NATIONAL BLOOD AUTHORITY
AUSTRALIA

GUIDANCE FOR THE PROVISION OF INTRAOPERATIVE CELL SALVAGE

APPENDIXES

Guidance for Australian Health Providers

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This report is available online at: www.blood.gov.au

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Appendixes

Appendix I

Business Case Guidance

This business case is a generic framework intended to form the basis of a bid for funding by a large tertiary hospital, or smaller hospitals where the implementation could be justified, to introduce Intraoperative Cell Salvage. The text is unprotected and can be amended to suit local requirements. It is based on the UK Cell Salvage Action Group Business Case developed in 2007.

This business case focuses on the contract and investment required for the:

- acquisition of new Intraoperative Cell Salvage equipment
- disposable equipment cost
- implementation of a new Intraoperative Cell Salvage service
- training and maintenance of competency
- salaries and call out fees
- documentation and audit processes.

This is how the additional costs will be offset by the savings.

Wider cost savings may be realisable from the financial impacts of a potential shorter patient length of hospital stay, reduced incidence of complications specifically associated with allogeneic blood transfusion such as reduced infection rates and reduction of immunomodulation. More information on the advantages of Intraoperative Cell Salvage is included in Section 3 of the main document.

The Provision of

Intraoperative Cell Salvage

Business Case

Executive Summary

- Intraoperative Cell Salvage is a recognised blood conservation technique that is suitable for use in the elective and emergency surgical setting in a wide variety of specialities.
- Intraoperative Cell Salvage is a recommendation in the Patient Blood Management Guidelines: Module 2 – Perioperative[1] and Module 4 – Critical Care[2].
- Intraoperative Cell Salvage has recognised benefits for patients, with minimal associated risks e.g. reductions in allogeneic blood transfusions, lower infection rates and shorter hospital stays when compared to patients who receive allogeneic blood.[3]
- This business case provides the tools to assess the financial impact of the implementation of a new intra-operative cell salvage service at hospital level.
- Intraoperative Cell Salvage, when used appropriately, can result in savings in blood budgets.[4]
- It is important to identify the requirement and facilities for your specific hospital and adapt the purchase and implementation of cell salvage according to these needs.
- The introduction of Intraoperative Cell Salvage into (insert organisation, department, or speciality details here), could potentially generate annual savings of (enter figure here).

Strategic Case

Introduction

The aim of this business case, with the support of (insert directorates here), is to justify the allocation of funds for the introduction of Intraoperative Cell Salvage into (insert organisation, department, or speciality details here) and to identify the cost benefit of such a service to (your hospital)

Whilst allogeneic (donated) blood is an essential adjunct to health care, it is a limited resource (subject to the threat of future shortages), increasingly expensive and can present a source of risk for patients, in particular the risk of "wrong blood" incidents as reported by the Serious Hazards of Transfusion (SHOT) steering group in the UK.[5]

The recent systematic review conducted for the Perioperative Module of the Patient Blood Management Guidelines found five Level I studies and nine Level II studies of fair to good quality supporting the use of Intraoperative Cell Salvage[1]. The studies were predominantly in adult orthopaedic and cardiac surgical populations. The meta-analyses found that, overall, the incidence and volume of allogeneic blood transfusion were significantly lower for the individuals who received Intraoperative Cell Salvage.[2] Carless et al estimated a saving of 0.68 units of allogeneic red blood cells per patient.[3] The systematic review also found a moderate reduction in the risk of infection and an increase in postoperative haemoglobin concentration and haematocrit in patients undergoing off-pump coronary artery surgery[3].

Intraoperative Cell Salvage

Intraoperative Cell Salvage can be used routinely in some areas of surgical practice. Using a modified aspiration line, blood lost from the surgical field is aspirated into a collection reservoir. Anticoagulant is used to prevent the collected blood from clotting. The modified aspiration line delivers the anticoagulant to the tip of the suction allowing the blood to mix with the anticoagulant as it is aspirated away from the surgical field. A filter in the collection reservoir removes large particulate debris. The salvaged blood is then centrifuged and washed to produce red blood cells suspended in saline which are sent to a reinfusion bag for reinfusion to the patient. The discarded products (plasma, platelets, anticoagulant etc) are mostly removed during processing. When used appropriately, by adequately trained staff, washed intraoperative cell salvage is a simple, safe and cost-effective method of reducing allogeneic transfusion.

Advantages:

Recognised benefits for patients:

- Preserves the patient's own red blood cells.
- Reduces exposure to allogeneic blood and therefore reduces exposure to the risks associated with allogeneic blood transfusions. These risks include but are not limited to: incorrect blood component transfused, handling and storage errors, acute transfusion reactions, haemolytic transfusion reactions, transfusion-transmitted infection and transfusion associated graft versus host disease.[5]
- Lower post-operative infection rates and shorter hospital stays when compared to patients who receive allogeneic blood.[3]

Intraoperative Cell Salvage has minimal risks (providing the manufacturer's guidelines are followed).

- For volume dependent systems, providing the minimum volume of blood has been collected, processing is quick and blood can be reinfused within minutes of the start of processing.
- Disposable kits cost less than a unit of allogeneic red blood cells and can process very large volumes of blood. Intraoperative cell salvage is therefore a cost effective alternative to allogeneic blood (especially for large blood loss cases).

Disadvantages:

- May be contraindicated in certain clinical circumstances (see Section 9 in the Guidance for the Provision of Intraoperative Cell Salvage).
- Adverse events such as hypotension associated with Intraoperative cell salvage is rare.

Choice of Equipment

There are a number of cell salvage devices available on the market, the most suitable equipment for (insert Organisation, department or surgical speciality here), was determined through a comparison based on the specific clinical requirements for (Inset your hospital name).

The suitability of the manufacturer chosen will need to be assessed for each individual hospital.

For aspects to keep in mind when choosing a manufacturer see Table 1.

Table 1: List of questions essential to the introduction of a new intraoperative cell salvage service.

EVALUATION OF INTRA OPERATIVE CELL SALVAGE SYSTEMS

Important questions to ask when purchasing an original intraoperative cell salvage product:

Most importantly:

1. How many cases with significant blood loss are done annually?
2. Which types of procedures or sub-specialities are involved?
3. The availability and speed of availability of allogeneic blood in your unit.
4. The ability of a manufacturer to support the implementation, education, maintenance and service required for the specific institution.
5. Does the requirement for intraoperative cell salvage in the specific unit mandate the availability of a dedicated autotransfusionist for intraoperative cell salvage, as opposed to the management of the intraoperative cell salvage process by, for example, an anaesthetic nurse and an anaesthetist?

About the Manufacturer:

1. Who is the manufacturer?
2. Where is the product manufactured?
3. What number of sets are kept in stock?
4. What quality systems are in place?
5. What contingency plans are in place for availability of consumables if the current manufacturer is unable to supply?
6. Who provides the clinical "back-up" for this device in Australia?
7. Who provides support to the customers?
8. What support is provided?
9. How is the initial contact for new customers made?
10. How is training provided in hospitals and to whom?
11. What is the service quality of the backup service?
12. Response time by engineer?

About the equipment:

1. Is the product latex free?
2. What is supplied in the pack?
3. What additional items may need to be purchased?
4. Does the system have universal fittings?

About Processing:

1. Totally automated?
2. Can the system be used as semi-automated?
3. Speed variability?
4. Can the volume of wash be adjusted?
5. Flexibility of equipment to suit different types of surgery where blood will be lost at different rates
6. Ability to separate collection and processing disposables

About safety, risk and waste management:

1. How easy is the machine to clean?
2. Contamination?
3. Changing waste bag?
4. Speed of the process?
5. Quality of process, Heparin assay, HCT, Free Hb in supernatant?

Training by company:

1. Is the training on site or off site?
2. Is there a training manual for the specific equipment available?
3. How is ongoing competency assessed and maintained?

Other general issues:

1. Is a patient information guide provided?
2. Bowl size: Children, Small adults, Full-size?
3. Is the vacuum on board or separate?
4. Acceptability by users, autotransfusionists, surgeons and anaesthetic staff?

5. Cost of machine (original purchase and maintenance)?
6. Cost of disposables?

It is important to use this information to identify the most suitable manufacturer and equipment for your particular institution.

The (**Enter machine chosen)** identified through this critical comparison process, as most suitable, had advantages over other commercially available equipment in the following areas:

(Enter criteria from critical comparison process under which decision was made e.g. ease of set up, speed, Quality Control of final product etc)

Economic Case

Options for Procuring Equipment

There are a number of options available for the introduction of Intraoperative Cell Salvage into (insert Organisation, department or surgical speciality here). These include:

- Outright purchase of the equipment of choice
- Outright purchase of alternative equipment of choice as financial constraints dictate
- Lease of equipment of choice via consumable charges
- Private Intraoperative Cell Salvage service hire for occasional elective cases or for 24 hour on call service.

Prior to comparing costs, the most suitable option determined through a comparison based on the specific clinical requirements for this hospital is the (enter option here) option. This option was identified as most suitable based on the following criteria:

(Enter criteria from critical comparison process under which decision was made e.g. quality, risk, patient benefit, availability etc)

Financial Case

The financial impact of outright purchase versus lease has been assessed by (enter details here e.g. Departmental Management Accountant).

Table 2 compares the direct costs generated by purchase/leasing a cell salvage machine against the cost of the allogeneic blood avoided. In addition, although hard to estimate, savings may also be generated through reduced length of stay for patients having received intraoperative cell salvage when compared to patients receiving allogeneic blood transfusions.

Table 2 Summary of Potential savings at Hospital Level

	Outright Purchase	**Lease**
Allogeneic Blood Savings	$_____	$_____
Costs generated by intraoperative cell salvage (year 1). Includes purchase of equipment and training of personnel etc.	$_____	$_____
Costs generated by intraoperative cell salvage (year 2 onwards). Consumables, competency maintenance, documentation and audit cost etc.	$_____	$_____
Annual Saving on Hospital Blood Budget (year 1)	$_____	$_____
Annual Saving on Hospital Blood Budget (year 2 onwards)	$_____	$_____

Table 3 Issues to be considered in the economic evaluation of outright purchase versus lease

A spreadsheet should be compiled by the departmental accountant to determine the potential cost savings associated with the introduction of Intraoperative Cell Salvage into the Organisation. Financial benefits of introducing Intraoperative Cell Salvage should be determined locally. As an example the spreadsheet is likely to include the following information:

		Outright Purchase	**Lease**
Number of cases suitable for intraoperative cell salvage performed each year	**a**	$_____	$_____
Mean allogeneic blood usage per case for procedures suitable for intraoperative cell salvage	**b**	$_____	$_____
Current cost of a unit of allogeneic RBCs	**c**	$_____	$_____
Current blood usages costs avoided per annum	**a x b x c**	$_____	$_____
Capital charges (equipment purchase) (Year 1)	**d**	$_____	Not Applicable
Cost of intraoperative cell salvage Consumables (each)	**e**	$_____	$_____
Consumable costs per annum	**f = a x e**	$_____	$_____
Maintenance contract costs per annum	**g**	$_____	$_____
Estimated electricity cost per intraoperative cell salvage case	**h**	$_____	$_____
Estimated electricity costs per annum	**i = a x h**	$_____	$_____
Estimated costs for staff training Year 1	**j**	$_____	$_____
Estimated costs for staff training Year 2 onwards	**k**	$_____	$_____
Additional costs incurred (year 1)	**d + f +g + i + j**	$_____	$_____
Additional costs incurred (year 2 onwards)	**f + g + l + k**	$_____	$_____

Annual cost saving - year 1 (Current blood usage costs avoided per annum –	$_____	$_____

Additional costs incurred (year 1))		
Annual cost saving - year 2 onwards (Current blood usage costs avoided per annum – additional costs incurred (year 2))	$_____	$_____

CASE STUDY: During a retrospective study at the Royal Brisbane and Women's Hospital (RBWH) in Brisbane, Queensland, the following was found:

Estimating the cost of maintaining an intraoperative cell salvage service:

The study was a retrospective audit, conducted in the RBWH in Brisbane, Australia, between January and December 2011.[4] Over this period Intraoperative Cell Salvage was set up for 302 surgical cases in theatre and 242 units of intra-operatively salvaged blood was transfused (192 cases transfused, 110 cases setup and not transfused/discarded).

1. We calculated the cost of the intra-operative cell salvage service to our hospital (this is a rough estimate):

Intraoperative Cell Salvage ongoing cost break down:		
Service		Annual Cost
Autotransfusionist Only after hours: On call (public holiday, nights weekends), called in or stayed in (1)		$26221
Consumables		$78395
Cost of cases processed and transfused*	$63757	
Cost of cases processed but not transfused*	$14638	
Machine: maintenance/ongoing cost (annual)		$730
		$105346

*__The purchase of the machine and implementation costs were not included as this is a well-established service__

Cost per unit Intraoperative Cell Salvage summary:	
The cost of Intraoperative Cell Salvage for 242 units transfused in 2011	$105346
Therefore the average cost per unit of Intraoperative Cell Salvage ($105346/242)	$435.32

2. The potential cost of allogeneic red blood cells as an alternative:

	Cost estimated per unit	Total potential cost	Potential saving
Allogeneic blood cost	$733.33**	$177466	
Intra-operative cell salvage	$437.94	$105346	
Annual potential saving if intraoperative cell salvage used instead of allogeneic blood			$72120

**This amount is calculated for the RBWH case study based on methodology used in Wood et al[7].

Variables that depend on the local service setup and type of manufacturer:

1. Call out rate and frequency of call out for technical/autotransfusionist staff. This variable depends on the size and service setup in the specific hospital. If the number of cases with potential significant blood loss is small it might not be financially viable to justify a complete service with a "dedicated intraoperative cell salvage autotransfusionist" separate to the anaesthetic team. Alternatives would include the availability of a private intraoperative cell salvage service on a case by case or on call basis or the purchase of a very simple intraoperative cell salvage machine that could potentially allow the anaesthetic team to manage the salvaging and transfusion process, as well as the anaesthetic conduct. However this option should be thoroughly worked through and all parties satisfied with their ability to participate in a safe manner.
2. Ability to identify and salvage only those cases that would most likely be transfused (where predicted blood loss estimated more than 20% of blood volume). Every case where an intraoperative cell salvage setup is done and no blood re-infused could be seen as waste and might reduce the cost benefit of the entire service. On the other hand if these cases are set up for clinical indications or risk management reasons it may be justifiable.
3. Machine maintenance and disposable equipment cost would be specific to the type of manufacturer or device in use.
4. The absolute cost for a unit of allogeneic red blood cells is unknown. We estimated the cost for a unit of red blood cells from a study done in Australia, in 2006[6] and estimated the expected cost for 2011 by using the inflation rate for allogeneic blood in our hospital[7].

Other costs (not included in above study) to consider when doing a business case for intraoperative cell salvage:

- Machine: 1) Initial outlay 2) Machine depreciation
- Training time
- Documentation
- Data collection
- Quality assurance: Impact on Haematology /Pathology services for quality assurance testing (examples include microbiology, HCT)

Management Case

Human Resources

1. **Essential staff involved in the management of an Intraoperative Cell Salvage service:**

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 Intraoperative Cell Salvage programme
- Agreeing on indications and operations where cell salvage can be used intra-operatively within the specific hospital
- Informing and discussing with colleagues the use of Intraoperative Cell Salvage in unusual circumstances e.g. malignancy, sepsis, and amniotic fluid contamination.
- Discuss the risks of these procedures and help make an informed judgement in matters such as the use of specific filters etc.
- Be responsible for the overall programme within an organisation and ensuring quality systems are in place.

Lead Manager

Ideally a member of the theatre management team, for example the director of the Anaesthetic department.

Their role is organisation and facilitation. They are responsible to:

- Identify a lead autotransfusionist 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

Cell Salvage Co-ordinator

The co-ordinator should be a member of the theatre staff i.e. perfusionist, anaesthetic nurse or anaesthetic technician.

Their role is functional, co-ordinating operations requiring intraoperative cell salvage.

They are responsible for:

- Training other members of staff in theatre and maintaining 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 Auditing purposes
- 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 re-infused 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.

2. **In general the introduction of Intraoperative Cell Salvage is likely to also have an impact on the following staff groups:**

Intraoperative Cell Salvage Equipment Autotransfusionists (Department Practitioners, Anaesthetic Nurses, Scrub Staff, Anaesthetists, Midwives, Anaesthetists, and Surgeons from applicable sub-specialities or any other staff group deemed appropriately qualified): The introduction of Intraoperative Cell Salvage will require an initial period of training and competency assessment. Once competency assessment has been completed, ongoing updates and refresher training will need to be delivered. Many manufacturing companies are kindly involved in ongoing competency training and assessments. Additional training may also be necessary if a training need is identified or a change of practice occurs. The resources to train new staff also need to be considered once the Intraoperative Cell Salvage service has been established.

It is not mandatory to have a "dedicated autotransfusionist" for the Intraoperative Cell Salvage procedure; however, in certain emergency situations (catastrophic haemorrhage) a dedicated autotransfusionist may be necessary. Even though the requirement to have a dedicated autotransfusionist for intraoperative cell salvage would impact on the cost of the service this aspect would need to be assessed on an individual basis for each hospital.

Anaesthetists: Anaesthetists should undergo basic training in Intraoperative Cell Salvage even if they will not be carrying out the procedure directly. The responsibility for the reinfusion of the Intraoperative Cell Salvage blood falls with the anaesthetist and/or surgeon and as such they should be aware of the potential benefits and risks and the procedure for reinfusing intraoperative Cell Salvage blood.

Surgeons: The introduction of Intraoperative Cell Salvage may have a significant impact on surgeons. There are many aspects of Intraoperative Cell Salvage equipment in theatre, such as the use of lower vacuum levels, specific suction devices, or dedicated Intraoperative Cell Salvage "second suction devices" and contraindications to the use of Intraoperative Cell Salvage that may require a period of adjustment.

Information technology: In cases where electronic data capture and documentation is required in the specific institution, information technology staff should be involved.

Ongoing clinical governance: Record keeping and audit processes.

Training

Intraoperative Cell Salvage manufacturers usually offer a period of free training in the workplace to support the introduction of the equipment. This might include general awareness sessions for those not directly responsible for carrying out the Intraoperative Cell Salvage procedure (Surgeons, Anaesthetists, theatre staff who are not being trained to use the equipment), and intensive theory and hands on practical training in the classroom and the clinical environment for "key trainers" within the department. These "key trainers" are then usually responsible for training, supervising and competency assessment of the other Intraoperative Cell Salvage autotransfusionists in the department. It may be appropriate for a core number of staff to attend an intensive off site training course to reduce risk.

Support

National Blood Authority of Australia website: www.blood.gov.au

Including:

- Generic Policy guidance that can be adapted to your local organisations educational resources and competency assessments
- Generic documentation and labelling
- Examples of procedures that would most likely present a cost benefit from the use of intraoperative cell salvage[6]
- Auditing processes

Organisational Risks

The organisational risks should be minimal providing the equipment is used following the manufacturer's guidance by adequately trained and competency assessed staff. The use of intraoperative cell salvage should decrease patient exposure to allogeneic blood and its associated risks.

Conclusion

Intraoperative Cell Salvage offers a way forward in reducing allogeneic blood use in appropriate surgical patient groups and has some cost benefit implications. The extent of the budgetary savings can be assessed via the information in Table 2. These savings and the benefit to patients as identified in this business case support the introduction of Intraoperative Cell Salvage into (insert organisation, department, or speciality details here).

Recommendations

Secure funding for the purchase/lease of equipment and continued running costs, to enable the provision of Intraoperative Cell Salvage for appropriate surgical procedures.

References

1. National Blood Authority. Patient Blood Management Guidelines: Module 2 - Perioperative. 2012.

2. National Blood Authority. Patient Blood Management Guidelines: Module 4 - Critical Care. 2012.

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4. Roets M. A prospective observational study on Intra-operative Cell Salvage. Identifying adverse outcomes and surgical procedures which present the greatest cost-benefit for the use of Intraoperative Cell Salvage in the Royal Brisbane and Women's Hospital. No Title. 2012.

5. Cohen H et al. Summary of 2011 Annual SHOT report. 2011.

6. Wood E et al. Transfusing a unit of Red Cells: What does it really cost? Australian Red Cross Blood Service, Flinders Medical Centre, Peter MacCallum Cancer Centre, Medical Society for Blood Management. Presented by the National Blood Authority Australia.; 2006.

Appendix IIa

Surgical Procedures where Intraoperative Cell Salvage may present a significant benefit towards the management of perioperative blood loss

Specialty	Surgical Procedure
Cardio-Thoracic	Valve Replacement
	Redo bypass grafting
	Aortic arch aneurysm
	Coronary artery bypass
	Valve / CABG combo
	Pneumonectomy / lobectomy
	Re-exploration Chest
Orthopaedics	Spinal fusion (≥ 2 levels)
	Revision hip arthroplasty
	Pelvic Fracture
	Resurfacing of joint
	Long bone fractures lower extremities
Urology	Radical retropubic prostatectomy (excluding robotic prostatectomy)
	Cystectomy
	Nephrectomy
Neurosurgery	Giant basilar aneurysm
	Cerebral aneurysm
Obstetrics/Gynecology	High risk pregnancy
	Uterine myomectomy
	Placenta accreta
	Abdominal hysterectomy
Plastics	Breast reduction / reconstruction
	Major Flaps
Vascular	Thoracoabdominal aortic aneurysm repair
	Aorto-bifemoral grafts
	Axillo-femoral bypass
	Abdominal aortic aneurysm repair
	Lower extremity revascularization
General	Liver resection
	Whipple Procedure
	Splenectomy – ruptured*
	Any open abdominal procedure
	Colectomy / Bowel resection **
Other	Any procedure for patients who for religious or other reasons, are unwilling to receive a blood transfusion

* For elective splenectomy set up ICS device and wash salvaged blood when there is blood loss of greater than 20% of estimated blood volume

** In cases whith no intra-abdominal fecal contamination.

Appendix IIb

Surgical Procedures – an Australian experience

Prospective Audit of current use of Intraoperative Cell Salvage at the Royal Brisbane and Women's Hospital (RBWH), Brisbane, Australia – May to October 2012.

1. Procedures with most benefit from prospective observational study – RBWH:

Surgical speciality	Type of Procedure	Autotransfused units per case on average
General Surgery		
	Laparotomy +Liver laceration	2
Gynaecology		
	Uterine Myomectomy	4
	Total abdominal hysterectomy (TAH)	1
Obstetrics		
	Lower section caesarean section (LSCS) for placenta percreta	3
	LSCS for Placenta accreta	1
Orthopaedics		
	Multilevel (>3 level) posterior fusion	1
Urology		
	Radical Prostatectomy	1.85
Vascular		
	Abdominal aortic aneurism repair (AAA) elective	1.79
	AAA ruptured	2
	Re-implantation of renal artery	4

2. Procedures with lower but still significant, potential benefit from prospective observational study – RBWH:

Surgical speciality	**Type of Procedure**	**Autotransfused units per case on average**
Orthopaedic		
	Total Hip replacement	0.33
	Total knee replacement	0.25
Vascular		
	Aorto-bifemoral	0.56

3. Procedures that showed less cost-benefit from prospective observational – RBWH:

   Generally significant blood loss could be expected from these procedures, however in the RBWH study it was found that these procedures did not present significant ICS cost- benefit.

Sub-speciality	**Procedure type**
General Surgery	• Trauma laparotomy Exploration
	• Splenectomy*
Gynaecology	• Total abdominal hysterectomy and bilateral salpingo-oophorectomy and tumor debulking
Neurosurgery	• Craniotomy
	• Craniotomy for pineal Tumour
Obstetric surgery	• Uncomplicated Caesarean section
	• Caesarean section for placenta previa grade 2,3 or 4
	• Caesarean section for HELLP syndrome
Orthopaedic surgery	• Multi-trauma: acetabulum, rib and clavicle fractures
	• 1 to 2 level anterior spinal fusion
	• 1 level spinal disc revision
	• 1 or 2 level Interbody fusion
	• 1 to 3 level laminectomy
	• 1 to 3 level lateral fusion
	• Open reduction internal fixation Acetabulum fracture
Urology	• Nephrectomy

* Set up ICS device and wash salvaged blood when there is blood loss of greater than 20% of estimated blood volume.

Appendix III

Audit Proforma

Example of an Audit Proforma for Intraoperative Cell Salvage (Please present your own hospital proforma)

Insert Organisation Name AUTOTRANSFUSION RECORD

PATIENT IDENTIFICATION LABEL:
UR No:.....
Name:.....
Address:.....
DOB: ...../...../.....

CELL SALVAGE PROCEDURAL INFORMATION: Booked ☐ Emergency ☐ Unscheduled ☐

CELL SALVAGE PROCEDURE:

Date:	Surgeon:
Start Time (of procedure):	Anaesthetist:
End Time:	Autotransfusionist:

PATIENT INFORMATION: Male ☐ Female ☐

Special Considerations:

Blood Group: ____ Haemoglobin:_____g/dl HCT: _____ Weight :_____

INTRAOPERATIVE CELL SALVAGE DEVICE USED: Device 1 ☐ 2 ☐ 3 ☐

Total volume in Intraoperative Cell Salvage suction	____ml	Anticoagulant Type :	
Total Saline Wash (Swabs)	____ml	Heparin 30,000iu in 1L NaCl ☐ A.C.D ☐	
Total Saline used by surgeon	____ml	Other concentration	_____
Total Volume after wash/Processed	____ml	Total Anticoagulant used	_____ml
Total washed Salvaged blood transfused	____ml	Allogeneic/lab blood transfused	_____u
Unwashed salvaged blood transfused	____ml	Reason Allogeneic blood transfused:	
Hb before Intraoperative Cell Salvage transfused	_____g/dl		
Suction pressure:	____ mmHg	Other blood products transfused:	
Processing Time:	_____	Platelets _____u	Clotting factors _____u
		Plasma _____u	Cryo _____u

SUPPLY INFORMATION (Affix Labels)

Suction/Anticoagulation Line:

Reservoir:

Autotransfusion Set

COMMENTS/ADVERSE EVENTS:

Filters used: Lipiguard ☐ Leukoguard RS 1VTE ☐ Other filter ☐

POST-OPERATIVE RESULTS:

Cell Saver blood: Hb___ Hct___ Patient FBC: Hb: preop___ inop___ postop___ g/dl Hct postop____

Microbiology: Positive ☐ Negative ☐

Autotransfusionist print name:_____ Signature: _____ Date: _____Time at machine: _____

Autotransfusionist print name:_____ Signature: _____ Date: _____ Time at machine: _____

INTRA-OPERATIVE CELL SALVAGE

Appendix IV

Intraoperative Cell Salvage
Competency Assessment Workbook

Contents

Introduction

This training framework for intraoperative cell salvage (ICS) autotransfusionists has been developed on behalf of the National Blood Authority (NBA). It has been reviewed by the NBA intraoperative cell salvage guidance writing group and has been adapted for the Australian health care setting from the UK Cell Salvage Action Group document.

To help address training concerns and the lack of competency assessments for autotransfusionists in this specialist field, this workbook has been developed in consultation with cell salvage "champions" and other national groups with patient blood management, blood safety and conservation as an essential part of their remit.

The competencies have been split into 5 sections to allow assessment to be tailored to the responsibilities of the individual learner.

Each section is then further divided into "Knowledge and Understanding" and "Performance Criteria". Learners must complete all indicators for both Knowledge and Understanding and for Performance Criteria within a section in order to be signed off as competent for that section.

Section 1	General (To be completed by all learners)
Section 2	Prepare equipment for intra-operative blood salvage collection
Section 3	Operate equipment for intra-operative blood salvage collection
Section 4	Prepare equipment for processing intra-operative salvaged blood
Section 5	Operate and monitor equipment for processing intra-operative salvaged blood and complete salvaged blood processing

It is essential that all staff involved in the operation of ICS machines are trained to the level at which they are expected to operate. **Training should include both theory and practice**. Autotransfusionists need to develop a broad understanding of the appropriate use of ICS including the contra-indications and implications of administration and reinfusion of salvaged blood. A theoretical course covering all aspects of intraoperative cell salvage (e.g. Australasian Board of Cardiovascular Perfusion autotransfusion course) should be completed. It is also recommended that along with theoretical training, practical training in a non-clinical environment should also be completed (e.g. Manufacturer provided intraoperative cell salvage courses).

NOTE: This workbook is provided as an example only. Individual hospitals may use this workbook in its current form or adapt its contents to suit their own circumstances.

Hospitals involved in training staff in the use of intraoperative cell salvage should adopt the following principles:

- Identify a key trainer/s (it is suggested that these people should have a recognised teaching and assessing qualification)
- Theory training and assessment of knowledge should be completed prior to undertaking practical training
- Staff should be allowed dedicated time for practical training which can be delivered by manufacturer and/or "in-house" trainers. ("In-house" training should be carried out by key trainers)
- "In-house" trainers should assess competency (it is suggested that "in-house" trainers have completed this workbook and that they hold a teaching and assessing qualification)
- Certificates of competence should be issued by the Organisation
- Documented training records should be kept by the Organisation and the learner.

Procedural documents/policies should be available to staff giving clear guidance on:

- Indications and contraindications
- Who can operate the machines and levels of independent operation
- How to operate the equipment
- Warnings regarding contamination of the surgical field
- Rules on labelling, expiry date and time of salvaged blood
- Reinfusion of salvaged red cells
- Recognising and reporting serious adverse events.

Maintaining competency

The Organisation should have a policy that clearly states the number of procedures a person should undertake in a designated period of time to maintain their competency. This policy should also include how often competency assessments should be performed. Where more than one type of ICS equipment is in use, the theory sections need only be completed once, however, the "Performance Criteria" sections should be completed for each type of device in use.

Learners should have a theory update and if necessary technical training when moving clinical speciality to ensure differences in practice have been covered.

It is envisaged that this workbook could be used to provide evidence of the knowledge and skills acquired by the learner with regards to ICS. It can also be used to identify any gaps between the skills and knowledge needed to do the job, and the current skills and knowledge of the individual member of staff.

Audit

It is recommended that Organisations should undertake periodic audit to verify that the principles outlined above are being adopted. It is suggested that a designated person is made responsible for this activity.

Pages from this workbook can be reproduced as required by the learner/trainer/supervisor and are available on the NBA website.

We would welcome feedback on the content of this workbook.

Record of Assessors Initials

All assessors should record their details on this sheet.

	Initials	Full Name (PRINT)	Job title	Signature	e-mail address	Telephone number
1						
2						
3						
4						
5						
6						
7						

Confirmation of Required Pre-assessment Training

This page must be completed prior to competency assessment. Candidates should not be competency assessed before they have completed the pre-assessment training requirements.

Type of Training	Date Completed	Candidate's signature (sign and date)	Assessor's signature (sign and date)
Theory (delivered through at least one of the following methods) Face to Face Learn Cell Salvage			
Practical (classroom) Set up of the ICS equipment in a non-clinical setting			
Practical (clinical) Supervised clinical training (recommended minimum of 10 cases 2 of which should be "emergency" cases)			

Supervised Clinical Training Record

A minimum of 10 supervised clinical cases should be completed by the candidate prior to competency assessment. Details of these cases should be entered into the table below.

Case	Date	Operation	Machine Type	Comments & supervisor's signature
1				
2				
3				
4				
5				
6				
7				
8				
Emergency 1				
Emergency 2				

Assessment Plan

This page should be completed at the end of the candidate's assessment and kept with the department's training records as evidence of staff competency.

Enter Candidate's Name: _____has undergone assessment and has demonstrated competency in carrying out the following tasks:

	Pre-assessment Agreement			Competency Assessment	
	Proposed Date of Assessment (or N/A)	Training Lead's Signature	Trainee's Signature	Completed on (date)	Assessor's signature
General (Everyone)					
Prepare equipment for intraoperative blood salvage collection					
Operate equipment for intraoperative blood salvage collection					
Prepare equipment for processing intraoperative salvaged blood					

Operate and monitor equipment for processing intraoperative salvaged blood and complete the salvaged blood processing						

ICS Competency Assessment

Section 1 General

Knowledge and Understanding	Assessment Method							
The trainee demonstrated knowledge and understanding of:	**DO**	**S**	**EW**	**PL**	**WQ**	**OQ**	**Assessor's Initials**	**Date**
National guidance (NBA ICS guidance), organisational policies and protocols related to the Intraoperative Cell Salvage (ICS) process.								
Their responsibilities and accountability in relation to the ICS process.								
The importance of working within their own scope of practice and competence,in relation to the ICS process.								
Infection prevention and control in relation to the ICS process and the potential consequences of poor practice.								
The rationale behind the use of autologous blood transfusion.								
The dangers of re-using equipment designed for single use only.								
The applications of ICS in relation to patients who refuse allogeneic blood on religious or other grounds.								

The importance of recording all information, clearly and precisely in the appropriate documentation.								
The importance of immediately reporting any issues which are outside your own sphere of competence without delay to the relevant member of staff.								

DO Direct Observation	S Simulation	EW Expert Witness	PL Prior Learning (evidence required)	Q Written Questions	OQ Oral Questions

Section 1 General

Performance Criteria	Assessment Method							
The trainee demonstrated, in a clinical setting, that they could:	**DO**	**S**	**EW**	**PL**	**WQ**	**OQ**	**Assessor's Initials**	**Date**
Apply standard precautions for infection control and other necessary health and safety measures.								

DO Direct Observation	S Simulation	EW Expert Witness	PL Prior Learning (evidence required)	WQ Written Questions	OQ Oral Questions

Section 2 Prepare equipment for intra-operative blood salvage collection

Knowledge and Understanding	Assessment Method							
The trainee demonstrated knowledge and understanding of:	**DO**	**S**	**EW**	**PL**	**WQ**	**OQ**	**Assessor's Initials**	**Date**
The role of the suction equipment in relation to Intraoperative Cell Salvage (ICS).								
The purpose of the collection set equipment.								
The rationale behind setting an appropriate vacuum level.								
The need for an appropriate anticoagulant and its correct preparation.								
The reason for setting up the collection equipment.								
The rationale for expiry time on the set up equipment.								
The role of the individual in preparing equipment for ICS and how this relates to other members of the theatre team.								
The importance of reporting all information to the relevant member of staff.								
How to recognise hazards, errors and malfunctions of equipment and the appropriate action to take.								

DO Direct Observation	S Simulation	EW Expert Witness	PL Prior Learning (evidence required)	WQ Written Questions	OQ Oral Questions

Section 2 Prepare equipment for intra-operative blood salvage collection

Performance Criteria	Assessment Method							
The trainee demonstrated, in a clinical setting, that they could:	**DO**	**S**	**EW**	**PL**	**WQ**	**OQ**	**Assessor's Initials**	**Date**
Ensure all members of the theatre team are aware that intra-operative cell salvage is planned.								
Select and set up collection equipment correctly following manufacturer's instructions: a. ensuring the correct equipment is safe to use								
b. using aseptic technique								
c. prepare the anticoagulant in accordance with national guidelines and local policy								
Inform the relevant member of staff that the collection equipment is fully prepared as necessary.								

DO Direct Observation	S Simulation	EW Expert Witness	PL Prior Learning (evidence required)	WQ Written Questions	OQ Oral Questions

Section 3 Operate equipment for intra-operative blood salvage collection

Knowledge and Understanding	Assessment Method							
The trainee demonstrated knowledge and understanding of:	**DO**	**S**	**EW**	**PL**	**WQ**	**OQ**	**Assessor's Initials**	**Date**
The indications and contraindications to the use of Intraoperative Cell Salvage (ICS).								
When and for whom collections for ICS could be started.								
The importance of labelling the collection equipment with unique patient identification.								
The importance of priming the collection equipment with anticoagulant to prevent blood clotting.								
The role of suction equipment in relation to ICS.								
The rationale behind setting an appropriate vacuum level.								
The components of whole blood.								
The functions of red cells in the delivery of oxygen to body tissues.								
The differences between salvaged red cells and whole blood.								
The effects of citrate or heparin anticoagulant on salvaged blood and the appropriate rate/ratio of anticoagulant.								
The possible contents of the collection reservoir during surgery, including potential contaminants.								

DO Direct Observation	S Simulation	EW Expert Witness	PL Prior Learning (evidence required)	WQ Written Questions	OQ Oral Questions

Section 3 Operate equipment for intra-operative blood salvage collection

Knowledge and Understanding Cont...	Assessment Method							
The trainee demonstrated knowledge and understanding of:	**DO**	**S**	**EW**	**PL**	**WQ**	**OQ**	**Assessor's Initials**	**Date**
The importance of immediately reporting sudden, unexpected increases in blood loss to the appropriate member of staff.								
The advantages and risks of swab washing.								
The process of salvaging blood from swabs.								
The rationale for weighing all swabs during ICS.								
How to estimate blood loss during ICS.								
The rationale for and calculation of expiry time of the salvaged blood.								
The role of the individual in collecting salvaged blood and how this relates to other members of the theatre team.								
How to recognise hazards, errors and malfunctions of equipment and the appropriate action to take.								

DO Direct Observation	S Simulation	EW Expert Witness	PL Prior Learning (evidence required)	WQ Written Questions	OQ Oral Questions

Section 3 Operate equipment for intra-operative blood salvage collection

Performance Criteria	Assessment Method							
The trainee demonstrated, in a clinical setting, that they could:	**DO**	**S**	**EW**	**PL**	**WQ**	**OQ**	**Assessor's Initials**	**Date**
Confirm decision to collect blood with the relevant member of staff.								
Accurately label the collection reservoir with patient's details.								
Correctly prime the collection equipment with an appropriate volume of anticoagulant solution following manufacturer's instructions.								
Start the collection using an appropriate vacuum level.								
Deliver or regulate the correct volume of anticoagulant in relation to blood loss.								
Monitor the progress of the procedure and immediately report any problems to the appropriate member of staff.								
Monitor the volume of salvaged blood being collected and immediately report sudden, unexpected increases in the rate of blood loss to the appropriate member of staff.								
Estimate and record the volume of blood collected on completion of the collection procedure.								
Report completion of the collection to the appropriate member of staff.								
Clear and dispose of waste in accordance with local guidelines.								
Complete and sign all relevant documentation.								

DO Direct Observation	S Simulation	EW Expert Witness	PL Prior Learning (evidence required)	WQ Written Questions	OQ Oral Questions

Section 4 Prepare equipment for processing intra-operative salvage blood

Knowledge and Understanding	Assessment Method							
The trainee demonstrated knowledge and understanding of:	**DO**	**S**	**EW**	**PL**	**Q**	**OQ**	**Assessor's Initials**	**Date**
The indications and contraindications of the use of Intraoperative Cell Salvage (ICS).								
Factors to be considered in the decision to set up the processing equipment.								
The types, purpose and functions of the ICS machines used in your work area.								
The purpose of the processing set equipment.								
The rationale for expiry time on the set up equipment.								
The choice of intravenous normal saline 0.9% as the wash fluid.								
The possible contents of the collection reservoir during surgery, including potential contaminants, in relation to the decision to set up to process salvaged blood.								
The advantages or risks of swab washing.								
How to estimate blood loss ICS.								
The rationale for and calculation of expiry time of the salvaged blood.								
The role of the individual in preparing equipment for processing salvaged blood and how this relates to other members of the theatre team.								

DO Direct Observation	S Simulation	EW Expert Witness	PL Prior Learning (evidence required)	WQ Written Questions	OQ Oral Questions

Section 4 Prepare equipment for processing intra-operative salvage blood

Knowledge and Understanding Cont...	Assessment Method							
The trainee demonstrated knowledge and understanding of:	**DO**	**S**	**EW**	**PL**	**WQ**	**OQ**	**Assessor's Initials**	**Date**
The importance of selecting the correct machine programme, where applicable, ready for use.								
How to recognise hazards, errors and malfunctions of equipment and the appropriate action to take.								

DO Direct Observation	S Simulation	EW Expert Witness	PL Prior Learning (evidence required)	WQ Written Questions	OQ Oral Questions

Section 4 Prepare equipment for processing intra-operative salvage blood

Performance Criteria	Assessment Method							
The trainee demonstrated, in a clinical setting, that they could:	**DO**	**S**	**EW**	**PL**	**WQ**	**OQ**	**Assessor's Initials**	**Date**
Check and confirm with the relevant member of staff the suitability of the salvaged blood for processing.								
Maintain strict asepsis at all times.								
Check and confirm that the correct processing equipment is safe to use.								
Load the processing equipment into the machine and connect to the collection equipment.								
Check and confirm that the wash fluid is intravenous normal saline 0.9% before priming the system.								
Set the correct machine programme ready for use.								
Inform the relevant member of staff that processing equipment is fully prepared as necessary.								

DO Direct Observation	S Simulation	EW Expert Witness	PL Prior Learning (evidence required)	WQ Written Questions	OQ Oral Questions

Section 5 Operate and monitor equipment for processing intra-operative salvage blood and complete salvaged blood processing

Knowledge and Understanding	Assessment Method							
The trainee demonstrated knowledge and understanding of:	**DO**	**S**	**EW**	**PL**	**WQ**	**OQ**	**Assessor's Initials**	**Date**
The indications and contraindications for the use of Intraoperative Cell Salvage (ICS).								
The role of the individual in operating and monitoring equipment for processing salvaged blood, completing salvaged blood processing and how this relates to other members of the theatre team.								
The components of whole blood and the basis of centrifugal separation.								
The functions of red cells in the delivery of oxygen to body tissues.								
The differences between salvaged red cells and whole blood.								
Factors to be considered in the decision to proceed with processing the reservoir contents.								
The types, purpose and function of ICS machines within your work area.								
The rationale behind the choices of machine programme for ICS machines in use in the work area.								
The purpose of the collection equipment and processing equipment.								
The effects of citrate or heparin anticoagulant on salvaged blood and the importance of documenting the amount of anticoagulant used.								

DO Direct Observation	S Simulation	EW Expert Witness	PL Prior Learning (evidence required)	WQ Written Questions	OQ Oral Questions

Section 5 Operate and monitor equipment for processing intra-operative salvage blood and complete salvaged blood processing

Knowledge and Understanding Cont...	Assessment Method							
The trainee demonstrated knowledge and understanding of:	**DO**	**S**	**EW**	**PL**	**WQ**	**OQ**	**Assessor's Initials**	**Date**
The possible contents of the collection reservoir during surgery, including potential contaminants.								
The choice of intravenous normotonic wash fluid.								
The importance of using an appropriate wash volume.								
The advantages and risks of swab washing.								
The process of salvaging blood from swabs.								
The rationale for weighing all swabs during ICS.								
How to estimate blood loss during ICS.								
The potential composition of the contents of the re-infusion bag.								
How the re-infusion bag should be labelled.								
The rationale for and calculation of expiry time of the salvaged blood.								
The types of filters used when re-infusing ICS blood and the potential limitations.								
The principles and methods of waste disposal related to the equipment.								
How to recognise hazards, errors and malfunctions of equipment and the appropriate action to take.								

DO Direct Observation	S Simulation	EW Expert Witness	PL Prior Learning (evidence required)	WQ Written Questions	OQ Oral Questions

Section 5 Operate and monitor equipment for processing intra-operative salvage blood and complete salvaged blood processing

Performance Criteria	Assessment Method							
The trainee demonstrated, in a clinical setting, that they could:	**DO**	**S**	**EW**	**PL**	**WQ**	**OQ**	**Assessor's Initials**	**Date**
Confirm decision to process salvaged blood with the relevant member of staff.								
Use intravenous normotonic wash fluid as recommended by the manufacturer.								
Monitor the progress of the processing procedure and report any problems to the appropriate member of staff.								
Correctly record the volume of processed salvaged cells for re-infusion.								
Report completion of the processing procedure to the relevant member of staff.								
Through a safe patient identification process, clearly label salvaged blood re-infusion bags with patient's name, hospital number, date of birth, 'use by' time and the volume of salvaged cells.								
Keep the processed blood with the patient.								
Clear and dispose of waste as appropriate in accordance with local guidelines.								
Complete and sign all relevant documentation.								

DO Direct Observation	S Simulation	EW Expert Witness	PL Prior Learning (evidence required)	WQ Written Questions	OQ Oral Questions

Reflective Learning Record

Procedure:	Date:	Case Log Number:
Additional Information:		

What have I learnt from this procedure?

How can I apply this to my future work?

What went well?	What could I have done differently?

Is there anything I didn't understand or need to explore further in order to consolidate my learning?

Signature of Learner.....

Post Competency Assessment Case Log

It is recommended that ICS autotransfusionists maintain an on-going case log following successful completion of the competency assessments. This can be used as part of the evidence of their on-going competency. It is recommended a minimum of 10 cases be completed in a calendar year to maintain sufficient competency. If 10 cases cannot be achieved then it is recommended that the ICS autotransfusionist should be reassessed as to their practical competency by completing the Assessment Plan as outlined above.

Log No.	Date	Operation	Machine type	Collect Only (CO) or Full Processing (FP)	Volume Reinfused	Comments

Appendix V

Use of Intraoperative Cell Salvage in Obstetrics

Intraoperative cell salvage is increasingly used internationally in obstetric surgery for women at risk from peri-partum haemorrhage during caesarean section. In the year 2005-2006, 38% of obstetric units in Britain used Intraoperative cell salvage in Obstetric surgery.[1]

Maternal haemorrhage during delivery is a significant risk in pregnancy. In the 2005 triennial Confidential Enquiry into Maternal and Child Health (CEMACH) report from the United Kingdom, maternal haemorrhage was the joint fifth leading cause of direct maternal death (causing death in 0.66 per 100 000 maternities). It should also be recognised that maternal haemorrhage may be a contributing factor to other maternal deaths, and a significant cause of maternal morbidity.[2] Obstetric haemorrhage accounts for 3 – 4% of all red cell units transfused in England and Wales, and it is likely that it accounts for a similar proportion of blood usage here in Australia.[3] The following CMACE release: Saving Mothers' Lives report – reviewing maternal deaths 2006-2008 reports that following the introduction of national clinical guidelines and standards there was a reduction in maternal deaths due to haemorrhage.[4]

The use of intraoperative cell salvage in obstetrics has been endorsed by:

- Centre for Maternal and Child Enquires [2]
- Joint Association of Anaesthetists Great Britain & Ireland and Obstetric Anaesthetists Association [5]
- National Institute for Health and Clinical Excellence (NICE)[6].
- The national Patient Blood Management Guidelines: Module 5 Obstetrics is currently under development.

Concerns for Intra-operative cell salvage in Obstetrics:

Early, theoretical concerns over intra-operative cell salvage for Obstetric surgery have not been borne out in clinical practice [1]These concerns include:

- The risk of amniotic fluid embolism with reinfusion of fetal squames/α-fetoprotein/lipid components
- Allo-immunisation with the exposure of an RhD negative mother to red cells of an RhD positive fetus.[6]

Amniotic fluid embolism

During intraoperative blood cell salvage in caesarean section, blood that is lost during the operation is aspirated from the surgical field and after filtering and washing reinfused into the patient. This aspirate may potentially include amniotic fluid and cells from the fetus [6].

"A leukocyte depletion filter is nearly always used in this process to reduce the amount of amniotic fluid contaminants in transfused blood to levels approaching those found in maternal blood" [7]. It is felt that the use of these filters, incorporating a small-pore microfiber web and a negative surface charge, have increased the safety of intraoperative cell salvage in obstetrics by removing the particulate contaminants felt responsible for amniotic fluid embolism associated with disseminated intravascular clotting (DIC). [8,9]

Leukocyte depletion filters remove products such as fetal squamous cells, lipids, amniotic fluid and vernix to produce levels either lower than or similar to those seen in maternal central blood samples at the time of uteroplacental separation [10]. Studies on post wash samples have found that the factors which are postulated to cause amniotic fluid embolism syndrome (e.g. α- fetoprotein, trophoblasts, lanugo hair, vernix caseosa and tissue factor) can be completely eliminated by using a leucodepletion filter.[8]

The use of two separate suction devices for amniotic fluid (initially) and blood (after delivery) is still common practise. Based on the amount of evidence available at this time this practise is still recommended, even though a single suction device has been used in case reports around the world. "Amniotic fluid should theoretically not be aspirated into the collection reservoir, but should be removed by separate suction prior to starting cell salvage. This recommendation will reduce the initial contamination, although in vitro evidence consistently demonstrates that the cell salvage/filtration process can effectively remove amniotic fluid contaminants whatever the initial load. [6,7] In life-threatening haemorrhage, therefore, a clinical decision to salvage red cells from the start of the procedure could be carefully considered, and is supported by current in vitro evidence." [1]

"A randomised trial performed in 2008 compared the use of one suction device only (aspiration of all fluid into the ICS system) versus two suction devices. The trial demonstrated that following the washing and filtering processing, using a leucodepletion filter, the level of residual amniotic fluid contamination was no different [11]

This study conducted in 34 patients over a 4 month period does provide some evidence of the potential safety of using one sucker device in combination with a leucodepletion filter, in relation to the presence of some fetal products believed to be involved in the "amniotic fluid embolism" syndrome. However more evidence would be necessary before recommendation could be provided to change towards the use of one suction device in standard practise.

It is important to recognise that, although cell salvage in combination with leucodepletion filters can eliminate amniotic fluid components, it will not prevent foetal red cells being transfused as the cell salvage system is unable to differentiate between maternal and foetal red cells. Reinfusion of salvaged blood containing foetal red cells may result in maternal allo-immunisation if there is an antigen incompatibility between maternal and foetal red cells. However, this risk is not considered to be any greater than that occurring at normal vaginal delivery[15]

Rh immunisation and Kleihauer testing

Feto-maternal haemorrhage (FMH) may occur at any stage of pregnancy and delivery in RhD negative mothers with RhD positive fetuses, if the maternal circulation is exposed to fetal red cells. Antibodies against the fetal red cells can cause haemolytic disease of the newborn in subsequent pregnancies if untreated. Consequently all Rh negative mothers of Rh positive babies should have Kleihauer testing performed to assess if there has been a significant FMH after any at risk event during pregnancy or following delivery.

Anti D immunoglobulin is given to prevent alloimmunisation from Rh positive red cells, with the dose given dependent upon the volume of red cells detected in the maternal circulation via the Kleihauer test. Testing for FMH should occur following the use of Intra-operative cell salvage particularly as an increased number of fetal red cells may have been reinfused during the cell salvage procedure. It is possible that a higher degree of fetal red cell exposure could occur requiring a higher dose of anti-D to be administered. A similar procedure is followed antenatally when incidents occur known to be associated with alloimmunization."[12]

The local policy for the management of Rh negative mothers who delivered should be followed for those who have undergone reinfusion of intraoperative cell salvage blood. The presence of fetal red cells in the intraoperative cell salvage blood is likely because the intraoperative cell salvage device cannot distinguish fetal from maternal red cells.

The sample for Kleihauer testing should be taken after the reinfusion of intraoperative cell salvage blood and administration of Anti-D should occur as soon as possible, within 48-72 hrs of delivery for successful immunoprophylaxis.[13]

In summary maternal alloimmunisation is a potential risk and therefore presents a risk of future haemolytic disease of the newborn, however this can be minimised by appropriate use of anti-D in consultation with the Obstetrician responsible for the care of the patient. Caution should be taken when Jehovah's Witness patients have a concern with receiving anti-D immunoglobulin.

Refer to local protocol regarding testing for and management of FMH. Guidelines for FMH testing have also been developed by the Australian and New Zealand Society of Blood Transfusion : www.anzsbt.org.au

Rebarber[14] reported the first triple-centre historical cohort study, comparing 139 patients who received cell salvaged blood during caesarean section to a group receiving allogeneic blood. There was no difference between the two groups which could be accounted to complications secondary to cell salvage [15]

According to the National Institute for Health and Clinical Excellence (NICE): "NICE considered the evidence relating to the efficacy and safety of intraoperative blood cell salvage in obstetrics in response to concerns expressed about theoretical risks associated with the procedure. These concerns were the possibility of amniotic fluid embolism and haemolytic disease in future pregnancies, when used in obstetrics. The

evidence relating to safety of cell salvage in these procedures was considered adequate and therefore NICE does not intend to review its use in other specific clinical situations unless notified of new indications for intraoperative cell salvage in which there may be new safety concerns" [6]

Patient Selection

Wherever possible, the advantages and risks of intraoperative cell salvage and allogeneic blood transfusion should be discussed with the patient prior to undergoing an obstetric surgical procedure and clearly documented. In an elective case this can usually be done during the pregnancy.

Indications for Intraoperative Cell Salvage
Patient selection for intraoperative cell salvage in obstetric surgery is at the discretion of the Obstetrician and Anaesthetist caring for the patient.

The type of obstetric cases that could be considered for selection includes:

Emergency situations:

1. Ruptured ectopic pregnancy.
2. Post-partum haemorrhage.
3. Return to theatre after caesarean section.

Elective situations:

1. Patients with an anticipated blood loss of >20% estimated blood volume.
2. Placenta accreta, Placenta increta and Placenta percreta.
3. Large uterine fibroids.

Other situations:

1. Patients who for religious or other reasons refuse allogeneic blood and have consented to the use of intraoperative cell salvage in elective or emergency procedures.
2. Significant anaemia or coagulopathy.

Cell Salvage of Vaginal Bleeding

The use of cell salvage during vaginal haemorrhage is currently under investigation. There is a theoretical concern that blood salvaged from the vagina peri-partum may be contaminated with bacteria. However, there have been case reports where this practise was used without obvious adverse outcome.

The benefit of this procedure should be weighed against the potential risk on a case by case basis by the clinician responsible for the patient. This practise may be considered for life threatening haemorrhage, for example where the patient refuses the use of allogeneic blood products. Thorough saline irrigation, the use of a leukocyte depletion filter and antibiotic prophylaxis would be recommended in this situation.

Caution concerning the use of Leukocyte depletion filters (LDF):

Proper training practices and the recommendations from the specific manufacturer should be adhered to when using leukocyte depletion filters.
Consider the following issues:

- Some filters may require special priming prior to use.
- Their effectiveness may become diminished as more units of blood are transfused through a single filter.
- The effectiveness of some of these filters is also diminished as a result of the increasing infusion rate through the filter (some filters have a maximum recommended infusion rate).
- Leukocyte depletion filters may lead to an increase in haemolysis.
- These filters are also more prone to occlusion than other filters.

In summary

The evidence for the safety of intraoperative cell salvage is favourable and the early theoretical concerns have not been seen in clinical practice to date.

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Appendix VI

Use of Intraoperative Cell Salvage in Malignant Disease

"The use of intraoperative cell salvage in patients undergoing surgery for malignant disease in the past, has not been recommended by manufacturers of intraoperative cell salvage devices. This is due to concern about the possibility of malignant cells being reinfused and giving rise to metastases. However, there are now a number of published reports in which the use of intraoperative cell salvage in cancer surgery has not been associated with early metastasis or a difference in biochemical recurrence and some hospitals now use intraoperative cell salvage routinely during surgery for malignant disease."[1]

"Aspiration of blood from around the tumour site should be avoided to minimise contamination of salvaged blood with malignant cells. The salvaged blood should be reinfused through a leucodepletion filter to minimise the reinfusion of any malignant cells which may have been aspirated into the collection reservoir".[1]

In contrast, there is evidence that allogeneic transfusion may independently be associated with an increased rate of both postoperative infection and disease recurrence.[2–5]

Intraoperative Cell Salvage in urological malignancies has been approved by NICE and is now used routinely.[6]

Theoretical context

If there is concern that circulating malignant cells may lead to systemic spread then it is inadvisable to reinfuse any malignant cells. If the cancer cells are present in the final intraoperative cell salvage blood for reinfusion, they must have been contaminating the collected blood prior to processing. These cells can only be present in the blood if:

- The tumour margins had been compromised at the time of resection making the whole operation palliative (as the likelihood of local recurrence would be high).
- The cancer cells were already blood borne at the time of surgery as resection of blood vessels distant from the tumour margins led to spillage of cancer cells directly from the circulating systemic blood.
- Cancer cells had already spread to the lymphatic system.[7]

Practical Issues

The use of a leucodepletion filter, with a significant reduction (up to 99.99%) in the number of nucleated (including malignant) cells present in the intraoperative cell salvage blood for reinfusion is recommended.[7]

The decision to use intraoperative cell salvage in the presence of malignant disease should be made by the surgeon and anaesthetist, in consultation with the patient whenever possible.

Safety Evidence

Leucodepletion filters has been shown in small non-randomized clinical studies to be an effective method for removal of malignant cells from intraoperative cell salvage blood.[8]

The likely low risk of metastatic spread from intraoperative cell salvage outweighs the risk of infection and immune suppression and consequent tumour cell survival associated with allogeneic red cell transfusion. [2,3,5,9]

In a retrospective database study by Nieder et. al. on a total of 1038 patients between 1992 and 2003, it was found that the use of intra-operative cell salvage during radical prostatectomy was not associated with a greater biochemical recurrence rate of malignancy.[10]

A retrospective study by Nieder et. al published in Urology in 2007 showed no increased risk of metastatic disease or death for those who receive cell-salvaged blood during radical cystectomy.[11]

When the impact of intraoperative blood salvage on neoplastic recurrence was studied during liver transplant for hepatocellular carcinoma it was shown not to modify the risk of neoplastic recurrence by Muscari et al. who published these findings in the International Transplant Journal in 2005.[4]

The NICE guidelines on this matter currently state: "The Committee noted concern about the theoretical risk of infusing viable cancer cells that might cause metastases. However, there was no evidence in reported series that this occurred, and any such theoretical risk needs to be balanced against the potential risks of allogeneic blood transfusion. The Committee did not consider it likely that further long-term research would identify metastases that might have been caused by re-infused malignant cells."[6]

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Appendix VII

Cell Salvage Patient Information Leaflet

Doctor's Name: _____

Patient's Name: _____

Date: _____

Fact Sheet: Red Blood Cell Salvage

Your doctor has given this fact sheet to you because you are going to have a procedure where there could be blood loss and if that loss is large, you may need blood replacement. This information gives you important information about Red Blood Cell Salvage (cell salvage) so you and your doctor can discuss any concerns or questions. It's all about helping you make an informed choice about whether cell salvage is appropriate for you. You may want to share this information so your partner and family can understand your choice.

The reason you might choose cell salvage is that it recycles your own blood, it reduces some of the risks of blood transfusions from donors and also saves donated blood for those people where cell salvage is not possible. You may also prefer cell salvage if you have religious or personal reasons for not wanting a donor transfusion.

Cell salvage collects your own lost blood during the procedure using gentle suction and adds an anticoagulant to stop the blood clotting. Your own salvaged red blood cells – the ones which carry oxygen – are then washed, filtered and returned back to you via an IV 'drip' (see diagram). Cell salvage has been used safely for more than 30 years and is subject to strict guidelines.

What are my options? If you need blood replacement you can either receive a blood transfusion from another person (donor blood), or your own blood collected and recycled during the surgery (cell salvage). In certain situations such as bowel surgery or if you have a serious infection, cell salvage cannot be used. If you are pregnant or have cancer you can still have cell salvage. Your surgeon or anaesthetist will be able to tell you if it is an option for you.

If you are iron deficient or anaemic prior to surgery this increases the likelihood that you will need a transfusion and may make recovery harder and slower for you. If your surgery is still some time in the future you can ask your doctor about testing for low iron levels and anaemia so that, if necessary, you can receive iron therapy ahead of surgery and perhaps avoid the need for blood replacement.

How will receiving a blood transfusion or cell salvage affect my health outcome? If you lose a significant amount of blood and don't receive blood replacement, it may be harder for your body to recover. Replacing the blood means faster recovery and feeling

better. Donor blood transfusions have a risk of immediate and delayed complications including fever, mild allergic reactions like a rash or serious ones like difficulty in breathing. These risks are reduced if you have cell salvage as it is your own blood. There is a small risk of infection with both donor blood and cell salvage.

What is the likelihood I will suffer a complication? The likelihood that you will experience a complication is small and varies depending on several factors including your individual characteristics, the type of blood product transfused and which procedure you have. You should ask your doctor about your individual risks so you can give informed consent for cell salvage.

Additional Information: You can obtain additional information from your clinicians (doctor, surgeon, anaesthetist, or nurse) or at www.blood.gov.au.

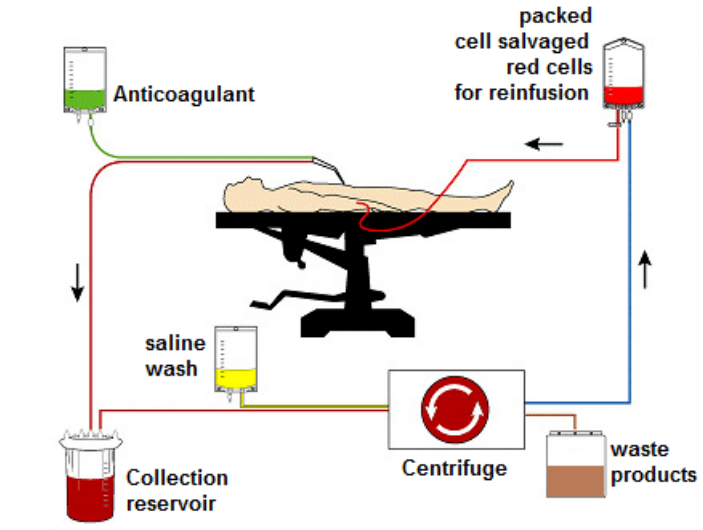

Diagram used with permission from the University Hospital of South Manchester NHS Foundation Trust, Department of Medical Illustration

Ref: Esper, S et al. Intra-operative cell salvage: a fresh look at the indications and contraindications. Blood Transfusion 2011 April; 9

Appendix VIII

Manufacturers' Guidelines

The organisation should attach a copy of the manufacturers' guidelines to this section

Appendix IX

Autologous Transfusion Label

An autologous transfusion label is available from some automated cell saver manufacturers. It should include the following information.

Intraoperative cell salvage

Patient ID/MRN number/Hospital Number_____
Last Name_____
First Name_____
DOB_____
Operator/Autotransfusionist name_____
Anaesthetist_____
Surgeon_____
Collection Site/Theatre_____
Infusion started_____
Expires/Reinfuse by: Date_____Time_____

Intraoperative Cell Salvage
Washed ☐
Unwashed ☐

Total volume for reinfusion _____ mls

(This section to be completed and affixed to patient's clinical record:)

Intraoperative Cell Salvage

Patient ID_____
Full Name_____
Intra-op cell salvage:
Washed ☐
Unwashed ☐

Total volume for reinfusion _____mls

Checked by:	
Administered by:	
Transfusion started:	Date_____Time_____

Appendix X

Fault log

Intraoperative Cell Salvage Device Fault Log

Device: _____

Serial Number: _____

Autotransfusionist: _____

Date	Nature of fault	Manufacturer contacted (Y/N)	Corrective action	Signature

Appendix XI

Patient material "About Patient Blood Management"

http://www.health.wa.gov.au/bloodmanagement/docs/fact_sheet.pdf


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