PROVISION OF INTRAOPERATIVE CELL SALVAGE POLICY

POLICY

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Approving Body	Hospital Transfusion Committee		
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For publication to external SFH website	**Positive confirmation received from the approving body that the content does not risk the safety of patients or the public:**		
	YES	**NO**	**N/A**
	X		
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Legal and/or Accreditation Implications	Required for future Anaesthesia Clinical Services Accreditation		
Target Audience	• Clinical Staff who have completed the E-learning module. • Clinical staff trained and competent in operating the autologous transfusion system.		
Review Date	January 2026		
Sponsor (Position)	Medical Director		
Author (Position & Name)	• Dr Jeremy Andrews – Clinical Lead for Cell Savage and; • Dawn Ellis – Cell Salvage Lead		
Lead Division/ Directorate	Surgery		
Lead Specialty/ Service/ Department	Anaesthetics, Critical Care and CSSD – Anaesthetics/ Theatres and Recovery		
Position of Person able to provide Further Guidance/Information	• Dr Jeremy Andrews - Clinical Lead for Cell Savage and; • Dawn Ellis - Cell Salvage Lead		

Associated Documents/ Information	**Date Associated Documents/ Information was reviewed**
1. Reinfusion checklist for intraoperative Cell Salvage (ICS) – EXAMPLE shown in Appendix C 2. Autologous transfusion Label - EXAMPLE Shown in Appendix D 3. Audit proforma – EXAMPLE shown in Appendix E 4. Fault log – EXAMPLE shown in Appendix F 5. Patient information leaflet PITRANS001 – EXAMPLE shown in Appendix I 6. Quality Assurance of Machines Appendix J (to include EXAMPLE label)	*03/01/2019*
Template control	June 2020

CONTENTS

1.0 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) steering group[1].

The Health Service Circular (HCS), "Better Blood Transfusion: Safe and Appropriate Use of Blood" together with the most recent national initiative Patient Blood Management recommend that effective alternatives to allogeneic blood transfusion should be explored, including the appropriate use of autologous blood transfusion techniques such as Intraoperative Cell Salvage (ICS) which is used routinely in some areas of surgical practice.[2-3].

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 IV 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.

Blood salvaged from a cell saver has the advantage over banked blood of reducing disease transmission, reducing the risk of alloimmunisation, normal red blood cell oxygen carriage and 2,3-DPG (Diphosphoglycerate) levels, normal potassium concentration, removing activated clotting factors and inflammatory cytokines, being accepted by most patients that due to moral or religious reasons refuse to have donated blood and has an Haematocrit of 40-60%. It is difficult to find cases where salvaged blood had led to adverse events, unless there had been a technical fault or the operator was at fault.

When used appropriately, by adequately trained staff, ICS is a simple, safe and cost-effective method of reducing allogeneic transfusion[4-5.]

2.0 POLICY STATEMENT

This policy sets out the way in which ICS should be implemented and monitored across the Trust. It is only one facet of a comprehensive approach to blood conservation.

The use of intraoperative cell salvage is a clinical decision and each case should be considered on an individual basis at the discretion of the surgeon and anaesthetist caring for the patient. This is the policy in use. However there may be individual situations where the risk benefit ratio of intraoperative cell salvage is in the best interests of the patient to operate outside this policy e.g. uncontrollable haemorrhage when the demand on the blood bank may outstrip the supply. The interpretation and application of policy remains the responsibility of the individual practitioner.

Objectives

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

3.1 Promoting safer transfusion as part of clinical governance responsibilities.
3.2 Assisting clinical staff to provide appropriate advice on options for treatment, particularly where patients are anxious about risks associated with donor blood.
3.3 Providing clear written information about the risks and benefits of autologous transfusion's from blood salvaged intraoperatively.
3.4 Assisting clinical staff to minimise avoidable/potential risks of autologous transfusion's from blood salvaged intraoperatively.

Scope

Staff Group, Clinical Areas and Patient groups

This policy is for the use of ICS in the main operating rooms and obstetric theatre at Kings Mill Hospital for all adult patients; however Cell Salvage can also be used for paediatrics and adolescents following clinical discussion. It also covers its use in theatre recovery, Intensive Critical Care Unit and the Emergency Department

3.0 DEFINITIONS/ ABBREVIATIONS

Collector	all employees who have been trained to set up the equipment and system for the collection of blood used in intraoperative cell salvage.
Designated Operator	the trained qualified member of staff who has undertaken the required training and been assessed in practice to set up and process blood collected using the intraoperative cell salvage system.
Autologous blood transfusion	a transfusion to an individual of blood collected from him or herself
Allogeneic blood transfusion'	a transfusion to an individual of blood donated by another individual
Alloimmunisation	the production of antibodies directed against the foreign antigens
Closed system	the ICS is set up as a continuous system at the request of patients with religious requirements
DPG	Diphosphoglycerate
C.A.T.	Continual auto-transfusion device (the intraoperative cell salvage system)

4.0 ROLES AND RESPONSIBILITIES

4.1 All staff involved in any aspect of cell salvage are responsible for:

- Adherence to this policy
- Reporting any adverse events
- Ensuring that they are adequately trained and competent in the use of the ICS system and are aware of their individual responsibilities according to their area of work/speciality. I.e. operator, anaesthetic, scrub, recovery and ward staff.

Staff should not use the ICS system if their training and /or competency assessment has elapsed

4.2 Clinical lead

- The overall ICS programme for the Trust
- Development of and adherence to protocols guiding the use of cell salvage
- Organising a formalised training programme
- Quality assurance
- Providing information to the Hospital Transfusion Committee (HTC) as required

4.3 Anaesthetists/Surgeons

- Discussing with the patient prior to the procedure (wherever possible) the use of the cell saver using the Trusts patient information leaflet-PITRANS 001
- Documenting in the patient's case-notes and on the Theatre consent form all consent decisions for ICS whether accepted or refused.
- Contacting the theatre coordinator and completing the booking form as soon as a patient is identified as suitable for ICS to arrange a trained operator and ensure a machine is available.
- Alerting the ODP team leader or deputy if a 'closed system' is required.
- Ensuring the ODP is aware of any substances introduced into the surgical field and its suitability for ICS

4.4 Cell Salvage Lead

- Acting as a contact for communication and training.
- Arranging for ICS to be available at the Anaesthetists/Surgeons request
- Maintaining training records of staff who have received training in the use of the ICS device (held in the theatre coordinators office/ theatre educators office) and sending a copy to the training department to add to the staff members electronic staff record (ESR)
- Maintain service and Quality Assurance records for the Cell Salvage machines

4.5 Cell Salvage Practitioner

- Setting up the equipment and system for the collection of blood used in ICS
- Processing blood collected using the ICS system
- Complete Quality Assurance for the Cell salvage machines. Appendix J

4.6 Registered Practitioner or Assistant Nurse Practitioner

- Setting up the equipment and system for the collection of blood used in ICS
- If salvaged blood is collected –being aware of the contraindications, suction tubes and the process for swab washing

4.7 Recovery Practitioner

- Monitoring and recording the reinfusion of salvaged blood following the Trusts Transfusion Policy

A copy of the names of those who have been trained and assessed in practice to be a cell salvage operator must be kept available in the theatre coordinators office at all times

5.0 APPROVAL

Following consultation this revised policy (v3.0) has been approved by the trust's Hospital Transfusion Committee.

6.0 DOCUMENT REQUIREMENTS (POLICY NARRATIVE)

6.1 Indications and Patient Selection

ICS systems may be used in elective and/or emergency surgical procedures where the surgical field is not contaminated by faecal or infective matter and where no other contraindications exist (see section 7.2 and appendix B).

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

Providing that none of the contraindications listed in section 7.2 and appendix B exist, patients to be considered for ICS include:

- Adult patients undergoing elective or emergency surgical procedures where the anticipated blood loss is greater than 20% of the patient's estimated blood volume

This will include:

- Revision of prosthetic hip or knee joint
- Total hip replacement
- Knee replacement (if no Tourniquet is used)
- Technically difficult Caesarean Sections

- Traumatic liver or spleen injury not associated with perforated bowel
- Benign urological surgery
- Adult undergoing elective or emergency surgical procedures that have risk factors for bleeding or low preoperative Haemoglobin levels.
- Blood loss from a Haemothorax directly into a chest drain bottle (only when collected into normal saline 0.9% for intravenous use)
- Patients who have rare blood groups or multiple antibodies for whom it may be difficult to obtain allogeneic blood.
- Patients who, for moral, religious or other reasons, are unwilling to receive allogeneic blood and have given their consent to receiving autologous blood collected using ICS (all such decisions should be documented in the patient's clinical records). Reference should be made to the patient's Advanced Medical Directive where one exists.

If the surgical procedure to be carried out for patients in the latter two categories is associated with any of the contraindications as listed in section 7.2, the potential risks and hazards should be discussed with the patient and their agreement to undergo ICS documented in the patient's clinical records.

ALL patients considered likely to have ICS during planned surgery should receive information about ICS before their operation (Patient information leaflet PITRANS 001 (V2) can be used). The process should be discussed with the patient pre-operatively whenever possible and the discussion documented in the patient's clinical records.

If it is not possible to discuss the process with the patient pre-operatively (e.g. in an emergency procedure), it is good practice to inform the patient retrospectively.

Autologous transfusion may be accepted for use by Jehovah Witnesses, but must be discussed pre-operatively with the individual and their decision documented accordingly. If the Jehovah's Witness patient does not already have an advance decision document or another document indicating treatments that are acceptable, this should also be discussed. Cell salvage itself will not prevent patients from donating blood once they have fully recovered from their operation, but associated perioperative treatments that necessitate deferral as a blood donor should be discussed with the patient. This includes transfusion of allogeneic blood.

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

6.2 Contraindications, Warnings and cautions

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:

- Bowel contents in the surgical field*
- Heparin induced thrombocytopenia when heparin is the anticoagulant of choice (a citrate containing anticoagulant solution may be used instead)
- Patient declines the procedure
- Lack of trained, competent staff
- Infected surgical fields - the use of ICS in the presence of infection may result in bacterial contamination of the salvaged blood. The aspiration of blood from an infected site should be avoided and antibiotics should be given as appropriate.
- Sickle cell disease - there are concerns relating to the use of ICS in patients with sickle cell disease (SCD). Several reports have been published describing successful cell salvage use in patients with sickle cell trait. However, in SCD, 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. The use of ICS in patients with abnormal red cell disorders should be made on a clinical, individual patient basis.

*in the event of a catastrophic bleed where it is deemed necessary to use ICS consider

- Initial evacuation of the solid abdominal contents
- Additional washing (increase the volume of IV normal saline (0.9% NaCl)
- Ensure the use of broad spectrum antibiotics

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
- Distilled water
- Fibrin adhesives
- Hydrogen peroxide
- Betadine/Chlorhexidine

The use of ICS in the presence of **infection** may result in bacterial contamination of the salvaged blood. The aspiration of blood from an infected site should be avoided and antibiotics should be given as appropriate.

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.

Metal fragments from implants can be present in the surgical field in some orthopaedic procedures, e.g. although metallosis is rare, with an incidence of around 5% for metal on metal joint implants, it is unclear as to how successful ICS devices are in removing metal fragments. If there is evidence of metallosis, in most situations cell salvage should be avoided or the risk benefit carefully assessed in cases of high blood loss

The use of ICS in patients undergoing surgery for **malignant disease** is not recommended by the manufacturers of ICS devices. This is due to concern about the possibility of malignant cells being re-infused and giving rise to metastases. However, there are now a number of reports in the literature of the use of ICS in cancer surgery without obviously leading to early metastasis[8-10] and some hospitals now use ICS routinely during surgery for malignant disease. Aspiration of blood from around the tumour site should be avoided to minimise contamination of salvaged blood with malignant cells and the salvaged blood may be re-infused through a leukocyte reduction filter to minimise the reinfusion of any malignant cells which may have been aspirated into the collection reservoir.

Guidance on the use of ICS in radical prostatectomy and radical cystectomy is available from the National Institute for Health and Clinical Excellence[11]

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

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.

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 re-infuse the red cells quickly outweighs the risks associated with running the device in manual mode.

N.B. For a full list of contraindications refer to Appendix B

6.3 Practicalities-Blood collection

An aseptic technique should be maintained at ALL times

6.3.1 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 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.

6.3.2 Data proforma – example Appendix E

A data collection form MUST be completed for all cases where ICS is used regardless of whether the blood is processed or not. A copy to go in patients notes and a copy to enable data entry onto the ICS database held on Theatres shared drive.

6.3.3 Labelling example Appendix F

All salvaged blood **must** be hand labelled using the autologous blood transfusion label 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).

Addressograph labels **should not** be used because of the known associated risks[6]

All fields **must** be completed. **The patient's details should 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.

The peel out section of the label is to be attached to the patient's clinical record upon reinfusion of the salvaged blood.

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

For unknown patients follow the trusts Positive Patient Identification Policy to complete the patient's details.

6.4 Practicalities-Blood Processing

6.4.1 Decision to process

The decision to process must be based on adequate blood loss/volume of salvaged blood collected, further anticipated blood loss during the procedure and patient factors e.g. Low Hb, anticipated postoperative benefit. The decision to process must be weighed against the cost. It may be judged that the volume of blood produced will not be worth the cost of processing it. This decision rest with the cell salvage practitioner, after consultation with the surgeon and anaesthetist.

6.4.2 Closed circuit

For patients with religious requirements the ICS can be set up as a closed system

6.5 Practicalities-Blood Reinfusion

6.5.1 Prescribing

Salvaged blood reinfusion **must** be prescribed by the responsible clinician on the Blood Component authorisation and administration sheet

6.5.2 Reinfusion

Salvaged blood presents the same health and safety hazards as banked blood, therefore the same universal infection control precautions must be maintained. Used blood bags from the cell salvage procedure should be discarded in accordance with SFH Waste Management Policy.

Consideration should be given to the use of a leucocyte depletion filter for Obstetric or Malignant cases. Lipid depletion filters are also available which can be used for orthopaedics.

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. *(*SFH Transfusion Policy, Procedures & Guidelines - Document 4, Procedure for administration and traceability of blood)

The patient details on the reinfusion bag **should** 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 Pre-reinfusion checks sheet (example, appendix C) must be completed for each case

6.5.3 "Storage"

ICS blood **must not** be stored.
The reinfusion bag **must be** kept beside the patient at all times.
The reinfusion bag **must not** be placed into a refrigerator.
Reinfusion of salvaged blood must be completed within 4 hours from the completion of processing. 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 i.e**. the time when blood first enters the reinfusion bag.**

Any blood that has not been transfused within the timeframe **must** be disposed of in accordance with SFH Waste Management Policy.

6.6 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 resulting in a potential coagulopathy

In the event of a massive reinfusion (after 1000mls) 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. Blood samples should be taken and sent to Pathology in accordance with the Trust massive haemorrhage protocol

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

6.7 Quality Assurance

6.7.1 Personnel

The Trust ICS lead is responsible for ensuring that a safe and effective ICS service is provided by ensuring quality assurance systems are fully implemented.
Competent personnel in sufficient numbers must be available to provide the ICS service, including for out of hours cases if applicable.

6.7.2 Equipment

All ICS equipment should be appropriately maintained and annually serviced in accordance with the manufacturer's recommendations. Records of services, maintenance and faults must be retained for the life time of the machine. A Quality assurance sample should be sent for each machine every three months following QA process. Appendix J

Cleaning of the ICS equipment must be carried out after every use and in accordance with the manufacturers' guidance, ensuring that the centrifuge is cleaned with a moist cloth and thoroughly dried in order to avoid false alarm triggers by the leakage detector. Specific attention must be given to the PRC sensor and the two light sources as these must always be kept clean.

A cleaning record should be completed following each use and kept with each machine.
The Trust's Infection Control Policy must be adhered to and all disposable equipment should be disposed of in accordance with the SFH Waste Management Policy
The C.A.T.S *Smart* autotransfusion device must be stored vertically in a well-ventilated room with little variation in temperature. The range of the storage temperature is from –15 °C to +50 °C.

6.8 Adverse Event Reporting

ANY Adverse Events must be reported in accordance with SFH Incident Reporting Policy via the DATIX system to the cell salvage lead who will inform the ICS clinical lead and Transfusion Practitioner

The Transfusion Practitioner or a member of the Hospital Transfusion team (HTT) where appropriate will report any incident that has led to or, were it to occur again, could lead to death, life-threatening illness or injury to Serious Hazards of Transfusion (SHOT) and the Medicine and the Healthcare products Regulatory Agency (MHRA). [13]

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, or inadequate instructions and/or training[13].

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.
- Lack of trained competent staff to provide an ICS service for a pre-planned elective case

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

Technical problems with the ICS should be reported to the manufacturer via the ICS clinical lead.

7.0 MONITORING COMPLIANCE AND EFFECTIVENESS

Minimum Requirement to be Monitored (WHAT – element of compliance or effectiveness within the document will be monitored)	Responsible Individual (WHO – is going to monitor this element)	Process for Monitoring e.g. Audit (HOW – will this element be monitored (method used))	Frequency of Monitoring (WHEN – will this element be monitored (frequency/ how often))	Responsible Individual or Committee/ Group for Review of Results (WHERE – Which individual/ committee or group will this be reported to, in what format (eg verbal, formal report etc) and by who)
Compliance with policy	The clinical lead for intra-operative cell salvage.	The policy will be monitored on an ongoing basis through data collected via the Data collection proforma and the Trusts DATIX incident reporting scheme	Quarterly	A report will be completed quarterly and delivered to HTC. The report will identify the amount of salvaged blood collected and transfused and any non-compliance with this policy.
Completion of E-Learning record	The clinical lead for ICS and the cell salvage lead.	When ICS is booked the E-Learning record for the staff utilising the machine will be checked for completion and validity.	At the time of the booking cell salvage	HTC review data.

8.0 TRAINING AND IMPLEMENTATION

All members of staff identified as a cell salvage operator will:

- complete the learn cell salvage e-learning module via www.learnbloodtransfusion.org.uk AND read the ICS Education workbook prior to performing intraoperative cell salvage
- Be observed and supported in practice by a competent operator a minimum of 3 occasions until they are assessed as competent using the ICS competency assessment workbook.
- only set up or operate ICS equipment without supervision AFTER they have been deemed competent
- Maintain their competence by setting up and processing salvaged blood on a minimum of 5 occasions per year. Staff should keep an individual on-going log of all procedures they are involved in
- repeat their competency assessment every Three years.

All members of theatre staff qualified and unqualified may train to set up the cell salvage machine to **collect blood only**. This requires they attend a training session and demonstrate good practice to a competent operator.

Any newly appointed staff who have had experience in the use of cell salvage must be assessed in practice before they can act in this role without supervision

Update training is recommended under the following circumstances:

1. Where practical use of the ICS device exceeds one year.
2. A learning need is identified by an individual member of staff or supervisor.
3. The member of staff moves from one speciality to another.
4. Changes in the product from the manufacturer or a change in the product due to the Organisation trialling/purchasing new products.
5. Changes to national and/or local guidelines relating to any aspect of autologous transfusion (including changes to the Trusts Blood Transfusion Policy).

9.0 IMPACT ASSESSMENTS

- This document has been subject to an Equality Impact Assessment, see completed form at Appendix K
- This document has been subject to an Environmental Impact Assessment, see completed form at Appendix L

10.0 EVIDENCE BASE (Relevant Legislation/ National Guidance) AND RELATED SFHFT DOCUMENTS

1. Serious Hazards of Transfusion (SHOT) Report 2009.http://www.shotuk.org/wpcontent/uploads/2010/07/SHOT2009.pdf

2. Better Blood Transfusion: The Safe and Appropriate Use of Blood (2007) HSC 2007/001

3. Patient blood management- An evidence-based approach to patient care. (2013) National Transfusion Committee.

4. Murphy GJ, Rogers CS, Lansdowne WB, Channon I, Alwair H, Cohen A, Caputo M and Angelini GD (2005) Safety, efficacy, and cost of intraoperative cell salvage and autotransfusion after off-pump coronary artery bypass surgery: a randomized trial. *J Thorac Cardiovasc Surg*; 130(1); 20-8

5. James V (2004) A National Blood Conservation Strategy for the NBTC and NBS. http://www.dh.gov.uk/prod_consum_dh/idcplg?IdcService=GET_FILE&dID=26734&Rendition=Web

6. British Society for Haematology (2017). The administration of Blood Components. Transfusion Medicine:28,3-21.

7. British Committee for Standards in Haematology Blood Transfusion Task Force (1997) Guidelines for Autologous Transfusion II. Perioperative Haemodilution and Cell Salvage. *British Journal for Anaesthesia*; 78; 768-771.

8. Gray CL, Amling CL, Polston GR, Powell CR and Kane CJ (2001) Intraoperative cell salvage in radical retropubic prostatectomy. *Urology*; 58(5); 740-5.

9. Nieder AM, Carmack AJ, Sved PD, Kimm SS, Manoharan M and Soloway MS (2005) Intraoperative cell salvage during radical prostatectomy is not associated with greater biochemical recurrence rate. *Urology*; 65(4); 730-4.

10. Nieder AM, Manoharan M, Yang Y and Soloway MS (2007) Intraoperative Cell Salvage during radical cystectomy does not affect long term survival. *Urology*; 69(5); 881-4.

11. National Institute For Health & Clinical Excellence (NICE) (2008) Intra-operative Red Blood Cell Salvage During Radical Prostatectomy of Radical Cystectomy. http://www.nice.org.uk/nicemedia/live/11891/40380/40380.pdf

12. American Association of Blood Banks (AABB) (2005) Standards for Perioperative Autologous Blood Collection and Administration (2nd Edition)

13. Medicines and Healthcare products Regulatory Authority (MHRA) (2011) Device Bulletin: Reporting adverse incidents and disseminating medical device alerts. DB2011/01. http://www.mhra.gov.uk/home/idcplg?IdcService=GET_FILE&dDocName=CON111568&RevisionSelectionMethod=LatestReleased

14. Obstetric Intra-operative Cell Salvage Guidelines (Draft 1). *St Mary's NHS Trust* 2006.

15. The Association of Anaesthetists of Great Britain and Ireland (AAGBI) (2009) Blood transfusion and the Anaesthetist. Intraoperative Cell Salvage.

Related SFHFT Documents:

- Transfusion policy and associated procedures and guidelines (including massive haemorrhage/ blood loss in adults)
- Positive Patient Identification Policy

11.0 KEYWORDS

ICS, blood

12.0 APPENDICES

- As listed in contents table

Appendix A - INTRAOPERATIVE CELL SALVAGE IN OBSTERTICS

The main concern surrounding the use of ICS during obstetric haemorrhage is the risk of reinfusing foetal contaminants with the theoretical risk of causing amniotic fluid embolus.

ICS is being increasingly used in the UK in obstetrics for women at risk from massive obstetric haemorrhage during caesarean section. In the year 2005-06, 38% of UK maternity units used ICS, and 28% included the use of ICS in their Massive Obstetric Haemorrhage (MOH) protocol. Early theoretical concerns over amniotic fluid embolism have not been borne out in clinical practice, and 80% of maternity units identified lack of training, rather than safety concerns as the barrier to more frequent use of ICS.

The use of ICS in obstetrics has been endorsed by:

- Centre for Maternal and Child Enquiries (CMACE) (formerly CEMACH)Joint
- Association of Anaesthetists of Great Britain and Ireland/Obstetric Anaesthetists Association (AAGBI/OAA) Guidelines
- National Institute for Health and Clinical Excellence (NICE)

It is strongly recommended that any health care professional involved with obstetric ICS is familiar with all these guidelines.

Patient Selection and Preparation
Wherever possible, the advantages and risks of ICS and allogeneic (donor) blood transfusion should be discussed with the woman prior to undergoing an obstetric surgical procedure and documented on the consent form.

Indications for ICS
Case selection for ICS is at the discretion of the obstetrician and anaesthetist caring for the woman. The type of obstetric cases that should be considered for selection includes:

Emergency situations:

- Ruptured ectopic pregnancy -OPEN PROCEDURES ONLY
- Placental abruption
- Any emergency caesarean section where there is:
- An anticipated blood loss of >1000mls
- Surgical management of postpartum haemorrhage

Elective Situations:

- Risk factors for bleeding
- Low pre-operative haemoglobin
- Rare blood group / multiple antibodies
- Patients with an anticipated blood loss of >1,000mls e.g. placenta praevia with placenta accrete/increta or percreta, large uterine fibroids, and other predictable causes of MOH
- Women who, for religious or other reasons refuse allogeneic blood and have consented to the use of ICS in elective or emergency bleeding situations or in the presence of significant anaemia.

Practical measures necessary in obstetric ICS:

Amniotic fluid and use of Leukocyte Depletion Filter

Amniotic fluid should ideally not be aspirated into the ICS collection reservoir. A separate suction can be used to aspirate amniotic fluid prior to starting cell salvage. This recommendation will reduce the initial contamination, but it should be noted that the in vitro evidence suggests that the ICS process can effectively remove plasma phase elements of amniotic fluid (i.e. those less dense than red blood cells) whatever the initial load. Therefore, in life- threatening haemorrhage, a clinical decision to use ICS from the start of the procedure could be carefully considered and is supported by current in vitro evidence.

The UK Cell Salvage Action Group is aware that since 2008, when the paper by Sullivan et al[7] provided evidence that the one suction approach could be safely considered, a number of hospitals in the UK have adopted this approach irrespective of estimated blood loss.

The routine use of leukocyte depletion filters is not recommended. Their use has been associated with severe hypotension, particularly (but not exclusively) with concurrent use of a pressure device to speed up transfusion. It should be noted that leucocyte depletion filters are not validated for the removal of amniotic fluid and slow down the rate of reinfusion.

Rh immunisation and Kleihauer testing

In any pregnancy, if the mother is RhD negative and the fetus is RhD positive there is a danger of RhD immunisation if the maternal circulation is exposed to fetal red cells. Antibodies against the fetal red cells cause haemolytic disease of the newborn in subsequent pregnancies if untreated.

Therefore all RhD negative women who deliver an RhD positive baby will have a Kleihauer test performed post-delivery to establish the amount of fetal red cell exposure and ensure the recipient receives an appropriate dose of anti-D Immunoglobulin (usually 125 iu/ml of fetal blood).

The same protocol should be followed for Rh negative mothers who have undergone reinfusion of ICS blood. The presence of fetal red cells in the ICS blood is likely because the ICS device cannot distinguish fetal from maternal red cells.

The sample for Kleihauer testing should be taken 30 – 40 minutes after the reinfusion of the ICS blood

An initial dose of 1500IU anti-D is recommended and if indicated by the Kleihauer test a higher dose may need to be administrated.[9] Blood Bank will advise on this.

Administration of anti-D should occur within 72 hours of reinfusion of the salvaged blood

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Appendix B - Contraindications for Intraoperative Cell Salvage

Pharmacological Agents		
Substances	**Effects**	**Recommended Action**
Clotting agents		
Microfibrillar products examples: Avitene®, Helitene®, Oxycel®, Gelfoam® Powder, Instat® MCH	May cause platelet aggregation and clot formation. Reported to pass through a micro-aggregate filter into the bloodstream, causing emboli.	Avoid aspiration when product is being used. Resumption is an option after copious irrigation with 0.9% sodium chloride solution to an alternate suction source.
Sponge/Fabric materials examples: Surgicel™, NuKnit®, Gelfoam® Sponge, Helistat®, Instat™, Hemopad®, Super Stat®, HemoFoam®	Activates clotting sequence by acting as a contact agent. May clot off system.	Avoid aspiration in area where product is being used. Resumption is an option after copious irrigation with 0.9% sodium chloride solution to an alternate suction source.
Irrigating solutions		
Topical liquid examples: Thrombin–JMI™, Thrombostat®, Thrombogen®	Creates a fibrin clot by direct action on fibrinogen. May clot off system.	Avoid aspiration in area where product is being used. Resumption is an option after copious irrigation with 0.9% sodium chloride solution to an alternate suction source
Alcohol Betadine Chloropactin (Bleach) Hydrogen Peroxide Hypertonic Solution *Examples:* Sterile water Glycine	Causes red cell lysis	Avoid aspiration in area where product is being used. Resumption is an option after copious irrigation with 0.9% sodium chloride solution to an alternate suction source.
Antibiotics *Examples:* Bacitracin, Neomycin, Polymyxin	Can result in renal and neural toxicity if blood is not washed.	Increase amount of wash volume by 500ml.
Hypertonic Solution *Examples:* 3% NaCl, 7.5% NaCl, Dextrose solutions	Causes red cell crenation	Avoid aspiration in areawhere product is being used. Resumption is an option after copious irrigation with 0.9% sodium chloride solution to an alternate suction source

Substances	Effects	Recommended Action
Ringers Lactate (Hartmann's Solution) (in presence of citrate anticoagulant)* *Not an issue if heparin is the anticoagulant used.	Calcium present may bind with citrate, negating the anticoagulant effect.	Use 0.9% sodium chloride for irrigation instead of Hartmann's Solution.

Contaminants		
Substances	**Effects**	**Recommended Action**
Non biological contaminants		
Methylmethacrylate *Hardened Form*	May cause clogging of the system	Avoid aspiration in area where product is being used. Flush suction line occasionally with anticoagulant or normal saline to keep clear.
Methylmethacrylate *Liquid or Powder Form*	May cause circulatory collapse.	Avoid aspiration in area where product is being used. Resumption is an option after copious irrigation with 0.9% sodium chloride solution to an alternate suction source.
Biological contaminants		
Amniotic Fluid	Contains proteolytic enzymes that may activate clotting.	Amniotic fluid should ideally not be aspirated into the collection reservoir, but should be removed by separate suction prior to starting cell salvage. This recommendation will reduce the initial contamination, although in vitro evidence demonstrates that the cell salvage process can effectively remove plasma phase elements of amniotic fluid whatever the initial load. In life- threatening haemorrhage, therefore, a clinical decision to salvage red cells from the start of the procedure should be carefully considered. A number of hospitals in the UK have adopted the one suction approach irrespective of estimated blood loss.
Bone Chips/Bone Grafting Materials	May cause clogging of the system.	Flush suction line occasionally with anticoagulant solution or normal saline to keep clear.
Bowel Contents	Potential for bacteraemia.	Do not aspirate into system. Resumption is an option after copious irrigation with 0.9% sodium chloride solution to an alternate suction source.

Substances	Effects	Recommended Action
Fat	May not wash out completely.	Increase the wash volume. Reservoir and reinfusion bag should not be agitated (so that any fat can form a layer on top of the blood). A lipid filter may be used for reinfusion. If a visible layer of fat is present in

		the reservoir or reinfusion bag, processing/reinfusion of the salvaged blood should be halted to retain this layer in the reservoir/reinfusion bag.
Gastric and Pancreatic Fluid	Proteolytic enzyme may cause red cell lysis.	Do not aspirate into system. Resumption is an option after copious irrigation with 0.9% sodium chloride solution to an alternate suction source.
Infection at Site of Aspiration	Potential for bacteraemia.	Avoid aspiration in the presence of purulent material.
Skin Lesions (Infectious)	Incising a lesion may introduce organisms.	Blood recovery may be used if incision is not through a lesion.
Urine	Potential for bacteraemia if urinary tract infection is present.	Potential for bacteraemia if urinary tract infection is present.
Mucous Membrane Procedures Examples: Oral, nasal, vaginal	Potential for bacteraemia, due to normal resident bacteria.	Medical risks and benefits should be discussed between the surgeon and the clinician responsible for cell salvage.
Malignancy		
Primary at Operative site	Evidence indicates the procedure is safe and does not increase the incidence of metastatic disease. The decision to use cell salvage in malignancies must be left to the discretion of the surgeon.	Medical risks and benefits should be discussed between the surgeon and the lead clinician for cell salvage. Avoid blood recovery at tumour site. Consider the use of a leuoreduction filter.
Metastatic at Operative Site	Potential for further spread of disease.	Disease already systemic. Use at discretion of surgeon.
Phaeochromocytoma	Potential for marked hypertension due to high concentrations of catecholamines.	Avoid aspirating at the tumour site. Resumption is an option after copious irrigation with 0.9% sodium chloride solution to an alternate suction source.
Ascites	Tumour cells may be present	Avoid aspirating into the system if the surgical procedure is for ovarian malignancy.

Haematological Disorders		
Substances	**Effects**	**Recommended Action**
Sickle Cell Trait	Wash procedure produces potential sickling of salvaged cells.	Alert staff of potential for red cell sickling.
Confirmed Sickle Cell Anaemia	Wash procedure produces potential sickling of salvaged cells.	Medical risks and benefits should be discussed between the surgeon and the lead clinician for cell salvage.
Cold Agglutinin Antibody	Agglutination of red cells may occur at temperatures lower than 37°C(98.6°F).	If cold agglutinins show significant activity at room temperature recommend

	Cold agglutinins are in plasma and will be washed off.	transfusion of blood through a blood warmer.
Miscellaneous		
Titanium Alloy Prosthesis	Effect of darkened tissue or clots (blue/green/black) Surrounding prosthesis unknown to systemic circulation.	Discontinue cell salvage until the prosthesis and all darkened tissue have been removed. Resume after the wound has been irrigated with 0.9% sodium chloride solution to an alternate suction source.
Liposuction	Fat concentration in salvaged blood may be too high to remove by washing.	Avoid blood recovery.

The information contained in this appendix is from 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.

Appendix C

EXAMPLE

Reinfusion Checklist for Intraoperative Cell Salvage (ICS)

Pre-reinfusion Checks

Have any procedural issues been discussed with the clinician prior to prescription of the blood*?

☐ **Yes/Non-identified**

E.g. machine run in manual mode, suspected contamination

Has the blood been prescribed by a clinician?

☐ **Yes**

Does the blood appear suitable for reinfusion?

☐ **Yes**

E.g. there are no clots or visible debris

Is the blood within its expiry date and time/is there sufficient time to re-infuse the blood before it expires?

☐ **Yes**

Has positive patient identification been confirmed between the label on the ICS blood and the patient's identification band?

☐ **Yes**

Is a filter, appropriate to the type of surgery, available*?

☐ **Yes**

Have pre-transfusion observations been taken and documented in accordance with local policy?

☐ **Yes**

Is there any other reason why the reinfusion of the blood should not commence?

☐ **No**

E.g. the patient is a Jehovah's Witness who has not consented to the reinfusion of ICS blood

If ALL of the boxes are not ticked DO NOT begin reinfusion of the ICS blood

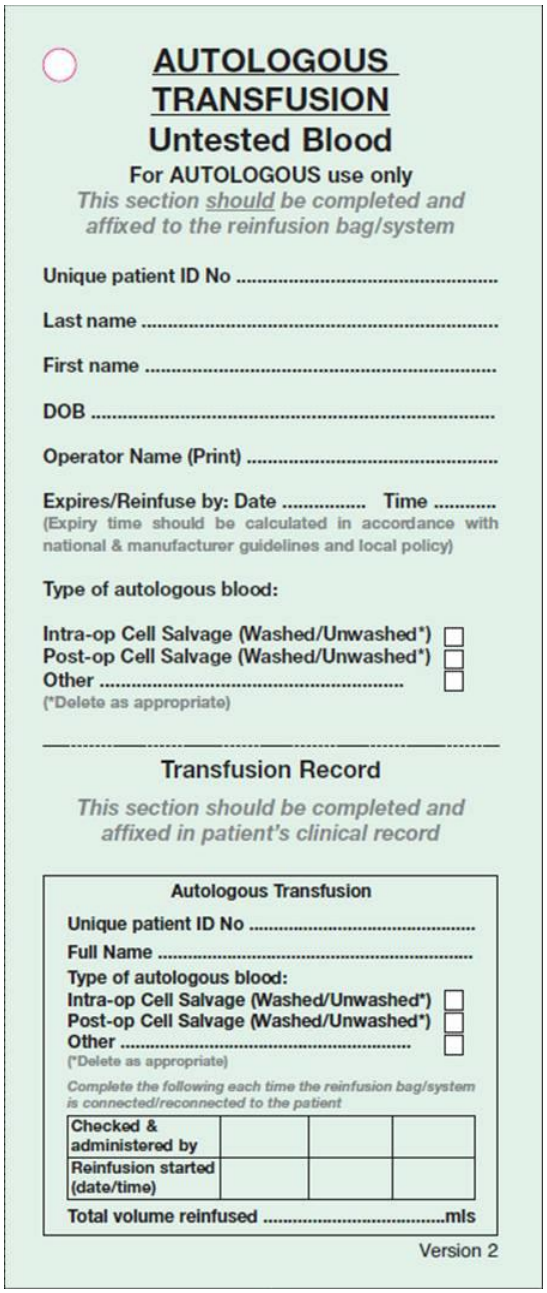
*** If reinfusion of the ICS blood is to begin outside of the operating theatre where the procedure has taken place, special requirements for reinfusion should be identified during the World Health Organisation Surgical Safety Checklist - SIGN OUT**

Appendix D

EXAMPLE

Autologous Transfusion Label

The following autologous transfusion label is available from your device manufacturer.



AUTOLOGOUS TRANSFUSION

Untested Blood

For AUTOLOGOUS use only

This section should be completed and affixed to the reinfusion bag/system

Unique patient ID No .....

Last name .....

First name .....

DOB .....

Operator Name (Print) .....

Expires/Reinfuse by: Date ..... Time .....
(Expiry time should be calculated in accordance with national & manufacturer guidelines and local policy)

Type of autologous blood:

Intra-op Cell Salvage (Washed/Unwashed*) ☐
Post-op Cell Salvage (Washed/Unwashed*) ☐
Other ..... ☐
(*Delete as appropriate)

Transfusion Record

This section should be completed and affixed in patient's clinical record

Autologous Transfusion

Unique patient ID No .....

Full Name .....

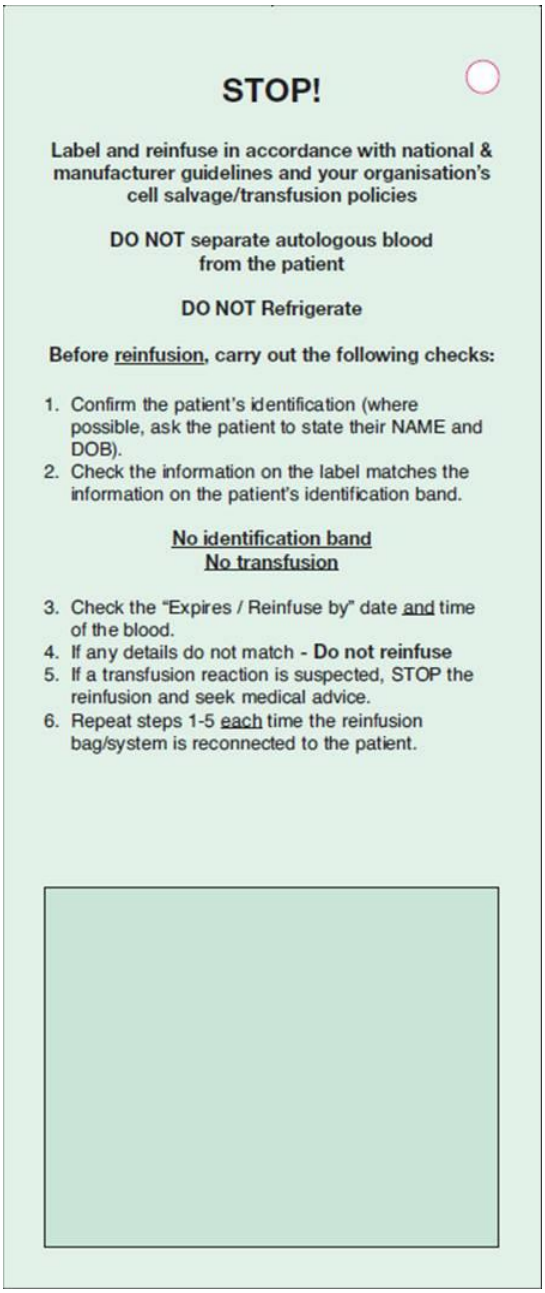
Type of autologous blood:
Intra-op Cell Salvage (Washed/Unwashed*) ☐
Post-op Cell Salvage (Washed/Unwashed*) ☐
Other ..... ☐
(*Delete as appropriate)

Complete the following each time the reinfusion bag/system is connected/reconnected to the patient

Checked & administered by			
Reinfusion started (date/time)			

Total volume reinfused .....mls

Version 2



STOP!

Label and reinfuse in accordance with national & manufacturer guidelines and your organisation's cell salvage/transfusion policies

DO NOT separate autologous blood from the patient

DO NOT Refrigerate

Before reinfusion, carry out the following checks:

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's identification band.

No identification band
No transfusion

3. Check the "Expires / Reinfuse by" date and time of the blood.
4. If any details do not match - **Do not reinfuse**
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.

Appendix E

EXAMPLE

Audit Proforma

1. Patient details (use addressograph label)						2. Procedure details	
Surname Forename Gender District Number NHS Number D.O.B						Procedure: Date of Procedure:	
							Trauma
							Emergency
							Elective
							Jehovah's Witness
							Malignancy
	Gen surgery Vascular		Orthopaedic Gynaecology *		Urology Obstetric*		9-6pm (core hours) 9pm-9am (out of hours)
*Inform Blood Bank 3620/1 (Bleep 251) to determine Rh D status and if Anti-D required Time Blood Bank informed ..... Name of Blood Bank staff informed						Surgeon Anaesthetist Name of machine operator Signature of machine operator	

3. Cell Salvage Items Used			
Machine number		Leucodepletion filter used Y/N	

4. Reason WHY Collection SET Used, but Blood NOT Processed					
Inadequate volume collection		Technical problem (state below)		Other, specify:	

5. Blood Volume Details			
Total volume processed (ml)		Time collection started (24 hr)	
Volume PRC produced (ml)		Time processing started	
Volume PRC transfused (ml)		Time transfusion started	
Estimated total blood loss		blood bank units given	
Was the Massive Haemorrhage protocol activated Y/N		Anticoagulant : type used	

6. Comments/Problems/Critical Incidents. DATIX Y/N Number	
Process Issue	
	In adequate anticoagulation – clotting in reservoir
	Non IV saline used for wash
	Contraindicated substances aspirated into the collection reservoir
	Reinfusion bag not labelled for the patient
	Time exceeded for collection and or reinfusion of salvaged blood
	Incorrect swab washing
	Other Operator Issues that Impact on Patient Care
Clinical Issue	
	Air/ Fat embolism
	Signs of acute haemolytic transfusion reaction – pyrexia , rigors etc.
	Hypotensive episode on reinfusion of processed red cells – not related to hypovolaemia
	Anaphylaxis or other allergic reaction
	Blood processed but not all given to patient – please give details:
	Machine System Failure - Any stoppage of the machine where operator has not made the decision to halt the procedure. Please give details:
	Other – please give details:
Further notes/comments about this case (please use additional sheets if required)	

Clinical coding circle code	Collection X36.4	Processed/Transfused X33.7	if processed and transfused please circle both codes

Appendix F

EXAMPLE

Fault log

Intraoperative Cell Salvage Machine Fault Log

Machine: _____

Serial Number: _____

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

Appendix G – NICE Guidance

Cell salvage and tranexamic acid

1.1.5 Offer tranexamic acid to adults undergoing surgery who are expected to have at least moderate blood loss (greater than 500 ml).
1.1.6 Consider tranexamic acid for children undergoing surgery who are expected to have at least moderate blood loss (greater than 10% blood volume).
1.1.7 Do not routinely use cell salvage without tranexamic acid.
1.1.8 Consider intra-operative cell salvage with tranexamic acid for patients who are expected to lose a very high volume of blood (for example in cardiac and complex vascular surgery, major obstetric procedures, and pelvic reconstruction and scoliosis surgery).

National Institute For Health & Clinical Excellence (Nice) (2015), Alternatives to transfusion for patients having surgery, Cell Salvage and tranexamic acid, Blood transfusion(NG24)

Appendix H - Cell Salvage in Jehovah's Witness patients

The information in this Appendix has been adapted from the UK Cell Salvage Action Group Technical Factsheet (6) which is available to download at www.transfusionguidelines.org.uk

UK Intraoperative Cell Salvage Action Group Technical Factsheet 6
Cell Salvage in Jehovah's Witness patients

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). This is usually documented on an Advance Medical Decision that they carry on their person.

JW patients make a personal decision on whether or not to accept the various blood conservation measures available. These include intraoperative and postoperative cell salvage. Ideally, this should be discussed and recorded on a specific document, detailing exactly what is and is not acceptable to the patient.

JW patients who accept cell salvage may specifically request that the system be set up to allow for continuous connectivity. In these cases, the details outlined below should prove helpful. Informed consent should be sought as for all patients.

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

Procedure

Setting up a continuous circuit

Although there will be technical differences between devices, the same general principles apply.

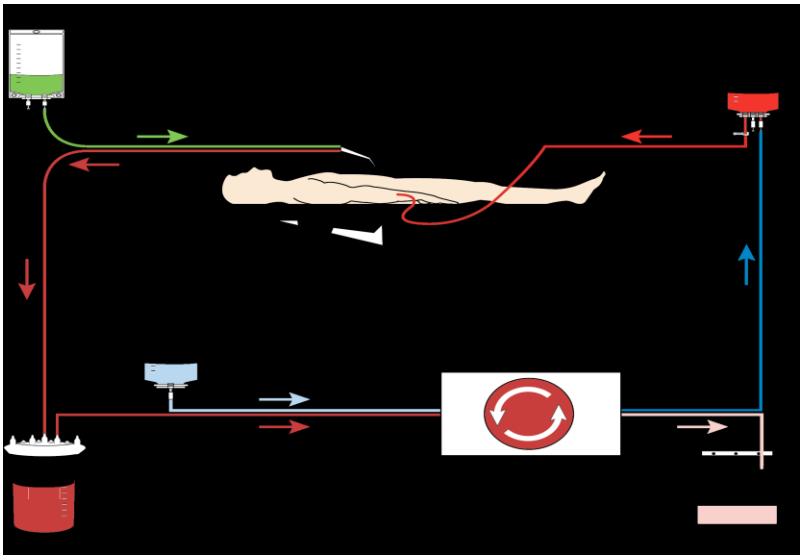
1. Set up the machine for collection and processing with standard disposables (in bowl based machines consider using a low volume bowl to reduce blood stasis).

2. Prime the circuit with saline ensuring that saline enters the reinfusion bag (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 18).

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 18. Representation of a Continuous Circuit



Special requirements

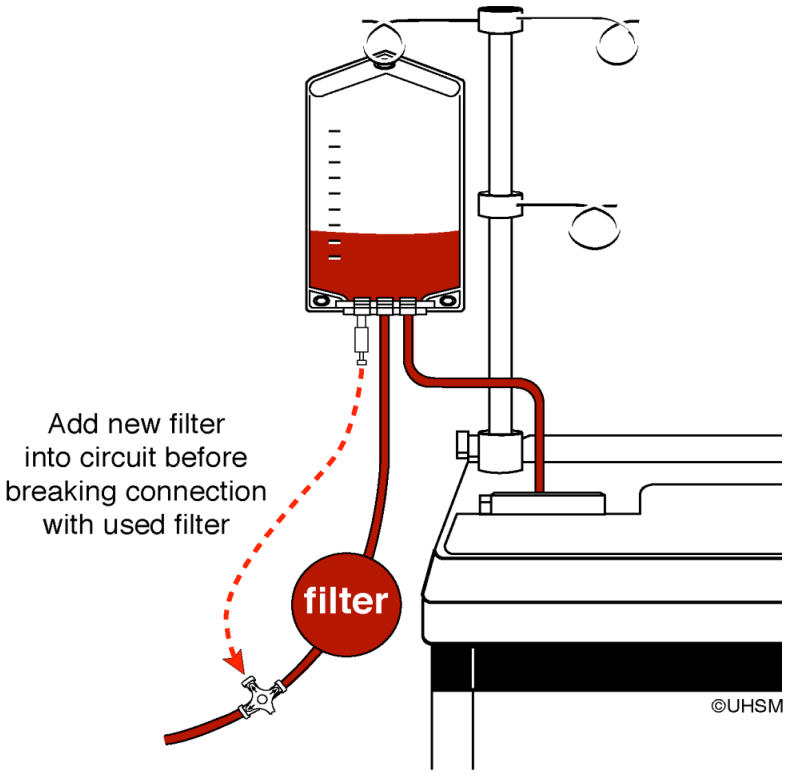
In some cases a leucocyte depletion filter may be needed for reinfusion of the salvaged blood. A standard giving set should be set up with a 3-way tap in line before blood collection begins. The giving set should be primed with saline to complete the circuit. When a volume of blood is ready to be reinfused, 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 19 opposite).

The LD filter should not 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. In a worst case scenario the leucocyte depletion filter may need to be isolated from the circuit and replaced with a standard giving set. This must be done without breaking the circuit in order to maintain continuity. During management of life threatening haemorrhage in a JW, 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 replace the leucodepletion filter with a normal giving set, so that blood can be transfused rapidly to prevent exsanguination. This must be done without breaking continuous connectivity of the circuit.

Figure 19. Replacing a Filter without Breaking Continuity



This original factsheet on which this appendix has been based was verified by representatives of the Jehovah's Witness community.

Appendix I – Cell Salvage Patient Information Leaflet EXAMPLE

Please ask

UK CELL SALVAGE ACTION GROUP
FACTSHEET

NHS
Sherwood Forest Hospitals
NHS Foundation Trust

about CELL SALVAGE

What is Cell Salvage?

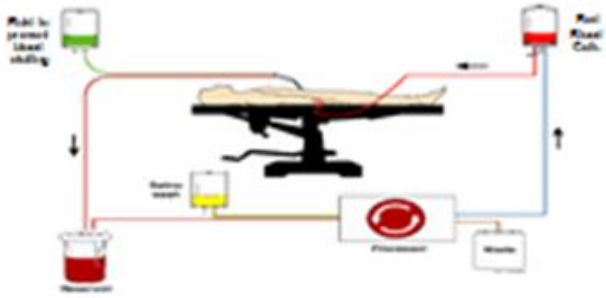
Cell salvage is a way of collecting the blood that is lost during, or just after your operation, so that it can be given back to you. It is sometimes called autologous blood transfusion (using your own blood).

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 blood. Cell salvage can help reduce the need for a blood transfusion donated by a blood donor. Cell salvage can therefore reduce the very small risks associated with receiving donor blood.

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/tics/index.htm

PITRANS 001 (V3)
Issued: Feb 2019 Review date: Feb 2022

Appendix J – Quality Assurance of Cell Salvage Machines

Guidelines for taking sample for Q/C of Cell Salvage machines

The manufacturer of the CATS cell salvage machine (Fresenius Hemocare) states in its Operating Instructions (4/10.97) the CATS Cell Salvage machine produces Blood for re-infusion with a high Haematocrit, (Hct of >50%).

Each machine will have a sample of blood from the re-infusion bag tested at three monthly intervals to ensure the blood for re-infusion has a Hct of >50%.

If the Hct should fall below this level it indicates a malfunction of the machine and will be taken out of the clinical area until the machine has been checked and the fault rectified.

1. Spike re-infusion bag with normal blood giving set with three way tap attached to patient end, prime giving set with processed blood.
2. Before attaching to patient, attach 10ml syringe to three way tap and draw off required amount of processed blood for a full blood count.
3. Remove the top off the sample tube and syringe in processed blood (do not use a hypodermic needle on the syringe to place blood into tube as this will damage the red blood cells and could give a false result).
4. Complete the details on the cell salvage Q/C label and attach to sample form and send to lab for full blood count.

Quality Assurance Label

Cell Salvage Machine Quality Assurance
For Full Blood Count
Serial No of Machine……..
Amount processed mls……..
Date / Time…… …….
Th/Area…….
Wash Programme…….
Name of Staff……..
Please send report to Deborah king/ Dr Andrews
KMH main theatres
Deborah.king16@nhs.net
Jeremy.andrews1@nhs.net
Version 1 DKing/J Andrews 09/01/2019

Appendix K - EQUALITY IMPACT ASSESSMENT FORM

Name of service/policy/procedure being reviewed: Provision of Intraoperative Cell Salvage Policy			
New or existing service/policy/procedure: Existing			
Date of Assessment: January 2023			
For the service/policy/procedure and its implementation answer the questions a – c below against each characteristic (if relevant consider breaking the policy or implementation down into areas)			
Protected Characteristic	**a) Using data and supporting information, what issues, needs or barriers could the protected characteristic groups' experience? For example, are there any known health inequality or access issues to consider?**	**b) What is already in place in the policy or its implementation to address any inequalities or barriers to access including under representation at clinics, screening?**	**c) Please state any barriers that still need to be addressed and any proposed actions to eliminate inequality**
The area of policy or its implementation being assessed:			
Race and Ethnicity	N/A	N/A	N/A
Gender	N/A	N/A	N/A
Age	N/A	N/A	N/A
Religion	N/A	Identified in policy	N/A
Disability	N/A	N/A	N/A
Sexuality	N/A	N/A	N/A
Pregnancy and Maternity	N/A	N/A	N/A
Gender Reassignment	N/A	N/A	N/A
Marriage and Civil Partnership	N/A	N/A	N/A
Socio-Economic Factors (i.e. living in a poorer neighbourhood/ social deprivation)	N/A	N/A	N/A
What consultation with protected characteristic groups including patient groups have you carried out? • None			

What data or information did you use in support of this EqIA? • This policy is based on current NICE guidance.
As far as you are aware are there any Human Rights issues be taken into account such as arising from surveys, questionnaires, comments, concerns, complaints or compliments? • This policy is based on current national NICE guidance which has been assessed nationally and therefore this will have been taken into account at a national level and addressed.

Level of impact

From the information provided above and following EQIA guidance document Guidance on how to complete an EIA (click here), please indicate the perceived level of impact:

Low Level of Impact

For high or medium levels of impact, please forward a copy of this form to the HR Secretaries for inclusion at the next Diversity and Inclusivity meeting.

Name of Responsible Person undertaking this assessment: *Dr Jeremey Andrews*

Signature:

Date: *January 2023*

Appendix L - ENVIRONMENTAL IMPACT ASSESSMENT

The purpose of an environmental impact assessment is to identify the environmental impact, assess the significance of the consequences and, if required, reduce and mitigate the effect by either, a) amend the policy b) implement mitigating actions.

Area of impact	Environmental Risk/Impacts to consider	Yes/No	Action Taken (where necessary)
Waste and materials	• Is the policy encouraging using more materials/supplies? • Is the policy likely to increase the waste produced? • Does the policy fail to utilise opportunities for introduction/replacement of materials that can be recycled?	NO NO NO	
Soil/Land	• Is the policy likely to promote the use of substances dangerous to the land if released? (e.g. lubricants, liquid chemicals) • Does the policy fail to consider the need to provide adequate containment for these substances? (For example bunded containers, etc.)	NO NO	
Water	• Is the policy likely to result in an increase of water usage? (estimate quantities) • Is the policy likely to result in water being polluted? (e.g. dangerous chemicals being introduced in the water) • Does the policy fail to include a mitigating procedure? (e.g. modify procedure to prevent water from being polluted; polluted water containment for adequate disposal)	NO NO NO	
Air	• Is the policy likely to result in the introduction of procedures and equipment with resulting emissions to air? (For example use of a furnaces; combustion of fuels, emission or particles to the atmosphere, etc.) • Does the policy fail to include a procedure to mitigate the effects? • Does the policy fail to require compliance with the limits of emission imposed by the relevant regulations?	NO NO NO	
Energy	• Does the policy result in an increase in energy consumption levels in the Trust? (estimate quantities)	NO	
Nuisances	• Would the policy result in the creation of nuisances such as noise or odour (for staff, patients, visitors, neighbours and other relevant stakeholders)?	NO	