of salvaged blood should be accurately documented on an appropriate form such as that in Appendix I.

- The use of a generic autologous transfusion label is recommended (Appendix V; the peel out section of the label is completed and attached to the patient’s clinical record upon reinfusion of the salvaged blood.

- Adverse incidents and Serious Adverse Events should be documented / reported (see Section 13).

- Bedside pre-transfusion checks and patient observations prior to and during autologous blood reinfusion should be performed and recorded in the same way as transfusion of allogeneic blood - in accordance with the Organisation’s Blood Transfusion Policy. Additional observations are at the discretion of the clinical staff based on an individual patient assessment.

- The Organisation should ensure that adequate records are retained in all cases where ICS is used.

Disposal of used ICS equipment

- Following use, all ICS disposable equipment should be disposed of in accordance with the Organisation’s Health and Safety Policy for disposable of equipment contaminated with blood.

Cleaning and Disinfection of ICS Machines

- Following use, the cell salvage machine should be cleaned in accordance with the manufacturers’ guidance and the Organisation’s Infection Control Policy), including procedures for cleaning equipment following high risk cases.

- Following contamination of the equipment internally, the equipment should be removed from use, identified as a potential biohazard and referred to the manufacturer.

Maintenance of Equipment

- All ICS equipment should be serviced regularly in accordance with the manufacturer's recommendations. A maintenance record and fault log (Appendix VI should be kept for each machine.

11 The Management of Massive Reinfusion

As with the transfusion of large volumes of allogeneic red cells, the return of large volumes of salvaged red blood cells will coincide with the depletion of platelets and clotting factors associated with massive blood loss.

In the event of a massive reinfusion of salvaged red blood cells, it is vital to consider the need for additional appropriate transfusion support e.g. platelets, fresh frozen plasma and cryoprecipitate.

Staff should be alert to a large blood loss into the collection reservoir and report this to the surgeon and / or anaesthetist.

12 Adverse Event Reporting

- Technical problems with the ICS device should be reported to the manufacturer.

- Serious Adverse Events must be reported to the clinical lead for ICS and the Organisation's Transfusion Practitioner. Any adverse events relating to the ICS device must be reported via the DATIX system. Additionally, where appropriate, reporting to the relevant external bodies should be undertaken e.g. Serious Hazards of Transfusion (SHOT), Medicine and Healthcare Products Regulatory Agency (MHRA), especially if the incident has led to, or were it to occur again could lead to, death, life-threatening illness or injury. Other minor safety or quality incidents (caused by human error) should also be reported as these can help demonstrate trends or highlight inadequate manufacturing or supply systems, instructions and / or training[12].

- Adverse events should be documented in the patients' clinical records.

- Examples of Adverse Events include:
    - Severe reaction on reinfusion of salvaged blood.
    - Non-labelling / incorrect labelling of salvaged blood.
    - Equipment malfunction.
    - Communication failure leading to inappropriate reinfusion of the salvaged blood e.g. contamination occurred within the surgical field and this was not communicated to the operator / anaesthetist.

Reporting of ICS incidents to SHOT is encouraged. The SHOT data collection form can be downloaded at: http://www.shotuk.org/sabre/. Once completed, this should be forwarded to the Hospital Transfusion Team or the ICS lead clinician.

13 Resources

The provision of safe ICS requires adequate resources for the formal, documented training of all staff who set up or operate the equipment and for the regular maintenance and prompt repair of all ICS equipment.

14 Implementation and Distribution of the Policy

- This policy document should be circulated to all relevant personnel and implemented in all areas which may be involved in ICS e.g.
    - Medical Director
    - Nursing Director
    - Consultant Lead for Transfusion
    - Clinical Lead for ICS
    - Theatre lead for ICS
    - Theatre trainer for ICS
    - Directorate Manager for Theatre
    - Transfusion Practitioner
    - Jehovah's Witness Hospital Liaison

- The procedure document will be reviewed at timely intervals and when new information becomes available.

- Guidance on and queries relating to the document should be addressed to the Organisation's clinical lead for ICS.

15 Acknowledgements

- Maria Roberts, Transfusion Practitioner, Welsh Blood Service/ Cardiff and Vale HB for her original Postoperative Cell Salvage procedure document on which this policy has been based.

- The members of the UK Cell Salvage Action Group.

- Royal Brompton & Harefield NHS Trust – Policy for the provision of Perioperative Red Cell Salvage.

- St Mary's NHS Trust – Obstetric Intraoperative Cell Salvage Guidelines[15].

- Association of Anaesthetists: cell salvage for perioperative blood conservation 2018

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Appendix I

Audit Proforma

Example of an Audit Proforma for Intraoperative Cell Salvage

All Wales Intraoperative Cell Salvage Data Collection Form

This form should be completed for every intraoperative cell salvage procedure EVEN if the blood collected is not processed

Please complete in BLOCK CAPITALS

DO NOT write on anything placed on top of this form

1. Hospital Details

Name of Hospital

2. Patient Details

Hospital/NHS Number	Age at time of surgery
Surname	
First Name	
D.O.B	
Address Addressographs may be used (top copy only)	☐ Male ☐ Female

3. Procedure Details

Name of procedure	*(tick one)*	*(tick any that apply)*
Date of operation / /	☐ Elective	☐ Malignancy
Surgeon	☐ Emergency	☐ Obstetrics
Anaesthetist	*(tick one)*	☐ Infected fields
Cell Salvage Operator(s)	☐ In hours	☐ Trauma
	☐ Out of hours	☐ Jehovah's Witness

4. Cell Saver Equipment Used

Machine *(tick one)*	☐ CATS ☐ Cell Saver Elite ☐ Autolog ☐ Electa ☐ Other *(specify)* ☐ Cell Saver 5 ☐ OrthoPat ☐ BRAT ☐ Xtra	
Disposables used	Collection Reservoir ☐ Yes ☐ No Processing Set ☐ Yes ☐ No	Please affix disposable lot number stickers in this space
Anticoagulant *(tick one)*	☐ ACD-A (citrate) ☐ Heparin	
Reinfusion Filter *(tick one)*	☐ 40µ filter ☐ None ☐ Leucodepletion filter ☐ Lipid Filter ☐ Other *(specify)*	

5. Salvaged Blood Volume Details

Was the collected blood processed? ☐ Yes ☐ No *(If no, go to Section 6)*

Processing Details

Intra-op processed (ml)		Time collection started	
Anticoagulant used (ml)		Time re-infusion started	
Swab wash used (ml)		Was the processed blood reinfused to the patient? ☐ Yes ☐ No *(If no, please complete Section 6)*	
Irrigation used (ml)			
Total volume of RBCs (ml)		If yes, what volume of blood was reinfused (ml)?	

Additional Information

Was ICS continued into the postoperative period (wound drainage)? ☐ Yes ☐ No	
If yes, what volume of processed wound drain blood was reinfused to the patient (ml)?	

6. Reason If Blood Was Not Processed/Reinfused

☐ Inadequate volume collected	☐ Training purposes	☐ Technical/Procedural problem *(Section 7)*	☐ Patient died

7. Technical Problems

Technical	☐ Machine	☐ Bowl	☐ Harness	☐ Software
Procedural	☐ Operator error	☐ Communication failure	☐ Training issue	☐ Unforeseen circumstance
Other *(please specify)*				

8. Total No. of Allogeneic Units Transfused During Hospital Stay

Red cells		Platelets (adult dose)	
FFP		Other	
Cryoprecipitate			

9. Hb

	g/L	Date
Pre-Op Hb		
Discharge		

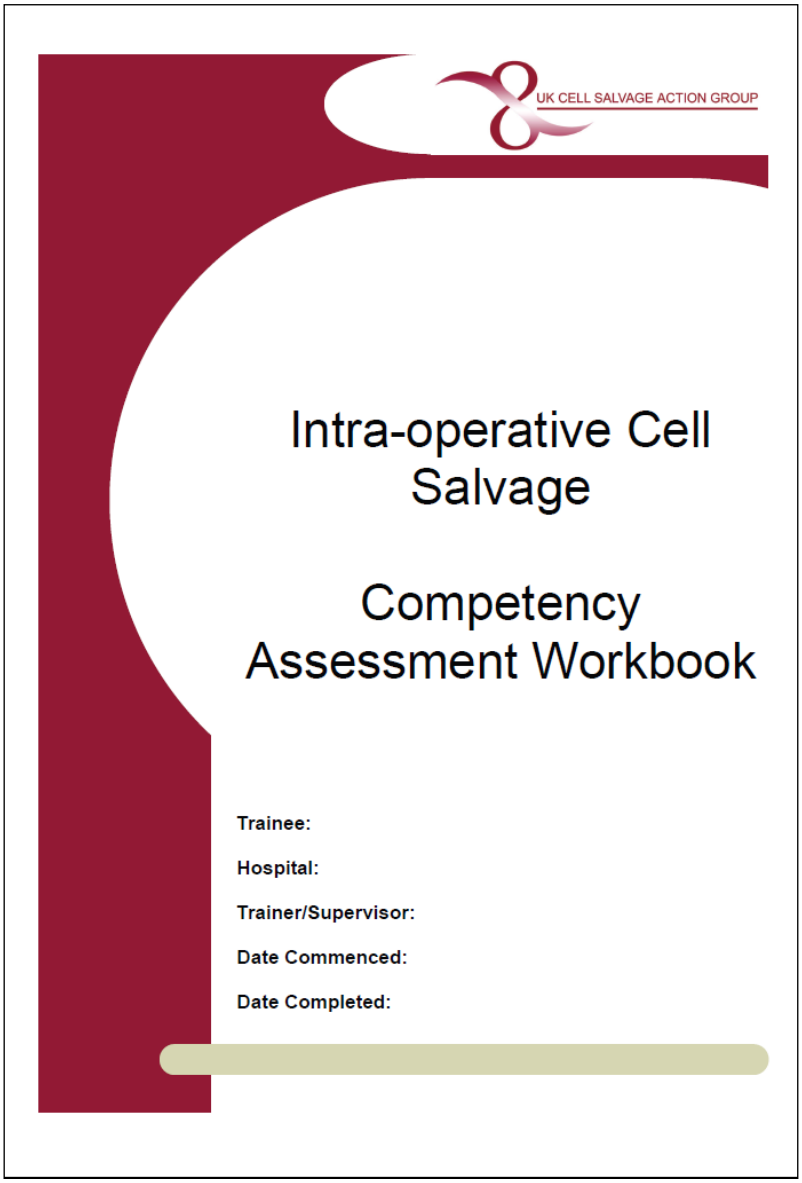
Top Copy – Hospital **Bottom Copy – Welsh Blood Service**

All Wales ICS Form Version 7 Revised May 2014

Appendix II

Intra-operative Cell Salvage Competency Assessment Workbook

The Intraoperative Cell Salvage Competency Assessment Workbook is available via the Transfusion Practice section of the JPAC website, at: www.transfusionguidelines.org.uk or for hospitals in England, the distribution hub, at: https://ww3.access-24.co.uk/Login.aspx?ReturnUrl=%2fWebSite%2fStock%2fHome%2fStock.aspx
User names and passwords are available from your RTC Administrator or NHSBT Customer Service Support Team (01865 381042).



Appendix III

"Cell Salvage" Patient Information Leaflet

The following patient information leaflet can be downloaded at:
http://www.transfusionguidelines.org.uk/transfusion-practice/uk-cell-salvage-action-group/patient-factsheet

Please ask

UK CELL SALVAGE ACTION GROUP
FACTSHEET

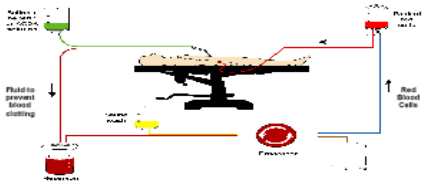
about CELL SALVAGE

What is Cell Salvage?
Cell salvage is a way of collecting the blood that is lost during, or just after your operation, so that it can be given back to you. It is sometimes called autologous blood transfusion (using your own blood).

How is it done?
There are two different types of cell salvage:

Blood collected during your operation. This is called Intraoperative Cell Salvage
Blood that is lost during your operation is collected using a cell salvage machine. This machine separates the different parts of your blood and collects just the red cells (which carry oxygen). These red cells can then be given back to you during or just after your operation. Your red cells will only ever be given to you and will never be used for someone else.

This type of cell salvage is only suitable for some operations. Ask your doctor or nurse if it is suitable for you.



Blood collected after your operation. This is called Postoperative Cell Salvage
Sometimes blood that is lost immediately after your operation can also be collected and returned to you (usually when you are back on the ward). This is called postoperative cell salvage and is usually used after certain operations e.g. knee surgery.

What are the benefits of cell salvage?
During certain operations you may lose some blood. Cell salvage can reduce the chance that you will need a transfusion of blood donated by a blood donor. This therefore reduces the very small risks associated with receiving this type of blood.

If you are a blood donor and have received only salvaged blood and no donor blood, it may be possible for you to continue as a blood donor if you wish to, once you have recovered from your surgery. (Patients who have received donor blood since January 1st 1980 cannot be blood donors as a precaution against the possible spread of vCJD by transfusion).

Jeff underwent hip resurfacing surgery and received autologous cell salvaged blood.

He did not require donor blood and recovered remarkably quickly returning to his managerial position at the head of a busy accident repair centre. He also continues with his active lifestyle golfing, fishing and looking after his grandchildren.

Which patients could benefit from cell salvage?
Patients having certain operations e.g. cardiac (heart) surgery. Cell salvage may reduce the amount of donor blood they need.

Patients who do not wish to receive blood from a blood donor.

Why isn't it suitable for everyone?
Not all operations result in enough blood loss to enable cell salvage to be used. For some operations cell salvage is not recommended e.g. some bowel surgery.

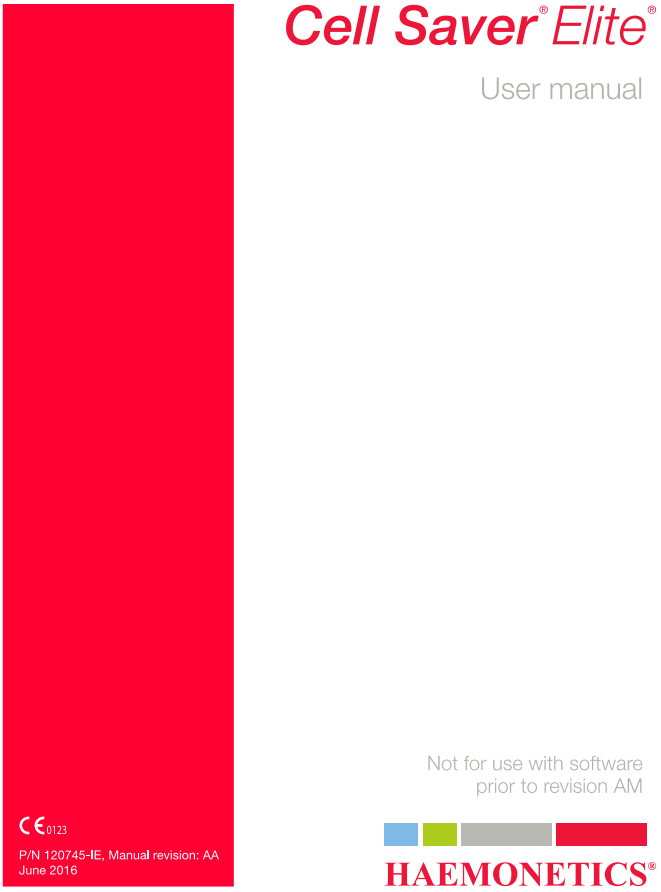
Where can I get more information?
Ask your hospital doctor or nurse if cell salvage is available in your hospital.

If it is, your doctor or nurse will be able to advise you if it is suitable for you and for the operation you are having.

For further information about cell salvage visit:
www.transfusionguidelines.org.uk/ics/index.htm

Appendix IV

Manufacturers' Guidelines



https://www.haemonetics.com/-/media/files/cell-saver-manuals/120745-ie-aa-pdf.pdf

Appendix V

Autologous Transfusion Label

The following autologous transfusion label is available from your device manufacturer.
N.B. cable ties or equivalents are not provided.

AUTOLOGOUS TRANSFUSION

Untested Blood

For AUTOLOGOUS use only

Complete this section and affix to the reinfusion bag / system

Unique patient ID Nº.....

Last name .....

First name .....

DOB .....

Operator name (Print) .....

Expires / Reinfuse by: Date.....Time.....

(Calculate expiry time in accordance with national & manufacturer guidelines and local policy)

Type of autologous blood: (*Delete as appropriate)

Intra-op Cell Salvage (Washed/Filtered*) ☐

Post-op Cell Salvage (Washed/Filtered*) ☐

Other: ..... ☐

Transfusion Record

Complete this section and affix in clinical record. Enter date/time/signature below, each time the reinfusion bag/system is connected to the patient

Unique patient ID Nº.....

Full name .....

Type of **autologous** blood: (*Delete as appropriate)

Intra-op Cell Salvage (Washed/Filtered*) ☐

Post-op Cell Salvage (Washed/Filtered*) ☐

Other-..... ☐

Checked & administered by			
Reinfusion started (date/ time)			
Reinfusion stopped/end time			

Total volume reinfused ..... mls

Version 3 April 2015

STOP!

Label and reinfuse in accordance with national and manufacturer guidelines and local cell salvage / transfusion policies.

DO NOT separate autologous blood from the patient

DO NOT refrigerate

Before reinfusion :

1. Confirm the patient's identification (where possible ask the patient to state their NAME and DOB)
2. Check the information on the label matches the information on the patient identity band

No identity band - No transfusion

3. Check the 'expires/reinfuse by' date **and** time of the blood
4. If any details do not match, **Do not transfuse**
5. If a transfusion reaction is suspected, STOP the reinfusion and seek medical advice
6. Repeat steps 1 - 5 each time the reinfusion bag/system is reconnected to the patient

Reverse of adhesive label

Original design by UK Cell Salvage Action Group

Appendix VI

Fault log

Intraoperative Cell Salvage Machine Fault Log

Machine: _____

Serial Number: _____

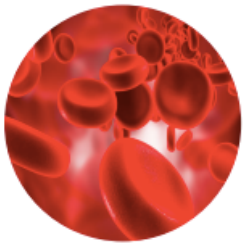
Date	Nature of Fault	Manufacturer Contacted (Y/N)	Corrective Action	signature

Appendix VII

Transfusion Leaflets

Please see below:
https://nhsbtdbe.blob.core.windows.net/umbraco-assets-corp/23998/inf1580-1-receiving-a-blood-transfusion-print-friendly.pdf

Page 1 of 7



Information for patients and their families, carers and guardians

Receiving a Blood Transfusion

Important information for all patients who may need a red cell, platelet or plasma transfusion.

Additional supplementary information for individual blood components, specific patient groups and younger children can be accessed via your local transfusion service.

BH-08: Issue 1
Effective: 01/07/2021 Review Date: 01/07/24

Appendix IX

Cell Salvage in Jehovahs Witness Patient Requesting Continuous Connectivity

UK CELL SALVAGE ACTION GROUP
TECHNICAL FACTSHEET

CELL SALVAGE IN JEHOVAH'S WITNESS PATIENTS

ICS Technical Factsheet Number 6

AREA of APPLICATION

Jehovah's Witnesses (JW) regard blood as sacred. On the basis of this deeply held core value, they decline treatment with allogeneic (donor) blood (red cells, white cells, platelets, and plasma).

With regard to autologous transfusion JW patients make a personal decision whether or not to accept such. Autologous transfusions that may be acceptable include all forms of perioperative/intraoperative blood salvage (cell salvage), haemodilution and postoperative blood salvage. While machines, systems and arrangements vary, each patient will decide how his/her own blood will be handled in the course of a surgical procedure, medical test, or current therapy. Predeposit (PAD) is not acceptable to Jehovah's Witnesses.

Among those prepared to accept autologous procedures, some may specifically request that the system be set up to allow for continuous connectivity. In such cases, the details outlined below should prove helpful. If no such specific request is received, then the equipment/machinery may be used in the usual way providing informed consent has been obtained (informed consent for autologous techniques should be obtained for all patients where it is intended that they be used).

STAFF

The patient's surgical team and all staff involved in the cell salvage process.

PROCEDURE:

Setting up continuous connectivity
Although there will be technical differences between devices, the same general principles apply.

1. Set up the machine for collection and processing with standard disposables (in bowl-based machines consider using a low volume bowl to reduce blood stasis).

2. Prime the circuit with saline ensuring that saline enters the reinfusion bag and the collection reservoir (remember to account for this volume when recording the final reinfusion volume).

3. Attach an appropriate blood administration set to the reinfusion bag. Prime the administration set and connect to the patient via a cannula for reinfusion. Once established, the connection between the patient and the reinfusion bag must not be broken. (Figure 1).

Version 3 Reviewed October 2012

4. Whilst surgery is ongoing, administer the saline at the slowest rate possible to maintain patency of the cannula until processed blood is available.

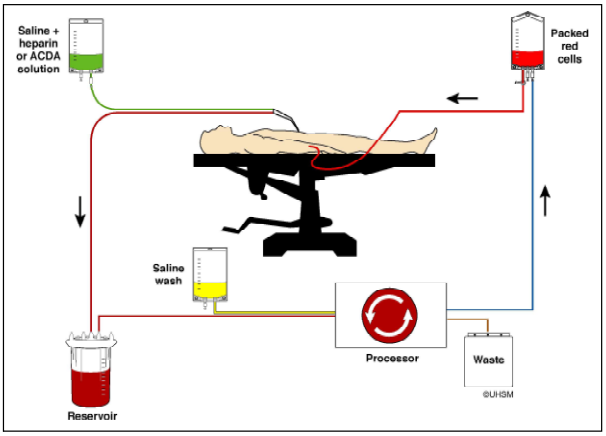


Figure 1. Representation of a continuous circuit

Special requirements

In some cases a leucocyte depletion filter may be needed for reinfusion of the salvaged blood. A standard giving set should be set up with a 3-way tap in line before blood collection begins. The giving set should be primed with saline to complete the circuit. When a volume of blood is ready to be reinfused, the leucocyte depletion filter can be spiked into the second reinfusion port on the reinfusion bag and primed. This is then attached to the 3-way tap, without breaking the circuit. Likewise, because the filters have a maximum throughput of 450mls, a new filter can be added if necessary by replacing the original giving set while leaving the original filter connected. (Figure 2).

The filter should <u>not</u> be flushed with saline after filtration of the salvaged blood

When blood loss is rapid, the flow rate through the filter may not be sufficient to transfuse large volumes of blood quickly. Using a filter in each port will double the flow rate. During management of life threatening haemorrhage in a JW patient, if the reinfusion rate of salvaged blood is too slow, even when using two leucodepletion filters, it may be necessary to make a clinical decision to isolate the leucodepletion filter from the circuit and replace with a standard blood administration set, so that blood can be transfused rapidly to prevent exsanguination. This must be done without breaking the circuit in order to maintain continuity.

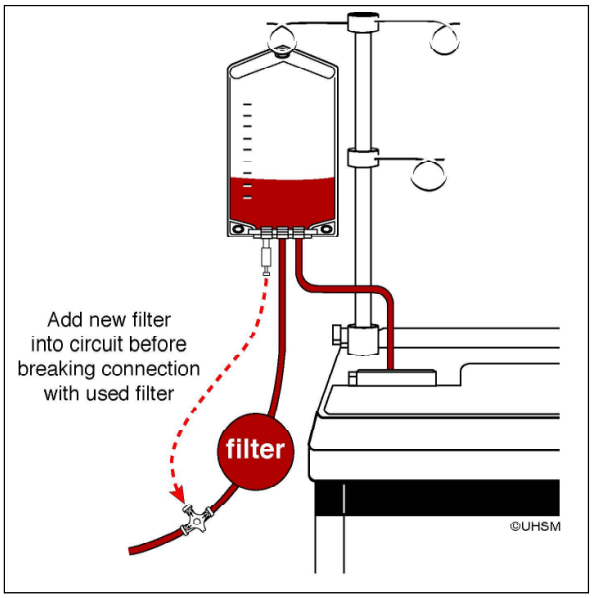


Figure 2. Replacing a filter without breaking continuity

This fact sheet has been verified by representatives of the Jehovah's Witness community.

The information contained in this ICS Technical Factsheet has been sourced from members of the UK Cell Salvage Action Group (UKCSAG) and is generally agreed to be good practice. The UKCSAG does not accept any legal responsibility for errors or omissions.

Version 3 Reviewed October 2012