CELL SALVAGE- PERFUSION AND NURSING - CHW

PRACTICE GUIDELINE ©

DOCUMENT SUMMARY/KEY POINTS

The aim of this document is to provide information that will allow clinicians to:

- Appropriately identify suitable patients, undergoing elective and/or emergency surgical procedures, where Intraoperative Cell Salvage could be of benefit.
- Safely utilise Intraoperative Cell Salvage in an effective manner.

The intraoperative collection and re-infusion of the patient's own red blood cells provides an important contribution to reducing the demand for allogeneic blood.[1, 7, 8] However, it is only one aspect of a strategic approach to safe and appropriate transfusion practice.

Utilising appropriate alternatives to blood transfusion is cost-effective, [9] complies with clinical governance requirements, [10] and falls within the scope of the National Safety and Quality Health Service (NSQHS) Standard 7: Blood and Blood Products.[2] (www.safetyandquality.gov.au)

The scope of NSQHS Standard 7: Blood and Blood Products covers all elements in the clinical transfusion process including the principles of patient blood management, which includes avoiding unnecessary exposure to blood components.

CHANGE SUMMARY

N/A – New guideline

This document reflects what is currently regarded as safe practice. However, as in any clinical situation, there may be factors which cannot be covered by a single set of guidelines. This document does not replace the need for the application of clinical judgement to each individual presentation.

Approved by:	SCHN Policy, Procedure and Guideline Committee	
Date Effective:	1st July 2018	**Review Period**: 3 years
Team Leader:	Perfusionist	**Area/Dept**: Heart Centre for Children

READ ACKNOWLEDGEMENT

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1 Introduction

This practice guideline aims to improve clinical practice and patient outcomes through alignment with the Patient Blood Management Guidelines.[1] The National Safety and Quality Health Service (NSQHS) Standard 7: Blood and Blood Products[2] requires blood and blood product policies and procedures to be consistent with national evidence based guidelines for pre-transfusion practices, prescribing and clinical use of blood and blood products.[2]

Patient Blood Management is a patient-focused approach to improving patient outcomes by minimising or avoiding unnecessary exposure to blood components. Intraoperative Cell Salvage can be considered an integral part of a Patient Blood Management program as it is an autologous blood conservation measure that decreases net perioperative blood loss, maintains postoperative haemoglobin and reduces the requirements for allogeneic blood transfusion.[3]

Intraoperative Cell Salvage can also be considered a Quality Improvement activity as it reduces the patient's exposure to allogeneic transfusion and the associated risks of infectious and non-infectious complications. Whilst allogeneic (donated) blood is an essential adjunct to health care, it is a valuable but limited resource and allogeneic transfusion can present a source of risk for patients. Evidence is accumulating for adverse transfusion outcomes that may increase hospital length of stay and may present significant morbidity in identified patient groups.[4–6]

This practice guideline is based on the National Blood Authority of Australia Guidance for the Provision of Intraoperative Cell Salvage, which itself is based on the UK Cell Salvage Action Group document Policy for the Provision of Intraoperative Cell Salvage.[28] The National Blood Authority Guideline has been reviewed by local clinicians to assess its applicability to the Australian health care setting.

All references to Intraoperative Cell Salvage in this policy, relate to WASHED systems only (unless otherwise stated).

This guidance has been written to support the use of washed Intraoperative Cell Salvage. It may also be applicable when washed Intraoperative Cell Salvage devices are used in the pre and/or postoperative environment and for devices specifically designed for combined washed Intraoperative Cell Salvage and Postoperative Cell Salvage.

This guidance does not relate to the use of unwashed cell salvage systems (e.g. postoperative autologous wound drains or combined unwashed Intraoperative Cell Salvage/postoperative cell salvage devices).

Information regarding the suppliers of washed Intraoperative Cell Salvage systems can be found at Appendix VI.

2 Background

Intraoperative cell salvage is used routinely in some areas of surgical practice. The technique involves the surgeon aspirating blood lost within the surgical field into a collection reservoir. Blood is mixed with an anticoagulant solution containing either heparin or Acid citrate dextrose (ACD) to prevent clotting. A modified aspiration line is used to deliver the anticoagulant to the tip of the suction. As blood enters the collection reservoir it is filtered to

remove large particulate debris. If there is insufficient blood to continue with processing, this is referred to as a 'collect-only' system and is therefore not re-infused.

'Collection and processing' refers to salvaged blood that is then centrifuged and washed to produce red blood cells (RBC) suspended in the wash solution used (Plasmalyte 148 at CHW) for re-infusion to the patient. The discarded products (plasma, platelets, anticoagulant etc.) are removed during processing and the washed red blood cells are transferred to a re-infusion bag. The patient is re-infused with their own washed red blood cells. This is referred to as an autologous red blood cell transfusion or autotransfusion.

An "autotransfusionist" operates the "collection and processing" cell salvage device. This person may be a perfusionist or an anaesthetic nurse, as long as they have received appropriate training in the operation of the device. Appropriate training is described in Section 6.

2.1 Advantages of Intraoperative Cell Salvage[11]

- The patient's own fresh red blood cells (that would otherwise be lost) are re-infused and have higher levels of 2,3-diphosphoglycerate than allogeneic blood, maintaining their flexibility in the microcirculation and becoming immediately active in tissue oxygenation.[12–14]
- Provides a ready supply of blood that is available in proportion to the losses that are occurring.
- Reduces exposure to allogeneic transfusion in surgical procedures associated with significant blood loss and therefore reduces transfusion associated risks.[8]
- According to evidence on adverse events[15] during allogeneic blood transfusion, a major risk includes the potential for a patient to receive 'the wrong blood' as a result of clerical or human error. However, in the case of Intraoperative Cell Salvage this risk is significantly reduced as the blood remains with the patient at all times.
- Acceptable to the majority of patients who may decline allogeneic blood.

2.2 Importance of Cell Salvage as a Patient Blood Management Initiative

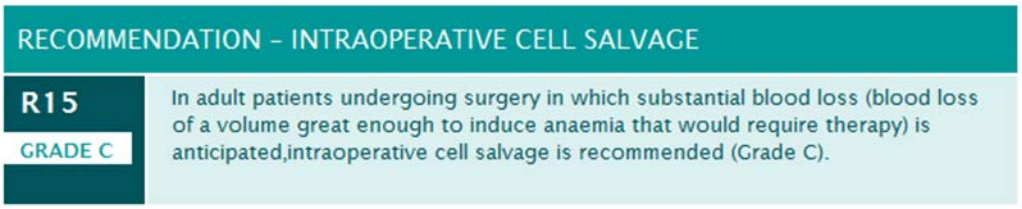
Patient Blood Management (PBM) is a patient-focused approach to improving patient outcomes by minimising or avoiding unnecessary exposure to blood components. Intraoperative Cell Salvage can be considered an integral part of a Patient Blood Management program, as it is an autologous blood conservation measure that decreases net perioperative blood loss, maintains postoperative haemoglobin and reduces the requirements for allogeneic blood transfusion.[3]

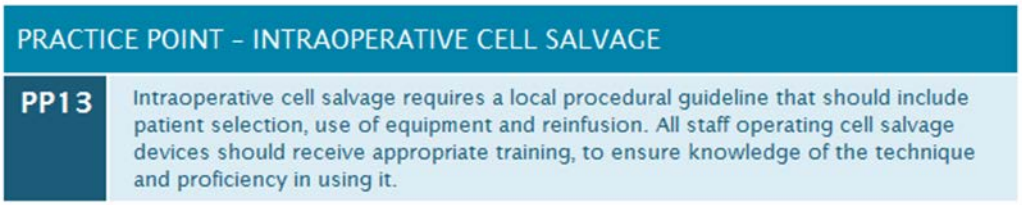
Intraoperative Cell Salvage has been reviewed in the Patient Blood Management (PBM) Guidelines Module 2 – Perioperative[1] and Module 4 - Critical Care.[16] The following is the summary of the findings and recommendations or, where sufficient evidence was not available, practice points.

- Module 2 - Perioperative

The systematic review found that, overall, the incidence and volume of allogeneic blood transfused were significantly lower for the individuals who received Intraoperative Cell Salvage.[1]

The PBM Guidelines "Module 2 – Perioperative" contains the recommendation and practice point below, relating to Intraoperative Cell Salvage. The meta-analyses conducted found that, overall, the incidence and volume of allogeneic blood transfused were significantly lower for the individuals who received Intraoperative Cell Salvage.[1]





- Module 4 - Critical Care

  The systematic review was designed to evaluate the benefit and also the safety of cell salvage in Intraoperative Cell Salvage for trauma and non-trauma patients. In trauma patients, the use of cell salvage does not appear to have an effect on mortality, but does reduce the volume of allogeneic blood transfused.[16] However; concerns remain about patient selection and safety.

  In particular, the re-infusion of contaminated blood in the "contaminated" trauma patient may pose a significant risk and hence further research into this area is indicated.[16]

  In patients with massive blood loss in a clean uncontaminated operative field the advantages of Intraoperative Cell Salvage are considerable.

Whilst allogeneic blood is an essential adjunct to health care, it is a valuable but limited resource and transfusion can present a source of risk or adverse outcomes for patients (see Table 1). Intraoperative Cell Salvage can be considered a patient safety initiative as it reduces the patient's exposure to allogeneic transfusion and many of the associated risks of

transfusion. While some risks stem from human and systems error and should be amenable to corrective and preventive measures, some are related to the very nature of blood products and the only way to avoid them may ultimately lie in avoiding blood transfusions altogether.[17]

- Risks associated with allogeneic blood transfusion include (but are not limited to):
  - wrong blood incidents
  - transmission of blood borne infections
  - haemolytic transfusion reaction
  - immunosuppression[18,19]

Table 1: Reported adverse outcomes associated with allogeneic blood transfusion[17]

Infection	Cardiac arrest
Septicaemia	Renal failure
Transfusion-related acute lung injury (TRALI)	Stroke
Multisystem organ failure (MOF)	Thromboembolism
Systemic inflammatory response syndrome (SIRS)	Diminished postoperative functional recovery
Acute respiratory distress syndrome (ARDS)	Bleeding requiring re-operation
Prolonged mechanical ventilation	Increased admission to ICU
Vasospasm	Increased ICU length of stay
Low-output heart failure	Increased hospital length of stay
Atrial fibrillation	Increased hospital readmission

3 Haemovigilance

The transfusion of blood and blood products can lead to complications and adverse outcomes for patients. The risks associated with transfusion of blood and blood products usually fall into two categories:

3.1 Errors in procedure

These errors may include:

- incorrect patient identification
- inaccurate blood sample labelling

- administration of blood or blood products to the wrong patient

3.2 Transfusion reactions

Human errors continue to contribute significantly to transfusion-related adverse events. However, the introduction of mandatory reporting of adverse events under the NSQHS Standard 7: Blood and Blood Products[2] contributes to the understanding of transfusion related errors, and allows for identification of safety and quality measures to deliver better transfusion outcomes.

Adverse events related to exposure to allogeneic and autologous blood should be reported to Haemovigilance programs. Haemovigilance can provide valuable data on the occurrence of transfusion-related adverse events, and as a result drive the introduction of initiatives such as Intraoperative Cell Salvage, which by reducing exposure to allogeneic blood and procedural risks, enhances the safety of the transfusion process.

The most recent Australian Haemovigilance Report[20] details the numbers of serious adverse events by blood product reported from 2010-11 to 2013-14. They found that:

- Red blood cells were the products most often implicated in serious events for this period, accounting for 63.8% of the reports, followed by fresh frozen plasma (19.0%) and platelets (17.1%).
- The majority of serious allergic and anaphylactic reactions were related to the transfusion of fresh frozen plasma and platelets.

In common with other OECD countries, such as the United Kingdom, New Zealand, Sweden and Canada, the majority of the reported transfusion errors resulted from preventable human error.

4 Aims

The aim of this document is to provide information that will allow clinicians to:

- Appropriately identify suitable patients, undergoing elective and/or emergency surgical procedures, where Intraoperative Cell Salvage could be of benefit.
- Safely utilise Intraoperative Cell Salvage in an effective manner.

5 Responsibilities

Responsibilities within the cell salvage program include:

- Documenting and document control of the hospital's Intraoperative Cell Salvage procedures
- Implementation of the program within the hospital's quality framework
- Prescribing and labelling activities
- Training, development and proficiency testing activities
- Enrolment in an appropriate quality assurance or accreditation program

- Clinical governance and periodic auditing of the program to ensure the program continues to meet its stated aims

5.1 Prescribing Responsibilities

Re-infusion of salvaged blood should be prescribed by the responsible clinician on the anaesthetic record sheet if the patient is in theatre, or the blood component order sheet for patient in PICU.

5.2 Labelling Responsibilities

The re-infusion bag should be labelled as soon as is reasonably practical. These details are explained in Section 9.4 of this document. The Autologous Transfusion label used to label the re-infusion bag can be found in Appendix II.

5.3 Individual Training Responsibilities

Individual staff should ensure that they are adequately trained and competent in the use of the Intraoperative Cell Salvage system and that their individual responsibilities comply with their scope of practice.

Staff should ensure that their technical ability, support, equipment and risk management complies with best international accepted practice. Staff should not use equipment for which they have not been trained and competency has been achieved or they are involved in the learning and development pathway.

5.4 Documentation Responsibilities

Staff should ensure that documentation (including all appropriate labelling) accurately reflects the Intraoperative Cell Salvage process. The documentation record should include:

- The Intraoperative Autotransfusion Patient Record (Appendix III)
- The Intraoperative Cell Salvage autologous transfusion label completed (Appendix II) and attached to the re-infusion bag. This process should comply with "the National Recommendations for User-applied Labelling of Injectable Medicines, Fluids and Lines."[23]. https://www.safetyandquality.gov.au/wp-content/uploads/2015/09/National-Standard-for-User-Applied-Labelling-Print-version-Aug-2015.pdf
- The appropriate labelling of heparinised saline anticoagulant at the start of the procedure, which also should comply with "the National Recommendations for the User-applied Labelling of Injectable Medicines, Fluids and Lines."[23] The heparinised saline anticoagulant is prepared in Pharmacy and should be checked for appropriate dose (30,000 IU of heparin in 1 litre of 0.9% normal saline), as well as that it is in date. If the supply of heparinised saline anticoagulant is low, more can be ordered by calling Pharmacy.
- Pre-transfusion bedside checks and patient observations must be performed and recorded during autologous Intraoperative Cell Salvage blood re-infusion, in the same way as for the transfusion of allogeneic blood, as per hospital policy and individual patient assessment. Refer to the Australian and New Zealand Society of Blood Transfusion (ANZSBT) / Royal College of Nursing Australia (RCNA) Guidelines for the Administration of Blood Products (2011)[27].

https://www.anzsbt.org.au/data/documents/guidlines/ANZSBT_Guidelines_Administration_Blood_Products_2ndEd_Dec_2011_Hyperlinks.pdf

- Adverse events and outcomes should be documented in the patient's clinical record and reported via the Incident Information Management System (IIMS), which is further described in Section 12 of this practice guideline.
- Documentation should include accurate details of the intraoperative procedure, equipment and staff.
- Adherence to the hospital's clinical governance framework.
- Staff training and competency records are maintained in the Perioperative Services folder on the internal shared K drive.
- In the case of a health service organisation employing outsourced staff to perform cell salvage-related activities (i.e. external contractors), it is up to that health service organisation to cover those outsourced staff on issues such as their qualifications, training, and agreement to act and perform tasks, the same as hospital staff.

6 Training

The perfusion department, in cooperation with the anaesthetic nursing department, will administer and track training of the autotransfusionists.

Theoretical and practical training should be undertaken by all autotransfusion anaesthetic nurses as described in the Autotransfusion Learning and Development Pathway. (See Appendix IV for the Autotransfusion Learning & Development Pathway)

Individual staff should receive training in the indications, contraindications and technical differences specific to the applicable surgical speciality. If a member of staff moves from one surgical sub-speciality to another, it is good practice to orientate them to any new aspects prior to using Intraoperative Cell Salvage in their new clinical environment.

Training will include: successful completion of the Australian and New Zealand College of Perfusionists Autotransfusion course, successful completion of the one day Autotransfusion Symposium lead by the Intraoperative Cell Salvage co-ordinator, successful completion of two cell salvage cases supported by CHW perfusionists, successful completion of the Autotransfusion Competency, reading of the NSW MoH Policy Directive Management of Fresh Blood Components and undertaking further reading to enhance understanding of autotransfusion and the impact on patient care.

In order to maintain certification the following should be achieved: minimum of ten cases should be performed per year, attendance at a 2 hour continuing education session annually and meets regularly with the manager and CNS2 anaesthetics/recovery to discuss development.

Staff carrying out Intraoperative Cell Salvage for Jehovah's Witness patients should have received training and had their competency assessed in preparing the equipment and blood for re-infusion in accordance with the patient's religious beliefs prior to carrying out the procedure.

Updated training is recommended under the following circumstances:

- Any reasonable length of time without practical use of the Intraoperative Cell Salvage device.
- A learning need is identified by an individual member of staff or supervisor.
- Changes in the product from the manufacturer or changes due to the purchase of new equipment by the organisation.
- Changes to national and/or local guidelines related to any aspect of cell salvage and re-infusion.
- The occurrence of an adverse event or near miss that undermines the reliability of the Intraoperative Cell Salvage service.

7 Indications and Patient Selection

Intraoperative Cell Salvage systems may be used in elective and/or emergency surgical procedures where the surgical field is not contaminated by gastrointestinal tract contents (including faecal contamination) and infective matter and where no other contraindications exist (see Section 8).

Traditionally Intraoperative Cell Salvage was contraindicated in obstetrics and malignancy, however, in light of new research and experience it has been proven to be safe and endorsed by National Institute for Health and Care (NICE) guidelines.[24, 25]

Patient selection for Intraoperative Cell Salvage is at the discretion of the surgeon, anaesthetist, perfusionist, nurse caring for the patient and capabilities of the organisation. See Appendix I: A list of procedures with significant potential benefit for Intraoperative Cell Salvage.

Providing that none of the contraindications listed in Section 8 exist, patients to be considered for Intraoperative Cell Salvage include:

- Adult patients undergoing elective or emergency surgical procedures where the anticipated blood loss is great enough to induce anaemia[1] or expected to exceed 20% of estimated blood volume, or in paediatrics 15%.[11] This will include but not be limited to: Cardiothoracic Surgery, Vascular, Urology, Orthopaedic, Obstetrics and Gynaecology and Trauma surgery.
- Patients undergoing elective or emergency surgical procedures who have risk factors for bleeding or low preoperative haemoglobin level (including Haemophilia and Thalassemia, when in consultation with a haematologist).
- Patients who have rare blood groups or antibodies for which it may be difficult to obtain allogeneic blood, in consultation with Haematology/Blood bank.
- Patients who, for religious or other reasons, are unwilling to receive allogeneic blood and have consented to receiving autologous blood via Intraoperative Cell Salvage (all such decisions should be documented). Reference should be made to the patient's Advanced Health Directive where applicable.

If the surgical procedure to be carried out for patients at high risk, as nominated above, is associated with any of the contraindications as listed in Section 8, the medical clinician

involved should discuss the potential risks with the patient/family if possible, and the agreement to undergo Intraoperative Cell Salvage should be documented.

8 Contraindications and Warnings

The surgeon and anaesthetist responsible for the patient's care should assess the risk-benefit ratio of Intraoperative Cell Salvage for each individual patient.

8.1 Contraindications

Intraoperative Cell Salvage is currently not recommended when bowel content or infected material is present in the surgical field.

8.2 Warnings / Caution

- Hypotension.

  Caution is required when Acid citrate dextrose (ACD) and leucocyte depletion filters (LDF) are used in combination. The 2010 Serious Hazards of Transfusion (SHOT) report identified four cases of hypotension that occurred following rapid re-infusion of cell salvaged blood. The cause of this reaction is still unknown and is being investigated. [19] As reported - 'One of these occurred with the transfusion of unwashed cell salvaged blood[3] and where a combination of ACD and a leucodepletion filter were used'. [19] This phenomenon has been recognised in the Association of Anaesthetists Great Britain and Ireland (AAGBI) Safety Guideline on cell salvage.[7] "These patients may be hypovolaemic and therefore more susceptible to the vasoactive cytokines re-infused. All patients experienced transient but significant hypotension corrected by the cessation of infusion and/or vasopressors. No long-term sequelae of this hypotension were noted."

- Heparin induced thrombocytopenia

  Acid Citrate Dextrose (ACD) should be used instead of Heparin when Heparin induced thrombocytopenia is suspected. The decision to use ACD should be made on a clinical basis. Even though there is not a lot of evidence (only occasional case reports), there may be some concern about the potential of hypotension when using ACD as anticoagulant. ACD can be obtained directly from Baxter.

8.3 When Intraoperative Cell Salvage should be temporarily discontinued

Intraoperative Cell Salvage should be temporarily discontinued when substances that are not licensed for intravenous (IV) use are used within the surgical field to prevent the aspiration of these substances into the collection reservoir. The standard theatre suction should then be used to aspirate (to waste) from the surgical field and the wound irrigated with generous amounts of 0.9% IV Sodium Chloride, before resuming the collection of blood for the Intraoperative Cell Salvage process.

Examples of materials that are not licensed for intravenous use, or materials that impair the filter mechanism, include:

- Antibiotics not licensed for IV use.
- Iodine.
- Topical clotting agents (microfibrillar, sponge or topical liquid form that causes platelet aggregation, clotting activation or creates fibrin clot).
- Freshly curing orthopaedic cement where some solvent may be temporarily released.
- Irrigation solutions such as alcohol or betadine, bleach, hydrogen peroxide, hypertonic solutions or hypotonic solutions The use of Hartmann's Solution or Lactated Ringer's will inhibit the action of citrate based anticoagulants (ACD) and therefore should not be used as irrigation or wash solution, when ACD is used as the anticoagulant.
- Bone reaming fragments.

The presence of such substances would require adequate 0.9% IV Sodium Chloride irrigation and suction to waste, prior to conducting or recommencing Intraoperative Cell Salvage.

- The use of Intraoperative Cell Salvage in the presence of infection may result in bacterial contamination of the salvaged blood. The aspiration of blood from an infected site should be avoided and antibiotics should be given as appropriate.
- Gastric or pancreatic secretions should not be aspirated into the Intraoperative Cell Salvage system. These secretions may cause enzymatic haemolysis and are not reliably removed by the washing procedure.
- Pleural effusions should not be aspirated and should be drained prior to cell salvage. However, blood which subsequently accumulates in the pleural space may be aspirated.
- There are concerns relating to the use of Intraoperative Cell Salvage in patients with sickle cell disease. The use of Intraoperative Cell Salvage in patients with abnormal red cell disorders should be made on a clinical and individual patient basis and in consultation with a haematologist.

9 Intraoperative Cell Salvage Procedure

9.1 Use of the Intraoperative Cell Salvage Equipment

The Intraoperative Cell Salvage system should be used in accordance with the manufacturer's guidelines (see Appendix VI).

All Intraoperative Cell Salvage products and critical materials used in their processing, as well as laboratory samples and patient records must be identifiable and traceable. The autotransfusion excel spread sheet as well as the autotransfusion patient record are used to record this data.

Contraindications should be considered as identified in Section 8.

All staff setting up or operating Intraoperative Cell Salvage systems should receive theoretical and practical training as per the Autotransfusion Learning and Development Pathway (see Section 6).

Staff should comply with hospital policies for infection control, management of sharps and blood transfusion.

Aseptic technique should always be used to reduce the risk of infection.

9.2 Anticoagulant

The type and concentration of anticoagulant used should be documented on the cell salvage record for each case.

As stated in section 5.4, the heparinised saline anticoagulant is prepared in Pharmacy and should be checked for appropriate dose (30,000 IU of heparin in 1 litre of 0.9% normal saline), as well as that it is in date. If the supply of heparinised saline anticoagulant is low, more can be ordered by calling Pharmacy.

If the heparinised saline anticoagulant runs out after hours, it is possible to make this up manually by adding 30,000 IU heparin into a 1 litre bag of 0.9% NaCl. This should be double checked and appropriately labelled and also should comply with "the National Recommendations for the User-applied Labelling of Injectable Medicines, Fluids and Lines,"[23] as stated in Section 5.4.

If it is necessary to use an alternate anticoagulant then see Section 8.2.

9.3 Wash Solution

Plasmalyte 148 (intravenous or IV Grade) should be used as the wash solution. This stored in the Perfusion Pump room adjacent to theatre 5. If this supply is low, more Plasmalyte 148 is stored in the fluid supply room.

9.4 Labelling

All salvaged blood (the re-transfusion bag) should be identified with a label, (see Appendix III) which includes:

- Patient's full name
- Date of birth
- Hospital number
- Collection start date and time
- Expiry date and time
- Type of autologous blood (intra-op/washed)
- Name of the autotransfusionist involved in the case
- Volume of blood collected to be re-infused.

9.5 Re-infusion

Prescribing Responsibilities: Salvaged blood re-infusion should be prescribed by the responsible clinician on the documentation approved by the organisation.

Intraoperative Cell Salvage may be set up as a "closed-circuit" system. Blood is aspirated from the surgical field, processed and transferred to a re-infusion bag. The re-infusion bag is simultaneously connected to the patients IV cannula via an appropriate filter (see below). Caution should be taken to prevent air embolism.

An external pressure bag should not be applied to increase the flow rate because of the risk of air embolism, unless the re-infusion bag has been disconnected from the Intraoperative Cell Salvage device and the air eliminated. The same collection bag may fill and empty many times during an operation.

Alternatively, Intraoperative Cell Salvage may be set up without simultaneous connection of the collection bag to the patient (as above). In this case, the collection bag is disconnected from the Intraoperative Cell Salvage device when it is full or at the end of the surgical procedure and is subsequently connected to the patient and transfused within 4 hours.

A filter, appropriate to the type of surgery, should be used for re-infusion. A blue, Haemonetics™ LipiGuard, 40 µm filter should be used for orthopaedics. As per manufacturer's guidelines, this filter is designed for the reduction of fat particles, microaggregates and leucocytes for up to 1 unit of washed blood. An orange, Haemonetics™, 40 µm microaggregate filter should be used for cardiac surgery. Leucocyte reducing filters are used for patients with malignancies.

The re-infusion bag should be kept beside the patient at all times.

The re-infusion bag should not be placed into a refrigerator. Re-infusion of the salvaged blood should follow standard blood transfusion practice. Refer to the ANZSBT/RCNA Guidelines for the Administration of Blood Products (2011)[27]. The responsible clinician should prescribe salvaged blood for re-infusion in the same manner as for allogeneic blood and document the transfusion in the standard anaesthetic documentation.

Intraoperative Cell Salvage products must be administered only to the patient from whom the blood was collected. There should be positive identification of the patient and product. When not immediately re-infused in theatre, the patient details on the re-infusion bag should be carefully checked at the patient's side (by two staff members) against the details on the identification band attached to the patient before connecting the re-infusion bag to the patient.

Ensure all details on the ID band (full name, date of birth, medical record number) are:

- Identical to those on the prescription, and
- Identical to those provided on the re-infusion bag label

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

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

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

The re-infusion of salvaged blood should be documented in the standard anaesthetic record and in the autotransfusion record. The formal autotransfusion record is placed in the patient's clinical record.

Salvaged blood should be transfused in the operating theatre, recovery unit or the paediatric intensive care unit only, as the patient will receive appropriate observation and access to anaesthetist for post-operative review.

9.6 Cautions

The use of Hartmann's Solution or Lactated Ringer's will inhibit the action of citrate based anticoagulants (ACD) and therefore should not be used as irrigation or wash solution.

9.7 Expiry

The collection, processing and re-infusion of salvaged blood should be completed within the timeframe recommended by the manufacturer.

The AABB Guidelines state the recommended re-infusion time for cell salvaged blood is within 4 hours from the completion of processing.[26] This policy at CHW states that salvaged blood must be re-transfused within 4 hours from completion of processing.

Any blood that has not been transfused within this timeframe should be disposed of in accordance with hospital policy.

9.8 Documentation

The collection and re-infusion of salvaged blood should be accurately documented on the official patient autotransfusion record (see Appendix II). Printed copies of these forms can be found in the Pump Room adjacent to Theatre 5. The forms can be found are on the Intranet (Sydney Children's Hospital Network Intranet → Form/Template Library → SCHN Clinical Forms → Perfusion (Heart Centre for Children) → Autotransfusion Record) if more need to be printed. All information should also be recorded in the autotransfusion excel spread sheet. The excel spread sheet can be opened from the shared computer using the application window, open ABCI Logbooks then click the cell saver tab.

Adverse events should be documented and reported (see Section 12).

9.9 Disposal of used Intraoperative Cell Salvage equipment

Following use, all Intraoperative Cell Salvage disposable equipment should be disposed of in accordance with the Hospital's Health and Safety procedure for disposal of equipment contaminated with blood. Yellow, bio hazardous waste bags are located under the dirty sink in the pump room, which can be used to dispose of the cell salvage disposables. The waste bag can then be placed into one of the large yellow, bio hazardous waste containers.

9.10 Cleaning and Disinfection of Intraoperative Cell Salvage Devices

Following use, the cell salvage device should be cleaned in accordance with the manufacturer's guidelines and the Hospital's Infection Control Policy. A neutral detergent and Rediwipes are used to disinfect the cell saver surfaces.

In the case of a 'cracked bowl' with the Medtronic Autolog Cell Saver:

- Place a flat container under the machine to collect the disinfecting solution used during the cleaning process.
- Caution: Use appropriate blood borne pathogen and engineering controls such as eye protection, mask and gloves to protect the user from the blood, cleaning fluids, and to discard the used fluids.
- Switch the machine off, and then turn it back on while pressing the Go key. This places the machine in a centrifuge cleaning mode. Press Go again to start the centrifuge rotating.
- Caution: There is no safety catch. Do not put your fingers into the centrifuge chamber while it is running.
- Slowly, over a 1-2 minute period, pour 1 L of a 10% bleach solution or other appropriate disinfectant solution into the centrifuge while it is rotating. Press Stop, turn the machine off, and wait until the centrifuge has completely stopped rotating before placing your fingers into the centrifuge chamber. Dry the chamber with a soft cloth.[27]

Specific procedures required for cleaning equipment following high risk cases should be followed.

9.11 Maintenance of Equipment

All Intraoperative Cell Salvage equipment should be serviced regularly in accordance with the manufacturers' recommendations. Biomedical Engineering keeps a detailed log of each device including preventative maintenance schedule.

Issues arising with the cell salvage devices should be reported to the Perfusion Department and the Biomedical Engineering Department.

10 The Management of Massive Re-infusion

As with the transfusion of large volumes of allogeneic red cells, the return of large volumes of salvaged red blood cells will coincide with the depletion of platelets and clotting factors. This is also normally associated with massive blood loss.

In the event of a massive re-infusion of salvaged red blood cells, it is important to consider the need for additional appropriate transfusion of other blood products e.g. platelets, fresh frozen plasma and cryoprecipitate (similarly to when a massive transfusion of allogeneic red blood cells is given).

Autotransfusion staff should identify and report a large blood loss in the collection reservoir to the anaesthetist and the surgeon.

Consideration should be given to the use of thromboelastography (TEG) for a rapid assessment of factor deficiency, and to assist in the targeting of blood product transfusion.

See Massive Transfusion Protocol Procedure SCHN at http://webapps.schn.health.nsw.gov.au/epolicy/policy/2045/

See PBM Guidelines: Module 1 Critical Bleeding/Massive Transfusion - Massive transfusion Protocol (http://www.nba.gov.au/guidelines/module1/index.html)

11 Quality Assurance

The perfusion department maintains a quality assurance system to ensure the provision of a safe, optimum Intraoperative Cell Salvage service. This service has a process to collect and evaluate quality indicator data on a scheduled basis. The frequency of testing is determined by the Autotransfusion Supervisor, in agreement with the Head of Perfusion.

11.1 Product

In order to ensure a good quality product, partially filled bowls are not processed with the Medtronic Autolog. The manufacturer guidelines recommend:

- Final Cycle/Return Function – Press the Incrementation (+) key, then the Go key to confirm the final cycle. The machine will finish filling a partially filled bowl with concentrated cells from the holding bag and start the wash phase of the cycle. This function should only be used to supplement the volume of the blood in the bowl to allow the remainder of the blood to be processed. Do not over process the blood by repeating the return function multiple times for the same blood volume. Once a bowl has been processed using the return function, it should be transferred to a blood bag for subsequent administration to the patient as soon as possible. If the volume remains insufficient, "INCOMPLETE BOWL RECOVERABLE? NO" is displayed. The operator should reply "NO" by pressing the Go key. Medtronic does not have sufficient data to support the safety and efficacy of returning washed cells from partially filled bowls and therefore cannot recommend that practice.[27]

The quality control testing is as follows:

- Blood Culture
- Percentage of haemolysis – calculated by using the following formula:

  Percentage of haemolysis (%) = {(fHb/ Hb) x (1- Hct)} x 100%

  The percentage of acceptable haemolysis in processed blood should be <0.7%.
- Check blood gas analysis for potassium. This value should not be out of normal range (3-5 mmol/L).

11.2 Personnel

A designated perfusionist and anaesthetic Clinical Nurse Specialist (CNS) 2, under the supervision of the head of Perfusion and head of Anaesthesia, is responsible for ensuring that a safe and effective Intraoperative Cell Salvage service is provided and that clinical governance systems are fully implemented.

The senior supervising autotransfusionist should ensure that competent personnel in sufficient numbers are available to provide the Intraoperative Cell Salvage service, including for out of hours cases. Personnel involved in Intraoperative Cell Salvage should have undergone appropriate training and competency assessment, and the anaesthetic nursing department should maintain training records for all staff involved in the Intraoperative Cell Salvage process. It is recommended that individuals maintain a case log of all procedures in their own portfolios.

The autotransfusionist will:

- Remain in theatre for a minimum of 20 minutes after initial operative incision and ensure the suction of the cell saver is at an appropriate level and that the equipment is working properly.
- Carry a pager to ensure that they are contactable, in the event that they need to leave the operating theatre.
- Return to check in on the cell saver and the team every 20 minutes at a minimum, if the autotransfusionist does need to leave the theatre.
- Communicate with the team to ensure that they are present for the final stages of the procedure including sponge washing, final processing, labelling, charting and clean up.

11.3 Equipment

All Intraoperative Cell Salvage equipment should be appropriately maintained. General maintenance will be performed annually in cooperation between the manufacturer, perfusion department and biomedical engineering department.

12 Adverse Event Reporting

Technical problems with the Intraoperative Cell Salvage service should be reported, in the first instance, to the Perfusion department and the Biomedical engineering department. Intraoperative Cell Salvage devices should only be used in accordance with the manufacturer's instructions.

Under the NSQHS Standard 7: Blood and Blood Products[2] hospitals must ensure blood and blood product adverse events are included in the incidents management and investigation system. The Incident Information Management System (IIMS) is used to report adverse events at the Sydney Children's Hospital Network. Further information regarding how to use this management system can be found in the SCHN ePolicies under Incident Management. http://webapps.schn.health.nsw.gov.au/epolicy/policy/3795

Adverse events must be reported to the clinical lead specialist for Intraoperative Cell Salvage and the senior autotransfusionist. Any adverse events relating to the Intraoperative Cell Salvage device and/or re-infusion of the autologous blood must be reported in accordance with the hospital's incident reporting system as the reporting of adverse events may help to identify concerns and prevent potential problems for the future. These concerns may include problems involving manufacturing, supply, inadequate instructions, training and human error.

Adverse events must be documented in the patient's clinical records and investigated for causality.

Examples of adverse events include:

- Severe reaction on re-infusion of salvaged blood, such as hypotension.
- Non-labelling / incorrect labelling of salvaged blood.
- Clotting in the reservoir or filtering system.

- Equipment malfunction.
- Communication failure leading to inappropriate re-infusion of the salvaged blood (e.g. contamination occurred within the surgical field and this was not communicated by the surgeon to the autotransfusionist or anaesthetist).
-

13 Resources

The provision of safe Intraoperative Cell Salvage requires adequate resources for the formal documented training of all staff that setup or operate the equipment and for the regular maintenance and prompt repair of all Intraoperative Cell Salvage equipment. The appendixes in this Guidance offer practical resources/tools to assist in the provision of Intraoperative Cell Salvage.

- Appendix I Surgical Procedures where Intraoperative Cell Salvage presents significant benefit towards the management of perioperative blood loss.
- Appendix II Patient Autotransfusion Record
- Appendix III Autologous Transfusion Label
- Appendix IV Autotransfusion Learning and Development Pathway
- Appendix V Use of Intraoperative Cell Salvage in Malignant Disease
- Appendix VI a Manufacturers' Guidelines – Autolog
- Appendix VI b Manufacturers' Guidelines – Fresenius

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15 Appendix I - Surgical Procedures where Intraoperative Cell Salvage presents 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 cell salvage device and wash salvaged blood when there is blood loss of greater than 15% of estimated blood volume

** In cases with no intra-abdominal faecal contamination.

16 Appendix II - Autologous Transfusion Label

INTRAOPERATIVE CELL SALVAGE

PATIENT LABEL

LABEL CHECKED 1._____ 2._____
AUTOTRANSFUSIONIST NAME _____
ANAESTHETIST _____
SURGEON _____
COLLECTION SITE/THEATRE _____
INFUSION STARTED _____
EXPIRES/REINFUSE BY:
DATE _____TIME _____
INTRAOPERATIVE CELL SALVAGE:
WASHED ☐ UNWASHED ☐
TOTAL VOLUME FOR REINFUSION _____ MLS
PRODUCT HCT _____%

INTRAOPERATIVE CELL SALVAGE

PATIENT ID _____
FULL NAME _____
INTRA-OP CELL SALVAGE:
WASHED ☐ UNWASHED ☐
TOTAL VOLUME FOR REINFUSION _____ MLS
CHECKED BY: 1. _____ 2._____

17 Appendix III - Patient Autotransfusion Record

NSW GOVERNMENT Health

The Sydney children's Hospitals Network
care, advocacy, research, education

Facility:

AUTOTRANSFUSION RECORD

FAMILY NAME	MRN
GIVEN NAME	☐ MALE ☐ FEMALE
D.O.B. _____/_____/_____	M.O.
ADDRESS	
LOCATION / WARD	
COMPLETE ALL DETAILS OR AFFIX PATIENT LABEL HERE	

Date	Time Start	Time Finish	Theatre Number
Surgeon	Anaesthetist	Autotransfusionist	Autotransfusionist 2

Patient Information

Operation			
Weight	ABO Group	Pre-Op HCT	Post-Op HCT

Equipment

Autotransfusion Device	Bowl Size	Anticoagulant Type	Wash Solution
Reservoir Lot	Suction Lot	Centrifuge Lot	Filter
Reservoir Lot (2)	Suction Lot (2)	Centrifuge Lot (2)	Filter (2)

Processing Volumes

Total Processed	Homologous RBC	Residual CPB	Anticoagulant	Wash Solution	Volume Returned

Homologous Blood Products Transfused

Packed Cells	Platelets	FFP	Cryoprecipitate

Comments

Holes Punched as per AS2828.1: 2012
BINDING MARGIN - NO WRITING

AUTOTRANSFUSION RECORD

SCN080.001

CHW Intranet - 092015

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Appendix IV- Autotransfusion Learning and Development Pathway

Located on the K drive → Perioperative Services → Autotransfusion → Autotransfusion Learning and Development Pathway

Autotransfusion Learning and Development Pathway

18 Appendix V- 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]

18.1 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]

18.2 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.

18.3 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]

18.4 Use of Intraoperative Cell Salvage in Malignant Disease at CHW

The current recommendation at CHW is collect blood in accordance with the above recommendations, but only to reinfuse in situations where the patient may be placed at risk. The reinfusion of blood in such situations is always in consultation with the lead surgeon and attending anaesthetist, and ALWAYS re-transfuse through a leukocyte depleting filter. Leukocyte depleting filters are kept by the perfusion department in the CSSD store room.

18.5 References

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19 Appendix VI- Manufacturer's Guidelines

Located in the G drive – operating theatres