

CLINICAL GUIDELINE FOR INTRAOPERATIVE CELL SALVAGE

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Approved by:	Maternity Governance Meeting	
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Key Amendments

Date	Amendments	Approved by

A. Objectives of this pathway

1.The objectives of this policy are to provide a rational and practical framework on which to maximise patient safety during Intraoperative Cell salvage. They will include specific guidance for use of ICS within subspecialties (Maternity, Urology and Orthopaedics across the trust) –

Appendix 3.

2.Assisting clinical staff in the identification of patients and procedures considered suitable for ICS, outlining the indications/contraindications and possible hazards.

3.Providing clear written information about the risks and benefits of autologous Transfusions from blood salvaged intra-operatively.

4.Assisting clinical staff to minimise avoidable risks of autologous transfusions from blood salvaged intra-operatively.

5. Assisting clinical staff to provide appropriate advice on options for treatment particularly where patients are anxious about risks associated with allogeneic blood transfusion.

6. Promoting safer transfusion is part of clinical governance responsibilities.

B. Equipment set up for Intraoperative Cell Salvage

1. The ICS system should be used in accordance with the manufacturer’s guidelines, modified by research.
2. The ICS system should be run in automatic mode.

3. **Contradictions must be considered as in Appendix 2.** Any issues or concerns should be discussed with the team at the WHO briefing before the elective list starts or an appropriate time in an emergency.
4. All staff who set up or operate ICS systems will have received formal documented competency based training.
5. Staff must comply with hospital policies for infection control, management of sharps and blood transfusion.
6. Aseptic technique must be used at all times.
7. Anticoagulant

Citrate is routinely used across the Trust however if an alternative is deemed necessary, any anticoagulant prepared by the operator (e.g. heparinised saline) must be labelled clearly.

8. Wash Solution

0.9% Intravenous grade Saline should be used as the wash solution. This includes washing blood soaked swabs for aspiration.

The minimum wash volume as outlined in the manufacturer's guidelines for the size of the centrifuge bowl in use and the type of surgical procedure should be used in all but the most urgent situations.

A 225ml bowl should be used routinely in maternity as for other sub-specialities

Any heavily soaked swabs from the surgical field should be washed (**see appendix 4 for procedure**) in 0.9% Saline. The volume used should be 500 mls unless alternative volume required.

9. Labelling

All salvaged blood must be labelled and include the following details:

Full Name
Date of birth
Hospital number
Collection start date and time
Expiry date and time

The autologous re-infusion label with time infusion started and patient details must be stuck to the reinfusion bag at infusion. It is not acceptable to label the bag before the patient is in the operating theatre or after cell salvage is complete and the patient has moved away from the ICS device. The patient details must be taken from the identification band attached to the patient not from any medical records or charts that may be present in the operating theatre.

C. Re-infusion of Cell salvaged blood

1. **Prescribing Responsibilities: Salvaged blood reinfusion must be prescribed by a doctor (usually the anaesthetist) on documentation approved by the Trust.**
2. Blood should be collected into a reinfusion bag which is not connected by an intravenous fluid administration set to the patient. The bag is disconnected from the ICS device when it is full or at the end of the surgical procedure and is subsequently connected and reinfused to the patient as in a “closed- circuit” system. **See appendix 3 for set up of a Closed-loop circuit preoperatively.**

Connecting any salvaged blood to the patient should routinely occur in theatre before the patient is transferred to recovery. If not, the reinfusion bag must be kept beside the patient at all times until connected.

The reinfusion bag must not be placed into any refrigerator

The evidence to support the recommendation for use of a leucodepletion filter routinely is poor and it is acceptable for the prescribing clinician to omit the leucodepletion filter in obstetric patients, especially in the context of unexplained hypotension on reinfusion of cell salvaged blood.

Reinfusion of other salvaged blood should follow standard blood transfusion practice i.e. using a standard blood giving set to reinfuse red cells as directed in the Blood Transfusion Policy.

The doctor should prescribe salvaged blood for re-infusion after surgery in the same manner as allogeneic blood. The patient details on the reinfusion bag must be carefully checked against the details on the identification band attached to the patient before connecting the reinfusion bag.

The expiry time on the re-infusion bag must be checked prior to commencing the reinfusion and the prescription must be signed.

The reinfusion of salvaged blood must be documented on the patients' fluid prescription chart.

As per Trust blood transfusion monitoring guidelines, a minimum set of observations at 15 minutes after starting the infusion should be completed (HR, BP, SpO₂, respiratory rate, tympanic temperature). These criteria should be met routinely if the infusion is started in theatre or recovery and at least 15 minutes are spent in the recovery area.

Transfusion must be complete before the patient leaves the recovery area

3. Expiry

The collection, processing and reinfusion of salvaged blood should be completed within the Trust timeframe of **6 Hours**.

Any blood that has not been re-infused within the time frame specified in the guidelines should be disposed of appropriately.

D. Documentation

The collection and reinfusion of salvaged blood must be accurately documented including the occasions when it is not re-infused. (see **appendix 6 audit form**)

All adverse incidents must be documented in the patients' medical records and in accordance with the Trust Blood Transfusion Policy. If necessary a DATIX report should be completed in accordance with the Trust Incident Reporting policy

Bedside pre-reinfusion checks and patients' observations must be performed and recorded during autologous blood reinfusion in the same way as transfusion of allogeneic blood – in accordance with the Trust Blood Transfusion Policy. Additional observations are at the discretion of the clinical staff based on an individual patient assessment.

The Trust/organisation must ensure that adequate records are retained in cases where ICS is used.

E. Equipment management post-procedure

1. Following use, all cell salvage disposable equipment will be disposed of in accordance with the Trust Health and Safety Policy for disposable of equipment contaminated with blood (see policy for clinical waste)
2. Following use, the cell salvage machine will be cleaned in accordance with the Trust Infection Control Policy, including procedures for cleaning equipment following high risk cases.
3. Following contamination of the equipment internally, the equipment should be removed from use, identified as a potential biohazard and referred to the Blood Conservation Service.

F. Technical Problems

1. Technical problems with the ICS should be reported to the cell salvage co-ordinator (Sr Karen Davies in Worcester, Andrew Fryer SODP at the Alexandra Hospital) who will then contact the manufacturer if applicable.

2. All technical problems with machines will be documented and outcomes actioned.

3. Any adverse events relating to the ICS device must be reported in accordance with the Trust Incident Reporting Policy using Datix. Additionally, where appropriate, reporting to the relevant external bodies should be undertaken e.g. SHOT, Medicine and Healthcare products Regulatory Agency (MHRA)

Appendix 1:

Indications and Patient Selection

Intraoperative Cell salvage systems may be used in all adult and paediatric patients undergoing elective and/or emergency surgical procedures where treating clinicians feel there is a potential for significant blood loss, provided there are none of the above contraindications.

Particular indications for ICS include:

1. Patients who have **rare blood groups or multiple antibodies** for whom it may be difficult to find allogeneic blood
2. Patients with an increased risk of blood loss **or**, for moral, religious or other reasons, are **unwilling to receive allogeneic blood** and have given their consent to receiving autologous blood collected using ICS (all such decisions must be documented – see appendix 7).

If the surgical procedure to be carried out for patients for whom ICS is indicated but is also associated with any of the listed contraindications, the potential risks and hazards must be discussed with the patients and their agreement to undergo ICS documented.

Patient Information

Patients likely to lose a significant amount of blood in and after routine surgery should receive information about Blood Transfusion and alternative resources such as ICS. This should happen at initial booking for surgery and include the leaflet below (**Appendix 7**)

For patients undergoing emergency surgery the decision to use ICS is at the discretion of the surgeon and anaesthetist.

Appendix 2:

Contraindications and Warnings

The risk benefit ratio of ICS must be assessed for each individual patient and ultimately the responsibility lies with the senior clinicians involved in looking after the patient.

Contraindications

There are currently no large trials to mandate regular use of ICS in most of the situations below but there are numerous case reports and series suggesting no untoward sequelae (eg. malignancy and infection). Most contra-indications will be relative and as always, an individualised assessment of risk of harm versus benefit should be undertaken:

1. Bowel Contents in the surgical field (including large amounts of frank meconium in obstetrics)
2. Overt systemic infection
3. Heparin induced thrombocytopenia when heparin is the anticoagulant of choice (a citrate containing anticoagulant solution may be used instead). Citrate is routinely used at both the Alexandra hospital and WRH)
4. Malignancy. The use of ICS in patients undergoing surgery for malignant disease is controversial. Although there is increasing evidence that supports its safe use in cancer surgery and some hospitals now use ICS routinely during surgery for malignant disease. The decision to use cell salvage in the presence of malignant disease should be made by a surgeon and an anaesthetist familiar with the issues.

Warnings for consideration

1. Pain busters (infusions of Bupivacaine local anaesthetic used in orthopaedic surgery) should not be used concurrently with cell salvage devices which use blood collected from drains post-operatively. This is due to the potential risk of re-infusing blood contaminated with Bupivacaine.
2. ICS must be temporarily discontinued when substances not licensed for IV use are used within the surgical field and could potentially be aspirated into the collection reservoir. The standard theatre suction should be used to aspirate the surgical field and the wound should be irrigated with 0.9% Sodium Chloride before resuming ICS.
3. Some examples of NON IV-safe materials that should not be aspirated into the Intraoperative Cell Salvage system include:
 - Antibiotics not licensed for IV use
 - Iodine

- Topical Clotting Agents
- Orthopaedic Cement
- Hydrogen Peroxide
- Chlorhexidine Irrigation
- Misoprostol (Obstetrics)

4. Gastric/pancreatic secretions should not be aspirated into the system as they 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.

5. Amniotic Fluid. There is no evidence to support initial aspiration of amniotic fluid to waste. Amniotic fluid is removed during the washing process and with no cases ever been proven related to cell salvage, the risk of amniotic fluid embolism has largely been dispelled

See appendix 1 “Intraoperative Blood Cell Salvage for Obstetrics”

6. The use of Hartman’s Solution will inhibit the action of citrate based anticoagulants (e.g. ACDA)

7. A pressure cuff must not be used for re-infusion and where possible, air should be evacuated from the reinfusion bag prior to reinfusion. Reinfusion of blood from the reinfusion bag when it is still connected to the cell saver or when it has been disconnected but air remains in the bag, may lead to air embolism.

Appendix 3.

“Closed Loop” Re-infusion

Rarely, ICS is requested to be set up as a “closed-circuit” system (in continuity) where blood aspirated from the wound is processed and passed into a reinfusion bag connected by an intravenous fluid administration set (suitable for blood transfusion) to an intravenous cannula in the patient. This request will require forward planning.

The “closed circuit” allows adjustment of the rate at which the red cells are re-infused by adjusting a roller clamp on the fluid administration set and the height of the reinfusion bag. A pressure cuff should not be applied to increase the flow rate because of the risk of air embolism. The same reinfusion bag may fill and empty many times during an operation.

NOTE – This should only be undertaken by an experienced user as the risk of air embolus is increased

Appendix 4.

Use in special clinical situations:

Additional information:

OBSTETRICS

The Maternity unit at the Alexandra hospital has closed and so this section only applies to maternity cases at Worcestershire Royal Hospital.

All patients booked for planned caesarean section should be consented for potential use of Intra-operative cell salvage when blood transfusion discussed; this will then be recorded on the consent form by the obstetrician booking/consenting the patient at that time. An obstetric specific patient information leaflet should be given to the patient at this stage (**Appendix 7**)

Indications for use will be specific to individual patients. The use of cell salvage should be discussed at the WHO meeting with decision to use made jointly between consultant Anaesthetist and Obstetrician.

With the machine and disposables in theatre, the set-up time for a trained ODP should be minimal. If at any time use of cell salvage compromises the ODP's ability to assist the anaesthetist with patient care, it should be abandoned if no other staff are available to help.

A 225ml bowl should be used as routine in maternity. This will default the machine to appropriate settings and these should not be changed manually unless the operator has specific training and experience.

The theoretical risk of Amniotic Fluid embolism has largely been dispelled. A double wash (2000ml) cycle is currently used in Maternity but this slows processing and the need for this is questionable.

There are no robust criteria to guide when to use cell salvage to ensure a high volume/quality return. Factors such as: patient co-morbidity, pre-operative Hb level, estimated total or ongoing blood loss will all be relevant but the key factor determining initial, preoperative decision to use IOCS should be **ARE WE EXPECTING SIGNIFICANT BLEEDING**.

Quality of processed cells and clinical benefits of washing a partial bowl in obstetrics have not been demonstrated. Safety cannot be assured so we do not support this practice within the trust.

Use of an LDF filter for re-transfusion has been found to cause intractable hypotension in a group of urology patients and so with lack of any safety benefit, should no longer be used in Maternity.

Usually transfusion of processed blood should be complete before patient is discharged back to the post-natal ward. Any deviation should involve consultant Anaesthetist discussing with post-natal ward manager and document in notes.

Red Cell sensitisation

Recent evidence has suggested an increase in maternal red cell sensitisation by re transfused cell saved blood. This results in abnormal Kleihauer tests in **Rhesus -ve women**, with a requirement for significantly increased doses of Anti-D to reduce incidence of Haemolytic disease of the Fetus and Newborn (HDN) in future pregnancies.

“Where intra-operative cell salvage (ICS) is used during Caesarean section in D negative, previously non-sensitised women, and where cord blood group is confirmed as D positive (or unknown), a minimum dose of 1500 IU anti-D Ig should be administered following the re-infusion of salvaged red cells, and a maternal sample should be taken for estimation of FMH 30–45 min after reinfusion in case more anti-D Ig is indicated. It is important that clinicians inform the transfusion laboratory if ICS has been used to ensure that correct dose of anti-D Ig is issued (Grade 2C).”

A surveillance form (Appendix 6) must be completed for every patient whose blood is collected or reinfused. The form is located on the cell salvage machine in maternity theatre and once completed must be filed in the patients notes. The results of Kleihauer tests in Rhesus -ve women need to be documented on the form along with dose of Anti-D given. These should then be available on EZ notes for audit purposes.

A patient ID sticker should be placed in the record book stored in the maternity anaesthetic room filer, with details of Rhesus status and whether processed blood transfused. This is **ESSENTIAL** for reference and audit purposes.

Reference: The use of anti-D immunoglobulin for the prevention of Haemolytic disease of the fetus and newborn H. Qureshi, E. Massey, D. Kirwan, T. Davies, S. Robson, J. White, 2014 British Society of Haematology <http://onlinelibrary.wiley.com/doi/10.1111/tme.12091/full>

RCOG, Green Top guideline 47, Blood Transfusion on Obstetrics, 2015.

Urology:

NICE guidance suggests that based on current evidence, IOCS in both radical cystectomy and prostatectomy can be used safely.

All patients should be consented at booking for surgery or pre-operative assessment and given a patient information leaflet to read. Documentation of this can either be in the outpatient notes or on the anaesthetic chart.

See section 2.7.1.4 for guidance around concerns over re-infusion of malignant cells

A Leukocyte depletion filter should be used for each case to minimise the risk of re-infusing malignant cells or urine.

Reference: <https://www.nice.org.uk/guidance/ipg258/chapter/1-Guidance>

Orthopaedics:

There is good evidence to suggest that IOCS can be used safely in both hip and Knee arthroplasties. It has been shown to reduce both the number of patients and mean number of units transfused post operatively.

All patients need appropriate consent at booking for surgery or pre-operative assessment and given a patient information leaflet to read. Documentation of this can either be in the outpatient notes or on the anaesthetic chart.

Contraindications include:

Local or systemic infection (relative)

Indication for surgery being adverse reaction to metal debris (ARMD)

Revision of metal on metal hip replacements

In major joint replacement surgery there may be concerns regarding the aspiration into the collection reservoir of potentially hazardous substances, e.g. chlorhexidine and bone cement. These difficulties may be avoided by having two sets of working suction apparatus – one to the cell salvage collection reservoir, and the other to standard collection (for disposal), and by ensuring that the surgical field is irrigated well with normal saline before recommencing collection for cell salvage.

Reference: www.transfusionguidelines.org.uk

Appendix 4 –

Salvaging Red cells from blood soaked swabs

Blood retrieved from washing of swabs can constitute up to 50% of total surgical blood loss volume

1. Empty 1000ml of 0.9% saline solution from the Polyfusor containers into a sterile bowl
2. Blood soaked swabs can then be soaked and agitated gently in the saline
3. Towards the end of the procedure the solution should then be aspirated into the collection bowl for salvage
4. Before aspirating solution from bowl, the ODP operating the cell salvage machine must be informed to ensure the reservoir bowl has enough room to accept fresh aspirate.

NB.

- **DO NOT WIRING BLOOD FROM SWABS BEFORE PUTTING THE SWABS INTO THE BOWL – IT WILL DAMAGE /DESTROY RED BLOOD CELLS**
- **DO NOT USE SWABS CONTAMINATED WITH IODINE**
- **DON'T NOT ASPIRATE FOR SALVAGE ANY SWAB SOLUTION THAT HAS STOOD FOR MORE THAN 6HRS**

Appendix 5 -

Training and Governance

The provision of safe ICS requires adequate resources for the formal, documented training of all staff who set up or operate the equipment and for the regular maintenance and prompt repair of ICS equipment.

The Blood Transfusion Link nurse on any site providing IOCS will maintain records of all persons who have received training in the use of the cell salvage devices.

Worcestershire Royal Hospital – Karen Davies

Alexandra Hospital – Andrew Fryer

Theoretical and practical training should be delivered and individual staff competency assessed before staff set up or operate ICS equipment without supervision.

Update training is recommended after any reasonable length of time without practical use of the ICS device; If a learning need is identified by an individual member of staff or supervisor; if there are any changes in the product from the manufacturer or a change in the product due to the Trust trialling/purchasing new products; if there is any change to national and/or local guidelines relating to any aspect of autologous transfusion (including changes to the Trust Blood Transfusion Policy)

Individual Responsibilities

Individual staff must ensure that they are adequately trained and competent in the use of the ICS system and their individual responsibilities according to their area of work, i.e. operator, anaesthetic, scrub, recovery and ward staff and to act within the NMC/HPC code of conduct and scope of professional practice as extended by this protocol.

References

www.transfusionguidelines.org.uk

Appendix 7 – Patient information factsheet

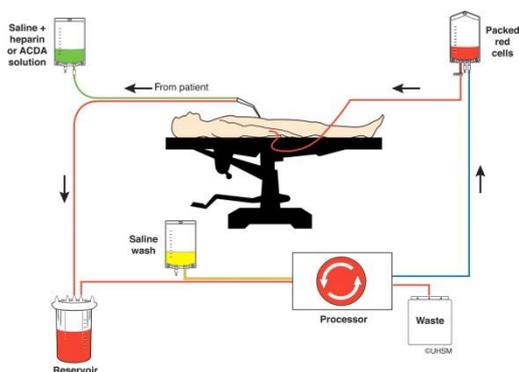
Intra Operative Cell Salvage (IOCS)

What is cell salvage?

Cell salvage is a way of collecting the blood that is lost during or just after your operation, so that it can be given back to you. It is sometimes called autologous blood transfusion (using your own blood).

How is it done?

Blood that is lost during your operation is collected using a cell salvage machine. This machine separates the different parts of your blood and collects just the red blood cells which carry oxygen. These red cells can then be given back to you during or just after your operation. Your red cells will only ever be given back to you and never be used for someone else.



This type of cell salvage has been used for the last 15 years for an ever wider variety of surgical operations.

Cell salvage in Obstetrics

When delivering a baby by caesarean section you may lose blood. Intra operative cell salvage (ICS) can help reduce the need for a blood transfusion donated by a blood donor. Cell salvage can therefore reduce the very small risks associated with receiving donor blood.

Baby's blood mixes with mother's at delivery. Any women who have a Rhesus –ve blood type will have a special blood test after delivery to tell us how much Ant-D antibody we will need to give you to prevent problems in future pregnancies.

Cell Salvage in Urology

You will have a discussion with you anaesthetist about whether he or she feels you may be at risk of losing enough blood to warrant using the Cell saver.

Certain situations such as cancer operations may need special discussion.

Cell salvage in Orthopaedics

Some operations may predictably cause much more blood loss than others and for patients who are frail or who have low blood counts to start with, ICS may be particularly helpful in avoiding use of donated blood.

There are certain drugs and materials used in some orthopaedic operations which can make using the cell saver unsafe. Your anaesthetist will advise you on whether cell salvage would be safe and whether it may benefit you.

Which patients could benefit from IOCS?

Any patient having an operation may lose more blood than expected and so benefit from return of blood collected by IOCS. Some patients will have a much greater risk of excessive blood loss and so will benefit much more.

There are also patients who do not wish to receive donated blood for religious or other reasons.

Any patients who are blood donors are unable to donate again if given donated blood. IOCS would be an appropriate and safe option for them to enable them to continue donating to the National Blood transfusion service.

Why isn't it suitable for everyone?

IOCS would not be suitable for use in all situations where you need planned or emergency delivery. These situations can be discussed with your anaesthetist or surgeon before your operation.

Not all operations result in enough blood loss to enable the cell salvage to be used.

Where can I get more information?

You will have the opportunity to discuss the risks and benefits with your anaesthetist on the day of your caesarean. You can also contact the anaesthetic department, labour suite or surgical secretary to discuss more about cell salvage for further information.

The transfusion practitioners are available to answer any queries you may have and are contactable on 01905 733317.