# Section 7
## Indications and Contraindications

### Aim

- To highlight the surgical areas where Intraoperative Cell Salvage (ICS) is indicated or **may** be contraindicated

### Learning Outcomes

- To identify the indications for ICS
- To identify the relative contraindications for ICS
- To outline when the risks/benefits of using/not using ICS change

### Introduction

The routine use of ICS is recommended in many surgical procedures providing there are no local factors which may make its use inappropriate e.g. lack of competent staff. There is evidence from randomised controlled trials (RCT) and observational reports of decreases in allogeneic (donor) blood transfusion when ICS has been used.

The decision to collect blood is often based on a number of factors including:

- The anticipated blood loss for a particular surgical procedure
- Patient factors including:
  - Risk factors for bleeding
  - A low preoperative haemoglobin
  - Religious or other objections to receiving allogeneic (donor) blood

These factors are discussed in more detail in this section.

Each organisation should have a policy in place for ICS which includes the indications and contraindications for use.

A generic policy is available on the Department of Health Better Blood Transfusion Toolkit at *www.transfusionguidelines.org.uk*

### 7.1 Indications and Patient Selection

- ICS systems may be used in elective and/or emergency surgical procedures where the surgical field is not contaminated by faecal or infective matter and where no other contraindications exist (see 7.2).
- Patient selection for ICS is at the discretion of the surgeon and anaesthetist caring for the patient.

- Providing that none of the contraindications listed in Section 7.2 exist, patients to be considered for ICS include:
  - Adult and paediatric patients undergoing elective or emergency surgical procedures, where the anticipated blood loss is greater than 20% of the patient's estimated blood volume. Areas where there seems little debate that ICS can be employed are listed below (this is not an exhaustive list).
    - Total knee replacement (if no tourniquet is used)
    - Revision total hip replacement
    - Total hip replacement
    - Spinal surgery
    - Abdominal aortic aneurysm surgery
    - Traumatic liver or spleen injury not associated with perforated bowel
    - Thoracic aneurysm surgery
    - Cardiac surgery
    - Benign urological surgery
  - Adult and paediatric patients undergoing elective or emergency surgical procedures who have risk factors for bleeding or low preoperative haemoglobin levels.
  - Patients who have rare blood groups or multiple antibodies for whom it may be difficult to obtain allogeneic (donor) blood.
  - Patients who, for moral, religious or other reasons, are unwilling to receive allogeneic (donor) blood and **have given their consent** to receiving autologous blood collected using ICS (all such decisions should be documented). Reference should be made to the patient's Advance Medical Directive where one exists.
- If ICS is to be used for patients who have rare blood groups/multiple antibodies or who have moral, religious or other objections to receiving allogeneic (donor) blood, and the surgical procedure is associated with any of the contraindications as listed below, the potential risks and hazards should be discussed with the patient and their agreement to undergo ICS documented.

## 7.2 Contraindications, Warnings and Cautions

The risk/benefit ratio of ICS should be assessed for each individual patient by the surgeon and anaesthetist responsible for the patient's care.

### Contraindications

ICS should not be used in the following situations:

- Bowel contents in the surgical field (this is discussed in more detail later – see 7.3)
- Heparin induced thrombocytopenia if heparin is the only available anticoagulant for ICS (a citrate anticoagulant solution may be used instead)

## Warnings

- ICS should be temporarily discontinued when substances not licensed for intravenous (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 copious IV normal saline (0.9% NaCl) before resuming ICS.

  Examples of non-IV materials that should not be aspirated into the ICS system include:

  – Antibiotics not licensed for IV use

  – Iodine

  – Topical clotting agents

  – Orthopaedic cement

  A list of potential contaminants and their associated problems can be found in the UK Cell Salvage Action Group document "Technical Factsheet 9 – Contraindications to ICS"[1].

- The use of ICS in the presence of **infection** may result in bacterial contamination of the salvaged blood. The aspiration of blood from an infected site should be avoided and antibiotics should be given as appropriate.
- **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.
- There are concerns relating to the use of ICS in patients with **sickle cell disease**. The use of ICS in patients with abnormal red cell disorders should be made on a clinical, individual patient basis.

### Cautions

- The use of Hartmann's Solution will inhibit the action of citrate based anticoagulants (e.g. ACD) if used as an irrigant or wash solution.
- Air will be present in the primary reinfusion bag when it is still connected to the cell saver or when it has been disconnected but air has not been evacuated. Where possible, all air should be evacuated from the primary reinfusion bag prior to reinfusion. Manufacturers advise NOT to use a pressure cuff as there is a risk of air embolus and some devices may also detect a back pressure if the reinfusion line is open.
- Manual mode – It is recommended that ICS devices are not run in manual mode as this may lead to reduced quality, insufficient washing of the final red blood cell product and the possible reinfusion of potentially harmful contaminants e.g. heparin. Machines should be run in automatic mode and manual mode should only be used when the benefits of doing so outweigh the risks, e.g. emergency situations where the need to reinfuse the red cells quickly outweighs the risks associated with running the machine in manual mode.

## 7.3 Areas for Further Consideration

The remainder of this section examines the use of ICS in procedures where there is the potential for contamination from within the surgical field.


**The decision to use blood that is potentially contaminated with bacteria, amniotic fluid or malignant cells should be made by the clinicians caring for the patient, taking into account the latest evidence and considering the risk and benefits for the individual patient.**

### Bowel Contamination

As outlined earlier, the use of ICS in the presence of bowel contents is contraindicated unless there is catastrophic haemorrhage.

If deemed clinically necessary the following practical tips may help:

- Initial evacuation of the soiled abdominal contents
- Additional washing (increasing the volume of IV normal saline (0.9% NaCl) the machine uses to wash the salvaged blood)
- Ensure use of broad spectrum antibiotics

It is unlikely that bowel contamination in such traumatised individuals will lead to problems in decision making about the use of ICS, but hopefully the points raised can enable all concerned to make informed management choices.

## Malignancy

The use of ICS in patients undergoing surgery for malignant disease is not recommended by the manufacturers of ICS devices. This is due to concern about the possibility of malignant cells being reinfused and giving rise to metastases. However, there are now a number of published reports outlining the use of ICS in cancer surgery without obviously leading to early metastasis, some hospitals now use ICS routinely during surgery for malignant disease. Aspiration of blood from around the tumour site should be avoided to minimise contamination of salvaged blood with malignant cells. The salvaged blood should be reinfused through a leucodepletion filter to minimise the reinfusion of any malignant cells which may have been aspirated into the collection reservoir.

### *Theoretical context*

If there is concern that circulating malignant cells may lead to systemic spread then it is inadvisable to reinfuse any malignant cells. If the cancer cells are present in the final ICS blood for reinfusion, they must have been contaminating the collected blood prior to processing. These cells can only be present in the blood if:

- The tumour margins had been compromised at the time of resection making the whole operation palliative (as the likelihood of local recurrence would be high).
- The cancer cells were already blood borne at the time of surgery as resection of blood vessels distant from the tumour margins led to spillage of cancer cells directly from the circulating systemic blood.
- Cancer cells had already spread to the lymphatic system.

### *Practical Issues*

- The use of a Leukoguard® RS filter (Pall Medical), a leucodepletion filter, is likely to lead to a 99.99% reduction in the number of nucleated (including malignant) cells present in the ICS blood for reinfusion.
- In large cancer centres it may be possible to safely organise irradiation of the collected blood. This would destroy all viable cancer cells within the ICS blood for reinfusion (see the 'Caution Box' on the next page). It has been recommended that a dose of 50Gy be used.[2]


Under European legislation[3], the irradiation of red cells requires hospitals to register as a Blood Establishment and the irradiated ICS blood product would be subject to the requirements of the Medicines and Healthcare products Regulatory Agency (MHRA).

In addition, if the red cells are removed from the patients side (i.e. to another area of the hospital) to be irradiated, the risk of administration errors (the most frequently reported allogeneic (donor) blood incident) increases.

## Obstetrics

The main concern surrounding the use of ICS during obstetric haemorrhage is the risk of reinfusing fetal contaminants with the theoretical risk of causing amniotic fluid embolus.

ICS is being increasingly used in the UK in obstetrics for women at risk from massive obstetric haemorrhage during caesarean section. In the year 2005-06, 38% of UK maternity units used ICS, and 28% included the use of ICS in their Massive Obstetric Haemorrhage (MOH) protocol. Early theoretical concerns over amniotic fluid embolism have not been borne out in clinical practice, and 80% of maternity units identified lack of training, rather than safety concerns as the barrier to more frequent use of ICS.

The use of ICS in obstetrics has been endorsed by:

- Confidential Enquiry into Maternal and Child Health (CEMACH)
- Joint Association of Anaesthetists of Great Britain and Ireland/Obstetric Anaesthetists Association (AAGBI/OAA) Guidelines
- National Institute for Health and Clinical Excellence (NICE)

It is strongly recommended that any health care professional involved with obstetric ICS is familiar with all these guidelines.

### *Patient Selection and Preparation*

Wherever possible, the advantages and risks of ICS and allogeneic (donor) blood transfusion should be discussed with the woman prior to undergoing an obstetric surgical procedure. The NICE guidance "Intraoperative 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 should discuss the advantages and risks of ICS with the woman, and document clearly her agreement to undergo the procedure. Such detailed consent may not be practicable in an emergency, as for allogeneic (donor) transfusion.

### *Indications for ICS in Obstetrics*

Case selection for ICS is at the discretion of the obstetrician and anaesthetist caring for the woman. The type of obstetric cases that should be considered for selection include:

- Emergency situations:
  - Ruptured ectopic pregnancy
  - Intra-partum haemorrhage requiring surgical intervention
  - Post-partum haemorrhage requiring surgical intervention
- Elective situations:
  - Patients with an anticipated blood loss of >1,000mls e.g. placenta praevia with placenta accrete/increta or percreta, large uterine fibroids, and other predictable causes of MOH.
- Other situations:
  - Women who, for religious or other reasons refuse allogeneic blood *and have consented* to the use of ICS in elective or emergency bleeding situations or in the presence of significant anaemia.

### *Practical Measures in Obstetric ICS*

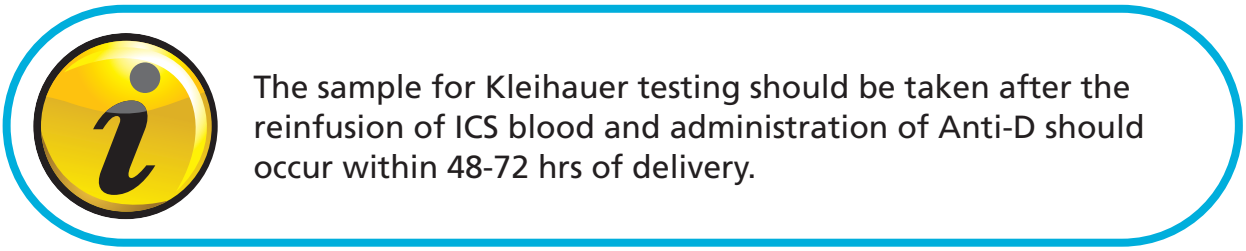
- Amniotic fluid and use of leucodepletion filter – Amniotic fluid should ideally not be aspirated into the ICS collection reservoir. A separate suction can be used to aspirate amniotic fluid prior to starting cell salvage. This recommendation will reduce the initial contamination, but it should be noted that the *in vitro* evidence suggests that the ICS process can effectively remove plasma phase elements of amniotic fluid (i.e. those less dense than red blood cells) whatever the initial load. Therefore, in life-threatening haemorrhage, a clinical decision to use ICS from the beginning of the procedure could be carefully considered.

  After processing, a leucoreduction filter (LeukoGuard® RS filter (Pall Medical)) should be used to reinfuse ICS blood. This is the only filter proved to effectively eliminate residual particulate elements of amniotic fluid (i.e. those not removed by the washing process alone). In life-threatening haemorrhage a clinical decision to reinfuse ICS blood without this filter can be considered.

- Rh Immunisation and Kleihauer testing – In any pregnancy involving an Rh negative mother and an Rh positive foetus there is a risk of Rh immunisation if the maternal circulation is exposed to fetal red cells. If untreated, antibodies against the fetal red cells may form and these can cause haemolytic disease of the newborn in subsequent pregnancies. Consequently all Rh negative mothers of Rh positive babies will have a Kleihauer performed in the immediate post partum period.

  Kleihauer testing is required to establish the amount of fetal red cell exposure and ensures that the mother receives an appropriate dose of Anti-D immunoglobulin (usually 125iu/ml of fetal blood). Depending on the results of the Kleihauer, a minimum of 500iu Anti-D will be offered in the post partum period to Rh negative mothers with Rh positive babies.

The same protocol should be followed for Rh negative mothers who have undergone reinfusion of ICS blood. The presence of fetal red cells in the ICS blood is likely because the ICS device cannot distinguish fetal from maternal red cells. The dose of Anti-D will be determined by the result of the Kleihauer test.



**The sample for Kleihauer testing should be taken after the reinfusion of ICS blood and administration of Anti-D should occur within 48-72 hrs of delivery.**

## Key Points

- ICS is of proven benefit in certain elective and emergency surgical procedures where the predicted blood loss is in excess of 20% of the patient's estimated blood volume.
- ICS should only be used in malignancy when the benefits outweigh the risks.
- ICS should be available for obstetric cases where there is the potential for massive haemorrhage.

## References


1. UK Cell Salvage Action Group (2008) Technical Factsheet 9 "Contraindications to ICS". *Better Blood Transfusion Toolkit* *www.transfusionguidelines.org.uk*
2. Hansen E., Bechmann V. and Altmeppen J. (2002) Intraoperative blood salvage in oncologic surgery. Answers to current questions. *Infus Therap Transfus Med; 29: 138-41*
3. Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 (2003) Setting Standards of Quality and Safety for the Collection, Testing, Processing, Storage and Distribution of Human Blood and Blood Components and Amending Directive 2001/83/EC. *Official Journal of the European Union,* V46: L33/30-40 *http://eur-lex.europa.eu/JOIndex.do*

## Further reading

### UK Cell Action Group Publications.

The following publications are available to download at: *www.transfusionguidelines.org.uk*

- Policy for the provision of Intraoperative Cell Salvage
- Technical Factsheets: 8 – Intraoperative Cell Salvage in Obstetrics
  9 – Contraindications to ICS

### Randomised Controlled Trials/Observational Reports


- Bridgens J.P., Evans C.R., Dobson P.M. and Hamer A.J. (2007) Intraoperative red blood-cell salvage in revision hip surgery. A case-matched study. *J Bone Joint Surg;* 89(2):270-5
- Goel P., Pannu H., Mohan D. and Arora R. (2007) Efficacy of cell saver in reducing homologous blood transfusions during OPCAB surgery: a prospective randomized trial *Transfus Med;* 17(4):285-9
- Healy C.F., Doyle M., Egan B., Hendrick B., O'Malley M.K. and O'Donohoe M.K. (2007) Transfusion requirements and outcomes in patients undergoing abdominal aortic surgery using intra-operative cell salvage. *Ir J Med Sci;* 176(1):33-6


### Malignancy


- National Institute For Health & Clinical Excellence (NICE) (2008) Intraoperative red blood cell salvage during radical prostatectomy or radical cystectomy – Guidance *http://www.nice.org.uk/nicemedia/pdf/IPG258Guidance.pdf*


### Obstetrics


- Catling S.J., Williams S. and Fielding A.M. (1999) 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. *Int J Obs Anesth;* 8; 79-84
- Hall M. (2000 – 2002) Why Mothers Die – Report on confidential enquiries into maternal deaths in the United Kingdom. Chapter 4 (Haemorrhage). *Confidential Enquiry into Maternal and Child Health (CEMACH);* p91-92
- Obstetric Anaesthetists Association (OAA)/Joint Association of Anaesthetists of Great Britain and Ireland (AAGBI) (2005) Guidelines for Obstetric Anaesthetic Services revised Edition; p25
- Obstetric Anaesthetists Association (OAA) (2007) Survey of UK Maternity Units
- National Institute For Health & Clinical Excellence (NICE) (2005) Intraoperative Blood Cell Salvage in Obstetrics – Guidance *http://www.nice.org.uk/nicemedia/pdf/ip/IPG144guidance.pdf*
- Waters J.H. Biscotti C. Potter P.S. Phillipson E. (2000) Amniotic fluid removal during cell salvage in the cesarean section patient. *Anesthesiology;* 92; 1531-1536


### Other


- American Association of Blood Banks – Standards for Perioperative Autologous Blood Collection and Administration 3rd Edition (ISBN-978-1-56395-248-7)