Title of Guideline: Cell Salvage – Paediatric Intraoperative Autotransfusion.

Key words: cell salvage, autologous transfusion, red blood cells, re-infusion autotransfusion, paediatric.

1. Overview/procedure description

The purpose of this document is to:

Provide information that will assist clinicians to identify suitable patients where intraoperative cell salvage can be part of a comprehensive Patient Blood Management (PBM) program at The Royal Children's Hospital (RCH).

This procedure ensures compliance with Australian Commission on Safety and Quality in Health Care:

Standard 7 Blood and Blood Products.

National Blood Authority (NBA) Patient Blood Management Guidelines:

Module 2 Perioperative and the NBA Guidance for the Provision of Intraoperative Cell Salvage: 2014

Module 6 Neonatal and Paediatrics: 2016

Association of Anaesthetists Guidelines:

"Cell Salvage for Perioperative Blood Conservation": 2018

2. Related Policy

Blood Product Transfusion

Blood Refusal – Management of Procedure

Patient Identification Procedure

Massive Transfusion and Critical Bleeding Procedure

Cleaning, Disinfection and Sterilisation of Reusable Medical Equipment

Clinical Waste and Sharps Management

3. Definition of Terms

ICS – Intraoperative Cell Salvage

Cell salvage is a key part of paediatric intraoperative blood management at RCH.

It is an effective blood conservation technique that can reduce the requirements of allogeneic blood transfusions and can maintain post - operative haemoglobin concentration in paediatric patients.

Intraoperatively, blood is aspirated from the surgical field and mixed with anticoagulant, either heparinised saline or citrate dextrose formula A (ACD-A).

At RCH, anticoagulant Citrate Dextrose Solution Formula A (ACD-A) is the preferred anticoagulant for cardiac procedures.

Particulant matter is separated during collection into the inline filter and red cell volume remains in the reservoir, prior to processing.

Processing refers to salvaged blood that is centrifuged and washed. The patient's own red blood cells (RBC), are suspended in IV grade 0.9% sodium chloride for re-infusion.

Processed RBCs are transferred to an inline re-infusion bag, ready for reinfusion. This is referred to as an autologous red blood cell transfusion or auto transfusion (see Diagram 1).

On completion of processing, discarded products, plasma, platelets, anticoagulant, surgical wash and IV grade irrigation fluid are removed during the automatic process.

When collected blood is insufficient to process, it is referred to a "collection only" and is discarded.

Autotransfusionist – Cell Saver Operator

At RCH clinicians allocated to operate the ICS, may be an Anaesthesia Technologist or Perfusionist who meet the qualification recommended by the National Blood Authority (NBA) 2014.

3.1 Advantages of ICS :

Patients own RBCs .

Reduces risk related to patients receiving incorrect blood.

Reduces exposure to allogenic transfusion and eliminates transfusion related complications.

Reduces demand on donor blood supply.

Acceptable to some patients who decline allogenic blood – blood refusal.

Intraoperative Cell Salvage:

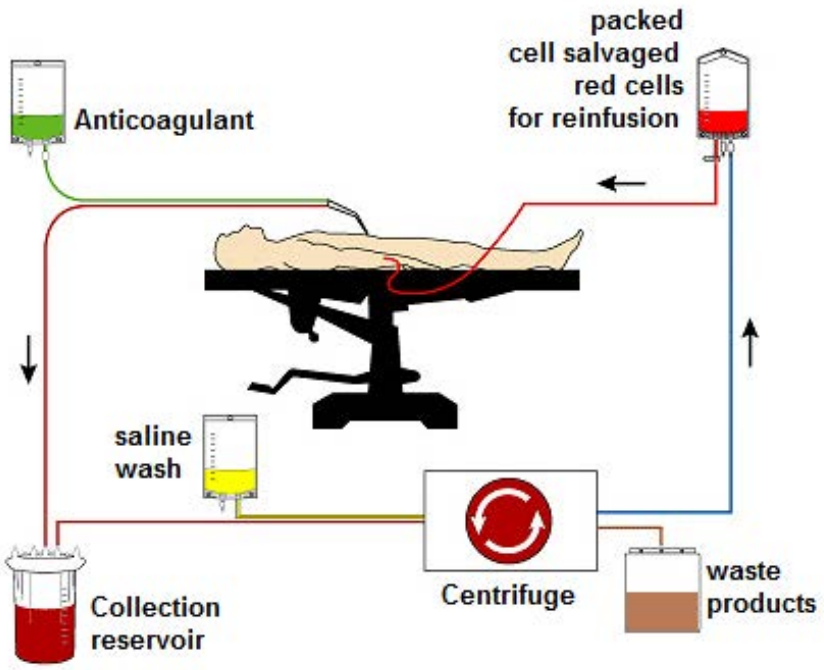
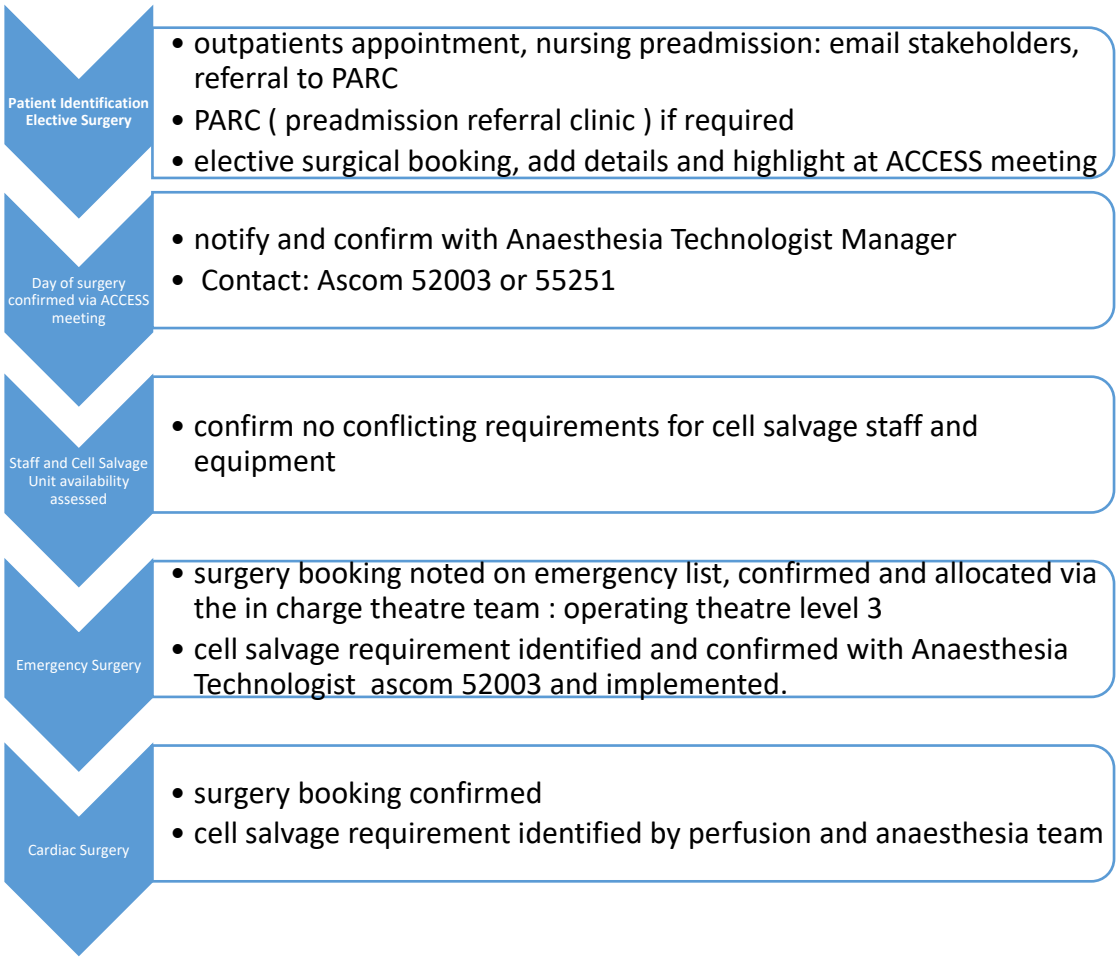


Diagram 1: Intraoperative Cell Salvage / Autotransfusion

3.2 Booking Cases

Cell Salvage Booking Requirement Workflow Process



3.3 Equipment

- Mobile processing units (2 only) and consumables are stored for use in the perioperative suite Level 3.

4 Procedure details

4.1 Patient information:

- The anaesthetist and surgeon discuss ICS with the patient and/or family and carers as appropriate.

4.2 Patient selection for ICS:

- Blood loss >10% of calculated blood volume and a decreasing haemoglobin, or 8ml /kg in children over 10kgs.

- Careful consideration should be used for neonates and small infants based on variable blood volumes for the pre term infants with anticipated high blood loss.

- Elective or emergency surgery where, substantial blood loss is anticipated and no contraindications exist.
- Rare blood groups or antibodies where it may be difficult to obtain allogeneic blood in consultation with Clinical Haematology/Blood Bank.
- Risk factors for bleeding or low pre-operative haemoglobin level (i.e. Haemophilia and Thalassaemia in consultation with Haematologist).
- Unpredictable blood loss.
- Rare, urgent and extreme occasions, the CS may be required in RCH Intensive Care Unit (Rosella) this will be assessed on a case to case basis.

Paediatric procedures requiring ICS at RCH include:

Congenital cardiac defects

Craniofacial abnormalities

Congenital spinal correction surgery

Organ transplantation

Major trauma

Patients who for religious or other reasons are unwilling to receive allogeneic blood.

Traditionally, ICS was contraindicated in malignancy, sepsis and obstetrics. With current emerging evidence, the use of ICS in these clinical scenarios is now (2018) endorsed by the Royal College of Anaesthetists, The Royal College of Surgeons, The Association of Paediatric Anaesthetists of Great Britain and The Association of Perioperative Practice and the National Blood Authority (NBA) Australia.

4.3 ICS contraindications:

- Patient refusal is the only absolute contraindication
- Relative contraindications can include the presence of amniotic fluid, bowel contents, malignancy and sepsis. At RCH procedures in these category will be assessed on a case by case basis by the consultant surgeon, consultant anaesthetist and cell salvage operator.

4.4 ICS warnings/cautions:

- Heparin Induced Thrombocytopenia when heparin is the anticoagulant of choice.
- Gastric or pancreatic secretions – may cause enzymatic haemolysis and are not reliably removed by the washing procedure.
- Sickle cell disease and abnormal red cell disorders – decision to utilise ICS should be made in consultation with a Haematologist and on an individual patient basis.

4.5 Use of ICS:

- A dedicated ICS operator will be allocated and not be required to assist with alternative duties.
- All ICS data is to be documented on EPIC, the current RCH electronic medical record system. This information is recorded under the equipment category during perioperative phase of care.

4.5.1 Preparation and Assembly:

- The unit must be assembled and operated by a qualified operator as defined in point 3.
- Use and prepare ICS products in accordance with manufacturer guidelines.
- All ICS products and units must be traceable and identifiable: EPIC entered data.
- Assemble, collect and process red cells in conjunction with RCH infection control, asceptic technique and management of sharps procedures.
- Suction to be maintained at -100mmhg for optimal intraoperative collection of RBC.
- All ICS RBC for reinfusion administered to the patient prior to the conclusion of the procedure or discarded if not required.

Paediatric low volume collection program:

CS unit dependant: a low volume program, if available, should be selected based on a15-30ml circuit volume required to process when used for low weight patients (Fresenius Kabi 2007).

4.5.1 Collection:

- Blood loss from the surgical field is collected in the ICS reservoir via a modified suction line that delivers anticoagulant to the suction tubing tip. Anticoagulant solutions coat all plastic surfaces to prevent haemolysis during red cell recovery.
- Intra-operative surgical swab washing by the surgical scrub team in IV grade 0.9% Sodium Chloride maximises the efficiency of red cell recovery. The wash is suctioned into the ICS reservoir after gentle swab compression at the operators request.
- All salvaged blood is filtered as it enters the reservoir, washed with IV grade 0.9% Sodium Chloride or Plasmalyte -148 producing red cells for reinfusion to the patient.
- Plasma, platelets and anticoagulant are removed during processing and washed red cells are automatically transferred to an inline reinfusion bag, ready for reinfusion.
- Blood available for processing and reinfusion is dependant on the system in use.

4.5.2 Labelling of re-infusion bag

- Reconfirm patient's identification as per the RCH Patient Identification Procedure.
- Label re-infusion bag at the bedside following patient confirmation with patient label and intraoperative "time out" process.
- Document expiry time, 4 hours after the completion of processing.

4.5.3 Prescribing:

- No prescription is required.
- Total RBC reinfused are documented in the patient electronic medical record, (EPIC) located in "data "via Anaesthetist's documentation site.

4.5.4 Storage of re-infusion bag:

- The re-infusion bag must stay with the patient until reinfusion is complete.

4.5.5 Re-infusion

- Re-infuse within 4 hours of completed processing.
- Discard any blood not able to be transfused within 4 hours.
- Do not use any pressure devices/bags .
- The same re-infusion bag may be filled and emptied many times.
- 40 micron filters must be used when re infusion commences.
- Leukocyte depletion filters are indicated in cases where sepsis or malignancy is present.
- ICS processed red cells must not be refrigerated.

4.6 Temporarily discontinuing ICS:

If substances not licensed for intravenous (IV) use are used within the surgical field, these could potentially be aspirated into the collection reservoir.
Actions: 1. Use standard operating room suction (not ICS) to waste.

2. Irrigate the wound with considerable amounts of 0.9% sodium chloride suitable for IV administration.

3. Resume ICS once the field deemed clear of contamination.

Examples of non IV materials or materials that may impair the filter mechanism.

- Antibiotics not licensed for IV use.
- Topical clotting agents.
- Freshly curing orthopaedic cement where some solvent may be released.
- Irrigation solutions such as alcohol iodine, betadine, hydrogen peroxide, hypertonic solutions.
- Bone reaming fragments.

4.7 Staff training:

- Anaesthesia Technologist Manager or delegated staff member will supervise training and competencies of individual Anaesthesia Technologists who perform ICS.
- Training records will be maintained, documenting training received and the use of ICS unit. Training records are made available as requested by RCH Transfusion Committee
- Individual staff ensure that they are adequately trained and competent in the use of ICS and that their individual responsibilities comply with their scope of practice (Anaesthesia Technologist)
- Staff ensure technical ability, support, equipment and risk management complies with best international accepted practice
- Staff should not use equipment that they have not been trained and competency assessed. Staff operating specific devices will complete mandatory training provided by the manufacturer

- National theoretical training for autotransfusionists / cell saver operators is available through the Australasian Board of Cardiovascular Perfusion (ABCP) and is the minimum acceptable standard at RCH, as recommended by the NBA

- Training specific to equipment can be provided by the manufacturers or designated local trainers

Theoretical and practical training are to be completed and staff competency assessed prior to operating ICS equipment without supervision.
NBA recommends that trainees should undertake a minimum of 10 complete cases (with at least two of these cases being classed as emergency/time-critical cases).
Complete cases involves 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 require the use of cell salvage in a time-critical manner, will often involve different skills/knowledge to elective non time-critical cell salvage.
Supervision is provided by the co-ordinator or a senior member of the RCH group ensuring the trainee is familiar with all aspects.
A minimum of 10 cases should be performed per year and a bi annual mandatory competency assessment covering both the theoretical and practical components of operating the ICS device to maintain competency.
Staff carrying out ICS for **Jehovah's Witness** patients are to be 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:
When operators fail to meet the recommended (NBA 2014)10 cases per year without practical use of the ICS 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 and the occurrence of an adverse event or near miss that undermines the reliability of the ICS service.

Outsourced staffing will be required to abide with the guidelines here in.

Management of Massive Transfusion:

- Identify and report large blood loss in the collection reservoir to the anaesthetist and the surgeon.
- If massive re-infusion of salvaged red blood cells, consider transfusion of other blood products e.g. platelets, fresh frozen plasma and cryoprecipitate
- Activate RCH Massive Transfusion Procedure if indicated. http://www.rch.org.au/policy/policies/Massive_Transfusion_and_Critical_Bleeding_Procedure/

Disposal of used ICS equipment:

- Dispose of equipment in accordance with Division of Surgery Local Procedure – *Peri operative Waste Management.*
- Clean the ICS machine in accordance with the manufacture guidelines and RCH Infection Control procedures.
- If internal contamination of equipment; remove from use, identify as a potential biohazard and refer to the manufacturer.

Adverse events:

- Report adverse events via VHIMS and patient record if affected or near miss.
- Report technical issues to Anaesthesia Technologist Manager or in their absence, directly to RCH Biomedical Department.

Maintenance of equipment:

- ICS equipment to be serviced annually by the RCH Biomedical Engineering Department in accordance with the manufacturer's instructions.
- Associated documentation maintained by RCH Biomedical Engineering Department.

Cell salvage governance:

- ICS utilisation is reported to both the RCH Transfusion Committee and the Division of Surgery Management Committee.
- Annual reports will include:
    1)Utilisation
        - Number of patients requiring CS, collection only, processing and or introduction of procedure changes
        - Amount of blood re-infused
        - Potential number of allogenic blood units 'saved'
    2) Adverse incidence or outcomes (reported in VHIMS)
    3) Near-miss events (reported in VHIMS)
    4) Usage and discard
    5) Quality improvement activities

- Reports complied on an annual basis.
- Quality assurance (blood gas) tests on RBC for reinfusion are performed in the perioperative suite prior to reinfusion to assess haemoglobin concentration.
- Quality assurance: equipment failures or malfunction recorded on EPIC
- Cell saver operators are responsible for individual case governance.

Data collection:

Cell salvage data is documented on the RCH electronic medical recording (EMR) system EPIC with formatted hard stops on an integrated designed smart form with access to annual reports and specific data snap shots.

Completed by individual CS operators.

4 Reference

1: AAGBI Safety Guideline. Blood Transfusion and The Anaesthetist – Intraoperative Cell Salvage 2009

2: UK Cell Salvage Action Group

3: National Blood Authority Australia Intraoperative Cell Salvage Guidance Module 2: 2014, Module 6: 2016.

4: Association of Anaesthetists Guidelines: cell salvage for perioperative blood conservation 2018.

5: JPAC Joint United Kingdom (UK) Blood Transfusion and Tissue Transplantation Services Professional Advisory Committee.
UK Cell Salvage Action Group
Cell Salvage Technical Fact Sheets

5 Contacts

Procedure number	RCH####
RCH Strategic goals	[Delete as appropriate] Excellence in Healthcare Focus on Quality and Safety Leadership in Research Education Partners in Paediatric Care Improved Organisational Environment

Category	Access Care Planning & Implementation Child Protection Communication Consumer focused equitable care Emergency Management Facilities Management Financial Management Governance Health Information Human Resources Infection Control Information Technology Intellectual Property Legislative Compliance Medication Management Quality & Improvement Research Risk Management
ACHS Function	[Delete as appropriate] Clinical Support Corporate
Policy type	Policy Procedure
Revision	0 (view history)
Author/Reviewer	Jenny Fuller Anaesthesia Technologist Clinical Specialist Anaesthesia and Pain Management
Authoriser	Policy and Procedure Committee
Date authorised	DD-Mmm-YYYY
Next review date	DD-Mmm-YYYY
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