2 INTRAOPERATIVE MANAGEMENT

2.3 INTRA-OPERATIVE CELL SALVAGE

2.3 INTRA-OPERATIVE CELL SALVAGE (ICS)

1. PURPOSE
To ensure that ICS is used safely and appropriately thus avoiding the risks of unnecessary allogeneic transfusion in our patients. Utilising appropriate alternatives to blood transfusion is cost-effective and complies with state-wide patient blood management (PBM) recommendations.

The collection and re-infusion of autologous blood provides an important contribution to reducing the demand for allogeneic blood. However, it is only one aspect of a strategic approach to safe and appropriate transfusion practice.

To enable clinical staff to:

- Utilise ICS in a safe and effective manner
- Ensure high quality autologous blood
- Ensuring patients who receive autologous blood do so appropriately and safely in line with the Australian Commission on Safety and Quality in Health Care requirements 2012 (standard 7)
- Safely identify suitable patients undergoing elective and/or emergency surgical procedures where ICS could be used

To maximise patient safety during ICS by:

- Promoting one of the pillars of PBM principles through management of the patients own blood.
- Assisting clinical staff in the identification of patients and procedures considered suitable for ICS and outlining the indications and contraindications.
- Assisting clinical staff to provide appropriate advice on options for treatment particularly where patients are anxious about risks associated with donor blood
- Providing clear written information about the risks and benefits of autologous transfusions from blood salvaged intraoperatively
- Assisting clinical staff to minimise avoidable/potential risks of autologous transfusions from blood salvaged intra-operatively
- Adhering to quality assurance requirements and delivering upon agreed quality indicators

2. PROCEDURE

ROLES AND RESPONSIBILITIES
KEMH have defined clear roles and responsibilities to ensure the effective delivery of the ICS programme and includes:

The Cell Salvage Committee is responsible for:

- providing a multidisciplinary reference/governance group to oversee and direct the ICS programme at KEMH
- providing a summary report of ICS activity to the Chair of the Hospital Transfusion Committee

The Clinical Lead is responsible for:

- the overall ICS programme within KEMH
- ensuring that agreed procedures and protocols are adhered to
informing clinical staff about the benefits of the autologous programme identifying clinical situations where cell salvage can be used
• advising on the use of ICS in special circumstances
• developing a safe out of hours ICS service
• liaising with the Operational Manager to produce to provide a summary report to the Cell Salvage Committee

The current clinical lead is: Dr Roger Browning, Dept Anaesthesia and Pain Medicine

The Operational Manager is responsible for:
• being involved in the purchase of equipment and service contracts
• co-ordinating the ICS service
• liaising with the Clinical Lead to produce and implement protocols and guidelines
• delivering and recording of training and competency assessment
• arranging for cell salvage to be available at the Clinician’s request
• ensuring audit is complete
• ensuring quality controls are performed and documented
• liaising with the Clinical Lead to produce to provide a summary report to the Cell Salvage Committee

The current operational manager is: Linda Long, Dept Anaesthesia and Pain Medicine

Prescribing Responsibilities
Salvaged blood for reinfusion should be prescribed by the responsible clinician on the Intravenous Fluid and Additive Order Sheet (MR740).

Labelling Responsibilities
The reinfusion bag should be labelled as soon as is reasonably practical (i.e. When the patient is in theatre or as soon as the processing set is loaded if a “collect only” system has been used initially.) The patient details should be handwritten and include the following:
• full name
• date of birth
• hospital number
• collection start date and time
• expiry date and time
• the wording “autologous blood”

Addressograph labels must not be used because of the known associated risks.5 To avoid errors in patient identification, an autologous transfusion label should be completed at the patients’ side, when the patient has arrived in theatre i.e. the reinfusion bag should not be pre-labelled prior to the patients’ arrival in theatre or labelled after the patient has left theatre. The patient details should be taken from their identification band and not from any clinical records or charts that may be present in the operating theatre. All fields on the label should be completed in full.

Individual Responsibilities
Individual staff should 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. Individual staff should ensure they are adequately trained and competent in the use of ICS in each of the specialities they work in.

Documentation Responsibilities
Staff should ensure that documentation (including all appropriate labelling) accurately reflects the ICS process. The documentation record should include:

1. The collection and reinfusion of salvaged blood should be accurately documented on the appropriate ICS audit form
2. The autologous transfusion label should be completed and attached to the reinfusion bag.

3. At the time of reinfusion of the salvaged blood, the peel out section on the autologous transfusion label should be completed and attached on the Blood Transfusion record form MR735 in the patients’ clinical records - KEMH Transfusion Medicine Protocols Section 6.1 Bedside Procedure and 15.1 Intraoperative Cell Salvage.

4. Appropriate labelling of heparin saline anticoagulant at the start of the procedure.

5. Bedside pre-transfusion checks and patients' observations should be performed and recorded during autologous blood reinfusion in the same way as transfusion of allogeneic blood - in accordance with Organisations Blood Transfusion Policy - KEMH Transfusion Medicine Protocols Section 6.1 Bedside Procedure, 8.1 Care and Monitoring of Transfused Patients and 15.1 Intraoperative Cell Salvage. Additional observations are at the discretion of the clinical staff based on an individual patient assessment.

6. Adverse incidents and adverse events should be documented/ reported using KEMH clinical incident (AIMS) form. These will be monitored by the Cell Salvage Committee and a summary provided to the Hospital Transfusion Committee on a 3 monthly basis (see Section 13).

- KEMH should ensure that adequate records are retained in all cases where ICS is used

**6 Training**

- The operational manager will supervise training and assess competency of individual anaesthetic technicians to perform ICS. They will maintain training records documenting staff who have received training in the use of the ICS device. They will provide an annual training summary to the ICS Committee and thereby minuted at the Hospital Transfusion Committee.

- Training of anaesthetic technicians to perform ICS at KEMH entails:
  - Initial completion of a formal external training course run by Medtel, which includes written theory, a practical 1 or 2 day workshop and a final formal written test.
  - Completion of a KEMH condensed ICS booklet
  - Initial direct supervision of clinical practice, set up and save initially and then processing & reinfusion.
  - Independent unsupervised practice is only allowed after this period of directly supervised practice when deemed competent by the operational manager (or other nominated supervising practitioner).
  Once deemed capable of independent practice of ICS, they can go on to complete a formal competency to gain formal recognition and progression up the pay scale.

- This training shall include those specific to the care of Jehovah's Witness patients including preparing the equipment and blood for reinfusion in accordance with the patients' religious beliefs prior to carrying out the procedure.

- It is strongly recommended that once assessed as competent, individuals keep an ongoing log of all the ICS procedures they carry out.

- Update training is recommended under the following circumstances:
  1. Greater than 6 months without practical use of the ICS device
  2. A learning need is identified by an individual member of staff or supervisor
  3. Changes in the product from the manufacturer or a change in the product due to trialling/purchasing new products
4. Changes to national and/or local guidelines relating to any aspect of autologous transfusion (including changes to KEMH Blood Transfusion Protocols)

7 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 section 8).

- Patient selection for ICS is at the discretion of the surgeon and anaesthetist caring for the patient. The use of ICS should be discussed with the patient and their consent obtained preoperatively, with the exception of life threatening emergencies where this may not be possible.

- Providing that none of the contraindications listed in section 8 exist, patients to be considered for ICS include:

1. Patients undergoing elective or emergency surgical procedures where the anticipated blood loss is greater than 20% of the patient’s estimated blood volume (e.g. approx 1000ml). This will include:

Obstetrics
- See Appendix 1

Gynaecology
- Major gynaecologic surgery
  e.g. Open myomectomy, ruptured ectopic pregnancy, hysterectomy

Gynaec-oncology
- Major open abdominal procedures

2. Patients undergoing elective or emergency surgical procedures who have risk factors for bleeding or low pre-operative haemoglobin levels

3. Patients who have rare blood groups or multiple antibodies for whom it may be difficult to obtain allogeneic blood

4. Patients who, for moral, religious or other reasons, are unwilling to receive allogeneic blood and have given their consent to receiving autologous blood collected using ICS. This decision should be documented on the KEMH form MR295.99 “Refusal to permit blood transfusion”.

- If the surgical procedure to be carried out for patients in 3 and 4 above is associated with any of the contraindications as listed in section 8, the potential risks and hazards should be discussed with the patients and their agreement to undergo ICS documented in the patients medical records.
8 Contraindications and Warnings

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
- Heparin induced thrombocytopenia when heparin is the anticoagulant of choice (a citrate containing 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 0.9% IV Sodium Chloride 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

- 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 broad spectrum 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

- Amniotic fluid should not be aspirated into the system due to theoretical concerns related to Amniotic Fluid Embolism. See Appendix I for obstetric ICS usage

- Vaginal bleeding See discussion in Appendix I for obstetric ICS usage

- 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 reports in the literature of the use of ICS in cancer surgery (including gynaecological malignancies\textsuperscript{15-16}) without obviously leading to early metastasis\textsuperscript{19}. Some hospitals now use ICS routinely during surgery for malignant disease. The National Institute for Health and Clinical Excellence (UK) now endorse the use of ICS for prostatectomy / cystectomy for urological malignancy.\textsuperscript{18} The decision to use ICS also needs to be balanced against some evidence in the literature for an association between perioperative allogeneic transfusion and worse long term outcomes in some types of cancer surgery.\textsuperscript{17} Aspiration of blood from around the tumour site should be avoided to minimise contamination of salvaged blood with malignant cells and the salvaged blood should be reinfused through a leucocyte reduction filter to minimise the reinfusion of any malignant cells which may have been aspirated into the collection reservoir.

The decision to use ICS in the presence of malignant disease should be made by the Surgeon and Anaesthetist in consultation with the patient and be clearly documented in the patient’s medical records.

Cautions

- The final red cell products re-infused into the patient are depleted of clotting factors; the Surgeon and Anaesthetist must monitor the patients haemostasis; particularly in large volume re-infusion of cell salvaged blood
- 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 re-infuse the red cells quickly outweighs the risks associated with running the machine in manual mode. If the ICS is run in manual mode, it should be clearly documented in the patients medical records and identified on the ICS audit form
- Suction pressure greater than 200 mmHg may cause haemolysis of red cells.

9 Patient Information

- Patients considered likely to have ICS during planned surgery should receive information about ICS before their operation. The process should be discussed with the patient pre-operatively whenever possible. Written information is available to support the discussion. ICS Patient Information Leaflet, Appendix II.
- For patients undergoing emergency surgery, the use of ICS is at the discretion of the surgeon and anaesthetist responsible for the patients care when it cannot be discussed with the patient prior to surgery. Unless the patient has previously identified and documented that ICS
in unacceptable. If ICS is used in an emergency without the patients prior consent, they should be informed by the Surgeon/Anaesthetist post-procedure and before discharge.

10 Conditions for Using ICS

Use of the ICS Equipment

- The ICS system should be used in accordance with the manufacturer’s guidelines

- All procedures should be carried out in accordance with the hospitals ICS guideline and procedural documents

- The ICS system should be routinely run in automatic mode (see Cautions - section 8)

- Contraindications should be considered as identified in Section 8

- All staff who set up or operate ICS systems should receive theoretical and practical training (see section 6).

- Staff should comply with hospital guidelines for infection control, management of sharps and blood transfusion protocols.

- Clean/non-touch/aseptic technique should be used as appropriate, to reduce the risk of infection

Anticoagulant

- The type of anticoagulant used should be documented on the cell salvage record for each case

- Anticoagulant prepared by the operator (e.g. heparin saline) should be labelled clearly to avoid error

Wash Solution and Process

- 0.9% IV Grade Saline should be used as the wash solution

- The minimum wash volume, as outlined in the manufacturers’ 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

- ICS may be set up as a “closed-circuit” system. Blood is aspirated from the surgical field, processed and transferred to a reinfusion bag. The reinfusion bag is simultaneously connected to the patients IV cannula via an appropriate filter (see below). The person administering the reinfusion adjusts the rate at which the red cells are reinfused using a clamp on the administration set and by adjusting 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.

- Alternatively, ICS may be set up without simultaneous connection of the reinfusion bag to the patient (as above). In this case, the reinfusion 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 the “closed-circuit” system
A filter, appropriate to the type of surgery, should be used for reinfusion. In most cases this will be a 200 um filter found in a standard blood administration set. In certain circumstances e.g. obstetrics and malignancy, a leukocyte depletion filter may be indicated.

The reinfusion bag should be kept beside the patient at all times.

The reinfusion bag must not be stored or placed into a refrigerator for later use.

Reinfusion of the salvaged blood should follow standard blood transfusion practice - KEMH Transfusion Medicine Protocols Section 6.1 Bedside Procedure and 15.1 Intraoperative Cell Salvage.

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 to the patient.

**Expiry**

The collection, processing and reinfusion of salvaged blood should be completed within the timeframes as recommended by the manufacturer. This should be in accordance with guidance from the American Association of Blood Banks (AABB) and the Organisations Transfusion Policy (KEMH Transfusion Medicine Protocols 15.1 Intraoperative Cell Salvage).

The AABB Guidelines state the reinfusion times for cell salvaged blood as follows:

- Intraoperative Cell Salvage: 6 hours from initiating collection process.

Any blood that has not been transfused within the timeframe specified in the guidelines should be disposed of in accordance with infection control guidelines for dealing with liquid biohazardous waste. See WNHS Waste Management Policy.

**Disposal of used ICS equipment**

Following use, all ICS disposable equipment should be disposed of in accordance with the WNHS Waste Management Policy. See WNHS Waste Management Policy.

**Cleaning and Disinfection of ICS Machines**

Following use, the cell salvage machine should be cleaned in accordance with the manufacturers’ guidance and the KEMH Infection Control guidelines including procedures for cleaning equipment following high risk cases.

Following contamination of the equipment internally, the equipment should be removed from use, identified as a potential biohazard and referred to the manufacturer.

**Maintenance of Equipment**

All ICS equipment should be serviced regularly in accordance with the manufacturers’ recommendations. A maintenance record and fault log should be kept for each machine. The fault log will be monitored by the Cell Salvage Committee and any concerns and trends escalated to the Hospital Transfusion Committee as required.
11  The Management of Massive Reinfusion

As with the transfusion of large volumes of allogeneic red cells, the return of large volumes of salvaged red blood cells will coincide with the depletion of platelets and clotting factors associated with massive blood loss.

In the event of a massive reinfusion of salvaged red blood cells, it is vital to consider the need for additional appropriate transfusion support e.g. platelets, fresh frozen plasma and cryoprecipitate.

Staff should be alert to a large blood loss into the collection reservoir and report this to the Surgeon and/or Anaesthetist.

12  Quality Assurance

KEMH is committed to maintaining comprehensive quality assurance systems to ensure the provision of a safe, high quality ICS service.

Personnel
KEMH has identified the Clinical Lead for ICS with responsibility for ensuring that a safe and effective ICS service is provided via the Cell Salvage Committee. They responsible for ensuring that quality assurance systems are fully implemented, clearly documented and reported to the Cell Savage Committee. Any quality assurance concerns regarding ICS will be escalated to the Hospital Transfusion Committee.

KEMH should ensure that competent personnel in sufficient numbers are available to provide the ICS service, including for out of hours cases if applicable. Personnel involved in ICS should have undergone appropriate training (see section 6) and competency assessment. KEMH will maintain training records for all staff involved in the ICS process and suggests individuals maintain a case log of all procedures in their own portfolios.

Equipment
All ICS equipment should be appropriately maintained. Maintenance should include both an operator maintenance programme and regular company maintenance visits. Operator maintenance programmes should include the implementation of a documented cleaning and minor checking system and the use of a machine specific fault log. Company maintenance visits must be carried out by an authorized service engineer who will perform a series of documented maintenance controls and fine tune the device for maximum performance.

Product Quality

A Cell Salvage Quality Control form is completed for each patient that ICS is setup for with a copy is retained by the CNS Anaesthetic and Pain Services. If the patient receives a reinfusion of salvaged blood then a copy is also placed in the patient records and a copy is sent to the Transfusion Coordinator in Blood Bank.

The Transfusion Coordinator and Scientist in Charge in TMU will ensure that a coded comment is added to the Transfusion Medicine Computer System to record that the patient has received ICS and the quantity and date and time of infusion. This will enable the TMU staff to highlight the issue should the patient develop an atypical antibody.

All autologous blood that is reinfused has a sample taken directly from the reinfusion bag for formal Hb and Hct testing in the laboratory with the results from this recorded on the data sheet.

Any faults / errors or events are also noted on the datasheet and these will be summarised and reported at the cell salvage and transfusion committee meetings.
13 Adverse Event Reporting

- Technical problems with the ICS should be reported to the manufacturer.

- Adverse Events must be reported to the clinical lead for ICS, the operational manager and the blood bank. The blood bank scientists will then inform the KEMH haematologist and CNC for PBM. Any adverse events relating to the ICS device must be reported in accordance with KEMH Clinical Incident Policy. Any further investigations will be undertaken at the discretion of the haematologist. Other minor safety or quality incidents (caused by human error) should also be reported as these can help demonstrate trends or highlight inadequate manufacturing or supply systems, or inadequate instructions and/or training. Adverse events should be documented in the patients’ clinical records.

Examples of Adverse Events include:

- Severe reaction on reinfusion of salvaged blood
- Non-labelling / incorrect labelling of salvaged blood
- Equipment malfunction
- Communication failure leading to inappropriate reinfusion of the salvaged blood e.g. contamination occurred within the surgical field and this was not communicated to the operator/anaesthetist.

14 Resources

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

15 Implementation and Distribution of the guideline

This policy document will be implemented in all areas which may be involved in ICS. It will be circulated to all members of the Cell Salvage and Transfusion committees, and placed on the intranet so it is available for reference. The procedure document will be reviewed at timely intervals and when new information becomes available.

Guidance on and queries relating to the document should be addressed to the Organisation’s clinical lead for ICS:
Dr Roger Browning
Department Anaesthesia and Pain Medicine
REFERENCES (STANDARDS)


National Standards – 7 Blood and Blood Products
Legislation - Nil
Related Policies - Nil
Other related documents – Acknowledgement: The members of the UK Cell Salvage Action Group for the provision of their template document which has been used as a basis for this guideline
Appendix I

Intraoperative Cell Salvage in Obstetrics

ICS is being increasingly used in the UK in obstetrics for women at risk from post-partum haemorrhage during caesarean section. In the year 2005-2006, 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 the barrier to more use as lack of training rather than safety concerns.

The use of use of ICS in obstetrics has been endorsed by:

- CEMACH
- Joint AAGBI/OAA Guidelines
- NICE

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

PATIENT SELECTION AND PREPARATION

Wherever possible, the advantages and risks of ICS 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 during the pregnancy. It is recommended that patients receive the Intraoperative Cell Salvage Patient Information Leaflet (Appendix II).

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 the obstetrician or anaesthetist should discuss the advantages and risks of ICS 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.

INDICATIONS FOR ICS

Patient selection for ICS is at the discretion of the obstetrician and anaesthetist caring for the patient. The type of obstetric cases that should be considered for selection are (already discussed in section 7) any case with the potential for > 1000ml blood loss for example:

- Elective CS procedures at increased risk of bleeding:
  - e.g. Placenta praevia, accreta, maternal bleeding disorders, history of uterine atony, twins/multiple gestation, fibroid uterus, previous myomectomy.
- Emergency CS procedures:
  - e.g. Abruption, placenta praevia, prolonged or obstructed labour, maternal bleeding disorder, HELLP syndrome, thrombocytopenia.
- Laparotomy for post-partum haemorrhage

Other situations:
- Patients 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 significant anaemia.
• Patients with antibodies or rare blood groups.

Additional measures necessary in obstetric ICS:

Amniotic fluid and use of Leukocyte Depletion Filter

Amniotic fluid should ideally not be aspirated into the ICS collection reservoir, but should be removed by separate suction prior to starting cell salvage. This recommendation will reduce the initial contamination, but it should be noted that the in vitro evidence is that the ICS process can effectively remove plasma phase elements of amniotic fluid whatever the initial load. A randomised trial performed in 2008 compared the use of one suction device only (aspiration of all fluid into the ICS system) versus two suction devices. The trial demonstrated that following the washing and filtering process the level of residual amniotic fluid contamination was no different. A number of institutions in SW UK for 3-4 years have routinely used only one suction and have had no clinical problems (personal communication). Therefore, in life-threatening haemorrhage, a clinical decision to use ICS from the start of the procedure could be carefully considered.

After processing, a Pall RS filter (LeucoGuard® RS Leukocyte Reduction Filter, Pall Biomedical Products Co. East Hills, NY) should be used to reinfuse ICS blood. This is the only filter proved to effectively eliminate residual particulate elements of amniotic fluid. There have been some recent published case reports of hypotension occurring whilst reinfusing salvaged blood through leukodepletion filters, possibly due to bradykinin release. It should be remembered that prior to 2000 this filter was not available, over 250 obstetric cases worldwide safely received ICS blood without a problem prior to the availability of this filter. Therefore, if hypotension occurs or in life-threatening haemorrhage a clinical decision to reinfuse ICS blood without this filter could be carefully considered.

SENSITISATION TO FETAL RED CELLS, RH IMMUNISATION AND KLEIHAUER TESTING

In any pregnancy involving an Rh negative mother and an Rh positive fetus there is a danger of Rh 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 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 125 iu/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. Depending on the test results it may be that higher doses of Anti-D will need to be administered.

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.

The development of antibodies to other antigens can occur and these could pose a risk of fetal anaemia and haemolytic disease of the newborn in future pregnancies. The risk of this occurring and how it compares to the background risk of pregnancy in general is still not fully known. The one published follow up study to date of 70 reinfused women found 1 case of antibody formation. The transfusion of allogeneic blood can also lead to antibody formation and should also be kept in mind during any risk / benefit assessment.

All women who receive reinfused ICS blood at KEMH should be approached to have follow-up testing between 3-6 months post reinfusion.

Cell Salvage of Vaginal Bleeding

Background: There are concerns that cell salvage of vaginal blood may become contaminated by bacteria from the vagina. It is unknown whether after the processing, washing and filtering processes how likely this is to cause clinical adverse consequences. There are reports of vaginal cell salvage being used
successfully. Currently there are no published reports or studies to support or refute its use. A pilot study is underway in the UK at present.

Indications for Use at KEMH: Collection of vaginal blood can be undertaken in any women experiencing vaginal bleeding if they have refused allogeneic red cell transfusion but agreed to cell salvage techniques, (or women with rare antibodies whom compatible blood is not available). Reinfusion of processed blood should probably only occur if the patient experiences severe or potentially life threatening anaemia (e.g. Hb < 50g/L). This is a risk / benefit decision which can only be made by the treating team and patient. Do not collect vaginal blood contaminated with iodine or other topical antiseptic solutions. Only after the vagina has been thoroughly cleansed of these contaminants with copious saline irrigation, can collection can resume.

Suggested Regimen for reinfusion: If reinfusion is performed we recommend using a leucodepletion filter and administering antibiotic prophylaxis (Cephazolin 2g + Metronidazole 500mg).

References

i. Obstetric Anaesthetists Association (OAA) Survey of UK Maternity Units June 2007


ix. Ralph C, Sullivan I and Faulds J. Intraoperative cell salvaged blood as part of a blood conservation strategy in Caesarean section: is fetal red cell contamination important?. British Journal of Anaesthesia 2011; 107(3): 404-8
Appendix II

“Cell Salvage” Patient Information Leaflet

Intra Operative Cell Salvage

This leaflet is to provide you with some general information about cell salvage. We hope that most of your questions will be answered. However, you will need to have a discussion with your treating clinician. If you still have any concerns or need further information please don’t hesitate to discuss this with a member of your health care team.

What is cell salvage?
This is a process where the blood lost during a surgical operation is collected, washed, filtered and returned back to the patient. During the operation blood is removed from the wound and gentle suction. The machine mixes the blood with an anticoagulant to prevent it from clotting. After this it washes the blood and removes any unwanted contaminants and drugs to produce concentrated red cells ready for immediate use. The blood is returned to the patient whilst they are still in theatre through a ‘drop’ into their arm.

Why is it recommended to me?
Some patients having surgery need to receive blood transfusions from volunteer donors to replace blood lost during surgery. Having your own blood back will reduce the need to receive another person’s blood. Although blood transfusion is a safe procedure we often face donor blood shortages and we try and conserve our blood supply whenever possible. Your own blood is unique and because it is a perfect match there should be no ill effects. Some patients may refuse donor blood due to religious or personal reasons, and for these people having their own blood back is often acceptable.

The techniques and equipment for intra operative cell salvage have been in use since the 1970s and the procedure is safe and strict guidelines govern its use. Intra operative cell salvage cannot be used if you have a serious infection, if your surgery involves the bowel or if your surgery involves cancer. In pregnancy it is not used routinely so your surgeon or anaesthetist will be able to tell you if it is right for you.

You need to provide consent for intra operative cell salvage and if you have any objections it simply will not be used.

What if I have other worries about blood transfusion?
You may be afraid of needles, worried about being squeamish at the sight of blood or have had a bad experience related to a previous blood transfusion. Please tell your doctor or nurse about any concerns you may have, no matter how trivial you think they may be.

Other Information
If you are interested in finding out more about blood transfusions and have access to the Internet, you might find the following web site useful: www.transfusion.com.au

Please read this leaflet and discuss it with your partner and family, if you wish, so they can help and support you. There may be information they need to know especially if they are taking care of you following the procedure.

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Government of Western Australia
Department of Health
Do not keep printed versions of guidelines as currency of information cannot be guaranteed. Access the current version from the WNHS website.