University Hospitals of Derby and Burton NHS Foundation Trust

TRUST POLICY FOR THE USE OF INTRAOPERATIVE CELL SALVAGE

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Version / Amendment History	**Version**	**Date**	**Author**	**Reason**
	V1		S. Ralph	Governance arrangements and new policy for Red Cell Salvage. National guidance.
	V2	October 2018	Jenny Cuttell	Review
	V3	August 2022	Sameh Botros & Carly Moussa	Updated anaesthetic guidelines, Jehovah's Witness patients, patient information and training competency document

Intended Recipients: All managers, clinicians and personnel involved in the process of Intraoperative Cell Salvage (ICS) within Derby site only, whether in a permanent or temporary role.

Training and Dissemination: ICS Operator Training, ICS Working Group, Consultant Anaesthetic Lead for ICS.

To be read in conjunction with:

- Trust Transfusion Policy
- Trust Theatre Policy
- Trust Massive Haemorrhage Protocol
- Trust Health and Safety Policy
- Trust Infection Control Policy
- Trust Medical Device Policy.

In consultation with and Date: • ICS Working Group • Transfusion Practitioners • Hospital Transfusion Committee (HTC) • Safer Surgery Group • DQRG	
EIRA stage One	
Procedural Documentation Review Group Assurance and Date	No
Approving Body and Date Approved	Trust Operational Group – 02/11/2018 Minor amendments approved by Sharon Martin 28/12/2022
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Contact for Review	Carly Moussa – Senior Clinical Educator for theatres UHDB
Executive Lead Signature	 Sharon Martin, Executive Chief Operating Officer

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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 (Appendix 6).

The Health Service Circular (HSC), "Better Blood Transfusion: Safe and Appropriate Use of Blood" (2007) and subsequent National Blood Transfusion Committee publication, "Patient Blood Management: An evidence-based approach to patent care" (2014, England only) recommend that in order to make transfusion safer, provide better information for patients, avoid inappropriate blood transfusion and to ensure the best treatment, the patient must be at the heart of decisions made about blood transfusion.

Both publications recommend that effective alternatives to allogeneic blood transfusion be explored, including the appropriate use of autologous blood transfusion techniques such as Intraoperative Cell Salvage (ICS).

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. Purpose and Outcomes

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, this includes patients from the Jehovah 's Witness faith.
- 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.

3. Definitions Used

Intraoperative Cell Salvage (ICS): For the purpose of this Policy is the process which can also be known as Perioperative Red Cell Salvage (PRCS), Blood Recovery and Auto-transfusion using the Cell Saver Machine.

4. Key Responsibilities / Duties

ICS Working Group (Appendix 1)

- To report to the Hospital Transfusion Committee (HTC)
- To promote ICS across all theatre areas and identify areas for development
- To oversee, implement and update ICS Policy
- To ensure training meets the needs of ICS operators
- To co-ordinate ICS replacement, new purchase and service programmes
- To audit the use of ICS.

5. Policy Details

5.1 Scope

This Policy applies to the provision of ICS by or on behalf of the Derby site only:

- All staff involved in ICS should be aware of this Policy and its contents and any appropriate local Policies
- ICS must be conducted according to the procedures detailed in this Policy.

ICS is not used at the Burton site due to the nature of the clinical workload and a lack of predictable elective activity with patients requiring cell salvage. It would therefore not be possible for the staff running the cell salvage to maintain their clinical competence.

5.2 Standards and Procedure

ICS should be made available to all patients who would benefit from it. The benefits include reducing the need for allogenic blood transfusion and the risks thereof. There are considerable cost benefits to the Trust in implementing the full availability of ICS. There should be no instances of ICS not being available to those patients who would benefit. Every effort should be made to provide

additional, dedicated ICS personnel in emergency situations for example in Obstetrics and vascular surgery.

5.3 Indications for ICS

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. Specific indications may, in the absence of contraindications, include any patients undergoing routine or emergency surgery in which there is potential for blood loss to be greater than 500mls or greater than 10% of the patients calculated blood volume.

It may be cost effective to set up the suction apparatus and collection reservoir but only process the blood aspirated if the volume salvaged exceeds a specified amount.

Also, consideration to offer ICS may be relative to the following points:

- Any surgical procedure for which blood is routinely cross-matched
- Any procedure for which > 10% of patients require transfusion
- Any procedure for which the mean transfusion requirement exceeds 1 unit of Red Blood Cells
- Obstetric patients who have a high risk of bleeding at Caesarean Section
- Patient with multiple allo-antibodies or rare blood type, for whom it is difficult to obtain compatible blood
- Lack of available blood for other reason (emergency, lack of reserves, etc.)
- Patients who for moral and religious reasons are unable to undergo homologous blood transfusion but may consent to autologous transfusion.
- Patients at increased risk of bleeding due to coagulopathy or other risk factors.
- Patient is anaemic and surgery is urgent and there is no time for active management of anaemia before surgery.

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.

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

A list of suitable procedures is attached (Appendix 2).

Ideally ICS should be requested by the operating surgeon prior to the commencement of the operating list, preferably when the patient is booked for surgery via the electronic patient booking system for theatres at RDH (ORMIS), to allow for adequate staffing of the operating list. The need for ICS should also be discussed and documented at the “WHO Team Brief” at the start of the operating list.

5.4 Contraindications 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

Absolute contraindications to ICS are patient refusal and the lack of trained staff to collect and process the aspirate

Relative contraindications are the potential contamination of aspirated blood with bowel contents, infection or tumour cells.

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 / Chlorhexidine
    - Topical Clotting Agents
    - Freshly Curing Orthopaedic Cement
    - Irrigation Solutions such as Alcohol, Betadine, Bleach and Hydrogen Peroxide (H2O2)
- Tranexamic Acid is NOT a contraindication
- 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
- There are concerns relating to the use of ICS in patients with sickle cell disease. The use of ICS in patients with abnormal red cell disorders should be made on a clinical, individual patient basis taking the latest evidence into account
- Amniotic fluid should theoretically not be aspirated into the system, due to the risk of Amniotic Fluid Embolism (National Institute for Health and Care Excellence [NICE]) and should be removed by separate suction prior to starting cell salvage.

- 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 reinfused and giving rise to metastases. However, there are now several reports in the literature of the use of ICS in cancer surgery without obviously leading to early metastasis 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 reinfused through a leukocyte reduction filter to minimise the reinfusion of any malignant cells which may have been aspirated into the collection reservoir. The clinician should be aware that the use of a leukocyte filter can slow the flow rate when reinfusing.

- Guidance on the use of ICS in radical prostatectomy and radical cystectomy and 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.

Cautions

- The use of Hartmann's Solution will inhibit the action of citrate-based anticoagulants (e.g. ACD) if used as an irrigation 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.

5.5 Care of the Jehovah's Witness patient

In Jehovah's Witness patients, ICS, may be acceptable if performed appropriately, and **only if the patient consents.** The cell saver can be modified during the set-up phase to ensure a "closed-circuit". This involves running the system through with IV saline, to the reinfusion bag, which is then connected directly to the patients IV. A second cannulae for infusion via the cell saver is recommended. Any red cells that have been processed will run directly into the patient's IV line. 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.

Swab Washing

It should be confirmed with the patient prior to surgery during the consent process as to whether the patient will accept swab washing as part of the cell saver procedure.

It should be clearly explained to the patient what swab washing involves, and patients may vary on their stance on swab washing.

This should be clearly documented during the consent process.

'Swab washing' can increase the efficiency of red cell recovery in ICS and the hospital liaison committee will provide advice and guidance to the patient should this be required.

5.6 Bowel Surgery

The use of ICS in the presence of bowel contents is controversial. However, evidence indicates that wound infection rates after laparotomy for abdominal injuries is no different for patients receiving allogeneic or cell salvaged blood, with no correlation between organisms grown from the cell saved blood and those causing postoperative pneumonias, bacteraemia or urinary tract infections (AAGBI Safety Guideline).

The AAGBI Safety Guideline suggests that while salvage from grossly contaminated fields should be avoided, procedures involving bowel resection may use ICS for at least part of the procedure.

If deemed clinically necessary the following practical tips may help:

- Initial evacuation of the soiled abdominal contents
- Additional washing (increasing the volume of IV normal saline [0.9% NaCl] which the machine uses to wash the salvaged blood)
- Ensure use of broad-spectrum antibiotics.

It is unlikely that bowel contamination in such individuals will lead to problems in decision making about the use of ICS, but hopefully the points raised can enable all concerned to make an informed management choice.

5.7 The Haematological Management of the Patient during ICS

In common with the transfusion of large volumes of bank blood, the return of large volumes of red cells will lead to the depletion of platelets and clotting factors resulting in a potentially severe coagulopathy. Appropriate investigations should be performed according to clinical need (Full blood count, prothrombin time and activated partial thromboplastin time.) There is also the ROTEM (Rotational thromboelastometry) now available in both Obstetrics and general theatres, giving immediate results regarding the patients coagulation status.

In the event of a massive re-infusion of perioperatively salvaged red cells, it is strongly recommended that the patient has these investigations performed following the re-infusion of each litre of salvaged blood in order to rapidly detect and appropriately treat the potential coagulopathy. It is vital to ensure that these patients receive transfusion of platelets, fresh frozen plasma and cryoprecipitate in accordance with the Trust Transfusion Guidelines, in addition to the correction of developing hypocalcaemia. Under these circumstances it is advisable to initiate the Trust's Massive Haemorrhage Protocol.

5.8 Patient information

Patients considered likely to have ICS during elective surgery should receive information about ICS before their operation. This should be a part of the comprehensive patient blood management plan developed pre-operatively in consultation with the patient and for which they give documented informed consent.

For patients undergoing emergency surgery, where the procedure cannot be discussed with the patient or a third party prior to surgery, the use of ICS is at the discretion of the surgeon and anaesthetist responsible for the patient's care and documented in the patient record. Information to provide to the patient can be found at Appendix 3.

5.9 Protocol for Use

5.9.1 Use of the ICS Equipment

The ICS system should be used in accordance with the manufacturer's guidelines https://www.livanova.com/en-us/home/cardiopulmonary/autotransfusion/xtra [Accessed 30.07.2022]

Ideally staff operating ICS systems should not have other responsibilities within the theatre team, in particular airway responsibility. This is particularly important during emergency cases.

All procedures should be carried out in accordance with the Trust's ICS policy and procedural documents.

The ICS system should be routinely run-in automatic mode

Contraindications should be considered as identified in Section 5.4

All staff that set up or operate ICS systems should receive theoretical and practical training and should have completed the ICS Training Workbook (Appendix 7)

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.

5.9.2 Anticoagulant

The anticoagulant used should be ACD solution and documented. Heparin solutions should not be used.

5.9.3 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 https://www.livanova.com/en-us/home/cardiopulmonary/autotransfusion/xtra [Accessed 30.07.2022] 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.

5.9.4 Swab Washing (Scrub Practitioner)

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.

Evacuate the swab wash at least every 2 hours to avoid stagnation.

Monitor suction containers if a theatre suction line is used also for waste.

Be aware of potentially harmful substances in the surgical field and maintain sterility of suction apparatus.

A discussion should be had with those patients, such as from the Jehovah's witness faith as to whether swab washing is acceptable as part of their care during ICS.

5.9.5 Labelling

All salvaged blood should be labelled as per Appendix 5.

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".

To avoid errors in patient identification, 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 or the patient consent form. All fields on the label should be completed in full.

5.9.6 Re-infusion

ICS should normally be set up without simultaneous connection of the reinfusion bag to the patient. 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. Pressure Bags must not be used.

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. It is recommended that a leukocyte depletion filter is used for obstetrics and malignancy cases.

It is important when caring for the obstetric patient that the RhD status is determined by informing blood bank on ext. 88532/2 to establish if Anti D is required.

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. This should be the Blood Product Prescription Form / Anaesthetic Record.

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. Positive Patient Identification must be confirmed prior to reinfusion commencing.

The responsible clinician must ensure the reinfusion bag is free from air before reinfusion.

ICS products must be administered only to the patient from whom the blood was collected. There should be positive identification of the patient and product. Ensure all details on the identified band (full name, date of birth, medical record number) are identical to those provided on the reinfusion bag label.

The product must be inspected immediately before administration with verification of:

- Product appearance
- Product labelling
- Product content
- Expiration date and time.

If the product does not meet defined criteria, the product must not be used.

The reinfusion of salvaged blood should be documented in the standard anaesthetic record, the ICS Datasheet (Appendix 4) and ORMIS the electronic patient care record used in theatres at the Royal Derby Hospital.

Salvaged blood should be transfused in the theatre or recovery / intensive-care unit (ICU) area only, and not be transferred to any outside areas (i.e., stay in Recovery until reinfusion with ICS blood is completed, for appropriate observation and access to Anaesthetist for post-operative review).

5.9.7 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.

5.9.8 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 Trust 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 (PCS): 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

- 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 biohazardous waste

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

5.9.9 Patient Monitoring Observations and Documentation

The collection and reinfusion of salvaged blood should be accurately documented on a Cell Salvage Data Collection Form (Appendix 4).

The use of an autologous transfusion label is recommended, the peel out section of the label is completed and attached to the patient's clinical record upon reinfusion of the salvaged blood (Appendix 5).

Adverse incidents and Serious Adverse Events should be documented / reported.

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 Trust Transfusion Policy.

Additional observations are at the discretion of the clinical staff based on an individual patient assessment.

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

5.9.10 Disposal of used ICS equipment

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

5.9.11 Cleaning and Disinfection of ICS Machines

Following use, the cell salvage machine should be cleaned in accordance with the manufacturers' guidance and the Trust 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.

5.9.12 Maintenance of Equipment

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

5.9.14 Training and Assessment

ICS Operator training and assessments will be based on an annual Training Needs Analysis (TNA) for registered Theatre Practitioners.

Training will consist of a combination of: e-learning, a face to face study day lead by a consultant anaesthetist, a log book for a period of supervised practice and a formal 'sign off' assessment by a verified assessor.

It is anticipated that 10 experiences will be supervised prior to any sign off assessment.

It is recommended that a supervised practice experience in another speciality is beneficial to overall learning.

The training process and logbook are reviewed annually prior to new cohort.

Device training recorded as per Trust Medical Device Policy.

Training and completion record monitored regularly at ICS Working Group.

6. Monitoring Compliance and Effectiveness

The key requirements will be monitored in a composite report presented on the Trusts Monitoring Report Template:

Monitoring Requirement :	Quarterly by the ICS Working Group
Monitoring Method:	Audit of ICS data collection forms and incidents reported
Report Prepared by:	ICS Working Group
Monitoring Report presented to:	HTC
Frequency of Report	Quarterly

7. References

AAGBI Safety Guideline (2010) Blood Transfusion and the Anaesthetist Intraoperative Cell Salvage. AAGBI.

BCSH (2014) Guideline for use of Anti-D Immunoglobulin for the prevention of haemolytic disease of the fetus and newborn

www.bcshguidelines.com/4_HAEMATOLOGY_GUIDELINES.html

DOH (1998) Better Blood Transfusion: Improving Transfusion Practice HSC 1998/224

DOH (2002) Better Blood Transfusion: The Appropriate Use of Blood HSC 2002/009

DOH (2007) Better Blood Transfusion: Safe and Appropriate Use of Blood HSC 2007/001

https://www.livanova.com/en-us/home/cardiopulmonary/autotransfusion/xtra [Accessed 30.07.2022]

National Institute of Clinical Excellence, Interventional Procedure Guidance 144

National Institute of Clinical Excellence, Interventional Procedure Guidance 258

NBTC (2014) Patient Blood Management -An evidence-based approach to patient care http://www.transfusionguidelines.org.uk/uk-transfusion-committees/national-blood-transfusion-committee/patient-blood-management

Appendix 1

Terms of Reference for Cell Salvage Group

Objectives

To promote the safe and appropriate use of both Intra-operative and Post-operative Cell Salvage techniques within the Trust. This will include undertaking a variety of audits to evaluate the appropriate use and effectiveness of cell salvage and other blood conservation techniques as deemed appropriate. Ensuring that Cell Salvage and autologous transfusion maintains a high profile within the overall blood transfusion clinical governance agenda

Reporting and Monitoring Mechanisms

Reports to be submitted to Hospital Transfusion Committee, exception reports maybe required with recommendations.
Monitoring via annual Work Plan and Reports

Membership

The membership of the Cell Salvage group should be representative of the clinical specialities who employ cell salvage techniques. Varieties of healthcare professionals are involved in the use of cell salvage across the Trust and should be represented. It is recommended that membership includes:

- Chairperson — Consultant Anaesthetist
- Minutes — Administration support
- Transfusion Practitioner
- Blood Bank Manager
- Surgeon Representative(s)
- Representatives from theatres and associated areas
    - Anaesthetics
    - General Surgery / Urology / Vascular
    - Obstetrics and Gynaecology / Paediatrics
    - Pre-Operative Assessment
    - Trauma & Orthopaedics
    - Theatre Recovery Staff
    - Theatre Managerial staff
    - Theatre Night Staff
    - Representation from appropriate ward staff should be considered if any autologous transfusion issues will affect their practice ie Sister Orthopaedic / Specialist Nurse re autologous drains etc
    - Representative of the Jehovah's Witness Hospital Liaison Committee

This list is not exclusive and other clinical specialties who may be traditionally low users of Cell Salvage may wish to be represented or invited on an 'ad hoc' basis (e.g. Head & Neck Services, ICU).

Frequency of Meetings

Quarterly, prior to HTC.

Specific responsibilities of the Cell Salvage Group

Educational Responsibilities

- Promote best practice through local policies and protocols based on current guidance and clinical evidence
- Promote the education, training and competency assessments of all clinical and support staff involved in Cell Salvage
- Develop arrangements to ensure that patients are adequately informed about cell salvage. Related autologous transfusion and associated clinical governance issues.

Monitoring of Safety of Transfusion

- Review all adverse events and reactions relating to Cell Salvage and associated autologous transfusion techniques that are reportable within the Trust or to the Serious Hazards of Transfusion Scheme (SHOT) via the online reporting mechanism (Appendix 6).
- Action points and modifications to existing Cell Salvage and related autologous transfusion policies and protocols will be agreed
- Lessons learnt from adverse incident reports will be agreed for communication and action deemed appropriate by the Chairperson of the Cell Salvage Group.
- Evaluation and use of new products and changes to existing guidelines will be coordinated and communicated via the Cell Salvage Group
- Validation and maintenance schedules of Cell Salvage equipment will be the responsibility of a named individual via the Cell Salvage Group.

Quality Assurance

- To note, review and action, if necessary, any issues relating to the provision of Cell Salvage within the Trust that may be affected by internal or external influences
- To lead multi-professional audit of the use of Cell Salvage within the Trust, focussing on promoting the appropriate use of Cell Salvage
- Feedback on audit results and suggestions for improving Cell Salvage and related autologous transfusion practice and policies will be coordinated via the Cell Salvage Group
- Assuring Compliance with appropriate NHSLA standards
- Relevant requirements of the HSC 2007 Better Blood Transfusion and Patient Blood Management Strategy for action via the Chairperson of the Hospital Transfusion Committee.

Evaluation

The Cell Salvage Group will evaluate its performance by:

- Submitting quarterly reports to HTC and actioning any feedback from the HTC regarding usage, incidents, audits, policy, education
- Ensuring regular attendance from a variety of surgical clinical divisions
- Monitoring uptake of Cell Salvage training, education and competency assessments across clinical and support staff involved in the use of Cell Salvage
- Demonstrating compliance to related policies and protocols via audit.

Appendix 2

Procedures and situations which may be suitable for ICS

All surgical procedures where blood loss is expected to have an impact

Vascular Surgery
Open aortic aneurysm repair (elective and emergency)
Splenic / liver trauma

Trauma & Orthopaedics
Spinal surgery
Revision hip replacement
Pelvic and femoral fractures

Urology
Radical cystectomy
Radical prostatectomy
Nephrectomy
Pelvic exenteration

General Surgery
Elective colorectal resections
Abdominal / thoracic trauma
Emergency laparotomy

Gynecology
All major procedures, e.g. ultra-radical resections

Obstetric
Emergency use:
Major obstetric haemorrhage at caesarean section,
Laparotomy for postpartum haemorrhage
Genital tract trauma, etc.

Elective use:
Anticipated haemorrhage at caesarean section, e.g. placenta praevia / accreta, large fibroid uterus, etc.

Jehovah's Witnesses or any patient refusing a blood transfusion

This list is suggestive but not exclusive. Cell Salvage should be considered if clinically appropriate.

Maximum benefit of cell salvage can be gained by capture of emergency cases, which often require large volume blood component support.

Patient Information

NHS
University Hospitals of Derby and Burton
NHS Foundation Trust

Cell Salvage

Giving you back your own blood

What is cell salvage?

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

How is it done?

- **Blood collected during your operation (intraoperative cell salvage)**
  Blood lost during your operation is collected using a cell salvage machine. The red cells (the part which carries oxygen around the body) are separated out and given back to you during or just after your operation. Your red cells will never be given to someone else.
  This type of cell salvage is only suitable for some operations.

What are the benefits of cell salvage?

- **Your own blood is given back to you**. This reduces the need for a transfusion using blood from a donor and the small risks linked with this.
- **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 surgery (patients who have received donor blood since 1 January 1980 cannot be blood donors as a precaution against the spread of vCJD).

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?

Your doctor, nurse, or transfusion practitioner will discuss with you if intraoperative cell salvage is suitable for you and the operation you are having.

Useful contacts

Transfusion Practitioners Royal Derby Hospital: 01332 788530 or 788296

Pre-operative assessment clinic: 01332 785087 or 01332 787120

Website: https://www.transfusionguidelines.org/transfusion-practice/uk-cell-salvage-action-group/patient-factsheet

Adapted from: The UK Cell Salvage Action Group leaflet

P4284/1758/12.2021/VERSION3

Appendix 4

Data Collection Form

University Hospitals of Derby and Burton
Cell Salvage Data Collection Form

Please complete for EVERY surgical case EVEN if the blood collected is NOT processed

1. Patient Details (use patient sticker)	2. Procedure details
	Procedure:
	Date of Procedure:
	☐ Elective ☐ Jehovah's Witness ☐ Emergency ☐ Malignancy ☐ Trauma
	☐ 9-6pm (core hours) ☐ 6pm -9am (out of hours)
	Surgeon:
☐ Colorectal ☐ Trauma ☐ Gynaecological ☐ Urology ☐ Orthopaedics ☐ Vascular ☐ Paediatrics ☐ Obstetrics *Inform Blood Bank 88532/3 (Bleep 3090) to determine RhD Status and if Anti D required Time Blood Bank informed: Name of Blood Bank Staff informed:	Anaesthetist: Name of Machine Operator: Signature of Machine Operator:

3. Cell Salvage Items Used					
Machine Number:		Theatre Number:		Leukocyte Depletion Filter: Y/N	

4. Reason Why Collection Set Used, but Blood Not Processed		
☐ Inadequate Volume Collection	☐ Technical Problem (details below)	☐ Other, Specify:

5. Blood Volume Details			
Volume RBC produced (ml): Volume given (ml):		Time Collection Started (24 hr)	:
Estimated Total Blood Loss (ml):		Time Processing Started	:
Was Massive Haemorrhage Protocol activated? Y/N Time	:	Time Transfusion Started	:

6. Comments / Problems / Critical Incidents (please use additional sheets if required) *Datix* **Yes / No number: _____**

PROCESS ISSUE

- ☐ Patient identification error- Incorrect Blood Component Transfused (IBCT)
- ☐ 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
- ☐ Contra indicted procedure e.g.. infected hip

Please send completed form to Blood Bank FAO Transfusion Practitioner via Blue Tag Box

BBFORM118 – Cell salvage data collection form
Revision No: 1
Approved by: H Clarke
Date of review: 22nd August 2022
Expiry Date: 31st August 2024

Page 1 of 2

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
- ☐ Patient Died
- ☐ Blood processed but not all given to patient – please give details:

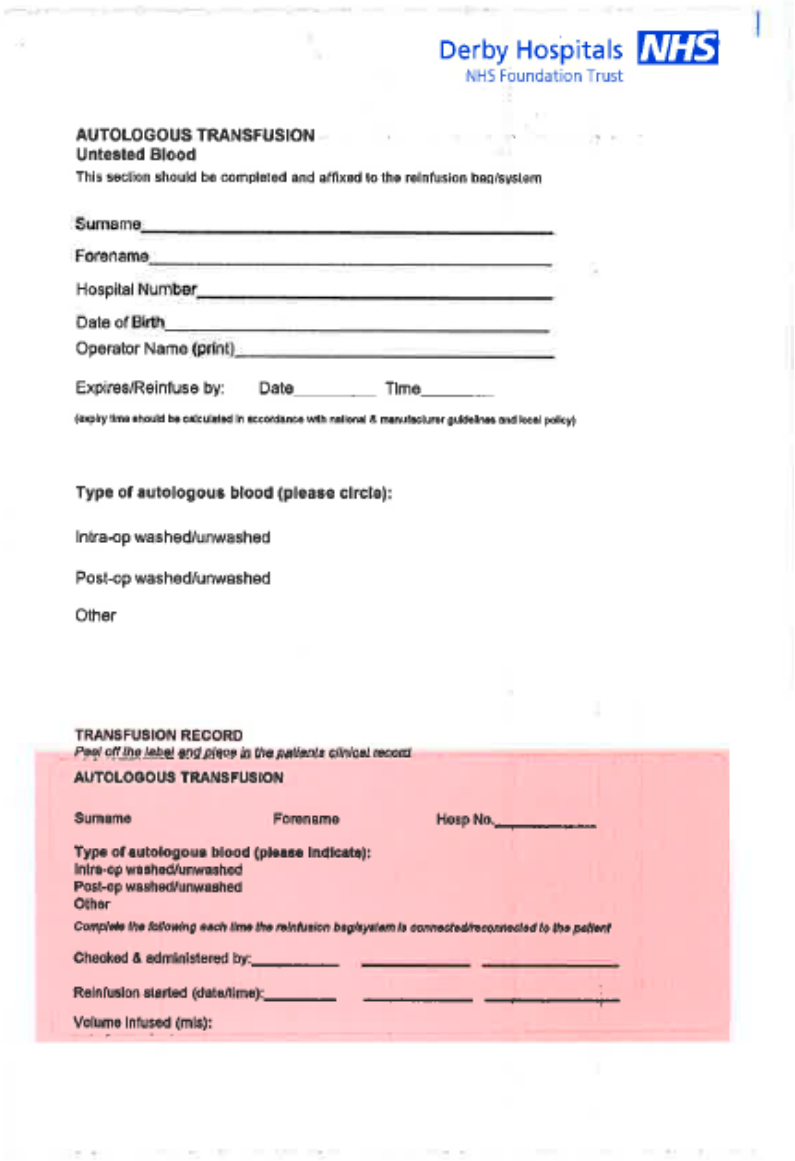
- ☐ Machine System Failure - Any stoppage of the machine where operator has not made the decision to halt the procedure. Please give details:

- ☐ Other – please give details:

Return to Blood Transfusion Practitioner
Transfusion Practitioner Office
Next to Blood Bank
Pathology
Level 5
Royal Derby Hospital
DE22 3NE

Appendix 5

Labelling



Derby Hospitals NHS
NHS Foundation Trust

AUTOLOGOUS TRANSFUSION
Untested Blood
This section should be completed and affixed to the reinfusion bag/system

Surname_____

Forename_____

Hospital Number_____

Date of Birth_____

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 (please circle):

Intra-op washed/unwashed

Post-op washed/unwashed

Other

TRANSFUSION RECORD
Peel off the label and place in the patient's clinical record
AUTOLOGOUS TRANSFUSION

Surname Forename Hosp No._____

Type of autologous blood (please indicate):
Intra-op washed/unwashed
Post-op washed/unwashed
Other

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

Checked & administered by:_____ _____ _____

Reinfusion started (date/time):_____ _____ _____

Volume infused (mls):

Appendix 6

SHOT Reportable incidents

UK CELL SALVAGE ACTION GROUP

SERIOUS HAZARDS OF TRANSFUSION SHOT

Reporting adverse events and reactions relating to Cell Salvage to SHOT

Guide for staff involved in the use of peri-operative and post operative cell salvage equipment

Introduction
SHOT is providing a new way to report adverse event and reactions related to the use of intra operative and post operative cell salvage. Following the successful pilot of the Cell Salvage incident reporting study, it was decided to include the reporting of these incidents into the new SHOT Dendrite online database.

What to report to SHOT
Any adverse events or reactions associated with intraoperative (ICS) and postoperative (PCS) cell salvage (washed or unwashed). Please note that adverse events and reactions associated with acute normovolaemic haemodilutioin and PAD (pre-operative autologous donation) can also be reported to SHOT but not via the cell salvage pathway. They must be reported to the hospital transfusion team in the same way as adverse events are reported for donor blood. In the table below is the list of trigger events to report and the categories that they fall into.

Category	What to report
Operator error	Patient Identification error – Incorrect blood component transfused (IBCT)
	Equipment not assembled correctly to include both collection and processing equipment
	Incorrect dilution of heparinised saline
	Inadequate anticoagulation - clotting in reservoir
	Non IV Saline used for the wash
	Contraindicated substances aspirated into the collection reservoir
	Reinfusion bag not labelled for the patient - either ICS or Post operative cell salvage (PCS)
	Time exceeded for collection and/or Reinfusion for either ICS or PCS
	PCS system not assembled correctly
	Incorrect swab washing
	Contraindicated procedure eg infected hip
Machine/System failure	Any stoppage of the machine where the operator has not made the decision to halt the procedure
	Reinfusion bag falls off (PCS)
Category	What to report
Clinical events	Air embolism
	Fat embolism
	Signs of acute haemolytic transfusion reaction - pyrexia, rigors etc
	Hypotensive episode on reinfusion of processed red cells - not related to hypovolaemia
	Bacterial contamination
	Anaphylaxis or other allergic reaction
	Other - please state

Making the Report
Please use a copy of the SHOT Dendrite data collection form to collect the data required to make the report. ***Once you have collected the data required for the report, please send it to the Hospital Transfusion Team who will enter the data onto the SHOT Dendrite database.***

Appendix 7

Cell Saver Operator training
Training and Competency Documentation

Name: _____ Date: _____

August 2022

Version Number: 4

Documentation control
Approved by:
Date of Approval:
Date of Next Review: August 2019
Author (s): Cell Saver Working Group
Department Responsible for Review: Clinical Education- Theatres

PLEASE PRINT ONLY THE WORKBOOK

CONTENTS

HOW TO USE CELL SAVER OPERATOR COMPETENCY DOCUMENTATION

Training is split into 3 phases:

1. Knowledge (delivered in-house) and by the NHS e-learning on-line training course
2. Practical training (delivered by SORIN and ICS assessors)
3. Supervised practice

This **training record** should be filled in as you progress. Once completed it is kept yourself as evidence of CPD for your personal portfolio.

The length of time to complete phase 3 will depend on the individual but it is recommended that a period of supervised practice is undertaken before being assessed by SORIN or an in-house ICS assessor as competent. This period of supervision ensures that formative assessments and progress are made.

It is up to the individual trainee ICS operator to identify opportunities in practice to complete training.

It is recommended, as far as practicable, that a range of specialities are covered to gain experience in the varied situations where the skill of an ICS operator is required in an emergency.

The trainee will seek opportunities to work in the same theatre as a competent ICS operator or ICS assessor when patients are requiring cell salvage.

The trainee will seek opportunities for support by the ICS assessor to agree when ready for final summative assessment.

The **medical device verified assessment** form is the Trust competency record and should be signed off on completion of each phase, by the person who has undertaken the formative assessment (in the grey column). Phase 3 training box should be signed only when ready for a final summative assessment.

The summative section can be signed off only when competence has been agreed by a nominated assessor.

Once the verified assessment has been signed off the document should be kept in the department's equipment training records.

Verified assessor to give the local medical device rep the verified assessment form. This will assure that training records are up to date.

The theatre clinical educators will request a certificate from SORIN.

PHASE 1: TRAINING

Knowledge

It is essential that all practitioners operating the cell saver are aware of the reasons for its use, contra-indications and potential problems that may occur. Assessment of the following knowledge outcomes is to be undertaken and is supported by the following:

- ✓ Manufacturers instruction manual
- ✓ NHS e-learning online training course
- ✓ Attendance at the in-house study day
- ✓ Mandatory Trust Blood Product Theory Training must be up to date
- ✓ UHDB Policy for Intra Operative Cell Salvage

Knowledge Outcomes

- Advantages of autologous blood transfusion
- Suitable cases
- Cell saver operator responsibilities
- Contra-indications
- Principles of cell salvage
- Supporting equipment
- Collection and anti-coagulation
- Processing
- Transfusion
- Disposal of equipment
- Responsibility of the scrub practitioner
- Principles of blood transfusion

Cell saver training day attended on:

Practice outcomes

Collection

- Set up of collection kit onto machine
- Anticoagulation selection
- Switch on machine vacuum
- Priming of collection reservoir with anticoagulant

Programme selection

- Select ATS programme suitable for an orthopaedic procedure
- Select ATS programme suitable for an emergency procedure
- Select ATS programme suitable for an elective vascular procedure

Processing

- Load wash / procedure set onto machine
- Process one full bowl in manual mode (if required)
- Process one full bowl in auto mode
- Demonstrate return function
- Demonstrate concentrate function
- Demonstrate removal of air from re-infusion bag

Quality control

- Perform blood loss calculation, using machine data
- Take sample from re-infusion bag

Problem solving

Identify the cause of, and then rectify various problems including.

- During collection set up
- With machine vacuum
- During programming
- During processing

Practice outcomes assessed at workshop by:

PHASE 3: TRAINING

Supervised practice log

The number of occasions for supervised practice required will be unique to the individual and it is their responsibility to ensure they are confident in ICS use before undertaking assessment.

The practice paperwork has 2 columns one for observed practice and one column to sign off competence.

It is not necessary for all supervised practice boxes and columns to be completed; however, it is essential that all boxes ARE signed off as competent.

It is advised that at least one supervised practice occasion should be carried out for a different speciality. This is to allow exposure during the training phase to support emergency practice in or out of hours.

.

Supervised Practice Log book

Process	Observed practice (sign/date)	Competence achieved Sign/date
Sets up equipment in the clinical environment for: ▪ Collect only ▪ Full processing		
Understands the need for and can demonstrate aseptic techniques		
Demonstrates use of correct anticoagulant and wash solutions to use within their clinical setting		
Can correctly prime the system prior to collection		
Evidence of completion of documentation used within the Organisation **NB All procedures should be documented**		
Demonstrates the necessary Health & Safety knowledge when setting up and disposing of the equipment for ICS		
Able to demonstrate simple machine troubleshooting eg: responding to alarm when wash solution empty		
Demonstrates correct labelling of the collection reservoir and the red cell re-infusion bag		
Salvages blood from swabs at the correct stage in the process		
Demonstrates use of the appropriate wash solution and volumes to be used i.e. IV saline to use in processing red cells		
Demonstrates use of the appropriate wash programmes in the different specialties		
Uses appropriate filter to re-infuse according to hospital policy		
Demonstrates how to prepare and re-infuse in accordance with patients religious or other beliefs. **NB must be done at least once during training (on non HW patient if necessary)**		

Log no.	Date	Operation	Set up only	Full processing kit	Volume infused
1.					
2.					
3.					
4.					
5.					
6.					
7.					
8.					
9.					

List of verified operators who can provide supervision during the training phase

	Name	Department
1.		
2.		
3.		
4.		
5.		
6.		
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41.		
42.		

List of nominated ICS assessors who can verify competence and 'sign off' the training

	Name	Department
1.		
2.		
3.		
4.		
5.		
6.		
7.		

List of Trainees requiring supervised practice

	Name	Department
1.		
2.		
3.		
4.		
5.		
6.		
7.		
8.		

Staff requesting refresher training

	Name	Department
1.		

Verified assessment v2.1

NHS
University Hospitals of Derby and Burton
NHS Foundation Trust

Competency Record

For University Hospitals of Derby and Burton NHS Foundation Trust Employees.

Staff Details: (please print)

Directorate and Profession	
Department/Ward	
Name (as on payslip)	

Equipment that you use in your area

(See reverse for full instructions)

Name of equipment (Model and Make)	Training		Assessors Signature
	Required at this time? (Y/N)	Given? (Date)	No signature = NOT Competent (Date)

Verified assessment form

Medical Devices Training

30/10/19