Document Control

Title

Intra-Operative Cell Salvage Standard Operating Procedure

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CONTENTS

1. Background

1.1. Intra-Operative Call Salvage (ICS) is a well-recognised method of reducing the demand on allogeneic (donor) red blood cells. It is considered a safe and cost effective technique. There is therefore a national expectation that Trusts provide an ICS service in a safe, appropriate and cost effective manner.

1.2. Use of ICS is recommended by the Association of Anaesthetists and is to be considered for surgery in non-obstetric adult patients where blood loss >500ml (or 10% of blood volume) is anticipated and in obstetric cases with pre-operative anaemia or deemed at risk of major haemorrhage. ICS is also to be considered in patients at risk of blood loss with rare blood anti-bodies or who object to allogeneic (donor) blood for religious or other reasons and will accept ICS blood.

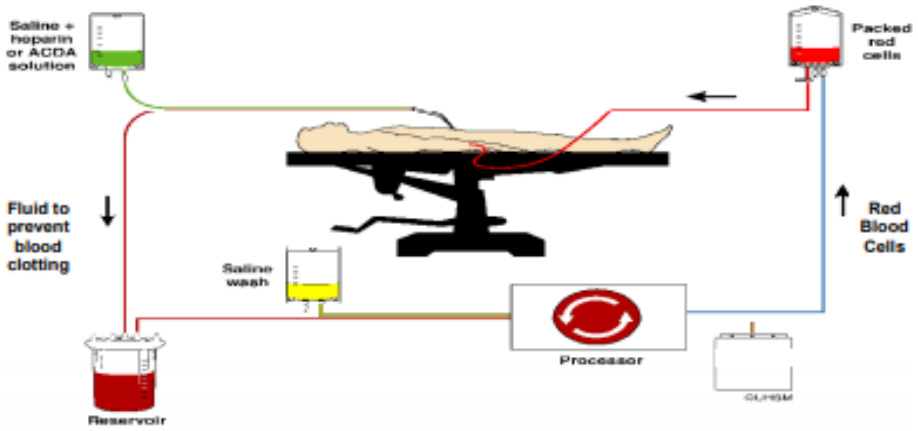
1.3. Children >10kg undergoing surgery where blood loss >10% calculated blood volume (>8ml/kg) should also be considered for ICS.

1.4. The Association of Anaesthetists' recommendations are that ICS be immediately available 24 hours / day in hospitals undertaking surgery where blood loss is a recognised complication. North Devon District Hospital (NDDH) fits this criterion, but there are insufficient cases where ICS is deemed appropriate to meet the training requirements for a 24 hour service. This will be recorded on the Risk Register.

1.5. Due to the issues of training and maintaining competence with ICS, once the service is established the expectation is that ICS should be available during working hours (Monday–Friday, 08:00-18:00) but cannot be guaranteed. Outside of those hours, availability of ICS will depend upon the skill mix of the staff on duty and must not be assumed to be available.

1.6. In practice, ICS for elective cases should be anticipated and booked in advance to ensure that trained staff are available. In emergency cases, ICS is to be considered if staff trained in its use are available.

1.7. Cell salvage works by collecting the patient's blood adding anti-coagulant and storing in a reservoir. Once sufficient blood has been collected, it can then be washed and centrifuged to remove debris before being suspended in saline for reinfusion to the patient:



1.8. To use ICS, staff must be trained and competent in the use of call salvage. Training will be in the form of e-learning, practical training from the machine producers and 'in-house' simulated and clinical training. Practitioners trained in ICS will keep a log of cases and may be required to demonstrate familiarity with the system in simulated conditions if significant periods of time have elapsed between cases.

1.9. On the basis of the SALVO trial (cell salvage during caesarean section: a randomised controlled trial),current recommendations in obstetrics are that ICS be considered in the 'collect only' mode for women who are: anaemic prior to surgery, if unanticipated haemorrhage occurs during surgery and for cases in which the woman is anticipated to be at high risk of haemorrhage during surgery. However, the Patient Blood Management Group at NDHT has agreed with indications for initiating collection of blood in accordance with paragraph 1.10. Progression to processing the collected blood should occur whenever sufficient volume is collected that it warrants doing so and can be offered back to the patient.

1.10. Indications for ICS in obstetrics include: pre-operative haemoglobin <100 g/l, placental position abnormalities which increase the risk of blood loss, abnormal blood antibodies, refusal of allogeneic blood, multiple pregnancies, multiple previous caesarean section, previous postpartum haemorrhage, medical conditions affecting coagulation such as haemophilia of Von Willebrand's Disease, surgical anticipation of significant blood loss.

1.11. Except in cases of patient refusal of allogeneic blood, if ICS trained staff are not available, allogeneic blood from blood bank should be used when necessary. In cases of major haemorrhage the Massive Blood Loss protocols should be activated in the usual manner and supplemented with ICS where possible.

2. Purpose

2.1. The Standard Operating Procedure (SOP) has been written to:

- Stipulate when and how Intra-Operative Cell Salvage (ICS) should be used and provide guidance on specific circumstances.
- Ensure that training, governance and audit processes are in place to utilise ICS within national guidelines.

3. Scope

3.1. This Standard Operating Procedure (SOP) relates to the following staff groups who may be involved in the assessment, production and delivery of Intra-operative Cell Salvage (ICS) produced red blood cells:

- Operating Department Practitioners (ODPs)
- Anaesthetic Nurses
- Anaesthetists
- Obstetricians / other Surgeons
- Midwives
- Recovery staff
- Ward nurses
- Transfusion laboratory staff

3.2. Attending medical staff, including anaesthetists are responsible for the decision to utilise ICS and ensure appropriate patient discussions and consent are undertaken.

3.3. Only Operating Department Practitioners (ODPs), Anaesthetic Nurses and Registered Nurses who have been specifically trained and certified as competent to utilise ICS are to manage the ICS machine. They should maintain sufficiently regular use to retain their competence. Continuing professional development can be performed via e-learning, supervised cases and simulated sessions.

3.4. Once processed and labelled, blood products produced through ICS must be kept with the patient and administered within 4 hours of production. Blood must be prescribed and administered by trained persons in accordance with the NDHT Blood Transfusion Policy.

4. Location

4.1. Collection and processing of blood is only to occur in operating theatres where competent staff are available to undertake this role.

4.2. Reinfusion of blood may occur in clinical areas where the staff are competent at managing blood transfusion.

4.3. Staff undertaking this procedure must be able to demonstrate continued competence as per the organisations policy on assessing and maintaining competence.

5. Equipment

The ICS machine utilised in NDDH is the 'Sorin Xtra'. Only manufacturer authorised parts may be used with this.

6. Procedure

6.1. **INDICATIONS:** ICS is indicated in all types of surgery (in non-obstetric adult patients) where:

- Blood loss >500ml (or 10% of blood volume) is anticipated.
- In obstetric cases it should be considered for patients with pre-operative anaemia or deemed at risk of major haemorrhage.
- ICS is also to be considered in patients at risk of blood loss with rare blood anti-bodies or who object to allogeneic (donor) blood for religious or other reasons and will accept ICS blood.

CONTRA-INDICATIONS:

- Gross infective contamination / bowel contents in surgical field.
- Heparin induced thrombocytopenia where heparin is the planned anti-coagulant (in which case use alternative anti-coagulant).
- Other specific contaminants such as antibiotics not licenced for IV use, iodine, gastric / pancreatic secretions and topical clotting agents should not be aspirated. When present in the surgical field, standard suction is to be used until these contaminants have been removed and the field irrigated. Afterwards, ICS suction may commence.
- Amniotic fluid, cancer surgery, laparoscopic surgery, bone cement and metal implants in orthopaedics are discussed separately in paragraphs 6.5 to 6.9.

6.2. The default location of the ICS machine is the Obstetric theatre. The booking procedure for all elective cases is:

- Consider indications for ICS at point of listing for surgery and highlight need for ICS on booking form.
- Contact theatre co-ordinator (Bleep 256) to liaise regarding staffing for ICS during case.
- Inform anaesthetic department by email ndht.anaestheticlead@nhs.net.

6.3. In massive haemorrhage ICS does NOT replace the need to activate the Massive Blood Loss Policy. However, effective use of ICS may help reduce significantly the amount of allogeneic blood required.

6.4. Set up of ICS is to be performed by trained personnel in accordance with the manufacturer's instructions. It should be run in automatic mode as standard unless clinic conditions are such to use manual mode.

6.5. Amniotic fluid in obstetrics is traditionally recommended by manufacturers to be removed separately via a different suction unit (known as 'double suction') before initiating ICS suction.

- It is now generally accepted that the ICS process is capable of removing plasma phase elements of amniotic fluid, making it safe to use the ICS suction for the whole case - including amniotic fluid (known as 'single suction').
- Single suction is supported by the Association of Anaesthetists' Cell salvage Guidelines 2018.
- The decision as to whether to use single or double suction lies with the operating surgeon.
- When using ICS blood, strict adherence to anti-D guidelines is required as maternal exposure to fetal red blood cells is very likely.

6.6. Use of leucocyte depletion filters (LDF):

- Obstetric use can further reduce risk of amniotic fluid reaching the mother but their use is not routinely recommended in ICS due to their reduction in flow rate, becoming saturated during use (thereby requiring replacement) and potential for causing bradykinin mediated hypotension.
- In cancer surgery the use of LDFs can reduce the number of malignant cells returned to the patient without impairing the quality of product. Therefore their use is recommended but proceeding without use of an LDF may be considered if the reduction in flow rate is of clinical concern.

6.7. ICS in cancer surgery carries the theoretical concern of spreading circulating malignant cells and as such manufacturers advise against its use. However, circulating cancer cells are present during surgery even if ICS is not used and the risks associated with these cells are thought to be low. This risk needs to be considered against the proven risks of immunomodulation due to allogeneic blood transfusion. Therefore, in cancer surgery the risks and benefits need to be considered on a case-by-case basis and should be discussed with the patient prior to surgery with specific consent obtained.

6.8. Laparoscopic surgery is compatible with ICS and may be useful in cases such as ectopic pregnancy. Advice regarding equipment is found at appendix 8.2.13: UK Cell Salvage Action Group Technical Factsheet 11 (Use of ICS Laparoscopic Surgery).

6.9. Sickle cell disease may reduce the efficiency of ISC production as cells are more fragile but should not prevent it being used.

6.10. Orthopaedic surgery considerations:

- Bone cement – do not use ICS while cement is being applied. ICS use can recommence once the cement has fully set.

- Metal in the surgical field may produce microscopic fragments that may not be eliminated by 40 micron filters. Therefore recommendations are that standard suction should be used until all metal fragments are removed and the surgical field irrigated. Afterwards, ICS suction can proceed.

6.11. Swab washing in sterile saline can significantly increase the yield for ICS blood and should be considered unless there are contaminants that prevent it. See UK Cell Salvage Action Group Technical Factsheet 1 (Swab Washing) for further details.

6.12. Audit data must be collected with each usage, using the 'ICS continuous audit data sheet' found at appendix 8.2.15. This data sheet is to be stored in the ICS file.

6.13. Cleaning of equipment is in accordance with manufacturer's instructions.

6.14. Consent for ICS produced blood transfusion must be obtained in accordance with the NDHT Consent Policy. Patient information leaflets from the UK Cell Salvage Action Group are available at Appendix 8.2.1 for non-obstetric surgery and Appendix 8.2.2 for Obstetric cases.

6.15. Using blood collected by ICS:

- All ICS collected blood must be labelled (with the patient present and identification band checked) at the beginning of processing and remain with the patient until either administered or discarded. Labelling must include the patient's first name, last name, date of birth and NHS number, along with date / time of expiry and signature block of the ICS practitioner.

- If the machine is set up for collection only, the collection reservoir must still be labelled as per paragraph 6.15.1.

- In practice, unless at least 350ml of red blood product has collected in the collecting bucket the machine will not have enough to process.

- It is a clinical decision as to whether blood collected should be processed and returned to the patient.

- Cell Salvaged blood must be fully checked against the patient's identification prior to re-infusion in the same manner as allogeneic (donor) blood.

- ICS blood for transfusion must be prescribed on the patient's drug chart. The drug chart must specify that this is ICS in origin "ICS packed red cells" with the volume and duration of transfusion.

- As a general rule, if enough blood has been collected to enable processing, it can be offered back to the patient after a process of informed consent. Except in emergencies, this discussion needs to occur before surgery. The decision to transfuse and patient's consent are to be documented in the patient's notes and the blood prescribed in the usual manner.

- Cell Salvaged blood is not to be administered under pressure due to the potential risk of air embolus and damage to red blood cells.

- Blood collected by ICS must be used within 4 hours of production or discarded.

- Patient observations and actions should be managed in line with the standard blood transfusion policy. https://www.northdevonhealth.nhs.uk/wp-content/uploads/2012/04/Blood-Transfusion-Policy-v5.2.pdf

6.16. Patients who may refuse blood products, such as Jehovah's Witnesses, should be managed in accordance with the NHDT 'Patients Refusing a Blood Transfusion' Policy. Many Jehovah's Witnesses are willing to accept ICS produced blood and this should be offered as an option. However, it must be noted that they may require ICS to be 'closed circuit' (see Appendix 8.2.9 UK Cell Salvage Action Group Technical Factsheet 6 (Use of ICS for Jehovah's Witnesses).

6.17. Maintenance of the ICS machine is to be according to the manufacturer's instructions and time schedules. Routine quality control sample tests to measure haematocrit and haemoglobin concentration are to be performed at least once per month.

6.18. Cleaning of the ICS machine is to be in accordance with manufacturer's instructions. Disposable components are to be managed as per hospital policy for equipment contaminated with blood. https://www.northdevonhealth.nhs.uk/wp-content/uploads/2018/09/Waste-Management-Manual-V2.pdf

7. References

- AAGBI safety Guideline, Blood Transfusion and the Anaesthetist, Intra-Operative Call Salvage, 2009.
- The Use of Blood Components and Their Alternatives, AAGBI, 2016
- Association of Anaesthetists Guidelines: Cell Salvage for Peri-operative Blood Conservation 2018

- UK Cell Salvage Action Group Guidance : https://www.transfusionguidelines.org/transfusion-practice/uk-cell-salvage-action-group
- UK Cell Salvage Action Group ICS Policy document
- Royal Devon and Exeter Guideline for Intra-operative Cell Salvage 2015

8. Associated Documentation

8.1. Northern Devon Healthcare NHS Trust Policies for :

- Blood Transfusion Policy
- Massive Blood Loss Policy
- Consent Policy
- Patients Refusing a Blood Transfusion Policy
- Waste Management

8.2. Appendices (Hyperlinks):

- UK Cell Salvage Action Group Patient Factsheet (General)
- UK Cell Salvage Action Group Patient Factsheet (Obstetrics)
- UK Cell Salvage Action Group Technical Factsheet 1 (Swab Washing)
- UK Cell Salvage Action Group Technical Factsheet 2 (Anticoagulation)
- UK Cell Salvage Action Group Technical Factsheet 3 (Collection of Blood)
- UK Cell Salvage Action Group Technical Factsheet 4 (Reinfusion of Salvaged Blood)
- UK Cell Salvage Action Group Technical Factsheet 5 (Administration of Salvaged Blood)
- UK Cell Salvage Action Group Technical Factsheet 6 (Use of ICS for Jehovah's Witnesses)
- UK Cell Salvage Action Group Technical Factsheet 7 (Use of Filters)
- UK Cell Salvage Action Group Technical Factsheet 8 (Use in Obstetrics)
- UK Cell Salvage Action Group Technical Factsheet 9 (Contraindications)
- UK Cell Salvage Action Group Technical Factsheet 10 (Staff Responsibilities)
- UK Cell Salvage Action Group Technical Factsheet 11 (Use of ICS Laparoscopic Surgery)

- UK Cell Salvage Action Group Technical Factsheet 12 (Metallosis)
- ICS continuous Audit Data Collection sheet (Appendix 1)

9. Appendix 1

ICS Continuous Audit Data Sheet

Date: DD/MM /YEAR

Patient NHS number: ……

Specialty: Obstetrics T+O General Urology Gynaecology

Procedure:

……
……..

Revision surgery? Yes / No

Machine Used: Sorin Xtra Other: …….

Elective: Yes / No

Urgent: Yes / No

Jehovah's Witness: Yes / No

Collection Only: Yes / No

Blood Processed: Yes / No **Total processed blood volume:** …….. ml

Blood Re-infused: Yes / No

Estimated blood loss: ……. Ml

Tranexamic Acid: Yes / No

Complications of transfusion: No problems Problem of
……..

Complications of transfusion are to be reported to SHOT (Serious Hazards of Transfusion). Please complete a DATIX to notify the Hospital Transfusion Team.