

ICS Frequently Asked Questions

AREA of APPLICATION

Wherever Intraoperative Cell Salvage (ICS) is used.

STAFF

- All staff trained in the use of ICS
- Staff in pre-operative clinics
- Medical, Nursing and Midwifery staff, Operating Department Practitioners, Biomedical Scientists and Healthcare Support Workers

IN WHICH PROCEDURES IS ICS INDICATED?

ICS is indicated in any surgical procedure, either planned or urgent, where the benefit results in the reduction or complete avoidance of allogeneic red cell transfusion.

There is no single selection criterion which would identify all patients that would benefit from ICS but indicating factors include:

Procedure related factors

- Anticipated blood loss is > 1000ml or > 20% circulatory volume
- Procedures where >10% of patients require an allogeneic transfusion
- The mean transfusion for the procedure exceeds one unit of allogeneic red cells

Patient related factors

- Refusal of allogeneic blood
- Difficulty in obtaining compatible allogeneic blood
- Patients with a low haemoglobin
- Increased risk of bleeding

Each patient presenting for surgery will have a greater or lesser risk of bleeding and consequently a varying threshold for requiring a transfusion. Any decision to use ICS should therefore, be made on an individual patient basis.

CAN ICS BE UTILISED WITH PULSE LAVAGE IN ORTHOPAEDICS?

Yes, although we would suggest that each organisation checks with their supplier to ensure that the saline used with these large irrigation systems is intravenous grade saline.

DOES IT MATTER WHETHER PLASTIC OR METAL SUCKERS ARE USED IN ICS?

The material and shape of the sucker is important, there is a sharper angle on metal suckers and this can destroy the red cells, it is for this reason that plastic Yankauer suckers are recommended.

CAN SUMP SUCKERS BE USED WITH ICS?

Yes, ICS can be used with sump suckers e.g. Pooles (Pennine Healthcare) for deep operating site suction where there is heavy bleeding.

WHAT FILTERS SHOULD BE USED FOR RE-INFUSING ICS BLOOD?

The American Association of Blood Banks (AABB) guidelines state that all salvaged blood should be filtered to remove potentially harmful contaminants.

A standard blood administration set incorporates a 200µm screen filter. For the majority of users this would appear sufficient. A blood administration set should therefore, be used as a minimum for the reinfusion of ICS blood where there is no indication for the use of a more specialised filter. Some users opt for a 40µm microaggregate blood filter which provides a finer screen.

When ICS is used for obstetrics and malignancy the use of a leucodepletion filter*, such as the Pall LeukoGuard RS Filter, is advocated to reduce amniotic fluid and malignant cell contamination. (Although it should be noted that the filters have not been validated by the companies for these uses).

This filter has a slower flow rate and may not be ideal in massive haemorrhage situations when the blood needs to be reinfused quickly. They also have a maximum capacity of around 450mls per filter and may therefore need to be replaced during the reinfusion of large volumes of salvaged blood. This filter however, is the only one that has been shown to effectively remove contaminants specific to these settings. Further research may give us more options in the future.

A leucodepletion filter may also reduce bacterial contamination, however, there has been little work done in this area.

* There have been reports of patients becoming hypotensive when receiving ICS blood through leucocyte depletion filters. While this appears to be a rare side effect, all such incidents should be reported to the Serious Hazards of Transfusion (SHOT) Scheme.

The use of microaggregate/leucoreduction filters in the cardiac setting, where the reinfusion of activated neutrophils may exacerbate reperfusion injury, may be of benefit, however, the evidence for this is not that robust.

In ICS in Orthopaedic surgery, there is a theoretical risk that fat globules released from the bone marrow may be reinfused, resulting in Fat Embolism Syndrome. A lipid depleting filter can be used if this is of concern to clinicians, but again there is little evidence either way. It is however, important to not agitate the ICS reinfusion bag prior to reinfusion. Not agitating the bag will allow fat to form a layer on top of the blood, if visible fat is present, the last few millimeters of blood can then be discarded to further reduce the risks.

For further information on filters for ICS see the UK Cell Salvage Action Group Filters Factsheet.

<http://www.transfusionguidelines.org.uk/transfusion-practice/uk-cell-salvage-action-group/technical-factsheets-and-frequently-asked-questions-faq>

CAN TRANEXAMIC ACID BE USED WITH ICS?

Yes. In general, any IV grade medication can be used with cell salvage. Antifibrinolytics such as Tranexamic Acid will not interfere with the ICS process, with the majority of the medication being washed out of the final red cell product.

DOES ICS REQUIRE A DEDICATED OPERATOR?

Each Organisation must determine how ICS will be run and should define this within the Organisation's ICS Policy.

There is no requirement for a dedicated operator for ICS i.e. an individual whose sole responsibility during the case is running the ICS machine. However, a single individual should be responsible for the ICS machine even if they are multitasking e.g. they are assisting the anaesthetist. Other staff should not take over running the machine or carry out any task with the ICS machine unless the individual responsible for running the ICS machine has asked them to or a formal handover has been completed during staff changeovers.

Hospitals who use ICS infrequently may decide it is appropriate to have an operator dedicated to running the ICS machine as they are less accustomed to carrying out the procedure.

A dedicated operator may also be appropriate in emergency cases due to the frequency with which the operator will need to attend to the machine e.g. to replace empty saline bags.

IS ICS CONSIDERED SAFE TO USE IN HIV / HEPATITIS C POSITIVE PATIENTS?

- There is no level A-C evidence on this topic. However, level D evidence from the UK, reports use of ICS in HIV positive patients with no adverse effects.
- Risks can be categorised into risks to patients with known blood-borne viruses (BBV) and risk to health care workers (HCW) treating patients with known BBV.

The patient risks of using ICS in a patient with known BBV are the same as the risks of cell salvage in patients without BBV.

The risk to HCWs is transmission of a BBV through percutaneous exposure to infected blood by "sharps" or "needlestick" injury. The risk of transmission to a HCW has been shown to be around:

- 1 in 3 when the patient is Hepatitis B surface antigen e positive
- 1 in 30 when the patient is Hepatitis C positive
- 1 in 300 when the patient is HIV positive

The additional risks to HCW from cell salvage include:

- Spillage of infected patient blood
- Skin puncture by bony spicules contaminated with infected blood during swab-washing in orthopaedic surgery

Precautions against exposure to BBV infection:

1. HCWs should, at all times, carry out clinical procedures in accordance with the written infection control policy produced by their employing authority.
2. HCW teams should discuss hazards involved in their current working methods and ways to reduce these. Pertinent to ICS, this includes risks involved during swab-washing in orthopaedic surgery and disposal of the ICS disposable. All blood should be regarded as potentially infectious.
3. In patients with known BBV, swab washing in orthopaedic surgery presents an increased risk of percutaneous transmission of infection to scrub staff.
4. Gloves cannot prevent percutaneous injury but may reduce the risk of acquiring a BBV infection.
5. The ICS disposable should be dismantled and disposed of according to manufacturer's instructions. It should be treated as "clinical waste" in accordance with the Health and Safety Commission's Health Services Advisory Committee's document, "Safe Disposal of Clinical Waste".

Recommendations:

1. The local infection control policy should be adhered to.
2. Universal precautions should be used when handling blood.
3. Care should be taken by the scrub nurse when swab-washing is employed especially in orthopaedic surgery where there is a risk of contamination by bony spicules mixed in with the swabs/saline.
4. In the event of spillage, the ICS should be temporarily abandoned and the contaminated blood spillage dealt with safely, according to local

infection control guidelines. Following this, the ICS machine should be completely decontaminated, according to local protocols. The risk, in the event of spillage, is to the HCWs. Adherence to local protocols should protect HCWs from contamination. There is no risk to future patients receiving ICS if the ICS machine is completely decontaminated and a disposable harness is used correctly to process and administer salvaged blood.

Ref: UK Health Departments Guidance for Clinical Health Care Workers: Protection Against Infection with Blood-borne Viruses Recommendations of the Expert Advisory Group on AIDS and the Advisory Group on Hepatitis

<http://www.hse.gov.uk/biosafety/blood-borne-viruses/health-care.htm>

IF A FULL CELL SALVAGE KIT FOR ICS IS ESTABLISHED FOR COLLECTING AND INFUSING AND IT HAS BEEN RUNNING FOR MORE THAN SIX HOURS, SHOULD THE DISPOSABLES BE CHANGED?

There is no national guidance or evidence with which to definitively answer this question so our advice is based on expert opinion. The UKCSAG recommend that intraoperatively salvaged blood is reinfused within four hours of the completion of processing (ref 1) and recommend that it is best practice to begin processing blood as soon as the minimum volume necessary to enable processing has been collected. This volume will vary depending on the machine type in use and bowl size where the system uses a bowl for processing.

This does not however, imply that the collection and processing disposables need to be changed after four hours. Cardiopulmonary bypass circuits do not get changed during a long case unless there is a fault or problem. Similarly, blood administration sets can be used for up to twelve hours (ref 2) even though each unit of blood must be given in under four hours (ref 3).

As with all questions of this nature, there needs to be a balance of risks and benefits. There are obvious risks associated with changing the disposables during the procedure, including the potential for contamination. The risk of bacterial proliferation in the collected blood may increase after several hours but there is little evidence that this is clinically significant in ICS, especially as most patients will be given perioperative antibiotic prophylaxis. Also, with washed systems, there is an opportunity to reduce the level of bacterial contamination (ref -4). If it is thought the ICS set may have been contaminated (with contraindicated substances aspirated from the surgical field or in any other way), then it may be appropriate to begin again with a fresh set.

Ultimate responsibility for the procedure rests with the clinician who is administering the blood and cases need to be assessed on an individual basis.

References:

1. American Association of Blood Banks (AABB) (2005) Standards for Perioperative Autologous Blood Collection and Administration (2nd Edition)
2. Loveday et al. (2014) epic 3: National Evidence-Based Guidelines for Preventing Healthcare-Associated Infections in NHS Hospitals in England, Journal of Hospital Infection (Electronic), 86S1, p. S50 Available:
http://www.his.org.uk/files/3113/8693/4808/epic3_National_Evidence-Based_Guidelines_for_Preventing_HCAI_in_NHSE.pdf Last accessed 16 Jan 2015
3. Norfolk, D. (ed.) (2013) Handbook of Transfusion Medicine, 5th edition, Norwich, TSO. Available:
<http://www.transfusionguidelines.org.uk/> Last accessed 16 Jan 2015
4. Boudreaux JP, Bornside GH, Cohn I Jr. Emergency autotransfusion: partial cleansing of bacteria-laden blood by cell washing. J Trauma 1983; 23: 31-5

HOW LONG CAN AN UNPRIMED ICS KIT REMAIN ATTACHED TO THE MACHINE, UNUSED BEFORE DISPOSING OF THE CONSUMABLES IF NOT USED?

There is no definitive guidance for this but, when reviewing what happens with apheresis machines, it would appear that unprimed disposables can be used for up to 24 hours providing they have not been primed. Once primed, they should be used within 8 hours or disposed of.

Tubing should not be left occluded by roller clamps or the machine valves during this time, as there is a risk that it could become deformed. This could potentially lead to damage of the salvaged red blood cells when cell salvage commences.

DOES A PATIENT HAVE TO CONSENT TO HAVING CELL SALVAGE?

If a patient is likely to have cell salvage as part of their operation the process should be discussed with them pre-operatively whenever possible and documented accordingly. A patient information leaflet from the UK Cell Salvage Action Group to support this is available to download from:
<http://www.transfusionguidelines.org.uk/transfusion-practice/uk-cell-salvage-action-group/patient-factsheet>

If it is not possible to discuss the process with the patient pre-operatively (e.g. in an emergency procedure), it is good practice to inform the patient retrospectively.

Autologous transfusion may be accepted for use by Jehovah Witnesses, but must be discussed pre-operatively with the individual and their decision documented accordingly. If the Jehovah's Witness patient does

not already have an advance decision document or another document indicating treatments that are acceptable, this should also be discussed.

Cell salvage itself will not prevent patients from donating blood once they have fully recovered from their operation, but associated perioperative treatments that necessitate deferral as a blood donor should be discussed with the patient. This includes transfusion of allogeneic blood.

The information contained in this Frequently Asked Questions document has been sourced from members of the UK Cell Salvage Action Group (UKCSAG) and is generally agreed to be good practice. However UKCSAG do not accept any legal responsibility for errors or omissions.