# Autologous Cell Salvage during surgery and acute trauma

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Who should read this document?

- Anaesthetists
- Surgeons
- Operating Department practitioners
- All staff working in theatre where ICS can be provided
- Staff working in the Emergency Dept where blood can be salvaged in trauma patients

Key Messages

- ICS should be considered as the first line for red cell transfusion, except where it is contra-indicated.
- ICS should be available for all cases of massive haemorrhage, except when contra-indicated.
- ICS should be available for immediate use during emergency trauma surgery (especially abdominal injury).
- ICS should be immediately available for patients with ruptured ectopic pregnancy.

Contraindications for ICS

- Patient refusal
- An operative site that is heavily contaminated blood aspirate (tumour, infective material, bowel contents, urine, metalosis from metal on metal prostheses)
- Lack of trained staff to collect or process the aspirate

Blood and fluid should not be aspirated for processing if it contains

- Fresh bone cement
- Topically applied pro-coagulant material (eg fibrin glue)
- Wash that is not IV saline
- Topical antibiotics
- Faecal material, pus, urine, high concentrations of tumour cells

- ICS requires the theatre staff to be aware of the safety issues regarding ICS delivery and theatre medical staff to understand safe collection of substrate.

- Scrub staff have a responsibility to support effective ICS usage, perform swab washing appropriately and in a timely fashion

- The ICS machinery is to be operated by a trained ICS Practitioner (ICSP)

- Intra-operative Cell Salvage (ICS) is integral in the Patient Blood Management approach to peri-operative blood loss and transfusion management

- ICS blood product (red cells suspended in normal saline) functions better than stored red cells in all aspects of erythrocyte function

- Donor Blood transfusion causes immunosuppression in a dose dependant fashion

### Background & Scope (1.0)

1.1 Intra-operative cell salvage (ICS) offers a method of harvesting red cells shed during surgery, processing them and preparing them for safe return to the patient’s own circulation as autologous red cell transfusion.

1.2 It is an integral part of the Patient Blood Management Program (as endorsed by the Chief Medical Officer), and contributes to the reduction in use of donor red cell transfusions.[1](National_PBM_recommendations.pdf: appendix 1)

1.3 It can be thought of as Point of Care Autologous blood donation, processing and re-infusion.

1.4 Clinical benefit:

   1.4.1 Donor red cell transfusion causes a dose dependant Transfusion Related immunosuppression (TRIM), this increases the patient’s risk to infection[2] and possibly increases the risk of tumour recurrence or metastatic growth[3] reduces the volume of red cell transfusion and hence reducing or eliminating TRIM.

   1.4.2 Transfusion of donor red cells causes sensitisation, which can result in antibody formation.

   1.4.3 Antibody formation following transfusion of donor red cells in women of child-bearing age increases the risk of haemolytic
complications in the foetus. Avoiding transfusion in this patient population is of particular importance[4]

1.4.4 Although transmission of infection through donor products is thought to be extremely small, reducing or eliminating donor transfusion by using ICS, reduces infection transmission.

1.4.5 ICS blood offer betters oxygen delivery than stored blood. This is because the red cells re-infused following ICS are not stored, (being extracorporeal for a maximum of 6 hours); normal deformability and physiological amounts of 2,3 DPG are hence maintained.[5] [6]

1.4.6 The concentration of free haemoglobin in ICS transfusion is probably less than seen in allogeneic (donor) transfusion. The concentration of free haemoglobin in donor transfusions increases over time(28uM at 35 days increasing to 80uM at 50 days). Red cell degradation also occurs during storage with storage age dependant release of free haemoglobin and release of immune-active substances[7]

1.5 Financial considerations.,
These can be divided into three categories.

1.5.1 Reduction of transfusion of allogeneic units; the cost of a single unit of blood is in the region of £125, however cross-match and processing costs lead to estimates of the first unit costing in the region of £400. Cost savings are therefore dose dependant[8].

1.5.2 As ICS reduces post-operative anaemia and reduces the dose of allogeneic transfusion, there is a reduced risk of post-operative morbidity resulting from reduced oxygen delivery and TRIM related infection.

1.5.3 Additional safety and cost benefits exist as peri-operative use of ICS can reduce the need for post operative ward transfusion of red cell products.

1.5.3 By using a new delivery model (the duel roll ICSP), delivery costs will be significantly reduced.

The ICS process

1.6 The Cell Saver system used at SRFT (Haemonetics 5 &5+) use the principles of filtration and centrifugation to prepare a suspension of red blood cells in normal saline from the substrate obtained from wound suction and swab washing.

1.6.1 A full bowl of processed red cells will have a haematocrit of between 50-60%.

1.6.2 The processing of a non- ‘Full Bowl” (known as a Partial Bowl) will generate salvage product of lower haematocrit, with the
potential to contain greater concentrations of contamination products, including free haemoglobin.

1.6.3 The processed salvage product will not contain clinically relevant platelets or clotting factors.

1.6.4 The processed product may contain small quantities of leucocytes and possibly individual cells (including malignant); it may contain micro-aggregates and may contain fat droplets (especially in the context of spinal and orthopaedic surgery).

1.6.5 Any anticoagulants used in the collection process are removed in the washing process.

What is new in this version?

- An increased emphasis is placed upon all members of the theatre team to consider ICS as part of the Patient Blood Management principles (avoiding the use of allogeneic transfusion)
- Clinical staff working with ICS require specific training to enable them to work in a clinical area where ICS is being utilised.
- ICS education will be provided by an “in-house” specialist team consisting of Consultant Anaesthetists, ICS Lead Educator and experienced ICS practitioners.
- Inclusion of ICS as a consideration during the Team Brief and the Time Out aspects of the WHO checklist.
- ICSPs will undergo yearly Appraisal and reaccreditation of their practise

Policy/ Guideline/ Protocol (2.0)

2. Recommendations for use of Cell Salvage (Adapted from AAGBI Guidelines, Massive Haemorrhage, ICS)

2.1 ICS is indicated and to be considered in surgery where

2.1.1 Anticipated blood loss of > 750mls or > 10% of estimated blood volume.
2.1.2 Patients with low Hb or increased risk factors for bleeding
2.1.3 Patients with multiple antibodies or rare blood groups
2.1.4 Those patients who refuse blood products for ethic, religious* or through choice should be considered for ICS when undergoing surgery where blood loss is anticipated.

*Jehovah’s witnesses have varying views regarding ICS, ranging from refusal, to the use of a closed circuit system, to standard ICS practise, with a non-complete circuit.
2.1.5 ICS should be standard equipment for patients experiencing massive haemorrhage.

2.1.6 The ICS machine should be brought to the ED when acute bleeding is experienced and the blood collection is appropriate. The ICS machine should be brought from the operating theatres in this situation.

2.2. Contra-indications for Cell Salvage

2.2.0 concepts governing collection of substrate are to avoid aspirating the following

2.2.1 material that does not contain red cells
2.2.2 drugs or compounds that are not licensed to be injected intravenously, specifically:
   2.2.2.1 Antibiotics not licensed for IV usage
   2.2.2.2 Iodine
   2.2.2.3 Topical clotting agents
   2.2.2.4 Fibrin based glues
   2.2.2.5 Orthopaedic cement
   2.2.2.6 Body fluids where possible such as urine, blood heavily contaminated by faecal material
2.2.3 Avoid aspirating when there is known or suspected sepsis at the operative site
2.2.4 Avoid aspiration in the vicinity of tumour cells-this reduces tumour load in the ICS substrate, therefore reducing the number of tumour cells in the processing stage of ICS.

2.3 ICS usage in Malignancy Surgery

2.3.1 The use of ICS in the presence of malignancy is the subject of debate. It is known that tumour cells may be present in the final product (Hansen. The tumour load can be significantly reduced by the use of a Leucocyte Depletion Filter (LDF)[9], however all tumour cells may not be removed[10].

2.3.2 Increasing evidence is emerging to demonstrate that the use of ICS in malignancy does not increase local recurrence of distant metastasis.[11]

2.3.3 The use of ICS in place of allogeneic transfusion may have a beneficial effect on local recurrence or distant metastasis on account of the dose dependant immunosuppressant effect of donor blood . This phenomenon is Transfusion Related Immunomodulation (TRIM).
2.3.4 Evidence exists to support the safety of ICS in various malignant conditions, with no increase in post-operative mortality or morbidity.[12-14]

2.3.5 The use of ICS in cystectomy and radical prostatectomy is recommended by NICE (see Appendix 1)

2.3.6 There is no evidence of metastasis when ICS is used in intrinsic brain tumour surgery or meningioma surgery.

2.3.7 ICS is not advised in patients having surgery for primary, isolated tumours of bone, where no histological diagnosis is known.

2.3.8 The use of an LDF is recommended when ICS is used in tumour surgery.[9 15-17]

2.3.9 Each case should be discussed where possible between surgeon and anaesthetist prior to offering ICS to the patient. Specific concerns can be discussed with the ICS Lead Clinician,

2.3.10 NICE guidelines (see Appendix 1) for the use of ICS urological malignancy currently advocate its use in cystectomy and open prostatectomy. It is used widely in Nephrectomy.

2.3.11 Cell Salvage is relatively contra-indicated in patients with haemoglobinopathy, such as sickle cell trait/disease, thalassemia's. This is due to red cell fragility, risk of deformation and potential for haemoglobin precipitation, it has however been used successfully in patients with Sickle Cell Disease[18]

2.3.12 Conditions such as cold agglutinin disease present problems with ICS, though on account of issues with antibodies and cross match, ICS should still be considered in such patients (noting that the salvage substrate and product should be kept above the agglutination temperature.

2.4 Conditions for Use

2.4.1 Cell Salvage should only be undertaken in situations where theatre staff (surgeon, scrub nurse, anaesthetist) are appropriately trained, and a trained (see 3.11) ICS Practitioner available to supervise the use of the ICS machinery.

2.4.2 The process of safe collection is the responsibility of the theatre team under the guidance of the ICS Practitioner: processing should be supervised at all times by the ICS practitioner OR the clinician responsible for the re-infusion of the salvage product.

2.4.4 In situations of massive haemorrhage, the ICS practitioner will have the single role of performing ICS and will be unable to
assist in other tasks within the theatre environment,. It is entirely possible that the ICS practitioner will require an assistant during situations of rapid, life threatening haemorrhage.

2.4.5 In situations where massive haemorrhage is expected (especially major trauma or vascular injury), ICS should be made immediately available, allowing for substrate collection from the time of first incision.

2.4.6 Collection of blood substrate using the ICS reservoir should be considered if a delay in setting the ICS machine is anticipated.

2.4.7 With any substrate collected in this way, the reservoir collection must be labelled and identified with the patient identification information (Name, Hospital Number, Date of Birth)

2.4.8 If the rapid IV infuser (Level 1®) is requested, ICS should automatically provided, unless there is an absolute contra-indication to ICS

2.4.9 The ICS service is supported by the presence of an ICS Coordinator or Floating ODP who is able to provide support in the event of anaesthetic complications or massive haemorrhage. In theatres where ICS is being provided the ODP is supported by a theatre Health Care Assistant /Support Worker who assists in the non clinical responsibilities of the ODP

2.5 WHO Theatre Discussions

2.5.1 At the time of team brief and WHO timeout, specific questions should be added to identify whether ICS is to be considered for the particular case.(see Figure 1)

2.5.2 In the situation where ICS is to be used, questions are to be asked to confirm that the theatre team are aware of the requirements for safe ICS practise

2.5.3 Identification of correct suction practise

2.5.4 Confirmation of agents not to be aspirated

2.5.5 The conduct of ICS and cleansing of a contaminated site to allow recommencement of the ICS collection

2.5.6 The type of anticoagulant to be used is confirmed

2.5.7 The decision regarding swab washing is taken and the correct practise reiterated. (See later)

2.5.8 When the wound is to be irrigated or swab washing used, the fluid to be used must be “Normal Saline for IV infusion”
1. Is ICS indicated in this case?

2. Are there any possible contra-indications: malignancy, infection, site of surgery etc?

3. Is swab washing being used?

4. Is all irrigation/swab wash fluid Saline for injection/IV use?

5. Are the staff skill levels proficient for using ICS safely?

6. Are all staff aware of what products can and can not be used in the surgical site with ICS?

7 Are the surgical team (including scrub team) aware of the techniques of suction that will reduce the risk of red cell trauma & collection of contaminants?

2.6 Conduct of ICS

2.6.1 The ICS practitioner is responsible for clarification and supervision of the theatre team with respect to issues raised during the ICS Time-out.

2.6.2 In the circumstances where issues are still unresolved, the ICS Lead Clinician should be contacted.

2.6.3 Where concerns are still raised with respect to suitability or safety, it will be the decision of the attending consultant anaesthetist and surgeon as to risk: benefit analysis

2.6.4 In situations of doubt, the recommendation should be to avoid using ICS.

2.6.5 It should be remembered that it is the responsibility of the ICS practitioner to oversee the safe collection and processing of the ICS product.

2.6.6 The ICSP has the responsibility to discuss with the responsible clinician (attending anaesthetist) whether there has been a problem with collection or processing, whether there is doubt relating to quality of the product.

2.6.7 Processing of a partial bowl requires either concentration from bagged product awaiting reinfusion (preferably) or a “double” wash

2.6.8 In the context of relative contraindications (malignancy and infection) it is the ultimate responsibility of the clinician administering the product to decide whether it should or should not be used.
2.6.9 The bag containing the cell salvage product should be clearly marked with the patient's identifiers; name, date of birth, hospital number.

2.6.10 The salvage product should be re-infused within 6 hours of collection.

2.6.11 Any salvage product infusion should be complete prior to leaving the operating theatre.

2.6.12 Re-infusion of the product under pressure is to be discouraged due to the risk of air embolus and bag rupture.

2.6.13 If there is fat present in the re-infusion bag, the fat should be allowed to coalesce, the re-infusion bag should not be emptied in order to limit fat re-infusion. (see below)

2.6.14 The quality of the product and the condition of the collection system, bowl and lines should be regularly inspected for signs of sludge and fat deposition.

2.6.15 IV paracetamol can cause clumping of ICS product in administration sets and filters; any IV line containing paracetamol should be flushed before commencing ICS transfusion. The infusion line should be flushed after completion of the infusion to reduce the risk of red cell clumping in the infusion line.

2.7 The Use of Filters during the reinfusion of ICS Product

2.7.1 A Lipid Reduction Filter (LipoGuard® SB Reinfusion Filter for Salvaged Blood) should be used when there is an increased risk of micro-aggregates or fat in the ICS substrate or fat is present in the tubing or re-infusion bag.

2.7.2 A Leucocyte Depletion Filter (LDF)**** should be used in cancer surgery. LDFs require priming and significantly reduce the rate of re-infusion. They should be replaced after 400mls of re-infusion.

2.7.3 Reinfusion Hypotension is relatively common, and can be extreme, when LDFs are used. This is a well recognised complication. Hypotension can be precipitated by squeezing the filter.

2.7.4 All reperfusions hypotension events such should be reported through the AIR reporting system with the Transfusion Practitioner submitting a SHOT report.
2.8 Setting up the Cell Saver 5 for Blood Collection

Supplies needed:
- LN 200 3 litre reservoir
- LN208 Aspiration & Anticoagulant Assembly (A&A line)
- LN261 or LN 263 Bowl Set
- Anticoagulant Heparin or ACDA
- IV. Saline
- Suction Source

(i). Install reservoir and close RED drain.


(iii). Attach suction source to YELLOW port.

(iv). From sterile field attach A &A line to BLUE port, close roller clamp.

(v). Hang anticoagulant bag from top pig-tail on IV pole, aseptically spike bag.

(vi). Open roller clamp, prime reservoir with anticoagulant, adjust roller clamp to set correct delivery rate of anticoagulant.

(vii). Install the bowl. Push the centrifuge chuck, lower the bowl port points to right.

(viii). Secure the bowl, move bowl arm and turn locking knob to 12 O’clock.

(ix). Thread tubing through Line Sensor.

(x). Hang re-infusion bag from top pig-tail on IV pole. Check BLUE connection. Close two RED slide clamps.

(xi). Hang waste bag and check connections. Check drain port is closed.

(xii). Install tubing manifold. Thread tubing around pump.

(xiii). Load pump and air detector. Close pump lever.
(xiv). Close manifold door.

(xv). Attach **RED** line to reservoir and open slide clamp.

(xvi). Hang the saline wash bags so that they cascade. Close both slide clamps before spiking the saline bags, unclamp one line at a time.

(xvii). Inspect all parts of disposable for twists, kinks or flat spots and all appropriate clamps and covers are closed.

(xviii). Press **START** once the system is properly loaded and the system will enter standby mode and be ready to start processing.
Intra-Operative Swab Washing

Using aseptic technique, fill a bowl with 1000ml of Normal Saline (IV). 5000 units of Heparin is added to this; the heparin is to be checked with the ICSP and set up a set of digital scales inside a clear sterile bag.

(If using 12x12 or 18x18 swabs, then use 2000ml Normal Saline with a further 5000mls Heparin)

Place a sterile receiver onto the scales and reset to zero. Weigh the saturated swabs before placing into the bowl, to ascertain the blood loss. Record the weight of the swabs.

Once the swabs have been weighed, place them into the bowl of citrate and leave to stand for 10 – 30 minutes.

The swabs may then be gently agitated and squeezed out into the bowl. DO NOT WRING OUT THE SWABS, as this will destroy viable red cells.

Ensure the reservoir on the machine is empty of previously processed contents, and that the blood loss has been recorded.

Aspirate the contents of the bowl into the collection reservoir and process in the normal way. This should be performed every 2 hours. More frequent aspiration is necessary with heavily blood soaked swabs.

The time from swab collection to completion of processing must not exceed SIX hours.

Dry Weight of Swabs

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Standards (3.0)

Standards exist for safe delivery and availability of ICS when indicated.

3.2 The Serious Hazards of Transfusion (SHOT) committee have issued audit standards as listed below

3.3 ICS should be available for all patients where it is clinically indicated.

3.4 ICS should be used for per-operative transfusion unless it is contra-indicated or the requirement for red cell transfusion exceeds the ICS product being generated.

3.5 All data relating to usage of ICS is recorded on the IoCS SUNRISE document. This includes episodes where no product is re-infused into the patient.

3.6 ICS episodes are registered as an ICS Health Issue on each occasion that it is used.

3.7 There is no paper documentation for the recording if ICS usage.

3.8 Adverse incident reporting

3.8.1 All ICS related adverse incidents (AIRs) are to be designated as Intra-Operative Cell Salvage events, under the parent category of Blood Transfusion.

3.8.2 All members of the ICS Delivery Group will be informed of the incident via Trust email account.

3.8.3 AIRs relating to ICS may be required to be submitted to SHOT; this is performed by the Trust Transfusion Practitioner, with support of the ICS Trust Lead.

3.9 No National Standards exist with respect to the qualification process for ICSP competency or accreditation of training. As a result, best practise is guided by the UK Cell Salvage Action Group (UKCSAG)

3.10 Standards for staff competency and appraisal are those developed and used by the Renal Services Team, in line with standards in delivery of Dialysis and Plasma Exchange

3.11 Trained staff, in this context refers to staff who have undertaken formal ICS training consisting of theory and practical training with in theatre assessment supervised by a ICS trainer, and deemed to have reached the required standard.
Explanation of terms & Definitions

**Patient Blood Management (PBM)**
The model used to reduce the unnecessary use of donor blood products. This evidence based approach has 3 pillars of practice
1) Management of pre-operative anaemia
2) limitation of peri-procedure blood loss
3) the use of restrictive transfusion

**Transfusion Related Immunomodulation (TRIM)**
The reduction in immune function seen following the use of donor blood products; this results in the increased risk of hospital acquired infection, wound infection and an increased incidence of tumour related morbidity (local and distant recurrence).

**IoCS**
The abbreviation for the Intra-Operative Cell Salvage documentation on SUNRISE

**Serious Hazards of Transfusion(SHOT)**
The National Reporting and Auditing database for complications and adverse events regarding patients who receive blood products.

**Intraoperative Cell Salvage Practitioners**
The qualified practitioners who oversee the process of collection, processing and re-infusion of autologous blood in the operating theatre

**Elective Surgical Pathway(ESP)**
The Elective Surgical Pathway refers to the documentation that accompanies the patient for visit to the Operating Theatre. This consists of the ELE (The Elective Pathway on SUNRISE) and the paper ESP that contains the consent and anaesthetic chart.

**Association of Anaesthetists of Great Britain and Ireland(AAGBI)**
The AAGBI has a broad constitution that enables it to promote and advance education, safety and research in anaesthesia, as well as the professional aspects of the specialty and the welfare of individual anaesthetists. With respect to ICS it has published guidelines relating to peri-operative blood transfusion. [http://www.aagbi.org/publications/publications-guidelines/](http://www.aagbi.org/publications/publications-guidelines/)

**Leucocyte Depletion Filters(LDFs)**
A filter added to the re-infusion line (in addition to the standard filter in the IV giving set), that reduces leucocytes, cellular tissue and possibly bacteria in the final re-infusion product. They reduce the flow rate of infusion and become inefficient following re-infusion of 400mls of blood. LDFs are associated with the recognised complication of reinfusion hypotension(see below)
Lipid Reduction Filter
An additional filter that can be included in the re-infusion line to reduce the lipid load that may be encountered during ICS where bone marrow or adipose tissue is aspirated during collection.

Reperfusion Hypotension
The recognised complication of reinfusion of ICS blood, most commonly seen when LDFs are used. All such re-infusion hypotension events should be reported to SHOT.

Autologous Transfusion
Re-infusion of the patient’s own blood products. In ICS this refers to red cells only.

Allogeneic Transfusion
Transfusion of blood products from the donor bank. This includes packed red cells and the pooled products used for coagulation correction.

References and Supporting Documents

15. <edelman.pdf>.
Roles and responsibilities

4.1 Executive Medical Director

Is accountable to the Trust Board for ensuring compliance with this protocol in all parts of the trust.

4.2 Hospital Transfusion Committee

Is the portal to the Trust Governance Process for the ICS service.

4.3 ICS Delivery Group

4.3.1 Is responsible for promoting the safe usage of ICS in all appropriate situations, monitoring and auditing practice to ensure compliance with this policy. The group has the responsibility to support the ICS aspects of Patient Blood Management.

4.3.2 The ICS Delivery Group consists of the following members

- Trust ICS Clinical Lead: Dr Craig Carroll
- Specialist Practitioner in Transfusion: Lydia Baxter
- Representative: Mr Rajat Verma
- Hospital Transfusion Committee: Dr Martin Thomas
- ICS Educator: Gareth Manning

4.4 The Trust Intra-operative Cell Salvage Clinical Lead

Has responsibility to report to the Hospital Transfusion committee. The ICS lead has a responsibility to promote safe, effective use of ICS and to support clinicians in the implementation of PBM (alternatives to red cell transfusion).

4.5 The Trust ICS Educator/Lead Practitioner

The ICS Educator has the responsibility to deliver training for all theatre staff who will be involved in cases where ICS is used, and oversee the education of ICS Practitioners.

4.6 All Staff where ICS is indicated and used.

Are responsible for checking that their activity complies with the guidance in this document.

4.7 Theatre Service Managers

Have the responsibility of ensuring that capacity exists for the delivery of ICS to any when it is clinically indicated.

4.8 Pre-Operative Clinicians and Nursing Staff

Have responsibility in identifying those patients who may be candidates to benefit from ICS. They are obliged to discuss the alternatives to
allogeneic transfusion with the patient. If the option for ICS exists and it can afford benefit to the patient, the patient is empowered to request ICS be made available during surgery (see appendix 1) (https://www.supremecourt.uk/decided-ases/docs/UKSC_2013_0136_PressSummary.pdf)

**Appendices**

**Appendix**


   Nice Guidelines Blood Transfusion[NG24]

   [https://www.nice.org.uk/guidance/ng24](https://www.nice.org.uk/guidance/ng24)

   NICE Guidelines for Intra-operative Cell Salvage for radical cystectomy and radical prostatectomy

   [https://www.nice.org.uk/guidance/ipg258](https://www.nice.org.uk/guidance/ipg258)