



NATIONAL BLOOD AUTHORITY  
AUSTRALIA

# GUIDANCE FOR THE PROVISION OF INTRAOPERATIVE CELL SALVAGE

Guidance for Australian Health Providers

MARCH 2014

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# Guidance for the provision of Intraoperative Cell Salvage

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## Guidance

**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 implementation and 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/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). A separate guidance document should be developed for these where these systems are employed.

The information in this guidance will be reviewed and updated as required.

Information regarding the suppliers of washed Intraoperative Cell Salvage systems can be found at [Appendix VIII](#).

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# 1 Executive Summary

This document is intended to inform health-care practitioners, health educators, health service managers and policy makers about **Intraoperative Cell Salvage** use for patients undergoing surgery or invasive procedures, particularly those in which blood loss is anticipated or unpredictable. It is aimed at supporting hospitals to develop and implement an intraoperative cell salvage program.

The Guidance aims to improve clinical practice and patient outcomes through alignment with the Patient Blood Management (PBM) Guidelines.<sup>1</sup> The National Safety and Quality Health Service (NSQHS) Standard 7: Blood and Blood Products<sup>2</sup> 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.<sup>2</sup>

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.<sup>3</sup>

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.<sup>4-6</sup>

The guidance document and accompanying resources in the appendixes, such as patient education materials, business case study and education competency workbook have been designed with the intention that they can easily be adapted to accommodate the local policies and practice of individual hospitals. They are available as generic baseline material to download, alter, and adapt as applicable to their local requirements.

This Guidance is based on the UK Cell Salvage Action Group document Policy for the Provision of Intraoperative Cell Salvage<sup>28</sup> and has been reviewed by local clinicians to assess its applicability to the Australian health care setting.

## 2 Guidance Statement

This guidance has been written to support the use of Intraoperative Cell Salvage in [enter organisation details](#).

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.<sup>1,7,8</sup> 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,<sup>9</sup> complies with clinical governance requirements,<sup>10</sup> and falls within the scope of the NSQHS Standard 7 Blood and Blood Products.<sup>2</sup> ([www.safetyandquality.gov.au](http://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.

Unwashed cell salvage devices have **not** been included in this guidance as further studies are required on their use in the intraoperative environment. Separate guidance on unwashed Intraoperative Cell Salvage systems will be considered in the future.

### 3 Background

#### What is Intraoperative Cell Salvage and autotransfusion?

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 citrate to prevent clotting. A modified aspiration line is used to deliver the anticoagulant to the tip of the suction. As blood enters the collection reservoir it is filtered to remove large particulate debris. If there is insufficient blood to continue with processing, this is referred to as a 'collect-only' system and is therefore not re-infused.

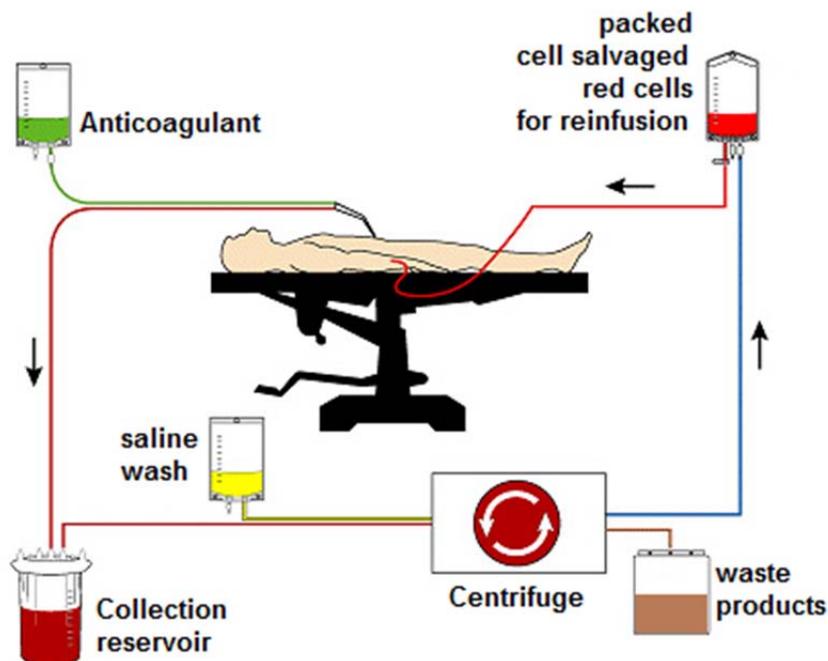


Diagram 1: Autologous red blood cell transfusion (autotransfusion)

'Collection and processing' refers to salvaged blood that is then centrifuged and washed to produce red blood cells (RBC) suspended in 0.9% normal saline 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 (see Diagram 1).

An "autotransfusionist" operates the "collection and processing" cell salvage device. This person may be an anaesthetist, anaesthetic technician, perfusionist or nurse, as long as they have received [appropriate training](#) in the operation of the device.

**Advantages of Intraoperative Cell Salvage include<sup>11</sup>:**

- 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.<sup>12-14</sup>
- 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 (20% estimated blood volume in adults) and therefore reduces transfusion associated risks.<sup>8</sup>
- According to evidence on adverse events<sup>15</sup> 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.

## Why is Intraoperative Cell Salvage important 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.<sup>3</sup>

Intraoperative Cell Salvage has been reviewed in the PBM Guidelines Module 2 – Perioperative<sup>1</sup> and Module 4 - Critical Care.<sup>16</sup> 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.<sup>1</sup>

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.<sup>1</sup>

#### RECOMMENDATION – INTRAOPERATIVE CELL SALVAGE

**R15**

**GRADE C**

In adult patients undergoing surgery in which substantial blood loss (blood loss of a volume great enough to induce anaemia that would require therapy) is anticipated, intraoperative cell salvage is recommended (Grade C).

#### PRACTICE POINT – INTRAOPERATIVE CELL SALVAGE

**PP13**

Intraoperative cell salvage requires a local procedural guideline that should include patient selection, use of equipment and reinfusion. All staff operating cell salvage devices should receive appropriate training, to ensure knowledge of the technique and proficiency in using it.

#### 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<sup>16</sup>. 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.<sup>16</sup>

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

#### PRACTICE POINT

PP13

In critically ill trauma patients and patients undergoing emergency surgery for ruptured abdominal aortic aneurysm, the use of cell salvage may be considered.

## Why is Intraoperative Cell Salvage important as a patient safety initiative?

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.<sup>17</sup>

Risks associated with allogeneic blood transfusion include (but are not limited to):

- wrong blood incidents
- transmission of blood borne infections
- haemolytic transfusion reaction
- immunosuppression<sup>18,19</sup>

Table 1: Reported adverse outcomes associated with allogeneic blood transfusion<sup>17</sup>

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

### 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:

1. Errors in procedure such as:
  - incorrect patient identification
  - inaccurate blood sample labelling
  - administration of blood or blood products to the wrong patient
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<sup>2</sup> contributes to the understanding of transfusion related errors, and allows for identification of safety and quality measures to deliver better transfusion outcomes.

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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 table below is extracted from the Australian Haemovigilance Report<sup>20</sup>

Table 2: Numbers of adverse events by blood component, 2008-09 to 2010-11

Adverse event/year	Whole blood	Red blood cells	Platelets	Fresh frozen plasma	Cryodepleted plasma	Cryoprecipitate	Unknown	Total
<b>FNHTR</b>								
2008-09	-	134	15	2	-	-	3	154
2009-10	-	143	14	1	-	-	-	158
2010-11	-	170	27	3	-	-	6	206
<b>Allergic</b>								
2008-09	-	40	19	27	-	1	-	87
2009-10	-	30	27	25	1	1	-	84
2010-11	-	33	27	41	1	-	1	103
<b>IBCT</b>								
2008-09	-	14	1	3	-	-	4	22
2009-10	1	16	5	-	-	-	1	23
2010-11	-	18	4	3	-	-	1	26
<b>Anaphylactic</b>								
2008-09	-	1	2	2	1	-	2	8
2009-10	-	5	1	1	-	-	-	7
2010-11	-	13	3	9	-	-	-	25
<b>TACO</b>								
2008-09	-	2	-	1	-	-	3	6
2009-10	-	8	-	-	-	-	-	8
2010-11	-	10	-	4	-	-	-	14
<b>DHTR</b>								
2008-09	-	1	3	-	-	-	-	4
2009-10	-	8	-	-	-	-	-	8
2010-11	-	6	-	1	-	-	-	7
<b>Bacterial TTI</b>								
2008-09	-	1	1	-	-	-	1	3
2009-10	-	2	5	-	-	-	-	7
2010-11	-	4	5	-	-	-	-	9
<b>TRALI</b>								
2008-09	-	1	-	1	-	-	1	3
2009-10	-	2	1	2	-	-	-	5
2010-11	-	5	-	-	-	-	-	5
<b>AHTR</b>								
2008-09	-	7	-	-	-	-	-	7
2009-10	-	6	-	-	-	-	-	6
2010-11	-	1	-	-	-	-	-	1
<b>PTP</b>								
2009-10	-	2	-	-	-	-	-	2
<b>Total</b>	<b>1</b>	<b>683</b>	<b>160</b>	<b>126</b>	<b>3</b>	<b>2</b>	<b>23</b>	<b>998</b>

Source: NBA

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.

## When can Intraoperative Cell Salvage be used?

Intraoperative Cell Salvage should be considered in surgery (see [Section 8](#)) in a clean operative field where substantial blood loss is anticipated. Substantial blood loss has been defined as:

- PBM Guidelines: Module 2 Perioperative - blood loss great enough to induce anaemia<sup>1</sup>
- AABB Guidelines - greater than 20% of blood volume or approximately **one litre** in an adult.<sup>11</sup>
- Because of the difficulty associated with the accurate prediction of substantial blood loss,<sup>21</sup> Intraoperative Cell Salvage should also be considered in cases where blood loss is potentially unpredictable (for example, caesarean sections).

**When used appropriately, by adequately trained staff, Intraoperative Cell Salvage** is a simple, safe and cost- effective method of reducing allogeneic transfusion.<sup>22</sup>

## 4 Aims

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

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

## 5 Objectives

To provide a national framework that would maximise patient safety during Intraoperative Cell Salvage use by:

1. Promoting safer transfusion practice in combination with the hospital's existing quality framework.
2. Promoting joint patient-clinician decision-making on perioperative blood management.
3. Assisting clinical staff in the identification of patients and procedures considered suitable for Intraoperative Cell Salvage.
4. Outlining the indications and contraindications for the safe use of Intraoperative Cell Salvage.
5. Assisting clinical staff to minimise the avoidable or potential risks of Intraoperative Cell Salvage.
6. Providing clear written information for patients about the risks and benefits of autologous transfusions from blood salvaged perioperatively.
7. Providing a competency-based training framework for Intraoperative Cell Salvage autotransfusionists.

## 6 Responsibilities

The healthcare organisation to which this guidance applies should define individual roles and responsibilities within the hospital's operating framework, and identify a lead clinician with overall responsibility for the Intraoperative Cell Salvage program.

These responsibilities 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

### 1. Prescribing Responsibilities

Re-infusion of salvaged blood should be prescribed by the responsible clinician on the applicable documentation approved by the hospital (e.g. anaesthetist or operative surgical team).

### 2. Labelling Responsibilities

The re-infusion bag should be labelled as soon as is reasonably practical.

These details are explained in [Section 11](#) – Intraoperative Cell Salvage Procedure.

### 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 (i.e. operator / autotransfusionist / anaesthetist). National theoretical training for autotransfusionists is available through the Australasian Board of Cardiovascular Perfusion (ABCP) by email on [secretaryboard@anzcp.org](mailto:secretaryboard@anzcp.org).

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 assessed. Staff operating specific devices should undertake mandatory training provided by the manufacturer(s) of the Intraoperative Cell Salvage equipment.

### 4. Documentation Responsibilities

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

1. The Intraoperative Cell Salvage audit form ([Appendix III](#))
2. The Intraoperative Cell Salvage autologous transfusion label completed ([Appendix IX](#)) 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".<sup>23</sup>

3. Appropriate labelling of heparin saline anticoagulant at the start of the procedure according to national labelling guidelines<sup>23</sup>
4. 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)<sup>27</sup>.
5. Adverse events and outcomes should be documented in the patient's clinical record and reported as in [Section 14](#) of this guidance.
6. Documentation should include accurate details of the intraoperative procedure, technique, equipment and staff.
7. Adherence to the hospital's clinical governance framework.
8. The hospital / relevant department maintain records of staff training and competency.

If a health service organisation employs outsourced staffing to perform cell salvage-related activities (i.e. external contractors), it is up to that health service organisation to cover those outsourced staff in their policy on issues such as their qualifications, training, and agreement to act and perform tasks, the same as hospital staff.

## 7 Training

**A key person** should be identified in each clinical area as a contact for communication and training. This person will maintain and update training records of all staff who have received training in the use of the Intraoperative Cell Salvage device.

**Contact details** for the hospital Transfusion Committee Coordinator, Haematologist, and Senior Perfusionist, should also be identified.

**Theoretical and practical training** should be undertaken and staff competency should be assessed before they set up or operate Intraoperative Cell Salvage equipment without supervision.

**It is recommended that trainees and new members** to the group should undertake a **minimum of 10 complete cases (with at least two of these cases being classed as emergency/time-critical cases).**

- Complete cases refers to consumable set-up, collection AND processing.
- A minimum of 10 cases is recommended to achieve a level of competency with the processes of cell salvage and familiarity with operating the equipment.
- Emergency cases are defined as cases where the need for cell salvage has not been planned (not elective). These cases which require the use of cell salvage in a time-critical manner, will often involve different skills/knowledge to elective non time-critical cell salvage.

These 10 complete cases should occur under the supervision of the Intraoperative Cell Salvage co-ordinator or a senior member of the group ensuring the new member has robust technique and familiarity with all aspects of cell salvage.

It is acknowledged that the number of completed cases may differ between hospitals.

**Training collaborations:** Some healthcare networks may consider training collaboration with high turnover centres to assist in achieving competency and technical proficiency of autotransfusionists. Centres that perform cardiothoracic surgery, vascular surgery and large orthopaedic centres generally have a high number of cell salvage cases.

**New members** of the group must be assessed and signed off by the Intraoperative Cell Salvage co-ordinator before they can operate or be on call on their own. Individual abilities also differ; therefore it is very valuable to have an experienced autotransfusionist responsible for this decision.

**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.

**A minimum of 10 cases** should be performed per year and a 12 monthly mandatory competency assessment covering both the theoretical and practical components of operating the Intraoperative Cell Salvage device to maintain competency.

Staff carrying out Intraoperative Cell Salvage for **Jehovah's Witness** patients should have received training and have been 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. Most jurisdictions have a Jehovah's Witness Hospital Liaison committee that should be identified including a contact number.

**Regular meetings** should occur to enable the detection of concerns.

**Updated training** is recommended under the following circumstances:

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

If a health service organisation employs outsourced staff to perform cell salvage-related activities (i.e. external contractors), it is the responsibility of that health service organisation to ensure the same Intraoperative Cell Salvage policies apply (e.g. training, qualifications, service provision) to outsourced staff that apply to hospital staff.

## 8 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 9](#) of this policy).

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.<sup>24,25</sup>

**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.

**Appendix IIa:** An example of a list of procedures with significant potential benefit for Intraoperative Cell Salvage.

**Appendix IIb:** An example of a list where the benefit for Intraoperative Cell Salvage would potentially be lower.

Providing that none of the contraindications listed in [Section 9](#) 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<sup>1</sup> or expected to exceed 20% of estimated blood volume.<sup>11</sup> 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 Thalassaemia 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 9](#), the medical clinician involved should discuss the potential risks with the patient if possible, and the agreement to undergo Intraoperative Cell Salvage should be documented.

## 9 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.

### Contraindication:

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

### Warnings / Caution apply:

#### 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.<sup>19</sup> As reported - 'One of these occurred with the transfusion of unwashed cell salvaged blood and 3 where a combination of ACD and a leucodepletion filter were used'.<sup>19</sup> This phenomenon has been recognised in the Association of Anaesthetists Great Britain and Ireland (AAGBI) Safety Guideline on cell salvage.<sup>7</sup> "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 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.

#### 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:

1. Antibiotics not licensed for IV use.
2. Iodine.
3. Topical clotting agents (in microfibrillar, sponge or topical liquid form that causes platelet aggregation, clotting activation or creates fibrin clot).

4. Freshly curing orthopaedic cement where some solvent may be temporarily released.
5. 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.
6. 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**.

## 10 Patient Information

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

For patients undergoing emergency surgery, where the procedure cannot be discussed with the patient or a third party prior to surgery, the use of Intraoperative Cell Salvage is at the discretion of the surgeon and anaesthetist responsible for the patient's care, and documented as per your jurisdiction's policy for emergency care. The patient's consent should be obtained and documented if possible.

Information to provide to the patient can be found at [Appendix VII](#) on Intraoperative Cell Salvage and [Appendix XI](#) on Patient Blood Management.

# 11 Intraoperative Cell Salvage Procedure

## Use of the Intraoperative Cell Salvage Equipment

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

All procedures should be carried out in accordance with the hospital-specific Intraoperative Cell Salvage guidelines and procedural documents. 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. There must be a process to identify the individuals performing each critical step in collection, processing, and administration of perioperative products and when each step was performed.

Contraindications should be considered as identified in [Section 9](#).

All staff setting up or operating Intraoperative Cell Salvage systems should receive theoretical and practical training (see [Section 7](#)) and should have completed the applicable Intraoperative Cell Salvage Competency Assessment process.

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.

## Anticoagulant

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

Anticoagulant prepared by the operator (e.g. heparin saline) should be labelled clearly to avoid error, and checked by a second staff member (e.g. anaesthetist, anaesthetic nurse, autotransfusionist), who should witness and sign the additives label in compliance with the national labelling requirement.<sup>23</sup>

## Wash Solution

Normal Saline 0.9% (intravenous or IV Grade) should be used as the wash solution.

Plasmalyte A (crystalloid solution) may be another option in high blood loss situations when concerned about the development of hyperchloraemic metabolic acidosis in association with high volumes of Normal Saline 0.9% use.

## Labelling

All salvaged blood should be labelled (e.g. see [Appendix IX](#)) with a label which includes:

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

To avoid errors in patient identification, the patient details should be confirmed by using the identification band on the patient and not only through the clinical record or chart present in the operating theatre.

If the system has been set up as a "collect-only" system (collection reservoir and aspiration and anticoagulant line only), the collection reservoir should be labelled in accordance with the above instructions for labelling a re-infusion bag. If a processing set is subsequently loaded into the Intraoperative Cell Salvage device, the autologous label on the collection reservoir should be transferred onto the re-infusion bag immediately or a new label completed (as above).

## 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 patient's IV cannula via an appropriate filter (see below). Caution should be taken to prevent air embolism.

The person administering the re-infusion adjusts the rate at which the red cells are re-infused using a clamp on the administration set and by adjusting the height of the collection bag. 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.

An external pressure bag can be applied to a blood bag after decanting and de-airing into one. However, caution should be taken to not allow air in the re-infusion blood bag.

A filter, appropriate to the type of surgery, should be used for re-infusion. As the manufacturer and specifics of these filters change with time, the filters that are appropriate for specific procedures should be identified by the co-ordinator and the clinical lead for Intraoperative Cell Salvage.

In certain circumstances (e.g. obstetrics and malignancy), a leukocyte depletion filter may be indicated (as discussed in [Appendix V](#) and [Appendix VI](#)).

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)<sup>27</sup>. 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 and a copy kept in the appropriate department in accordance with hospital policy.

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

## 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.

## 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<sup>26</sup>.

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

## Documentation

The collection and re-infusion of salvaged blood should be accurately documented on the official hospital Intraoperative Cell Salvage form (see [Appendix III](#))

Adverse events should be documented and reported (see [Section 14](#)).

The organisation should ensure that adequate records are retained in all cases where Intraoperative Cell Salvage is used.

## 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.

## 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.

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

If contamination of the cell salvage machine occurs internally, the cell salvage machine should be removed from use, identified as a potential biohazard and reported to the manufacturer. In normal operation all components that come into contact with blood are totally disposable therefore there is no risk of subsequent contamination due to a previous viral load.

## Maintenance of Equipment

All Intraoperative Cell Salvage equipment should be serviced regularly in accordance with the manufacturers' recommendations. A maintenance record and fault log should be kept for each cell salvage device in use.

## 12 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 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.

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

## 13 Quality Assurance

The Hospital should maintain comprehensive quality assurance systems to ensure the provision of a safe, optimum Intraoperative Cell Salvage service. The service must have a process to collect and evaluate quality indicator data on a scheduled basis. Process improvement activities must be reviewed and approved by executive management at defined intervals.

### Utilisation review of the service

The service must have a review process that monitors perioperative collection and administration practices. This process must be part of the institutional performance improvement process. Compliance of accepted recommendations must be monitored. The review must include:

1. Prescribing practices
2. Appropriateness of use (e.g. under and over utilisation)
3. Adverse events
4. Near-miss events
5. Usage and discard
6. Ability of service to meet patients' needs
7. Adverse outcomes

**The institution should determine the frequency of Blood sampling** sent to the Pathology department for quality assurance testing. Tests currently undertaken are: full blood count and blood cultures.

### Personnel

A clinical lead specialist should be identified who 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 appropriate 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.

### Equipment

All Intraoperative Cell Salvage equipment should be appropriately maintained. General maintenance should be performed by trained Hospital Biomedical Technology Services (BTS) / Biomedical engineering department who are accredited by the manufacturer.

Operator maintenance programmes should include the implementation of a documented cleaning and minor checking system and the use of a cell salvage device specific fault log.

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Company maintenance visits must be carried out by an authorized service engineer who will perform a series of documented maintenance controls to ensure maximum performance.

## 14 Adverse Event Reporting

Technical problems with the Intraoperative Cell Salvage service should be reported, in the first instance, to the Hospital BTS /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<sup>2</sup> hospitals must ensure blood and blood product adverse events are included in the incidents management and investigation system.

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).

## 15 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.](#) **Business Case Guidance**

The business case guidance 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.

The 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.

### [Appendix IIa](#) **Surgical Procedures where Intraoperative Cell Salvage presents significant benefit towards the management of perioperative blood loss.**

### [Appendix IIb](#) **Surgical Procedures – an Australian experience**

### [Appendix III](#) **Audit Proforma**

### [Appendix IV](#) **Intraoperative Cell Salvage Competency Assessment Workbook**

### [Appendix V](#) **Use of Intraoperative Cell Salvage in Obstetrics**

### [Appendix VI](#) **Use of Intraoperative Cell Salvage in Malignant Disease**

### [Appendix VII](#) **Cell Salvage Patient Information Leaflet**

### [Appendix VIII](#) **Manufacturers' Guidelines**

### [Appendix IX](#) **Autologous Transfusion Label**

### [Appendix X](#) **Fault log**

### [Appendix XI](#) **Patient material "About Patient Blood Management**

## 16 Implementation and Distribution of the Policy

This document should be circulated to all relevant personnel and implemented in all applicable areas which may be involved in Intraoperative Cell Salvage.

- Director of Anaesthetics
- Director of Haematology
- Director of Accident and Emergency
- Patient Blood Management Co-ordinator
- Clinical lead specialist for Intraoperative Cell Salvage
- Directors of all applicable surgical areas
- Autotransfusion Co-ordinator
- Autotransfusionists
- Nursing Director for Perioperative Services
- Available at the Operating Theatre Triage desk for immediate reference to the potential Surgical Team user
- Quality and Safety Officer
- Transfusion Governance Committees
- Incorporated in Anaesthetic and surgical training education modules
- Available on the Hospital computerized Information System for ready access.

The procedural document, including maintenance and Quality Control / Quality Assurance logs, should be version controlled and reviewed periodically for currency and as new information becomes available. Documents should be kept for the period specified in the hospital's quality system.

Guidance on, and queries related to, the document should be addressed to the organisation's clinical lead for Intraoperative Cell Salvage.

All surgical and anaesthetic staff involved in elective and emergency surgery associated with the real or potential risk of a patient's major blood loss should be directed to online access to this Guidance, to familiarise themselves to the benefits and risks of Intraoperative Cell Salvage.

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Members of the National Blood Authority Patient Blood Management Steering Committee (PBMSC).

Original authors of the UK policy document:

- Maria Roberts, Transfusion Practitioner. These guidelines are based on the Welsh Blood Service Cardiff and Vale NHS Trust Postoperative Cell Salvage procedure document
- Members of the UK Cell Salvage Action Group
- Royal Brompton & Harefield NHS Trust, Policy for the provision of Perioperative Red Cell Salvage
- St Mary's NHS Trust, Obstetric Intraoperative Cell Salvage Guidelines.

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## 19 Acronyms / Abbreviations

AAA	Abdominal Aortic Aneurysm
AAGBI	Association of Anaesthetists Great Britain and Ireland
ABCP	Australasian Board of Cardiovascular Perfusion
ACD	Acid Citrate Dextrose
ARTG	Australian Register of Therapeutic Goods
BTS	Biomedical Technology Services
CEMACH	Confidential Enquiry into Maternal and Child Health
CRG	Clinical/Consumer Reference Group
CWG	Clinical Writing Group
DHTR	Delayed Haemolytic Transfusion Reaction
DIC	Disseminated Intravascular Coagulation
FNHTR	Febrile Non-Haemolytic Transfusion Reaction
IBCT	Incorrect Blood Component Transfused
ICS	Intraoperative Cell Salvage
ICU	Intensive-Care Unit
IV	Intravenous
LSCS	Lower Segment Caesarean Section
MOH	Massive Obstetric Haemorrhage
NICE	National Institute for Health and Clinical Excellence
NHMRC	National Health and Medical Research Council
NSQHS	National Safety and Quality Health Service
PAD	Preoperative Autologous Donation
PBM	Patient Blood Management
PBMSC	Patient Blood Management Steering Committee
RBC	Red Blood Cells
RBWH	Royal Brisbane and Women's Hospital
SHOT	Serious Hazards of Transfusion
TACO	Transfusion Associated Circulatory Overload
TAH	Total Abdominal Hysterectomy
TTI	Transfusion Transmitted Infection
TRALI	Transfusion Related Acute Lung Injury

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