Intra-Operative Cell Salvage (IOSC) in Obstetrics

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1. Overview

Intra-operative cell salvage (IOCS) is a recognized & efficacious practice in many surgical specialties. It is also often acceptable practice to the Jehovah Witness population undergoing surgery. Peri-partum haemorrhage remains a significant risk factor for pregnant women. It remains one of the leading causes of maternal death and morbidity.

Intra-operative Cell Salvage (IOCS) is being increasingly used throughout the world for women at risk from postpartum haemorrhage during caesarean section. There are over 400 case reports in the literature. It has now become an internationally recognised good standard of care. In the year 2005-2006, 38% of UK maternity units used IOCS, and 28% included the use of IOCS in their Massive Obstetric Haemorrhage (MOH) protocol. Theoretical concerns over amniotic fluid embolism have not been borne out in clinical practice and 80% of maternity units surveyed identified the barriers more as lack of training rather than safety concerns.

The use of IOCS in obstetrics has been endorsed by:

- Confidential Enquiry into Maternal and Child Health (CEMACH)
- Joint AAGBI/OAA Guidelines
- National Institute of Clinical Excellence (NICE)

Because of the *theoretical* safety concerns in obstetrics, patients **must** have full informed consent. The procedure should also be performed by a team familiar with its use *specifically* in obstetrics. Because of these theoretical safety concerns it is ***not currently routine*** practice in all obstetrics.

There are useful resources available for the public published by NICE and the UK Cell Salvage Group (see references at end).

The primary safety concerns are a theoretical risk of amniotic fluid embolus and also haemolytic disease in future pregnancies in rhesus negative women.

In summary, blood is salvaged by a suction catheter from the operating field. This blood is suctioned into a reservoir which contains a large filter to remove large debris then washed, re-suspended in saline and returned to the patient as necessary. A leukocyte depleting filter is almost always used in obstetric cell salvage as a final filter of amniotic fluid debris and fetal cells. This practice is extremely efficacious at returning clean blood back to the patient.

Audit, review of practice and training of staff are key issues in this technique being as safe as possible. As such an Obstetric Cell Salvage Working Party in ADHB has been implemented, audit processes are in place and regular staff training is available.

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2. Patient Selection

Wherever possible, the advantages and risks of IOCS and allogeneic blood transfusion should be discussed with the patient prior to undergoing an obstetric surgical procedure. In a pre-planned case this can be done during antenatal care. It is recommended that patients receive the "Intra-operative Cell Salvage Patient Information Leaflet" and a copy of the "Frequently Asked Questions" sheet produced by the UK Cell Salvage Group. These are kept in the anaesthetic technicians room level 9 theatres .The NICE guidance "Intra-operative blood cell salvage in obstetrics" recommends that "whenever possible, the woman understands what is involved and the theoretical risks, and agrees (consents) to have the procedure". When obtaining formal consent for a caesarean section, the obstetrician or anaesthetist must discuss the advantages and risks of IOCS with the patient and document clearly the agreement of the patient to undertake the procedure. Such detailed consent may not be practicable in an emergency, as for allogeneic transfusion.

Patient selection for IOCS is at the discretion of the obstetrician and anaesthetist caring for the patient. The type of obstetric cases that should be considered for selection includes:

Emergency situations

- Ruptured ectopic pregnancy
- Postpartum haemorrhage for laparotomy
- Antepartum haemorrhage for emergency LUCS
- Any emergency LUCS at risk of Major Obstetric Haemorrhage (MOH)

Elective situations

- Patients with an anticipated blood loss of >1000ml e.g. placenta accreta, large uterine fibroids, and other predictable causes MOH
- Patients who for religious or other reasons refuse allogeneic blood and have consented to the use of Intraoperative Cell Salvage in elective or emergency bleeding situations or in significant anaemia
- Please note – IOCS is not appropriate for salvage of lost vaginal blood as there is a risk of bacterial contamination

It is important to anticipate the need for IOCS and thus start it at the beginning of high risk cases.

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3. Additional measures necessary in obstetric IOCS

Amniotic fluid should theoretically *not* be aspirated into the collection reservoir, but should be removed by separate suction prior to starting cell salvage. This recommendation will reduce the initial contamination, although *in vitro* evidence consistently demonstrates that the cell salvage/filtration process can effectively remove amniotic fluid contaminants whatever the initial load. In life-threatening haemorrhage, therefore, a clinical decision to salvage red cells ***from the start of the procedure*** could be carefully considered, and is supported by current *in vitro* evidence.

To ensure efficient washing, use a quality wash program and consider increasing the standard saline wash volume. Do not process incomplete bowls as this will compromise the washing efficiency (use “concentrate” where appropriate).In the event that use of “concentrate” is not an option due to insufficient red cells being available in the reinfusion bag, consideration may be given to a “double” wash volume being used for the processing cycle.

After processing, a Pall RS filter (LeukoGuard RS, Pall Biomedical Products Co., East Hills, NY) should be used to re-infuse the cell salvaged blood (see later). This is the only filter proved to effectively eliminate residual particulate elements of amniotic fluid. It should be remembered that prior to the year 2000, this filter was not available, but over 250 cases worldwide had safely received cell-salvaged blood without a problem. This filter slows infusion rates considerably. When blood loss is rapid, the flow rate through the filter may not be sufficient to give back large volumes of blood quickly. Using a filter in each port doubles the flow rate. The use of a pressure cuff is not advised due to the risk of air embolus and the unknown impact of pressure on the retention of amniotic contaminants within the filter. In life-threatening haemorrhage, however, where allogeneic blood may not be readily available or may be refused, a clinical decision to infuse under pressure in the first instance or remove the filter completely could be carefully considered.

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4. RhD immunisation and Kleihauer testing

In any pregnancy, if the mother is RhD negative and the fetus is RhD positive there is a danger of RhD immunisation if the maternal circulation is exposed to fetal red cells. Antibodies against the fetal red cells can cause haemolytic disease of the newborn in subsequent pregnancies if untreated. Consequently all RhD negative women who deliver a RhD positive baby will have a Kleihauer test performed post delivery. Kleihauer testing is required to establish the amount of fetal red cell exposure and ensure the recipients receive an appropriate dose of anti-D immunoglobulin. The same protocol should apply for RhD negative women who have received salvaged red cells. If cell salvage is used in such women, exposure to fetal red cells is very likely because the cell saver centrifuge cannot distinguish fetal from maternal red cells. Depending on the test results it may be that higher doses of anti-D will need to be administered. Administration of anti-D should occur within 48-72 hours of delivery.

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5. Swab Washing

The efficiency of red cell recovery by cell salvage is very much dependent on the ability to recover the blood lost in a useable form. During surgery, blood loss can be removed from the operative site by a combination of suction and swabs. Blood loss to swabs during surgery has been estimated at between 30% and 50% of the total surgical blood loss. By washing swabs, the blood that is normally discarded can be collected and the overall efficiency of red cell recovery improved.

Currently in obstetric cell salvage we DO NOT support the practice of swab washing because of the risks of contaminants.

6. Anticoagulation

Blood lost at the operation site **must** be appropriately anti-coagulated prior to aspiration into the blood collection reservoir. Insufficiently anti-coagulated blood will clot which can transfer into the blood processing set. These blood clots will then be present in the processed blood and can cause clogging of the system.

Heparin

Heparinised saline solution may be used for anticoagulation during blood collection. A solution of 25,000 - 30,000 IU of heparin per 1 litre of intravenous (IV) normal saline (0.9% NaCl) solution is recommended with a dosage of 20ml of solution per 100ml of collected blood. Alternatively, a drip rate of 1-2 drops per second depending on the rate of blood flow being processed. This type of solution is *not currently available commercially* and will need to be made up locally. It is imperative that the **heparinised** saline is labelled correctly to make it obviously distinguishable from saline wash solutions.

Citrate Anticoagulants (3% ACD-A or 4% Sodium Citrate)

Both ACD-A and 4% Sodium Citrate can also be used for anticoagulation during blood collection. The ratio of citrate anticoagulant solution volume to blood volume should range between 1:5 – 1:10 or approximately 70ml of citrate per 500ml of recovered blood (a volume of 15-20ml ACD-A per 100ml of collected blood). Pre-prepared 3% ACD-A and 4% Sodium Citrate solutions are available commercially for this purpose.

For either Heparin, 3% ACD-A or 4% Sodium Citrate, the quantity of anticoagulant introduced into the blood collection system must be adapted to the volume of blood loss. A rate of 60 to 80 drops of anticoagulant per minute is typical in moderate blood loss but **should be monitored closely and adjusted accordingly** to avoid clotting in the reservoir.

Points to note:

Heparin

- Heparin is a prescription only medicine.
- The UK Cell Salvage Action group recommend:
    - To help reduce the risk of administration error written documentation of the heparin requirement should not be entered on the general prescription chart but on the cell salvage chart/form
    - The batch number and dosage of heparin used should be documented

3% ACD-A and 4% Sodium Citrate

- 3% ACD-A & 4% Sodium Citrate are not prescription medicines
- If 3% ACD-A & 4% Sodium Citrate are quoted in the product specification (CE marking) for the cell salvage machine in use there is no requirement for 3% ACD-A or 4% Sodium Citrate to be prescribed
- If it is not part of the product specification then the 3% ACD-A or 4% Sodium Citrate used for cell salvage procedures should be documented and the following should apply:
    - To reduce the risk of administration errors, documentation for the use of 3% ACD-A or 4% Sodium Citrate should not be entered on the general prescription chart but on the cell salvage chart/form to help ensure that the anticoagulant is used correctly
    - The batch number and dosage of 3% ACD-A or 4% Sodium Citrate used should be documented

- When utilising either 3% ACD-A or 4% Sodium Citrate as the anticoagulant solution in cell salvage, calcium containing products should be avoided being aspirated from the surgical field via the suction or being added to the collection reservoir. Calcium present in these solutions may bind with the citrate contained in the anticoagulant solution and activate the coagulation sequence resulting in clotting of the blood in the collection reservoir or consumable circuit.

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7. Blood Collection

Blood lost within the surgical field is collected into the reservoir. Blood is mixed with an anticoagulant solution to prevent clotting. Collection can be undertaken with or without further processing and reinfusion. This is what we describe as a "*collect and see*".

Aspiration of blood and vacuum pressure

To reduce haemolysis the vacuum pressure should always be set as low as practicable. Typical values are between –100 and -150 mmHg (avoid excess pressures).
To optimize the yield and quality of salvaged blood a large bore suction tip (minimum 4mm; e.g. Yankauer sucker) should be used and *surface skimming minimized* (aspirating blood mixed with large quantities of air from the surgical field).
In the event of massive blood loss, the vacuum level can be temporarily raised to clear the field and then reduced to a lower level for lower flows.

Setting up the cell salvage equipment

Before setting up, check the mechanical integrity of the device by powering up to allow the "self-test" to be completed and any problems highlighted. When handling disposables maintain strict sterility at all times and always treat processed blood as being potentially infected.

Standby

In some circumstances it may be favourable to set up the equipment for cell salvage in advance, ensuring that it is available quickly when needed without unnecessary delay. The disposables are loaded "un-primed" on the device. Do not spike solution bags until actually needed (this will extend the useable time limit on the prepared machine). The dual lumen suction line can only be connected when the machine is used and it is passed from the sterile surgical field by the scrub nurse. To ensure a closed system, the caps protecting any unused port must remain in place. The time of set up and an expiry date and time should be recorded and the disposable set labelled accordingly for all staff to see clearly so that a compromised disposable is never used. There is no definitive guidance for how long the equipment can be left. When reviewing what happens with apheresis machines it would appear that un-primed system could be used for up to 24 hours but once primed (in this case the saline bags spiked) these should be used within 4 hours or disposed of. If the device and disposables are not used within the allotted time-frame, the device is cleared down and all the consumables discarded.

Collect only

In some situations it may be advisable to collect the shed blood and wait to see if sufficient volume has been collected before progressing to the processing phase. Most cell salvage devices will allow this approach, using only the reservoir and aspiration line in the first instance. Once sufficient blood has been collected the processing set can then be loaded. With experienced staff available changing to a collect and process circuit takes little time.

Collect and process

When it is likely that sufficient blood loss will be experienced to justify processing, the machine can be set up with the full disposable set at the beginning of the surgical procedure.

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8. Reinfusion of Salvaged Blood

Labelling

The reinfusion bag should be labelled with the patient's full name, NHI, the date and time of initiation of collection and the time of expiration.

Reinfusion

Red cells salvaged intra-operatively should be kept at room temperature and re-infused in accordance with local policy. Red cells salvaged intra-operatively should be re-infused within 4 hours of processing. Red cells salvaged intra-operatively should be given back to the patient using a leukocyte depleting filter (LDF) in *most* cases. If the clinical decision is such that a LDF is not used then the salvaged red cells should be filtered through a 40 micron microaggregate filter (Pall SQ40) attached to a standard blood administration set as recommended by AABB/NZBS. Cell salvage manufacturers advise NOT to use a pressure cuff as there is a risk of air embolus from the air in the

reinfusion bag. Some devices may also detect a back pressure if the reinfusion line is open. If necessary, the air can be removed by inverting the reinfusion bag and expelling the air via one of the giving set ports.

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9. Administration of Salvaged Blood

To ensure safe practice the same local procedures for the administration of allogeneic (donor) blood should be followed for the reinfusion of autologous blood. Positive patient identification is essential as the autologous blood is untested and there is a distinct risk of ABO-incompatibility if the blood is given to the wrong patient. Autologous blood should be kept with the patient at all times and be prescribed for the patient in the same way as any other blood or blood component transfusion. Pre-transfusion checks must be completed at the patients' bedside prior to commencing transfusion to ensure the right patient receives the right blood product in accordance with ADHB/NZBS policy. Ensure that documentation occurs in the patient's medical record.

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10. Jehovah's Witnesses

Jehovah's Witnesses (JW) regard blood as sacred. On the basis of this deeply held core value, they usually decline treatment with *allogeneic* (donor) blood (red cells, white cells, platelets, and plasma) even in the event of life threatening haemorrhage. With regard to *autologous* transfusion JW patients make a personal decision whether or not to accept such. This includes all forms of peri-operative/intra-operative blood salvage (cell salvage), haemodilution, and postoperative blood salvage. While machines, systems, and arrangements vary, each patient will decide how his/her own blood will be handled in the course of a surgical procedure, medical test, or current therapy. Among those prepared to accept autologous procedures, the usual request is that the system be set up to allow for continuous connectivity. In such cases, the details outlined below should prove helpful. Although there will be technical differences between devices, the same general principles apply.

Set up of Equipment for Jehovah's Witnesses

(a) Set up the collection reservoir and Cell Saver machine for collection and processing with standard disposables (in bowl based machines consider using a low volume bowl to reduce blood stasis).
(b) Attach an appropriate blood administration set and filter to the reinfusion bag.
(c) Power ON the Cell Saver system and using Manual Mode, press "**WASH**" to fill bowl with normal saline - allow the bowl to fill. When saline exits the bowl to the waste bag - press "**STOP**".
(d) Press "**WASH**" to fill bowl with normal saline - allow the bowl to fill. When saline exits the bowl to the waste bag - press "**RETURN**" to allow bowl contents to prime reservoir tubing and enter collection reservoir – press "**STOP**". Ensure red slide clamp at base of collection reservoir is open prior to performing this step.
(e) Press "**WASH**" to fill bowl with normal saline - allow the bowl to fill. When saline exits the bowl to the waste bag - press "**EMPTY**". This will allow the bowl contents to empty to the reinfusion bag. (Remember to account for this volume when recording the final reinfusion volume).

(f) Power OFF the Cell System prior to commencing the Cell Salvage procedure.
(g) Prime the administration set and filter prior to connection to the patient via a cannula for reinfusion. Once established, the connection between the patient and the reinfusion bag must not be broken. (Refer Figure 1 as an example of this type of set up).
(h) Attach anticoagulant and aspiration line to collection reservoir as with standard protocol and prime reservoir with approximately 150mls from anticoagulant solution bag. Power ON Cell Saver system and proceed to STANDBY.
(i) Whilst surgery is ongoing, administer the saline at the slowest rate possible to maintain patency of the cannula until processed blood is available.

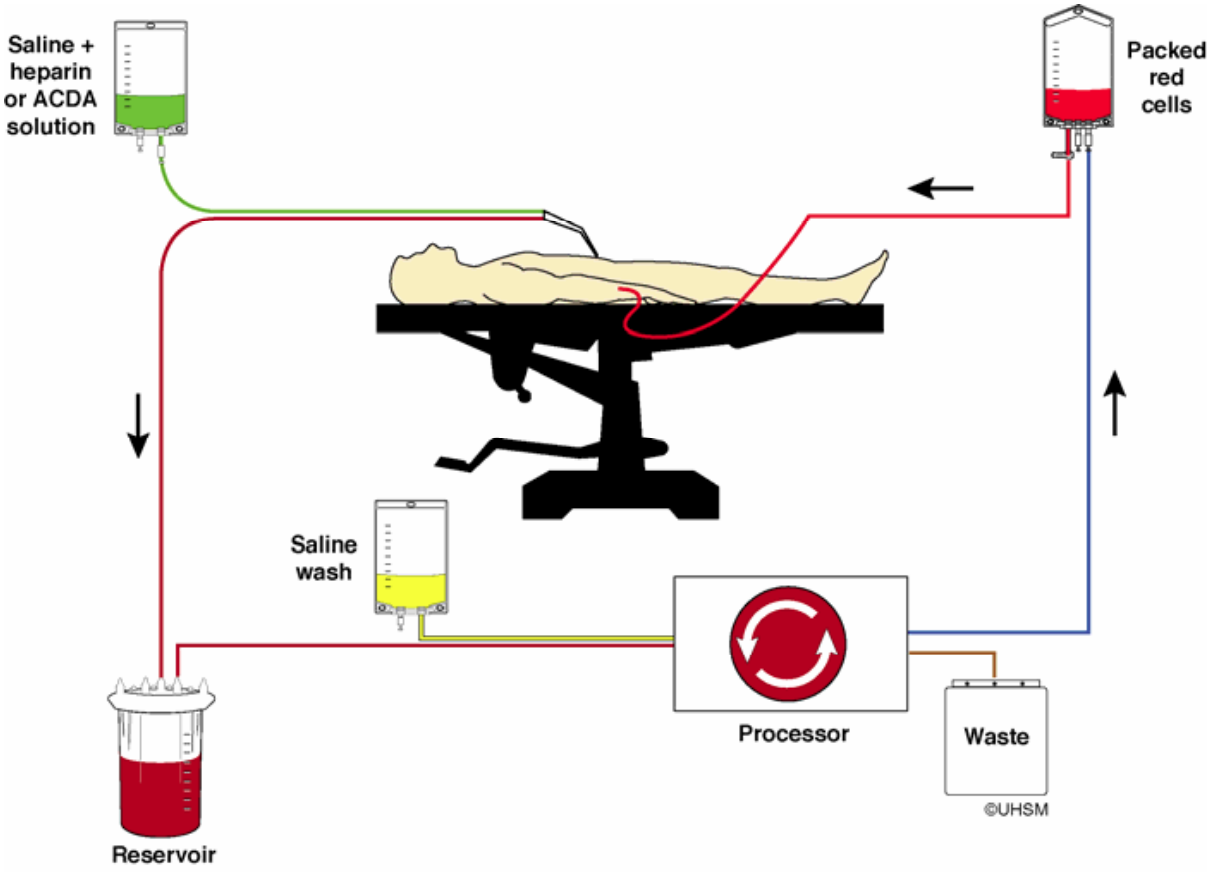

Figure 1: Representation of a continuous circuit

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11. Special requirements

In obstetric cell salvage and malignancy the use of a leukocyte depletion filter is recommended for reinfusion of the salvaged blood. A standard giving set should be set up with a 3-way tap in line before blood collection begins. The giving set should be primed with saline to complete the circuit. When a volume of blood is ready to be re-infused, the leukocyte depletion filter can be spiked into the second reinfusion port on the reinfusion bag and primed. This is then attached to the 3-way tap, without breaking the circuit. Likewise, because the filters have a maximum throughput of 450mls, a new filter can be added if necessary by replacing the original giving set

while leaving the original filter connected. (See figure 2 as an example). *Please note - The filter should not be flushed with saline after filtration of the salvaged blood*. When blood loss is rapid, the flow rate through the filter may not be sufficient to transfuse large volumes of blood quickly. Using a filter in each port doubles the flow rate. During management of life threatening haemorrhage in a JW, if the reinfusion rate of salvaged blood is too slow, even when using two leucodepletion filters, it may be necessary to make a clinical decision to replace the leucodepletion filter with a normal giving set, so that blood can be transfused rapidly to prevent ex-sanguination. This must be done without breaking the circuit in order to maintain continuity.

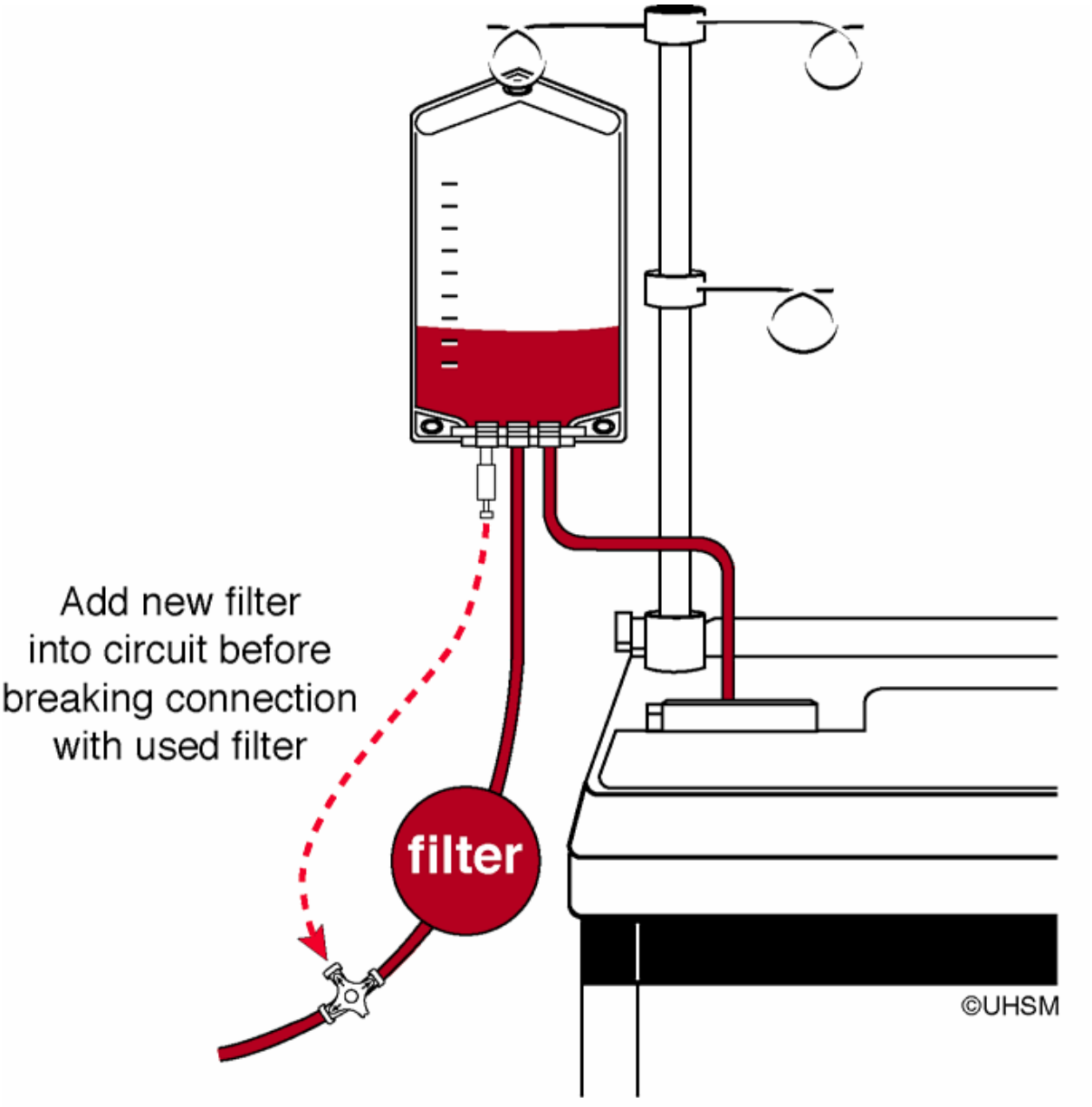

Figure 2: Replacing a filter without breaking continuity

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12. Contraindications to cell salvage

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The following table of contra-indications to intra-operative blood recovery has been recommended by AABB (American Association of Blood Banks), in their publication "Guidelines for Blood Salvage and Reinfusion in Surgery and Trauma, 1997".

Pharmacologic Agents: Clotting Agents

Substance	Effects	Recommended Action
Microfibrillar Products Examples: Avitene®, Helitene®, Oxycel®, Gelfoam ® Powder, Instat®	May cause platelet aggregation and clot formation. Reported to pass through a micro-aggregate filter into the blood stream, causing emboli	Avoid aspiration when product is being used in surgical field. Resumption is an option after copious irrigation with 0.9% sodium citrate solution and suction to an alternate source (discard suction).
Sponge/Fabric Materials Examples: Surgicel™, NuKnit, Gelfoam® Sponge, Helistat®, Hemopad® Super Stat, Instat™	Activates the clotting sequence by acting as a contact agent. May clot off the blood recovery system.	Avoid aspiration when product is being used in surgical field. Resumption is an option after copious irrigation with 0.9% sodium citrate solution and suction to an alternate source (discard suction).
Topical Liquids Examples: Thrombin-JMI™, Thrombostat®, Thrombogen®,	Creates a fibrin clot by direct action on fibrinogen. May clot off the blood recovery system.	Avoid aspiration when product is being used in surgical field. Resumption is an option after copious irrigation with 0.9% sodium citrate solution and suction to an alternate source (discard suction).

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Pharmacologic Agents: Irrigating Solutions

Substance	Effects	Recommended Action
Alcohol	Causes red cell lysis.	Avoid aspiration when product is being used in surgical field. Resumption is an option after copious irrigation with 0.9% sodium citrate solution and suction to an alternate source (discard suction).
Antibiotics Examples: Bacitracin, Neomycin, Polymyxin,	Can result in renal and neural toxicity if blood is not washed prior to reinfusion.	Increase amount of wash volume by 500ml.
Betadine,	Causes red cell lysis.	Avoid aspiration when product is being used in surgical field. Resumption is an option after copious irrigation with 0.9% sodium citrate solution and suction to an alternate source (discard suction).
Chloropatin (Bleach)	Causes red cell lysis.	Avoid aspiration when product is being used in surgical field. Resumption is an option after copious irrigation with 0.9% sodium citrate solution and suction to an alternate source (discard suction).
Hydrogen Peroxide	Causes red cell lysis.	Avoid aspiration when product is being used in surgical field. Resumption is an option after copious irrigation with 0.9% sodium citrate solution and suction to an alternate source (discard suction).

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Substance	Effects	Recommended Action
Hypertonic Solutions Examples: 3% NaCl, 7.5% NaCl, Dextrose Solutions,,	Causes red cell cremation.	Avoid aspiration when product is being used in surgical field. Resumption is an option after copious irrigation with 0.9% sodium citrate solution and suction to an alternate source (discard suction).
Hypotonic Solutions Examples: Bacitracin, Neomycin, Polymyxin,	Causes red cell lysis.	Avoid aspiration when product is being used in surgical field. Resumption is an option after copious irrigation with 0.9% sodium citrate solution and suction to an alternate source (discard suction).
Solutions containing Calcium (in the presence of citrate anticoagulants Examples: Lactated Ringers,	Calcium present may bind with citrate activating coagulation sequence.	Avoid aspiration when product is being used in surgical field. Calcium containing solutions should not be added to the blood recovery collection container. Resumption is an option after copious irrigation with 0.9% sodium citrate solution and suction to an alternate source (discard suction).

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13. Summary Points

- IOCS in obstetrics is endorsed at an international level.
- It is often acceptable to Jehovah Witness Patients.
- It is not without some *theoretical* risks of amniotic fluid embolus and also haemolytic disease in future pregnancies in rhesus negative women but this must be compared with known risks of allogeneic transfusion.
- Due to possible risks, patient selection & informed consent are important and there are patient information sheets available on L9.
- It is only available for LUCS not vaginal delivery due to infection risks.
- It should only be used by staff trained in the use of IOCS specifically in obstetrics as there are some differences to “standard” IOCS. Communication between all staff involved with its use in a case is vital.
- Generally a double suction technique is currently endorsed. The cell salvage sucker is used only AFTER the amniotic fluid has been suctioned from the field by the discard sucker. Prior to using the cell salvage sucker the abdomen is usually washed out to clear any debris. Exceptions to this (i.e. using a single suction into the cell saver from the start) would be in a high risk Jehovah Witness case when the balance of risks is probably in favour of using a single suction with a leucocyte depleting filter in situ as a higher RBC yield may be possible.
- Usually a second anaesthesia technician is required to operate the cell saver. Please liase with the technician in charge.
- It is important to give as much notice as possible when cell salvage is requested to allow for staff allocation & machine preparation. This is imperative for Jehovah witness patients who require a very specific set up for the machine.
- Often a “suck & see” set up can be arranged with a rapid (in minutes) change to a full wash/re-transfusion set up.
- In all cases a leucocyte depleting filter is recommended prior to re-infusing blood into the patient. If this slows the transfusion down then two filters in parallel can be used. In exceptional circumstances removal of the filters can be considered but this may add some theoretical risk to the patient and therefore must be balanced vs. any benefit.
- Transfusion triggers of cell salvaged blood should follow the same guidelines as banked blood. Higher transfusion triggers may be used for JW patients or patients with complex RBC antibodies which make cross match difficult and may cause delays.
- Blood from the cell saver must be properly labelled, kept at room temperature with the patient, used within 4 hours (or discarded) and re-transfused in accordance with ADHB guidelines.
- Audit is important - forms are filled in by the anaesthetic technician at the time & followed up by the level 9 Cell Salvage Committee.
- Any immediate safety concerns must be brought rapidly to the attention of the consultant anaesthetist & operating technician for the case.

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14. Supporting Evidence

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(b) Waters JH. Biscotti C. Potter PS. Phillipson E. Amniotic Fluid Removal During Cell Salvage in the Caesarean Section Patient (2000) Anaesthesiology; 92; 1531 1536.

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(d) M. Harkness, V. Clark. The Use of Cell Salvage during Obstetric Procedures: an Audit of Scotland's Maternity Units. Scottish Medical Journal (2008) Volume 53 Issue 3.

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(g) National Institute for Health & Clinical Excellence. Guideline IPG144: Intraoperative blood cell salvage in obstetrics (issued November 2005).

(h) Cell salvage in obstetrics: an evaluation of the ability of cell salvage combined with leucocyte depletion filtration to remove amniotic fluid from operative blood loss at caesarean section Catling SJ Williams S. Fielding AM. (1999). Int J Obs Anesth; 8; 79 84

(i) Haemonetics Cell Saver 5+ Operation Manual, Rev A, October (2004)

(j) AABB Guidelines for Blood Salvage and Reinfusion in Surgery and Trauma, 1997

(k) UK Cell Salvage Action Group Technical Factsheets 01-09 (Reproduced by kind permission Dr Daffyd Thomas).

(l) UK Cell Salvage Action Group - Factsheet for Patients

(m)Teig M, Harkness M, Catling S, Clark V. International Journal of Obstetric Anesthesia (2007) 1 , S30

(n) Marion Hall (2004) *in* Why Mothers Die 2000-2002 - Report on confidential enquiries into maternal deaths in the United Kingdom (CEMACH), Chapter 4 (Haemorrhage) pp91-92, RCOG Press.

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15. Associated ADHB Documents

- Caesarean Section - access to, preparation for, & care in operating room

16. Disclaimer

No set of guidelines can cover all variations required for specific circumstances. It is the responsibility of the health care practitioners using these guidelines to adapt them for safe use for the individual need of the patient.

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