

INTRAOPERATIVE CELL SALVAGE

"Getting Started"

Adapted from an original document developed in Wales by the Better Blood Transfusion Team

Version 1 July 2008

CONTENTS

1.	Introduction	Page 3
1.1	Intraoperative cell salvage (ICS)	Page 3
1.1.1	Advantages of ICS	Page 3
1.1.2	Use in Emergency	Page 3
2.	Getting started	Page 4
2.1	Lead Clinician	Page 4
2.2	Lead Manager	Page 4
2.3	Cell Salvage Co-ordinator	Page 4
3	Assessment of clinical case mix for ICS	Page 5
3.1	Procedures suitable for ICS	Page 5
4	Choosing your machine/system	Page 6
4.1	Cell washing devices	Page 6
5	Contaminants / Contraindications	Page 7
5.1	Fat	Page 7
5.2	Urine	Page 7
5.3	Amniotic fluid	Page 7
5.4	Bacterial contamination/ Bowel contamination	Page 7
5.5	Malignancy	Page 7
5.6	Others	Page 7
6	Education / Training	Page 7
6.1	General training	Page 7
6.2	Training for machine operators	Page 7
6.3	Support	Page 8
7	Documentation	Page 8
8	Quality control	Page 8
9	Costs associated with Cell salvage	Page 9
10	Safety issues	Page 9
10.1	Free Hb	Page 9
10.2	Dilutional coagulopathy Page 9	
10.3	Air embolus Page 9	
10.4	Contaminants Page 9	
11	Further reading	Page 10
12	References	Page 10
Appendix 1	Finding the right machine	Page 11
Appendix 2	Experienced ICS users and operators	Page 14
Appendix 3	Generic UK Autologous Transfusion Label	Page 15

Introduction to Intraoperative Cell Salvage

1. Introduction

Allogeneic (donor) blood is a valuable resource and although potentially life-saving, it is not without risks. Risks include wrong blood incidents, transmission of infection and immunosuppression.

The Health Service Circular 2007/001 Better Blood Transfusion Safe and Appropriate Use of Blood¹ requires Trusts to:-

"Ensure the appropriate use of blood and the use of effective alternatives in every clinical practice where blood is transfused"

Intraoperative Cell Salvage is a form of autologous transfusion where red cells which are lost during or immediately after surgery are recovered, washed and re-infused to the patient. This document is intended to be used as a guide prior to developing a cell salvage programme. It should be used in conjunction with the generic policy developed by the UK Cell Salvage Action Group.

1.1 Intraoperative cell salvage (ICS) is by far the most widely used and accepted method of autologous transfusion. Blood lost during surgery is recovered, the red blood cells are separated from the other components, washed and re-infused to the patient.

1.1.1 Advantages of Intraoperative cell salvage (ICS)

- May be easier to organise as all resources are contained within the theatre environment
- Not affected by the cancellation of surgery
- Applicable to both elective and emergency procedures
- Provides fresh red cells that would otherwise be lost
- Blood is recovered in proportion to blood loss
- Reduces allogeneic blood usage
- Cost neutral when used appropriately
- By minimising exposure to allogeneic blood, it reduces the risk of immunomodulation and post-operative infection
- Oxygen transport is preserved as 2,3 DPG levels are high
- There should be limited risk of clerical error
- Acceptable to most Jehovah's Witnesses

1.1.2 Use in Emergency

In trauma cases washed cell salvage can be used to re-cycle the drainage from chest drains. The conventional chest drainage system is primed with heparinised isotonic (0.9%) saline instead of water, the cell washing system is used to process the heparinised blood which is washed and immediately reinfused. Large volumes can be processed.

2. Getting started

Greater awareness of the need for blood conservation should help influence clinicians to make wider use of autologous blood recovery techniques.

2.1 Lead Clinician.

The lead clinician should ideally be someone working in the theatre setting i.e. consultant anaesthetist / surgeon. Their role is to provide information, support and direction and includes:

- Informing clinical staff about the benefits of the autologous programme
- Agreeing indications and operations where cell salvage can be used either intraoperatively and/or post-operatively within an Organisation
- Informing and discussing with colleagues the use of ICS is unusual circumstances e.g. malignancy, sepsis, and amniotic fluid contamination. Discuss the risks of these and help make an informed judgment in matters such as the use of filters etc.
- Be responsible for the overall programme within an organisation ensuring quality systems are in place

2.2 Lead Manager

Ideally a member of the theatre management team. Their role is organisation and facilitation. They should:

- Identify a lead operator who will take on the role of cell salvage coordinator
- Arrange for time for this person to become fully trained and competent
- Be involved in the purchase of equipment, contracts for disposables, choice of consumables

2.3 Cell Salvage Co-ordinator

(When starting out it may be that the duties listed below may need to be shared by the lead clinician and manager as it would be unlikely for an organisation to have a cell salvage co-ordinator from the outset)

The co-ordinator should be a member of the theatre staff i.e. ODP, perfusionist, anaesthetic nurse. Their role is functional, co-ordinating operations requiring ICS. They are responsible for:

- Training other members of staff in theatre and/or wards and maintain competency levels of trained staff
- Arranging for cell salvage to be available at a clinician's request
- Keeping records of staff training
- Keeping records of all procedures undertaken
- Providing statistics for the Hospital Transfusion Committee (HTC)
- Coordinating machine maintenance
- Writing Organisational policies and protocols for the use of machines
- Auditing the use of cell salvage in conjunction with the Blood Transfusion Laboratory
- Undertaking quality control testing of reinfused red cells
- Arrange, if appropriate, for cell salvage to be available 24/7 as cover for emergency procedures

The co-ordinator should be fully trained and competent in the operation of all machine types used in an Organisation.

3. Assessment of clinical case mix for ICS

It is essential that staff maintain competency in this area of clinical practice. Annual figures for appropriate surgical procedures may indicate that this technique is not appropriate in your organisation, however use of post-operative drainage may still apply.

ICS is indicated in surgery with:

- A clean operative field (see contraindications for procedures which *may* be considered unsuitable)
- Anticipated blood loss of >1000mls or >20% Estimated Blood Volume or a 2 unit cross-match (adults).

Other factors which may be influence the use of ICS (in procedures where the anticipated low volume blood loss would not usually warrant ICS):

- Patients with a low Hb or risk factors for bleeding
- Patients with multiple antibodies or rare blood types
- Patients with religious or other objections to receiving allogeneic (donor) blood

In all cases where a decision to use cell salvage is made it should be discussed with the patient by the anaesthetist and/or surgeon responsible for the patients care.

3.1 Procedures which may be suitable for ICS

Vascular surgery – Aortic aneurysm repair both elective and emergency

Trauma and

Orthopaedics	 Splenic/liver trauma Spinal surgery Revision hip replacement Pelvic and femoral fractures (In primary hip and knee replacement it may be better to consider post-operative drainage systems)
Urology	 Radical cystectomy Radical prostatectomy Nephrectomy Pelvic clearance
General Surgery	 Hepatectomy Abdominal / thoracic trauma Emergency laparotomy
Cardiac	 All major procedures (be aware that post-op drainage may be of use in mediastinal drainage)
Obstetric/ Gynaecology	 Placenta praevia/percreta Emergency bleeding following caesarean section
Head and Neck	

Surgery - Major procedures

Jehovah's Witnesses or any patient refusing a

blood transfusion - All surgical procedures where blood loss is expected to have an impact. Consideration should also be given to post-op drainage where indicated.

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

4. Choosing your machine/system

The following are areas that should be considered when purchasing a machine:

- Cost
- Machine maintenance
- Training programme / package, including post-sales support
- Flexibility for different types of surgery where blood loss will be at a different rates
- Ability to separate collection and processing disposables

Appendix 1. may be of use in helping to decide on the most appropriate machine for your organisation.

It is advisable to review all equipment available for the provision of cell salvage programmes as there are several options which are currently in use in the UK.

4.1 Cell washing devices

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

Centrifugal bowl system (fixed volume bowl)

Red cells are separated through centrifugation and washed with using saline. The guality of the red cells is dependent on the volume of the wash solution .i.e. Larger volumes are advised when tissue contaminants are likely e.g. in orthopaedic surgery. In these systems it is possible to set up the collection reservoir and only process should bleeding be excessive and if enough blood is collected to make transfusion worthwhile.

Continuous rotary system

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

Dynamic disc system

The dynamic disc system is similar in principle to the centrifugal bowl in the separation of red cells through centrifugation and washing with saline. However, this system has an elastic silicone diaphragm allowing for a variable volume of red cells to be processed i.e. it does not required a set volume of red cells for

processing to take place. This system is not normally used for high or rapid blood loss cases.

5. Contaminants / Contraindications

Washed and unwashed recovered blood differ in their potential for complications but modern devices are considered safe, with very few serious adverse events in the literature.²

5.1 Fat

During Orthopaedic surgery fat is processed along with red cells. There have been no reports of fat embolus so far, when cell salvage has been used, but larger wash volumes should be used to decrease the risk of fat embolism.

5.2 Urine

This does not appear to be a problem unless it is infected.

5.3 Amniotic fluid

While there is no in vivo evidence or clinical cases suggesting that unfiltered cell salvage blood causes harm, washing and filters are now standard practise to reduce the levels of amniotic fluid contaminants to levels at or below those in the maternal circulation..^{3,4,5}

5.4 Bacterial contamination/ Bowel contamination

If bacterial contamination of salvaged blood is suspected during trauma surgery reinfusion of blood is not contraindicated but broad spectrum antibiotics should be given⁶.

5.5 Malignancy

The surgeon should assess the risk benefit of its use. Clinical studies have failed to provide statistical evidence regarding tumour dissemination but this remains under review.⁷

5.6 Others

Alcohol, betadine, Fibrin Glue, Topical thrombin, Avitene, Superstat, Peroxide, Sterile water.

Whenever any of these are present suction should be temporarily discontinued until the area has been irrigated with sterile saline.

6. Education/Training

Ideally all ODP, perfusionists and anaesthetic nurses should be trained and assessed as competent to operate the cell salvage machines.

6.1 General Training

It is advisable to train all theatre staff, including surgeons and anaesthetists, to give them a broad understanding of the value of cell salvage, its contra-indications and what is provided in the end product.

6.2 Training for Machine Operators

Machine operators will need specific training from the company and /or by the organisations key trainer. It is initially necessary to build up local expertise through development of a core group of operators.

- Hospitals should identify the staff they wish to use the ICS equipment
- These staff should be allowed sufficient time for appropriate training
- Certificates of competence should be issued by the hospital
- A record of training and assessment and of on-going competency should be documented
- Competency Assessments are available on the Better Blood Transfusion Toolkit at: <u>www.transfusionguidelines.org.uk</u>

6.3 Support

Appendix 2 provides a list of experienced users and operators from the UK Cell Salvage Action Group who can be contacted for advice, liaison and practical information.

Standard Operating Procedures should be available to staff giving clear guidance on:-

- Indication and contraindications
- Who can operate the machines
- Warnings regarding contamination of the surgical field
- Rules on labelling, expiry time of salvaged blood
- Storage of recovered blood
- Documentation requirements (see section 7)

7. Documentation

It is important that red cells for reinfusion are adequately labelled and follow the same labelling principles as allogeneic red cells. To simplify identification of autologous transfusion in the patients' clinical record a different coloured label can be used. A sample of the UK generic autologous transfusion label is shown in Appendix 3. This label is currently being piloted and is available from the machine manufacturers.

It is important that a simple audit sheet is completed for each procedure as this will help compile:-

- Activity analysis
- Monitoring of untoward incidents
- Monitoring of use of disposables
- The volumes processed by each individual machine / machine operator
- Log of individual patient events

The UK Cell Salvage Action Group is currently working on development of a UK database which all organisations will be invited to contribute to.

8. Quality Control

It is important that the reinfused red cells are subjected to quality control measures on a regular basis. It is suggested that as a minimum the following are tested in at least 1% of cases or monthly where cases are infrequent:

- Hct
- Heparin assay (if appropriate)

Results should be regularly reviewed by the lead manager and Consultant as part of the ongoing quality management plan.

9. Costs associated with Cell Salvage

- Equipment costs
 - Machine initial outlay
 - o Machine depreciation
 - Machine maintenance
- Disposable costs
- Staff costs
 - o Training time
 - o Documentation
 - Data collection
- Quality assurance
 - o Impact on Haematology laboratory for QC testing

10. Safety Issues

Adequate staff training is essential. ICS machines must be operated in accordance with manufacturers' instructions according to company guidelines.

10.1 Free Hb

Reinfusion of free Hb, from damaged red cells, can be avoided if suction levels are not excessive and washing volumes are adequate.

10.2 Dilutional coagulopathy

Dilutional coagulopathy may occur when large volumes of blood are processed. In cases of massive blood loss and reinfusion of 1 - 1.5 litres of salvaged blood a Full Blood Count (FBC) and Clotting screen should be taken and advice sought as appropriate. Dilutional coagulopathy is a consequence of massive transfusion, not cell salvage *per se*.

10.3 Air embolus

Air embolism due to cell salvage is a potentially fatal complication but only results from operator error. It is essential to remove all the air from the reinfusion bag before attaching to the patient's intravenous Reinfusion line. **Reinfusion bags should not be pressurised.**

10.4 Contaminants

Blood collected via an unwashed system has significantly higher concentrations of contaminants compared to blood collected via washed systems. The person responsible for the procedure should be aware of the contaminants that may be present in the wound drainage to ensure that potentially harmful substances are not reinfused.

11. Further reading

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

www.sign.ac.uk

12. References

- 1. Department of Health (2007). Health Service Circular on *Better Blood Transfusion*: Safe and *Appropriate Use of Blood*. HSC 2007-001.
- 2. Faught C, Wells P, Fergusson D, Laupacis A. Adverse effects of methods for minimising perioperative allogeneic transfusion: a critical review of the literature. *Transfusion Med. Rev* 1998:12206-25
- 3. Waters JH, Biscotti C, Potter PS, Philpson E. Amniotic fluid removal during cell salvage in the caesarean section patient. *Anaesthesiology* 2000;92;1531-6
- Catling SJ, Williams S, Fielding A. Cell salvage in Obstetrics: an evaluation of the ability of cell salvage combined with leucocyte depletion filtration to remove amniotic fluid from operative blood loss at caesarean section. *Int. J. of Obstetric Anesthesia* 1999;8;79-8
- 5. National Institute For Health & Clinical Excellence (NICE) (2005) Intraoperative Blood Cell Salvage in Obstetrics – Guidance http://guidance.nice.org.uk/IPG144/guidance/pdf/English/download.dspx
- 6. Hughes LG, Thomas DW, Wareham K, Jones JE, John A, Rees M. Intraoperative blood salvage in abdominal trauma: a review of 5 years' experience. *Anaesthesia* 2001;56:217-20.
- Thomas MJ. Infected and malignant fields are an absolute contraindication to intraoperative cell salvage: fact or fiction? *Transfusion Med.* 1999;9:269-78.

APPENDIX 1.

Guide For Finding The Right Machine

EVALUATION OF INTRA OPERATIVE CELL SALVAGE SYSTEMS

COMPANY: PRODUCT:

Date of Evaluation:

Process	Score 1-10 (1 being least	Weighting factor 1-5	Total score for section
	acceptable)		

ORGANISATION

Where is the product manufactured?		
What number of sets are kept in stock?		
What quality systems are in place?		
What contingency plans are in place for production if the current building is unavailable?		
Who provides the clinical "back-up"?		
Who provides support to the customers?		
What support is provided?		
How is the initial contact for new customers made?		
How is training provided in hospitals and to whom?		

Process		Weighting factor 1-5	Total score for section
---------	--	----------------------------	-------------------------

PRODUCT

Is the product latex free?		
What is supplied in the pack?		
What additional items may need to be purchased?		
Is a patient information guide provided?		
Does the system have universal fittings?		

Processing		
Totally automated		
Can be used as semi-automated		
Speed variability		
Volume of wash can be adjusted		
Acceptability of machine to Jehovah Witness		
<u>Service</u> Quality of back up service		
Response time by engineer		
Health & Safety		
How easy is the machine to clean?		
Contamination		
Changing waste bag		

Process	Score 1-10 (1 being least acceptable)	Weighting factor 1-5	Total score for section
Speed of process			
Quality of process			
Heparin assay			
HCT			
Free Hb in supernatant			
Training by company			
On site			
Off site			
Training manual			
Bowl size			
Children			
Small adults			
Full-size			
Vacuum			
On board			
Separate			
Acceptability by users			
Operators			
Surgeons			
Anaesthetic staff			

Cost of machine:

Cost of disposables:

Signature of evaluator:

Experienced Users and Operators

Name	Base	Area of special interest	Contact Details Phone	Contact Details Email
Hannah Grainger	Cell Salvage Co-ordinator, Wales	Cell salvage education Cell Salvage in emergency / high blood loss surgery Appropriate use and provision of Cell Salvage	01443 622076	Hannah.grainger@wbs.wales.nhs.uk
Sarah Haynes	Autologous Transfusion Co- ordinator Wythenshawe Hospital Manchester	Blood conservation Education and training Research and development	0161 291 5838	sarah.haynes@manchester.ac.uk
Biddy Ridler	Clinical Blood Conservation Doctor,	Logistics, Audit , Research for Vascular, Orthopaedics, Urology Surgery	01392 402759 01392 402729	biddy.ridler@rdeft.nhs.uk j.f.thompson@exeter.ac.uk
John Thompson	Consultant Surgeon, Royal Devon and Exeter NHSFT			
John Faulds	Blood Conservation Co-ordinator, RCHT	Cell Salvage intra and post op, Quality Control.	01872 252743	john.faulds@rcht.cornwall.nhs.uk
Danny McGee	Specialist Practitioner in Operating Theatre Blood Conservation Better Blood Transfusion SNBTS	Operating Theatre Blood Conservation	0131 242 3229	Danny.McGee@luht.scot.nhs.uk
Malcolm Rees	Cell Salvage Co-ordinator Abertawe BroMorgannwg University NHS Trust	Training and service delivery	01792 703259	malcolm.rees@swansea- tr.wales.nhs.uk
Kirsty Bonar	Vascular Deputy Theatre Sister, Royal Victoria Hospital, Belfast	Use in vascular procedures	028 90635727	Kirsty.bonar@royalhospitals.n- i.nhs.uk
Dafydd Thomas	Intensive Care and Anaesthesia Abertawe BroMorgannwg University NHS Trust	Vascular, Trauma and ITU	07977 267201	dafydd.thomas@swansea- tr.wales.nhs.uk
Sue Catling	Anaesthetics/Obstetrics Abertawe BroMorgannwg University NHS Trust	Use of cell salvage in Obstetrics and malignant Gynaecology	01792 285427	sue.catling@btopenworld.com
Catriona Connolly	Anaesthesia Ninewells Hospital, Dundee	Obstetric Anaesthesia, Anaesthesia for vascular surgery	01382 660111 bleep 4864	c.connolly@doctors.org.uk

Vicki Clark	Anaesthesia	Obstetrics	01312423151	vickiaclark@yahoo.co.uk
	Royal Infirmary, Edinburgh	Orthopaedics		
		Regional anaesthesia.		
		Training at all levels		
Alastair Nimmo	Anaesthesia	Major vascular surgery	0131 536 1000	a.nimmo@ed.ac.uk
	Royal Infirmary, Edinburgh			
Francesco Torella	Cons. Vascular Surgeon University Hospital Aintree	Vascular Surgery	0151 5294957	f.torella@liv.ac.uk

Guide to Completing the Autologous Transfusion Label All autologous blood should be labelled as soon as collection begins

1. You must complete the following information at the start of the autologous procedure:

Patient details - HANDWRITE the details from the patient's identification band (or approved method of patient identification if the identification band is not accessible).

Operator Name - Name of the individual responsible for carrying out the autologous transfusion procedure.

Times and Dates - Record the time and date the collection began (start time) and the time and date of expiry. The expiry time should be in accordance with National guidelines and the organisations transfusion policy.

Type and volume - Tick relevant box/boxes (record the total volume of autologous blood for reinfusion – this can be done later when the final volume is known).

Produced by the UK Cell Salvage Action Group June 2008/Version 1

6 - 0
AUTOLOGOUS TRANSFUSION Untested Blood For AUTOLOGOUS use only
Hospital / NHS No
Last name
First name
DOB
Operator Name (Print)
Collection Date Time
Expiry Date Time
Type of autologous blood:
Intra-op Cell Salvage Post-op Cell Salvage (Washed) Post-op Cell Salvage (Unwashed)
Total Volumemls
AFFIX IN TRANSFUSION RECORD
(This section <u>should</u> be completed and affixed in patient's transfusion record)
Autologous Transfusion
Enli Name
Hospital / NHS No
Intra-op Cell Salvage
Post-op Cell Salvage (Washed)
Post-op Cell Salvage (Unwashed)
Administered by
Transfusion Started at: Date
Time

2. Attach to the bag – Attach the autologous label *immediately* to the autologous blood bag using a secure tie



3. Transfusion Record - Details of the autologous transfusion **MUST** be recorded in the patient's clinical notes / transfusion record. Complete the information required on the peel off section of the autologous label and affix in the appropriate place in the patient's clinical notes / transfusion record.

