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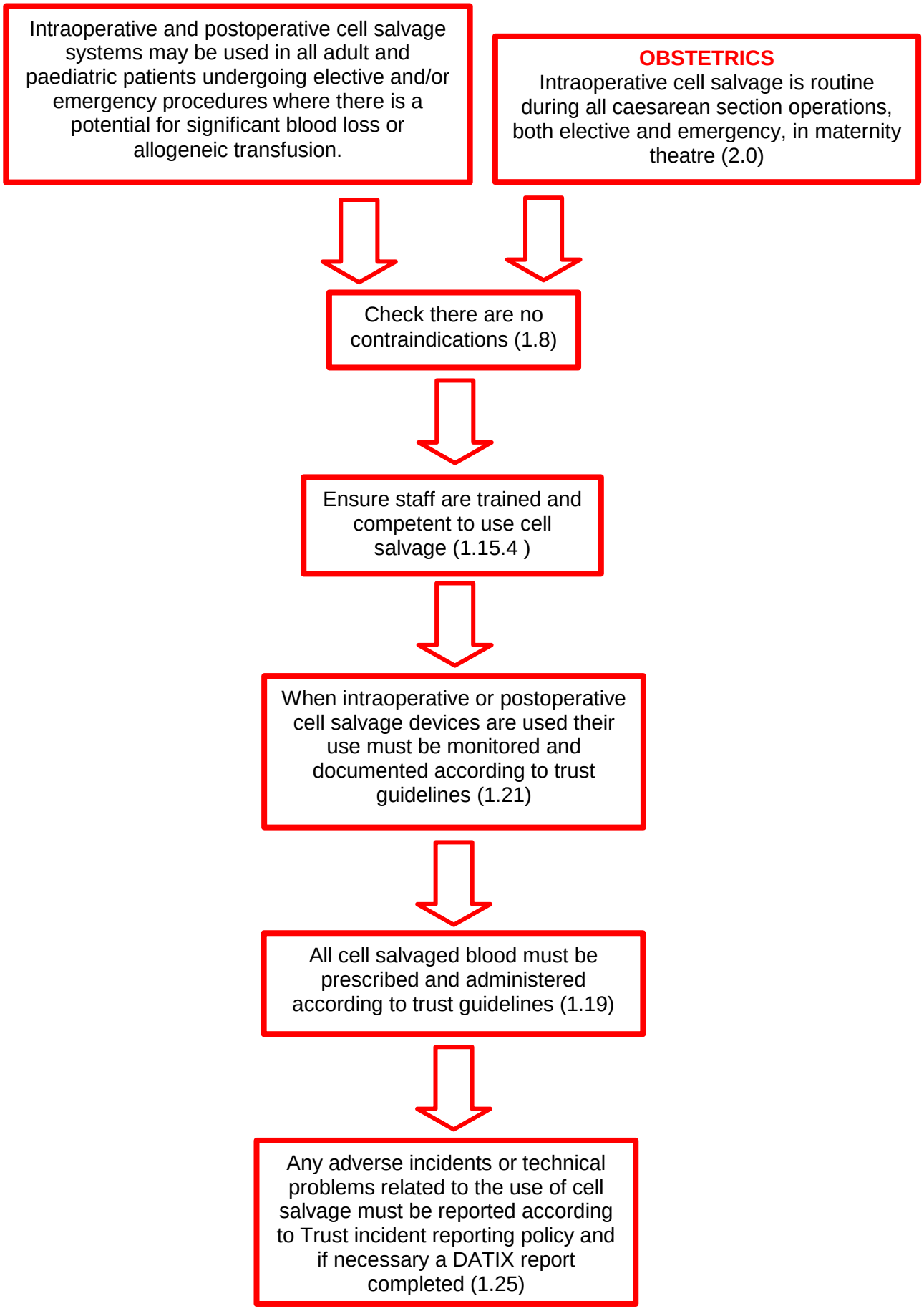
Royal Cornwall Hospitals NHS Trust

Intraoperative Cell Salvage Clinical Guideline

V4.0

December 2020

Intraoperative Cell Salvage Summary



1. Aim/Purpose of this Guideline

The aim of this policy document is to provide information that will allow Clinicians to safely identify suitable patients undergoing elective and/or emergency surgical procedures where cell salvage could be used and in a safe and effective manner.

Data Protection Act 2018 (General Data Protection Regulation – GDPR) Legislation

The Trust has a duty under the DPA18 to ensure that there is a valid legal basis to process personal and sensitive data. The legal basis for processing must be identified and documented before the processing begins. In many cases we may need consent; this must be explicit, informed and documented. We cannot rely on opt out, it must be opt in.

DPA18 is applicable to all staff; this includes those working as contractors and providers of services.

For more information about your obligations under the DPA18 please see the *Information Use Framework Policy* or contact the Information Governance Team rch-tr.infogov@nhs.net

2. The Guidance

2.1. While allogeneic (donated) blood can be lifesaving in heavy haemorrhage situations, it is a limited resource, subject to the threat of future shortages, increasingly expensive and is not without risk. In addition to the risks of transmitting infection and “wrong blood” incidents as reported by the Serious Hazards of Transfusion (SHOT) steering group, allogeneic blood also affects the immune system, which may cause an increase in post-operative infection rates and healing problems.

2.2. The Health Service Circular, “Better Blood Transfusion: Safe and Appropriate Use of Blood” (2007), recommends that in order to make transfusion safer, provide better information for patients relating to transfusion and avoid unnecessary use of blood in clinical practice, blood transfusion must be an integral part of care and clinical governance responsibilities.[1]

2.3. The circular further recommends that effective alternatives to allogeneic blood transfusion be explored, including further progress in the use of autologous blood transfusion techniques such as intraoperative (ICS) and postoperative (PCS) cell salvage.

2.4. ICS is used routinely in some areas of surgical practice. The technique involves the anticoagulation and aspiration of blood lost within the surgical field which is then collected into a reservoir. The anticoagulant solution contains either heparin or citrate to prevent clotting and is delivered via a double lumen line. As blood enters the collection reservoir, it is filtered to remove large particulate debris. If the salvaged blood is of a good enough quality, it can be processed by centrifugal separation to produce red blood cells, which are then washed and suspended in saline ready for reinfusion to the patient. The products (plasma, platelets, anticoagulant, etc) removed during processing are

eliminated into a waste bag. When used by appropriately trained staff, ICS is a safe and cost-effective method of reducing allogeneic transfusion.

2.5. PCS is generally used in orthopaedic surgery and involves whole blood that is lost from the wound post-operatively, and is collected into special autologous wound drains where it is filtered before being reinfused to the patient.

2.6. **Policy statement**

2.6.1. Utilising appropriate alternatives to blood transfusion is cost-effective and complies with clinical governance requirements, NICE and Association of Anaesthetists recommendations.[2,3]

2.6.2. The collection and re-infusion of autologous red blood cells provides an important contribution to reducing the demand for allogeneic blood. However, it is only one aspect of the Trust's Blood Conservation Strategy, which supports safe and appropriate transfusion practice.

2.7. **Objectives**

2.7.1. The objectives of this policy are to provide a rational and practical framework on which to maximise patient safety during cell salvage by:

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

2.7.3. Providing clear written information about the risks and benefits of autologous transfusions produced from salvaged blood.

2.7.4. Assisting clinical staff to minimise avoidable risks of autologous transfusions from salvaged blood.

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

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

2.8. **Contraindications**

2.8.1. The risk benefit ratio of autologous blood must be assessed for each individual patient and ultimately the responsibility lies with the clinicians caring for the patient.

2.8.2. Intra-operative Cell Salvage is not recommended for use in the following situations, however, for patients who have particular indications (see below) these contra-indications are relative and need to be considered in the context of an individual's balance of risk and benefit.

2.8.3. Bowel contents in the surgical field.

2.8.4. Overt infection.

2.8.5. Heparin induced thrombocytopenia when heparin is the anticoagulant of choice (a citrate containing anticoagulant solution may be used instead).

2.8.6. Malignancy. The use of ICS in patients undergoing surgery for malignant disease is controversial, although there is increasing evidence that supports its safe use in cancer surgery, with some hospitals now using it routinely. The decision to use cell salvage in the presence of malignant disease should be made by a surgeon and an anaesthetist familiar with the issues. The use of a leucodepletion filter should be considered for all re-infusions.

2.8.7. Metallosis is a medical condition involving the accumulation and deposition of metal debris in the soft tissues of the body occurring after “metal on metal” joint implants and hip replacements. The risk of using intra-operative cell salvage (ICS) with metallosis in situ during revision surgery should be carefully considered, by the clinical team, on an individual case basis and balanced against the benefits of using ICS. Early contact with the cell salvage co-ordinator will allow discussion to use a finer filter (20 micron) in the collection reservoir or a Leucodepletion Filter for re-infusion.

2.9. **Warnings**

2.9.1. Infusions of local anaesthetic into the surgical wound should not be used concurrently with post-operative cell salvage devices (PCS) due to the potential risk of local infusion toxicity and re-infusing blood contaminated with local anaesthetic.

2.9.2. ICS must be temporarily discontinued when substances not licensed for IV use are used within the surgical field and could potentially be aspirated into the collection reservoir. The standard theatre suction should be used instead to aspirate the surgical field and the wound irrigated with IV 0.9% Sodium Chloride before resuming ICS.

2.9.3. Some examples of non-IV materials that should not be aspirated into the Intra-operative Cell Salvage system include:

- Antibiotics not licensed for IV use
- Iodine
- Topical clotting agents
- Orthopaedic cement
- Hydrogen peroxide
- Chlorhexidine irrigation
- Misoprostal (obstetrics)
- 0.9% sodium chloride for irrigation.

2.9.4. Gastric/pancreatic secretions should not be aspirated into the system as they may cause enzymatic haemolysis and are not reliably removed by the washing procedure

2.9.5. 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.

2.9.6. Diathermy smoke should not be suctioned into the cell salvage suction as harmful chemicals from this smoke can contaminate the collection.

2.10. Using the leucodepletion filter (LDF)

2.10.1. Malignancy

The use of the LeukoGuard® RS Leukocyte removal filter for salvaged blood is recommended in malignancy. The flow rate is 82 (41-112) ml/min and the maximum capacity per filter is around 450ml (for washed intraoperatively salvaged blood). This filter is the only one that has been shown to effectively remove contaminants specific to these settings.

2.10.2. Orthopaedic surgery

2.10.2.1. Fat removal

In orthopaedic surgery there is a theoretical concern that fat globules released from bone marrow may be reinfused, resulting in fat embolism syndrome. To minimise this risk a leucodepletion filter can be used to re- infuse the autologous blood available or, any fat present can be allowed to settle, forming a layer at the top of the blood prior to reinfusion. Avoiding reinfusing the last few millilitres of blood where the layer of fat lies, should reduce the risk of this being returned to the patient.

2.10.2.2. Metallosis

If a fine filter collection reservoir (20 micron) has not been used during “metal on metal” surgery, a LDF should be considered for re-administration of any autologous blood, as this device is thought to remove fine particles including metal, although there is no evidence to confirm its effectiveness.

2.11. Cautions

2.11.1. The use of Hartmann’s solution will inhibit the action of citrate based anticoagulants (e.g. ACD-A).

2.11.2. It is not recommended to reinfuse the red blood cells while the blood bag is still connected to the cell saver device due to the risk of air embolus. Air should be evacuated from the reinfusion bag prior to reinfusion whenever possible. Pressure cuffs must not be used as complete air removal is not guaranteed.

2.12. Indications and patient selection

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

2.13. **Particular indications for cell salvage include**:

- Patients who have rare blood groups or multiple antibodies for whom it may be difficult to cross match allogeneic blood
- Patients who are anaemic
- 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 cell salvage (all such decisions must be documented)

2.13.1. If the surgical procedure to be carried out is likely to result in significant blood loss ICS should be set up for collection. Before re-infusion of any autologous blood, the potential risks and hazards must be discussed with patients and their agreement to receive a re-infusion of autologous blood documented.

2.14. **Patient Information**

2.14.1. Patients likely to lose a significant amount of blood in and after routine surgery should receive information about blood transfusion and cell salvage.

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

2.15. **Conditions for using intra-operative cell salvage (Appendix 4)**

2.15.1. The ICS system should be used in accordance with the manufacturer's guidelines, modified by research when appropriate.

2.15.2. The ICS system should be run in automatic mode.

2.15.3. Contradictions must be considered as listed above.

2.15.4. All staff who set up or operate ICS & PCS systems will have received formal documented competency based training.

2.15.5. Staff must comply with hospital policies for infection control, management of waste including sharps and blood transfusion.

2.15.6. Aseptic technique must be used at all times.

2.16. **Anticoagulant (Appendix 3)**

If the anticoagulant requires preparation (e.g. heparinised saline) this must be labelled clearly to include the quantity and concentration of the drug added, as well as the date and time of preparation and the name and signature of the person preparing it.

2.17. **Wash Solution**

Only 0.9% IV grade saline should be used as the wash solution during ICS. The minimum wash volume as outlined in the manufacturer's guidelines for the size of the centrifuge bowl in use and the type of surgical procedure should be used.

2.18. **Labelling**

2.18.1. All salvaged blood must be labelled by hand (a patient addressograph label is not acceptable) and include the following details:

Patient's Full Name
Date of birth
A unique identifying number e.g. Hospital number
Collection start date and time
Expiry date and time

2.18.2. The re-infusion bag must be labelled as soon as after processing has started as is practicable. It is not acceptable to label the bag when the patient is not in theatre. The patient details must only be taken from the identification band attached to the patient or from a document that has been checked in theatre against the patient's identification band e.g. consent form.

2.19. **Re-infusion (Appendix 5)**

2.19.1. **Prescribing Responsibilities:**
Salvaged blood for reinfusion must be prescribed by a doctor (usually the anaesthetist) on documentation approved by the Trust and on commencement of the re-infusion the prescription must be signed by the administrator. Consent for the re-infusion should be documented in the appropriate section of the patient notes.

2.19.2. A standard blood administration set or a LDF (if indicated) should be used for re-infusion of autologous blood

2.19.3. Rarely ICS is requested to be set up as a "closed-circuit" system (i.e. in continuity); however, due to the risks involved this is a procedure we are unable to support.

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

2.19.5. The reinfusion bag must not be placed into any refrigerator

2.19.6. Currently there are recommendations to use a leucodepletion filter for reinfusion of blood salvaged in the presence of malignancy and some orthopaedic cases. However, the evidence to support these recommendations is poor and it is acceptable for the prescribing clinician to omit the leucodepletion filter after due consideration for other indications (1.10).

2.19.7. Reinfusion of salvaged blood should follow standard blood transfusion practice i.e. using a standard blood giving set to reinfuse red cells as directed in the RCHT Blood Transfusion Policy. The doctor should prescribe salvaged blood for re-infusion in the same manner as allogeneic blood. The patient details on the reinfusion bag must be carefully checked against the details on the identification band attached to the patient before connecting the reinfusion bag to the patient.

2.20. **Expiry**

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

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

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

2.21. **Documentation**

2.21.1. The collection and reinfusion of salvaged blood must be accurately documented on the Trust specific cell salvage monitoring forms and should also include the documentation of when cell salvaged blood is not re-infused.

2.21.2. All adverse incidents must be documented in the patients' medical records and in accordance with the Trust Blood Transfusion Policy. If necessary a DATIX report should be completed in accordance with the Trust Incident Reporting policy which following review by the Blood Conservation team may require reporting to SHOT, MHRA and/or SABRE.

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

Record patient observations for the unit being transfused (red cells, platelets, FFP, cryoprecipitate or autologous blood) to include:	**Observed and discussed**
Pre-transfusion	Temperature, pulse, blood pressure and respiration rate
15 mins into transfusion	Temperature, pulse, blood pressure and respiration rate
End of transfusion	Temperature, pulse, blood pressure and respiration rate
Might further observations be required?	Yes, if there are any changes in observations, signs of a reaction or patient is unconscious.

2.21.4. The Trust must ensure that adequate records are retained in cases where ICS and/or PCS is used.

2.22. **Disposal of Used Cell Salvage Equipment (Appendix 6)**

Following use, all cell salvage disposable equipment will be disposed of in accordance with the Trust Health and Safety Policy for disposable of equipment contaminated with blood (RCHT policy for sharps and clinical waste).

2.23. **Cleaning and Disinfection of Cell Salvage Machines (Appendix 6)**

2.23.1. Following use, the cell salvage machine will be cleaned in accordance with the Trust Infection Control Policy and the Manufacturers guidance, including procedures for cleaning equipment following high risk cases.

2.23.2. Following contamination of the equipment internally, the equipment should be removed from use, identified as a potential biohazard

and cleaned according to Trust Policy. Such incidents should be referred to the Blood Conservation Team.

2.24. **The Management of Massive Transfusion**

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

2.24.2. In the event of a massive transfusion, it is vital to consider the need for additional transfusions of platelets; fresh frozen plasma and cryoprecipitate (see massive haemorrhage guideline).

2.25. **Technical Problems**

2.25.1. Technical problems with the ICS or PCS devices should be recorded on the Trust cell salvage monitoring forms and reported to the Blood Conservation Team or anaesthetic co-ordinator who will then contact the manufacturer if applicable.

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

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

2.26. **Resources**

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

2.27. **Training**

2.27.1. The Blood Conservation Service will maintain records of all persons who have received training in the use of the ICS / PCS devices.

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

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

2.28. **Individual Responsibilities**

Individual staff are responsible for ensuring they are adequately trained and for maintaining their competency in the use of the ICS or PCS systems according to their area of work, i.e. operator, anaesthetic, scrub, recovery and ward staff and to act within the NMC/HPC code of conduct and scope of professional practice as extended by this protocol.

2.29. **Obstetric Cell Salvage**

The following paragraphs apply to all health professionals involved in the collection, storage and reinfusion of blood cell salvage in maternity Theoretical safety concerns have slowed the introduction of intraoperative blood cell salvage in Obstetric settings, despite the endorsement of the Association of Anaesthetists[2] and the Obstetric Anaesthetics Association[4]. The National Institute for Health and Clinical Excellence reviewed the evidence in 2005 and 2012 and supported its use in Obstetrics subject to:[3]

1. Data collection
2. Reporting of complications to SHOT and the Medicine and Healthcare products Regulatory Agency (MHRA)
3. Patients should be fully informed 'whenever possible' of the potential complications
4. Performed by multidisciplinary teams who develop regular experience of intraoperative blood cell salvage

The collection of blood during all caesarean sections in the maternity theatre is now routine at The Royal Cornwall Hospital.

2.30. **Benefits of Obstetric Cell Salvage (OCS)**

- To avoid the risks associated with conventional donor blood transfusion
  - infection (viruses, bacteria and prions)
  - acute incompatibility / allergic reactions
  - hypothermia
  - cost/increasing scarcity

- To reduce the symptoms and consequences of post-operative anaemia
- To enhance the safety of Caesarean Section (CS) for patients who decline blood products from donors
- Cell salvaged blood is warm, has a haematocrit of approximately 50%, and has higher levels of active 2,3,DPG than allogeneic blood. This results in improved oxygen carrying capacity and delivery compared to allogeneic blood. (NEW 2020)[5]

2.31. **Theoretical risks**

2.31.1. **Amniotic Fluid Embolism (AFE).** There have been no reported cases to date of AFE associated with the use of cell salvage in obstetrics. Amniotic fluid embolism is now considered to be a type of anaphylactic reaction rather than an embolic disease. Furthermore, the washing and filter processes used in cell salvage have now been shown to effectively remove amniotic fluid contaminants, fetal squames and other debris.[6-12]

2.31.2. **Sensitisation to fetal red cells**. The cell salvage machine is unable to distinguish between maternal and fetal red cells. There is a theoretical risk that fetal blood cells may be collected and transfused back to the mother. The development of antibodies to fetal red cells may pose a risk of haemolytic disease of the newborn in future pregnancies.
In a case series of 647 women who received cell salvage at Royal Cornwall Hospital, only 2 women have had a positive antibody screen (anti-E). There have been no cases of Rh(D) incompatibility sensitisation.[6] For **Rhesus negative women**, Rh(D) incompatibility sensitisation can be prevented with adequate anti-D administration after delivery (NEW 2020).

2.32. Indications for obstetric cell salvage

The Association of Anaesthetists recommends cell salvage for all operations predicted to have >500ml blood loss[2] so by default, cell salvage is indicated for all emergency and elective caesarean sections.
All women having elective Caesarean sections (CS) are consented for the collection of blood. For all other operations in the maternity theatre, the collection of blood should be achieved whenever possible subject to staffing competencies.

Conditions predisposing to increased bleeding risk in elective or emergency caesarean sections for which ICS is particularly important include:

- Placenta praevia
- Placental abruption
- Suspected placenta accreta
- Classical incision
- Past history of uterine atony
- Maternal bleeding disorders
- Prolonged or obstructed labour associated with atony, head impaction or oedematous lower segment
- Maternal use of anticoagulants or maternal bleeding disorders

ICS is also of greater importance in the following situations:

- CS for women who have declined blood products (an advance directive filed in the front of the hospital notes and copied into the hand-held notes will identify which women have consented to the use of cell salvage)
- CS when there is difficulty with cross-matching due to antibodies or anaemia
- Laparotomy following postpartum haemorrhage

2.33. Administering reinfusion in obstetrics

2.33.1. Leucodepletion filters (Pall LeukoGuard ® RS Filter) are no longer used routinely in obstetrics at RCH due to lack of supporting evidence.[12] In a 10-year retrospective cohort study of 1170 patients at RCH all reinfusions of cell salvaged blood were administered with no evidence of maternal collapse or hypotension, with or without the leucodepletion filter.[6]

2.33.2. Cell salvaged blood must be prescribed both electronically (JAC EPMA) and on the paper fluid chart. Pre-infusion checks and bedside observations must be recorded as per section 1.21.3. There is a yellow sticker to record these observations in the patient's notes.

2.33.3. **Emergency use**. All people who are booked for elective caesarean sections will be consented for cell salvage during anaesthetic pre-assessment. In an **emergency case** if possible, obtain verbal consent prior to reinfusion. If the patient is under general anaesthesia, the decision to re-infuse will be medical. Manage cases of obstetric haemorrhage according to the RCHT guideline. **Do not pressurise or syringe cell salvaged blood to aid rapid administration** (syringing risks red cell destruction, the bag collection bag is not designed to be pressurised so risk of air embolus and bag rupture)

2.34. Vaginal Cell Salvage.
In life threatening situations for women who have declined blood products, blood may be salvaged following vaginal delivery. This is dependent on appropriately trained staff being present. Women receiving vaginally salvaged blood should have prophylactic antibiotic cover. For women who decline blood products there may be an opportunity to consent them pre-procedure. (See guideline for the care of women declining blood products). In emergency situations, the patient should be consented prior to re-infusion of vaginal blood if possible.

2.35. Follow up
It is uncertain if infusion of cell salvaged blood increases the inherent risk of fetal red cell sensitisation from pregnancy itself, or from a donor blood transfusion (see section 2.3.2). This may include clinically significant antibodies other than anti-D. We therefore invite all women to have a 4-6 month follow up blood sample to test for antibody formation (New 2020)

3. Monitoring compliance and effectiveness

Element to be monitored	All cell salvage use Cell Salvage training competencies All Cell Salvage Devices
Lead	Oliver Pietroni (Clinical Lead for Patient Blood Management), Katharine Sprigge (Clinical Lead for Patient Blood Management, Obstetrics), Carol McGovern (Blood Conservation Co-ordinator), Kelly O'Toole (Anaesthetic Services Co-ordinator)
Tool	Monitoring sheet for cell salvage use training database Machine logs (servicing, electrical safety checks and maintenance)
Frequency	Continuous: every blood collection is monitored. All training recorded Yearly machine servicing and electrical safety checks and all ad-hoc repairs Reported to Blood Conservation team as required Report shared to HTT-Monthly and HTC-Quarterly as required
Reporting arrangements	Monthly reports to Hospital Transfusion Team (HTT) Interrogated by members of committee and documented in minutes of HTT meeting. Quarterly reports to HTC meeting Datix reports of all incidents with attention blood transfusion for reporting to SHOT.
Acting on recommendations and Lead(s)	▪ Blood Conservation team, leads or coordinator will undertake any recommendations within reasonable timeframes ▪ Required training actions will be actioned by Carol McGovern

Change in practice and lessons to be shared	Required changes to practice will be identified and actioned within a month. The Blood Conservation coordinator or clinical leads will be identified to take each change forward where appropriate. Lessons will be shared with all the relevant stakeholders.

4. Equality and Diversity

4.1. This document complies with the Royal Cornwall Hospitals NHS Trust service Equality and Diversity statement which can be found in the 'Equality, Diversity & Human Rights Policy' or the Equality and Diversity website.

4.2. **Equality Impact Assessment**
The Initial Equality Impact Assessment Screening Form is at Appendix 2.

Appendix 1. Governance Information

Document Title	Intraoperative Cell Salvage Clinical Guideline V4.0		
This document replaces (exact title of previous version):	Clinical Guideline for Intra-operative Cell Salvage V3.0		
Date Issued/Approved:	December 2020		
Date Valid From:	December 2020		
Date Valid To:	December 2023		
Directorate / Department responsible (author/owner):	Olliver Pietroni – Blood Conservation Lead, Consultant Anaesthetist Katharine Sprigge – Obstetric Blood Conservation Lead, Consultant Anaesthetist Carol McGovern – Cell Salvage trainer and Blood Conservation Coordinator		
Contact details:	01872 25 3196		
Brief summary of contents	This policy covers all aspects of Cell Salvage in the Surgical and Midwifery & Obstetrics setting.		
Suggested Keywords:	Cell salvage. Obstetric cell salvage. Blood conservation.		
Target Audience	RCHT	CFT	KCCG
	✓		
Executive Director responsible for Policy:	Medical Director		
Approval route for consultation and ratification:	Blood Conservation Coordinator Hospital Transfusion Team Hospital Transfusion Committee Maternity Guidelines Group		
General Manager confirming approval processes	Mary Baulch		
Name of Governance Lead confirming approval by speciality and care group management meetings	Caroline Amukasana		
Links to key external standards	CQC16		
Related Documents:	**References** 1. Department of Health. Health Service Circular. Better Blood Transfusion: Safe and Appropriate Use of Blood. November 2007. 2. Klein et al. Association of Anaesthetists guidelines: cell salvage for peri-operative blood conservation 2018. *Anaesthesia* 2018; **73:** 1141-1150.		

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<tr><td></td><td colspan="4"><ol start="3">
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https://www.transfusionguidelines.org/
</td></tr>
<tr><td>Training Need Identified?</td><td colspan="4">Yes</td></tr>
<tr><td>Publication Location (refer to Policy on Policies – Approvals and Ratification):</td><td>Internet & Intranet</td><td>✓</td><td>Intranet Only</td><td></td></tr>
<tr><td>Document Library Folder/Sub Folder</td><td colspan="4">Clinical / Anaesthetics
Midwifery and Obstetrics</td></tr>
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Version Control Table

Date	Version No	Summary of Changes	Changes Made by (Name and Job Title)
27 Mar 12	V2.1	Warning added to paragraph 2.8.1	Catherine Ralph, Blood Conservation Lead
09 Dec 14	V2.2	Minor Changes	Catherine Ralph, Blood Conservation Lead
06 Jun 18	V3.0	Major changes Monitoring form removed Additional comment on section 2.8.6 regarding diathermy Updated Trust logo Updated Information Governance and IEIA forms	Catherine Ralph, Blood Conservation Lead and Carol McGovern, Cell Salvage Co-ordinator and Trainer
December 2020	V4.0	Major changes Combined with obstetric cell salvage guideline Appendices added detailing SOP for using the ICS devices process	Katharine Sprigge, Consultant Anaesthetist, Oliver Pietroni, Blood Conservation Lead and Carol McGovern, Cell Salvage Co-ordinator and Trainer

Appendix 2. Initial Equality Impact Assessment

<table>
<tr><th colspan="6">Section 1: Equality Impact Assessment Form</th></tr>
<tr><td colspan="6">Name of the strategy / policy /proposal / service function to be assessed:
Intra-operative Cell Salvage Clinical Guideline V4.0</td></tr>
<tr><td colspan="3">Directorate and service area:
Medical</td><td colspan="3">Is this a new or existing Policy?
Existing</td></tr>
<tr><td colspan="3">Name of individual/group completing EIA:
Katharine Sprigge</td><td colspan="3">Contact details:
01872 250000 (via switch)
Or 01872253196</td></tr>
<tr><td>1. Policy Aim
Who is the strategy / policy / proposal / service function aimed at?</td><td colspan="5">To provide information that will allow clinicians to safely identify suitable patients undergoing elective and / or emergency surgical procedures where Cell Salvage could be used and in a safe effective manner including all health professionals involved in the collection, storage and reinfusion of blood cell salvage in maternity</td></tr>
<tr><td>2. Policy Objectives</td><td colspan="5">To provide a rational and practical framework on which to maximise patient safety during collection and reinfusion of cell salvaged blood</td></tr>
<tr><td>3. Policy Intended Outcomes</td><td colspan="5">Safe and effective use of Cell Salvage during and after surgery and during obstetric procedures</td></tr>
<tr><td>4. How will you measure the outcome?</td><td colspan="5">Monitor all episodes of Cell Salvage usage.</td></tr>
<tr><td>5. Who is intended to benefit from the policy?</td><td colspan="5">All patients undergoing surgical procedures for which blood loss can be collected into the cell saver.</td></tr>
<tr><td rowspan="3">6a). Who did you consult with?

b). Please list any groups who have been consulted about this procedure.</td><td>Workforce</td><td>Patients</td><td>Local groups</td><td>External organisations</td><td>Other</td></tr>
<tr><td>X</td><td></td><td></td><td></td><td></td></tr>
<tr><td colspan="5">Please record specific names of groups
RCHT Surgical Patient Blood Management group
HTT (Hospital transfusion team)
Clinical Guideline Group
Obstetric and Gynaecology Directorate</td></tr>
<tr><td>c). What was the outcome of the consultation?</td><td colspan="5">Endorsed and ratified</td></tr>
</table>

7. The Impact
Please complete the following table. **If you are unsure/don't know if there is a negative impact you need to repeat the consultation step**.

Are there concerns that the policy **could** have a positive/negative impact on:

Protected Characteristic:	Yes	No	Unsure	Rationale for Assessment / Existing Evidence
Age		**X**		
Sex (male, female, non-binary, asexual etc.)		**X**		
Gender reassignment		**X**		
Race / Ethnic communities /groups		**X**		
Disability - Learning disability, physical disability, sensory impairment, mental health problems and some long term health conditions.		**X**		
Religion / other beliefs	X			Positive impact, Jehovah Witnesses can benefit.
Marriage and Civil partnership		**X**		
Pregnancy and maternity		**X**		
Sexual Orientation, (bisexual, gay, heterosexual, lesbian)		**X**		

If all characteristics are ticked 'no', and this is not a major working or service change, you can end the assessment here as long as you have a robust rationale in place.

I am confident that section 2 of this EIA does not need completing as there are no highlighted risks of negative impact occurring because of this policy.

Name of person confirming result of initial impact assessment	1. Catherine Ralph 2. Human Rights, Equality & Inclusion Lead

If you have ticked 'yes' to any characteristic above OR this is a major working or service change, you will need to complete section 2 of the EIA form available here:
Section 2. Full Equality Analysis

For guidance please refer to the Equality Impact Assessments Policy (available from the document library) or contact the Human Rights, Equality and Inclusion Lead debby.lewis@nhs.net

Appendix 3. Standard operating procedure for preparing HEPSAL (30 000iu in 1000 mls IV Sodium Chloride (NaCl) 0.9%)

(Prepare immediately prior to use except in obstetric setting: see below)

- x 1 bag of 1000 ml IV NaCl 0.9%
- x 2 ampoules of Heparin 1:1 000 iu (x1 20ml + x1 10 ml)
- x 1 20 ml syringe
- x 1 10 ml syringe
- x 1 filtered drawing up needle
- x 1 green hypodermic needle
- x 1 red RCHT HepSal label (completed with date, time, name (printed and signature) amount of Heparin (volume i.e. 30ml) and concentration (30, 000 iu))
- Obstetrics x 1 red cap for IV drug additive port

Obstetrics – A fresh bag of HepSal should be prepared each morning i.e. every 24 hrs and replaced when used. Any prepared bags that expire part way through the 24 hr period should be discarded unless there are elective cases where its use is guaranteed

Method

- As Heparin is a prescription only drug, preparation must be by a registered practitioner
- ANTT guidelines should be followed throughout
- Open plastic wrapper on IV fluid but retain to use the inside of the wrapper as the sterile field
- Maintaining sterility > open each syringe and attach one needle to each
- Drop onto sterile field
- Open both ampoules of Heparin
- Wash hands, dry and put on non-sterile disposable gloves
- Draw up either the 10 or 20 ml Heparin into the appropriate syringe using the filter needle
- Without touching the key parts, swap the filter needle with green hypodermic needle onto the syringe containing the Heparin. Transfer the filter needle to the empty syringe
- Inject Heparin into bag using green hypodermic needle
- Leave the needle and now empty syringe inside the IV NaCl bag and draw up the remaining volume of Heparin in the appropriate syringe using the filter needle
- Without touching the key parts, swap the empty syringe with the second syringe now containing Heparin and inject into the bag
- This swap should be done swiftly to avoid leakage of Heparin +/- saline via the green hypodermic needle
- **Before removing the green needle or the second empty syringe from the bag, label bag with the completed HepSal label**
- Remove the needle and syringe from the bag
- Dispose of all items according to Trust policy **except** for the two empty Heparin ampoules (these are retained for their lot numbers in case of a patient adverse reaction).
- If more than one bag is prepared, the bag and corresponding ampoules must be identified e.g. bag one and two
- Obstetrics: add red cap to IV drug additive port
- Obstetrics: place labelled HepSal bag in drug fridge in anaesthetic room unless needed imminently

Appendix 4.Standard operating procedure for intra-operative cell salvage (ICS) collection (Elite+ device)

(Not laparoscopic – see separate SOP)
ICS collection is when surgical blood is aspirated and mixed with anticoagulant via an aspiration and anticoagulation (A&A) line, into a collection reservoir. The collection reservoir contains a filter that removes clots and other gross particulate matter.

Equipment

- x 1 bag of anticoagulant
- x 1 collection reservoir
- x 1 ICS device (or reservoir bracket and drip stand if a device is not available)
- x 1 suction unit with a clean / dry filter
- x 1 clean length of suction tubing (cut length as required)
- x 1 A & A line (give to scrub practitioner)

Method

- Follow ANTT guidelines throughout
- *Hang the anticoagulant bag on the machine. (If a machine is not available, hang it on the drip stand with the collection reservoir bracket attached.)*
- The anticoagulant may require agitation prior to use (Heparin is heavier than saline and sinks to the bottom of the IV bag if left hanging for any length of time)
- Load the collection reservoir into the bracket on the machine or drip stand
- Clamp off the port that leads to the processing line (red capped port)
- Attach the clean suction tubing to the vacuum source making sure there is a secure connection
- Attach the other end of the suction tubing to the vacuum port on the collection reservoir (yellow capped port)
- After draping but prior to the start of the operation, ask the scrub practitioner to pass the spiked end of the double lumen A&A line out to the ICS operator
- Attach the non-spiked wide bore line to one of the three blue capped ports on the collection reservoir
- Close the roller clamp on the spiked small bore line of the A & A line and insert the spike into the port of the anticoagulant bag. Half fill the chamber
- Turn on the vacuum source **(For non-self regulating vacuums, set the vacuum between 100mmHg and –150mmHg)**
- *In procedures where there is an anticipated large volume of blood collected pre-operatively e.g. in the abdomen of a ruptured aneurysm or ectopic, it is recommended that the vacuum source used is able to reach the same pressure as surgical suction (i.e. > -500mmHg) to allow for the speedy removal of the collected blood and identification of the source of bleeding
- Fully open the roller clamp on the A&A line
- Allow 100ml to 150ml of anticoagulant to run through the A & A line to prime the line and the collection reservoir and filter
- Regulate the flow of anticoagulant to approximately one drop per second (*80-100 drops per minute for obstetric patients)
- Inform the surgical team that blood collection can begin
- Record the time blood first enters the collection reservoir

During collection, it may be necessary for the operator to make minor adjustments to the system:

- Regulating the vacuum pressure– it may become necessary during periods of high blood loss to increase the level of the vacuum at the request of the surgical team. The vacuum should be returned to a standard level, (approximately 100mmHg to –150mmHg) as soon as the bleeding is under control. This will minimise damage to the RBCs

- Regulating the anticoagulant flow – the flow rate of the anticoagulant must be regulated depending on the level of bleeding. Insufficient anticoagulant will result in the formation of blood clots.
- If the anticoagulant is left fully open and the whole litre runs into the reservoir, this is not an issue. Simply prepare a second bag of anticoagulant.
- Monitoring the volume of blood loss – when using a "collect only" system, the cell salvage operator must decide if it is appropriate to process the blood based on the volume and quality of the blood collected in the reservoir
- *In procedures where there is an anticipated large volume of blood loss e.g. ruptured aneurysm or ectopic, and if there is time, it is recommended that a processing set is loaded prior to the start of the procedure or as soon as possible. Also consider using a large bowl set (225ml).

There are several techniques that can be used to maximise the volume of RBCs available for reinfusion. These include:

- Low vacuum level: maintaining a low vacuum level minimises haemolysis, and therefore maximises the RBCs available for reinfusion. High vacuum levels cause RBC haemolysis, which can be measured by the concentration of plasma (free) haemoglobin (haemoglobin that has been released from haemolysed RBCs).
- Suction technique: where possible, the suction tip should be immersed in the blood and not skimmed across the surface of tissues or pools of blood. Skimming results in a large quantity of air mixing with the aspirated blood, this air interface causes haemolysis and therefore reduces the number of viable RBCs available for reinfusion. However, when blood and air are aspirated, as occurs naturally during most of the ICS process, even low vacuum levels can result in excessive haemolysis and therefore reduce the available RBCs for reinfusion.

Swab Washing

Swab washing allows blood that would normally be lost in surgical swabs to be salvaged during ICS and can significantly increase the volume of RBCs for reinfusion.

Equipment

- Sterile bowl
- 1000ml IV Normal Saline 0.9%

Method

- Using a sterile technique open the outer wrapping of a 1000ml bag of IV Normal Saline (NaCl) 0.9% and offer it to the scrub practitioner
- They will empty this into the sterile bowl and ensure that both remain within the sterile field throughout the procedure
- *2 litres of IV NaCl can be used in cases of excessive bleeding (to prevent the saline becoming saturated when a large number of swabs are used and/or to ensure that they are fully immersed)
- Bloody swabs should be fully immersed in the NaCl immediately to prevent the RBCs from drying out
- Leave swabs for a minimum of 5 mins
- Gently agitate swabs before squeezing them out using a milking action (do not wring)
- *In very bloody procedures, consider keeping the squeezed swabs and putting them through a second fresh litre of NaCl before they are counted out of the sterile field
- Dispose of swabs as per Trust guidelines
- At the end of the procedure (or sooner if necessary) the swab wash should be aspirated into the collection reservoir

- If the swab wash is aspirated before the end of the procedure then a fresh 1000ml of Normal Saline can be added to the sterile bowl for further bloody swabs
- *During lengthy procedures it is recommended that the swab wash is aspirated every 4 hours (UK Cell Salvage Action Group document ICS Technical Factsheet Number 1: Swab washing

Trouble shooting

- Loss of suction:
  - Switch off the flow of anticoagulant until vacuum is restored
  - Check the vacuum source
  - Check the suction tubing is securely connected to the vacuum source and the collection reservoir
  - Check the A&A line is securely connected to the collection reservoir
  - Check the A&A line has not been clamped or otherwise obstructed
  - Check the vacuum filter is not wet or discoloured and change if necessary
  - If an obstruction is seen consider increasing the vacuum pressure until it is free or massage along the A&A line if appropriate
  - Consider changing the yankeur sucker, A&A line and/or vacuum port of the reservoir depending on placement of the obstruction
- Clotting in the collection reservoir:
  - Check the anticoagulant is still flowing
  - Increase the anticoagulant flow rate (If excessive clotting has occurred it may be necessary to change the collection reservoir)
- Contamination with non-IV substances:
  - Contamination of the salvaged blood with substances not intended for IV use should be discussed with the lead clinician taking responsibility for ICS in the procedure. A clinical decision on how to proceed should be made by this lead clinician on a patient by patient basis looking at the risks and benefits as well as safe alternatives available. A list of potential contaminants and their associated problems can be found in the UK Cell Salvage Action Group document ICS Technical Factsheet number 9 – Contraindications to ICS
  - The decision to use blood that is potentially contaminated with bacteria or malignant cells should be made by the clinicians caring for the patient, taking into account the latest evidence and consideration of the risks and benefits of proceeding for the individual patient.

Documentation

ICS data form

The appropriate ICS data form (either obstetric or non-obstetric) must be completed (one form for each patient episode). ICS data forms can be found in a folder on each device. The following information must be included:

- The patient's details should be recorded on both the front and reverse of the form (full name, date of birth and a unique identifying number)
- These details (patient addressograph label or handwritten details) must be taken from/checked against the patient's wristband or the consent form after it has been checked against the patient's wristband
- The specific device used (all devices are labelled with a unique identifier) and the theatre
- The ICS operator's name (record any changes of staff in the space provided on the reverse of the form)
- The name of the Surgeon operating and the procedure planned

- The name of the Anaesthetist and the anaesthetic technique used
- The name of the person who prepared the anticoagulant (please print)
- The patient's most recent pre-op Hb and whether tranexamic acid has been administered
- The collection start time (this is the time blood enters the collection reservoir)
- The collection volume (the total volume in the reservoir at the end of the procedure)
- The estimated blood loss (please discuss this with the operating surgeon to agree the figure to be recorded in all patient documentation)
- Traceability labels from each ICS consumable used must be added to the reverse of the ICS data form and the patient's perioperative profile (CSSD page)

Completed ICS data forms **must remain in the folder at all times and must NOT leave theatre** or be filed in the patient's notes

Patient Peri-operative profile

Please document the use of cell salvage and the device asset number used in the patient profile in addition to the traceability labels mentioned above.

Galaxy

The model of device used (Elite+ 1-11 or CS5+ A or B) needs to be recorded along with the use of tranexamic acid if used. (This should be completed during collection).

The Loan Elite+ device (1-11) option should only be selected if the device is labelled "Loan 2". This is when a device cannot be repaired and has been replaced with a loan device.

Appendix 5. Standard Operating Procedure for intra-operative cell salvage (ICS) processing (Elite+ device)

ICS **processing** is when surgical blood that has been collected in the reservoir is processed using centrifugal force to separate the red blood cells (RBCs) from the waste products (plasma, clotting factors, platelets, anticoagulant etc). The RBCs are concentrated to produce a high haematocrit and washed with intravenous (IV) normal saline (0.9% NaCl). At the end of the processing phase the RBCs, now suspended in IV 0.9% NaCl, are pumped into the re-infusion bag.

The device used at RCHT (the Elite+) is a fixed volume bowl system which means a definitive amount of blood is required to fill the bowl. This definitive volume depends of the bowl size chosen.
The operator should process whenever they believe that a full bowl or more will be achieved. The decision to process is based on the colour, consistency and movement of the blood, the estimated volume of blood collected in the reservoir, the blood collected in the swab wash and the patient's starting haemoglobin (Hb), bearing in mind that whole blood comprises of 40-50% RBCs.
For cases where the decision to process is not obvious, the patient's general health, co-morbidities and availability of alternative treatments should be considered.
Full bowls are always preferable, so for an operation with a small to moderate loss and a patient with a low Hb, a 70 ml bowl may be the correct choice. For an operation with an expected large volume of blood loss e.g. a ruptured aneurysm a 225 ml bowl is preferable.

Equipment

- x 1 Bowl set (70 ml, 125 ml or 225ml)
- x 1 If a 70 ml bowl is selected a non-disposable adaptor is also needed
- x 1 ICS device with ICS Collection already set up
- x 1 or x 2 Bags of IV 0.9% NaCl 1000ml

Loading the bowl set

- Follow ANTT guidelines throughout
- *Hang the IV NaCl bag(s) on the machine using a different pole from anticoagulant. (These bags should be checked with another qualified staff member)*
- Open the chosen bowl set
- Scan the bar coded label contained within the bowl set and retain
- Remove the RBC bag and tubing (blue)
- Hang the RBC bag on the same IV pole as the anticoagulant solution
- Close both clamps (white) on the RBC bag outlet/giving ports immediately below the RBC bag
- Tighten the luer-lock connection part way down the blue re-infusion line
- Do NOT close the large white clamp on the re-infusion line
- Taking the bowl in your dominant hand and the remaining tubing in the other, remove from the packaging leaving the waste bag hanging free.
- Drop the bowl into the centrifuge with the waste bag to the left and the other lines to the right.
- If using a 70 ml bowl set, seat the non-disposable adaptor (white) securely in the well of the centrifuge before loading the bowl inside this adaptor.
- Tighten the luer-lock connection part way down the effluent line
- Do NOT close the large white clamp on this line
- Ensure that the waste bag outlet port is also firmly closed
- Hang the waste bag on the left hand side of the device (the line should not be twisted)
- Seat the bowl securely into the centrifuge and close the header arm fully (failure to do so may result in damage to the bowl and spillage of blood)
- Firmly locate the effluent line into the sensor using a stretching motion
- Place the remaining tubing through the pump, valves and other machine sensors

- Securely close all tubing retainers (light blue)
- Close the device lid ensuring that none of the tubing is trapped
- Clamp tightly both of the wash solution lines (yellow)
- Connect (spike) the wash solution line(s) to the IV 0.9% NaCl bag(s) and open the clamp on **one** line (yellow)
- Connect the collection reservoir line (red) to the base of the collection reservoir
- Open the clamp at the base of the reservoir (red)
- Do NOT close the large white clamp on this line
- Select "Start" on the screen once the bowl is fully loaded
- Check that the correct setting has been selected (obstetric, non-obstetric or fat reduction)
- Label the RBC bag using the label provided and including the following information: patient's full name, a unique identifying number, date of birth, the date and time collection started and the date and time of expiry
- NOTE: The label **must** be completed from either the patient's wristband or a document that has been checked against the patient's wristband e.g. the consent form
- Place a barcoded bowl label on the reverse of the ICS data form and in the patient's pre-operative booklet (see documentation section below)

Filling and Washing

- The device will automatically start to fill the bowl when the weight of a pre-set volume of blood is recognised in the reservoir
- When the bowl is full, the device will automatically start to wash with a minimum wash volume that is also pre-set (e.g. non-obstetrics and fat reduction settings the wash is 750 ml for a 125 ml bowl but for obstetrics this is 1500ml)
- The minimum wash volume set for each bowl size/setting should not be reduced but may be increased if the operator is concerned that contaminants may be present or if the effluent line is not running clear at the end of the automatic wash cycle
- The operator may need to replace the wash solution (IV 0.9% NaCl bags) during the procedure

Changing the RBC bag

- The RBC bag may be changed either because it is full or if the anaesthetist wishes to re-infuse the blood to the patient before the end of the surgery.
- All disconnected RBC bags should be kept with the patient until they are reinfused.
- The new RBC bag(s) should be labelled with another of the labels provided with the processing set and as described above.
- Remember to close both clamps (white) on the new reinfusion bag outlet / giving ports immediately below the RBC bag and ensure that the large white clamp on the blue line is open

Changing the waste bag

- When the waste bag is nearly full, the device will display a warning message. If it isn't changed at this time the device will go into standby once the waste bag is full
- Hang the new waste bag behind the full waste bag
- Ensure that the new waste bag outlet port is firmly closed
- Disconnect the full waste bag at the luer-lock connection part way down the effluent line and connect the new waste bag
- Using the cap provided, cap the full waste bag and remove from the device
- Ensure that the large white clamp on the effluent line is still open

To change either bag during processing, the device must be put into Standby by selecting the orange button to the right of the screen. This should only be selected once the bowl has emptied and before it starts to fill again. Processing should not be interrupted during the wash or empty stages.

- Follow the on screen instructions to restart the process
- At RCHT we do not recommend emptying the waste bag, however, if this is absolutely necessary, approximately a litre of waste fluid **must** be left in the bag
- Emptying the waste bag fully prevents the movement of fluid through the machine

Incomplete / partial bowls

- If all the blood in the collection reservoir has been taken into the bowl and an automatic wash has not been triggered (i.e. it is an incomplete bowl), one of the following three actions needs to be taken;
  a) If further blood loss is anticipated then no action is required. The device will enter standby after a few minutes and restart filling once further blood enters the reservoir
  b) If it is the end of the procedure, no further blood loss is expected, the swab wash has been processed but there *is blood in the RBC bag*, then the "Conc" (concentration) function should be selected. "Conc" draws washed red blood cells down from the RBC bag into the bowl until the bowl is full and triggers another automatic wash.
  c) If it is the end of the procedure, no further blood loss is expected, the swab wash has been processed but there is no blood in the RBC bag, then the operator must decide whether to abandon the process or to wash a partial bowl.
  If the bowl is 2/3rds or more full, the operator should wash a partial bowl. To ensure the quality of the salvaged blood available for re-infusion is maintained the bowl must be washed with double the minimum wash volume for the size of the bowl used e.g. for a partial 125 ml bowl the wash volume needs to be 2 x 750 ml = 1500 ml.
  In obstetrics all bowls, full and partial, require a minimum wash volume of 1500 ml (to wash out the amniotic fluid).

- Once the last bowl has been washed and emptied into the RBC bag, the blood in the re-infusion line can also be emptied into the RBC bag by selecting and confirming the "end procedure" function (dead space = approximately 20 ml).

- Air in the reinfusion bag. There is at least 20 ml of air in the re-infusion bag (from the re-infusion line when the first bowl empties into the RBC bag) therefore the blood should never be re-infused under pressure as there is a risk of air embolus.

- Disconnecting the RBC bag. If this is during processing please follow the instructions above for "changing the RBC bag".
  If this is at the end of the procedure, ensure that both white clamps on the (blue) re-infusion line (above and below the luer-lock connection) are closed. Disconnect the line at the luer-lock connection and cap both ends using the caps provided.

Troubleshooting

Machine alarms: if the machine detects a problem, it will stop processing and display information relating to the problem on the display screen. The operator should follow the on screen instructions to resolve the problem. All error messages should be recorded on the reverse of the ICS data form along with the actions taken to resolve the issue.

Documentation

Please see the documentation section of appendix 4: collection and use of the ICS data form. In addition, if blood is processed please also document:

- The “re-infusion time”: this is the time by which the salvaged blood should be re-infused and is **6 hours** after the collection start time.
- The processed volume (the total volume that has passed through the device at the end of the procedure)

Galaxy

The model of the device used (Elite+ 1-11 or CS5+ A or B) needs to be recorded along with tranexamic acid if used. (This should be completed during collection).

The Loan Elite+ device (1-11) option should only be selected if the device is labelled “Loan 2”. This is when a device cannot be repaired and has been replaced with a loan device.

Appendix 6. Standard operating procedure for intra-operative cell salvage (ICS) re-infusion (Elite+ device)

ICS blood is untested and intended only for the patient from whom it was collected.

Labelling

The RBC reinfusion bag should be labelled from the patient's identification wristband or the patient consent form (once it has been checked against the patient's wristband).

This should be completed as soon as possible after the processing set has been opened using only the RBC label provided and **must** be handwritten and legible.

The minimum data required is:

- Full name (first and last name)
- Date of birth
- One unique identifying number (either CR or NHS number)
- Date and collection start time
- Expiry time (six hours after the collection start time)

Once completed the RBC label should be secured to the reinfusion bag.

Patient addressograph labels are not acceptable on either the RBC bag or the RBC label.

Storage

In accordance with recommendations from the Serious Hazards of Transfusion (SHOT) for allogeneic (donor) blood, the reinfusion bag should be kept beside the patient **at all times** and **must not** be placed in a refrigerator.

Any blood that has not been reinfused within the timeframe should be disposed of in accordance with local policy for dealing with liquid biohazardous waste.

Obstetrics: if the patient has declined re-infusion, the bag should remain with the patient (in case of PPH) until **either** the 6 hour re-infusion time is up **OR** the patient leaves the Delivery Suite when it should be discarded.

Disconnecting the Reinfusion Bag

Reinfusion of ICS blood while the RBC bag is still attached to the processing set is not recommended at RCHT, as there is a risk of air emboli.

Spare reinfusion bags are available in all clinical areas that undertake cell salvage.

Each new bag must be labelled as described above

The reinfusion bag must **only** be disconnected **after** the bowl has **emptied** and before it starts to "Fill" again.

Method to change the RBC bag

- When the current bowl has emptied into the RBC bag but **before** it starts to fill again, select **Pause** using the orange button on the right hand side of the screen
- Clamp the blue line as close to the base of the RBC bag as possible, as well as just below the luer lock connection on the blue line
- Using ANTT and wearing full PPE, disconnect the RBC bag from the blue line. Secure the open end with the cap provided
- Maintaining sterility of the open (machine) end of the blue line, attach a new RBC bag
- Ensure that both large blue line clamps (above and below the luer lock connection) are open but that both small white administration ports at the base of RBC bag are closed
- Select **Fill/Start** to recommence processing the remaining blood

- Label the new RBC bag as described above ("Labelling") using one of the remaining three RBC bag labels. (In the event that there are no remaining RBC bag labels, please open a new processing bowl set and use the RBC bag labels)

Pre administration checks

- Reinfusion of salvaged blood should follow standard blood transfusion practice. The responsible clinician should authorise salvaged blood for reinfusion in the same manner as for allogeneic blood.
- In **Obstetric** patients, prescription on EPMA is required in addition to the patient's fluid prescription chart.
- Baseline observations should be taken and recorded in the patient's clinical record prior to commencing the reinfusion of ICS blood (temperature, BP, HR, RR and oxygen saturations).
- The patient details (full name, date of birth and unique identification number) on the autologous label attached to the reinfusion bag should always be carefully checked against the details on the identification band attached to the patient **prior** to commencing reinfusion of the ICS blood. If the identification band is inaccessible during surgery, due to surgical drapes, patient identification should be undertaken as per local protocol for these circumstances.
- The expiry time on the autologous transfusion label attached to the reinfusion bag should be checked prior to commencing reinfusion of ICS blood. Blood that is out of time should be disposed of according to hospital policy. (This should be recorded on the ICS audit form and in the patient's peri-operative booklet
- Check the reinfusion bag for any signs of leakage, clots, abnormal colour or particles. If present do not administer and record as for out of time blood. Retain the blood and all consumables for further investigation.
- In the event of a problem, close all clamps on the RBC bag and consumables. Send to the transfusion lab labelled FAO Ian Sullivan (in a yellow bag within a yellow waste box with lid on top but unsecured and inside a clear plastic bag which is cable tied.) Notify the Anaesthetic Co-ordinator, Blood Conservation Co-Ordinator and Ian Sullivan via email. Record the problem and actions taken on the reverse of the ICS audit form and report via the Trust incident reporting system (Datix).

Administration

- Use ANTT and appropriate PPE in accordance with local policy, administer using a standard blood giving set (200 micron)
- However, if the blood is believed to contain **bacteria, cancer cells or metal particles** a **Pall (RS1VAE) filter (20 micron) should be used**. Please note that administration through an (RS1VAE) filter will be **x 10 slower** than administration through a standard blood giving set.
- In cases when an RS1VAE filter is being used and the ICS blood is needed to resuscitate a patient it is the clinicians' decision to remove this filter based on the risk / benefits for the individual patient.

  The RS1VAE filter **must** be changed after each 450 ml of ICS blood is administered.
- Unlike donor blood, ICS blood can be preceded and / or followed by both IV Hartmann and IV Saline (Na Cl 0.9%) solutions as ICS blood only contains fresh red blood cells suspended in saline.
- Insert the appropriate administration set into one of the two small white ports on the RBC bag and once primed, connect to the patient's IV cannula. (The larger bore tubing must not be used as blood leaks around it)

- Whenever possible, reinfusion of ICS blood should only take place once surgical control is achieved.

- The red cells can be administered stat however, if the individual patient requires a slower rate this can be adjusted using the roller clamp on the administration set and by adjusting the height of the reinfusion bag.

- Pressure bags should **not** be used as there is a risk of air emboli, damage to the available RBC and rupture of the reinfusion bag

- Administration of ICS blood through a pressure infusor/rapid infusor is not recommended

- Observations should be carried out and recorded in the patient's clinical record as for donor blood transfusions

- **JW patients**: it is not possible to undertake ICS without a break in continuity at the site of surgery, so at RCHT we do not set up ICS any differently for JW patients (i.e. we do not use a continuity line). This should be explained to the patient as part of the process of informed consent to ICS.

- Should surgery look likely to exceed the 6 hour timeframe, at RCHT we recommend that any blood in the RBC bag should be re-infused to the patient. The swab wash should be taken up and new IV Saline given to the scrub nurse. The collection and processing components can be changed if the operator prefers but this is not necessary.

Documentation
Reinfusion of salvaged blood should be documented in the appropriate section of the patient's clinical record as specified in the organisation's transfusion policy as well as on the ICS audit form. In **obstetrics** a yellow sticker should also be used to record this information in the patient's clinical records.

Appendix 7. Standard operating procedure for intra-operative cell salvage (ICS) disposal and decontamination (Elite+ device)

- Turn off the power supply to the machine (machine and wall)
- Wear full PPE (eye protection, plastic apron, face mask and disposable gloves)
- Place yellow rectangular box to the right of the device
- Place clinical waste bag inside the yellow box

COLLECTION ONLY

- Ensure that the Aspiration & Anticoagulation line (including HepSal bag) has been removed and capped prior to being discarded into a clinical waste bag (use the cap provided)
- Disconnect suction tubing above the square filter
- Cap the aspiration and vacuum ports on the reservoir either by using the caps provided or by using both ends of the suction tubing
- Lift the reservoir out of the bracket and lay it in the clinical waste bag and diagonally across the bottom of the waste box
- Swan neck and cable tie the waste bag
- Seal the waste box lid securely all around its edges
- Label (using an indelible marker) with the hospital, specific theatre, the date and “blood products”
- Place in a yellow skip
- Please note: the waste box can take x 2 sets of reservoirs or processing sets, however, if you are leaving the department prior to a second case, please seal the waste box as described above and dispose of it
- Remove and dispose of PPE items according to Trust policy and wash hands

PROCESSING

- Clamp waste line (effluent line)
- Disconnect waste tubing from waste bag and cap both ends
- Remove waste bag from device and empty contents down a flush sluice
- Discard the empty waste bag in a clinical waste bag.
- Follow the instructions above (collection) for disposal of the A & A line and reservoir **plus**
- Clamp the red reservoir line above and below the connection to the processing set
- Clamp both yellow Saline lines
- Ensure the RBC bag has been removed if re-infusion is required
- Clamp and cap the blue line to the RBC bag using the cap provided
- Lift the reservoir out of the bracket and lay it in the clinical waste bag and diagonally across the bottom of the waste box
- Lift the lid on the device and remove the waste line from its sensor
- Release the header arm of the centrifuge
- Grasping the bowl by the hard shoulder, remove it from the centrifuge well
- Still holding the bowl, remove the tubing from the air sensor, pump and valve module
- Remove the saline bag(s) and place everything into the waste bag within the waste box (there should be room to one side of the reservoir)
- Swan neck and cable tie the waste bag
- Seal the waste box lid securely all around its edges
- Label, using an indelible marker, with the hospital, specific theatre, the date and “blood products”.
- Place in a yellow skip.
- Please note: The waste box can take x 2 sets of reservoirs or processing sets, however, if you are leaving the department prior to a second case, please seal the waste box as described above and dispose of it.
- Remove and dispose of PPE items according to Trust policy and wash hands.

ROUTINE DECONTAMINATION

- Ensure that the device is turned off before decontamination

- Wipe the external surfaces of the machine with clinical detergent wipes (these must be damp only).
- If the interior of the device needs to be cleaned only use damp detergent wipes on the general areas but completely AVOID all sensors, the centrifuge, pump and valve module
- To clean the bowl optical sensors in the centrifuge, use a clean, lint free cloth (e.g. soft paper hand towel) dampened with water only and dry. (Even water can leave smears which can affect the sensor reading)
- To clean the air and effluent line sensors, use the tubing provided in the processing set, to agitate through the sensor in a flossing motion. If this does not resolve the issue, clean as for optical sensors above

IN THE EVENT OF A BLOOD SPILL IN THE CENTRIFUGE

- Select the orange **Standby** button (bottom left of screen)
- If there is still blood in the reservoir that requires processing, use a second device and a new processing bowl set.
- To transfer the reservoir to the second device, clamp the red reservoir line above and below the connection to the leaking processing set
- Wearing full PPE and using ANNT, disconnect the reservoir tubing from the processing tubing
- Transfer the reservoir carefully to the bracket on the second device and connect to the new bowl set. Continue processing
- Device one: remove the processing set as described above (Processing)
- Using dry paper towels, mop up any excess blood from the centrifuge well.
- Ensure that the device is turned off before decontamination
- AVOIDING the optical sensors, and using a damp detergent wipe, clean any remaining blood from the well of the centrifuge
- Rinse using a lint free cloth dampened with Sterile Water (still avoiding the sensors)
- Remove the device from use and label “DO NOT USE. BLOOD SPILL”
- Report to Cell Salvage Trainer and Anaesthetic Co-Ordinator for immediate attention
- DO NOT remove the overspill bag even if it is contaminated
- Remove and dispose of PPE items according to Trust policy and wash hands
- Dispose of waste bag as described above in “Processing” section

Appendix 8. Intraoperative cell salvage (ICS) and reinfusion: summary information for clinical staff

WHAT IS ICS?

ICS is the collection of blood from the surgical wound site which is anti-coagulated with Heparin, filtered and then separated by centrifuge. White blood cells, platelets, plasma, Heparin and saline are spun off into the waste, along with any damaged red blood cells. This leaves intact red blood cells that are washed and suspended in IV sodium chloride 0.9%. These red blood cells are warm and ready to carry oxygen immediately following re-infusion to the patient (i.e. are high in 2,3 DPG). This reduces or may even eliminate the patient's need for a donor blood transfusion.

POINTS TO CONSIDER

- Donor (allogeneic) blood is a limited resource. Currently demand is outstripping supply.
- Anyone who has received one unit of donor blood cannot donate blood in future.
- One unit of donor blood currently costs the Trust £125.
- The transfusion rate at RCHT is very low: <1% for obstetric patients (ante and post-natal combined). The national average ranges between 3-6%.
- The majority of Jehovah witness patients will accept ICS **without** a continuity line in place. We therefore, do not routinely offer continuity of circuits for cell salvage in maternity.
- ICS may be considered for sickle-cell trait patients but is not recommended for use in sickle-cell anaemic patients.
- Currently ICS is only offered to patients where infection is present or for patients with curative cancer, when specifically requested by the surgeon. This is due to the risk of the systemic introduction of unwanted cells. We do, however, offer its use for palliative cancer cases where indicated.

ICS USE

- ICS is routinely offered for surgery where there is a risk to the patient of donor transfusion.
- In obstetrics, if surgical intervention is attempted vaginally, ICS may be considered in life threatening circumstances when there are no alternatives i.e. JWs.
- Currently we offer a 24-hour service but this is dependent on trained personnel availability. We have achieved usage for >98% of surgical operations on the delivery suite.
- The cell saver machine is used to collect or to collect and process, during surgery. The machines are suitable for small to large volumes of blood loss and have fixed volumes according to the bowl size chosen with a variable haematocrit of 30-50%.
- ICS machines are designed to identify red blood cells but cannot differentiate between maternal and fetal red blood cells. Consequently, it is likely that there are fetal red cells in all salvaged blood being re-infused.
- All ICS consumables are latex free.
- Anti-coagulation solution is 30,000 iu Heparin Sodium in 1000 mls of IV Saline 0.9%. This never comes into contact with the patient providing the suction is working correctly.
- **Anything that <u>cannot</u> be given to a patient intravenously <u>should not be collected</u> via ICS** e.g. faecal matter, sterile saline for Irrigation. Alternative suction must be used.
- As ICS collects RBCs, the greater the patient's Hb, the more RBCs are available in the volume of blood lost, and therefore the more blood that can be salvaged. This is one of the reasons patients are pre-optimised with IV Iron prior to delivery.
- Using Fibrin sealants: once these have set, ICS can be used again.

RE-INFUSION

- It is preferable to refrain from the re-infusion of salvaged blood until after control of surgical bleeding has been achieved, but can be used for resuscitation if necessary.
- A trigger Hb is not required before a re-infusion is given.
- Consent should be obtained from the patient by the Anaesthetist and in obstetrics should include the risk of isoimmunisation and theoretical risk of amniotic fluid embolus. This information is

available in a patient information leaflet and will have been given to all elective patients at their pre-op ante-natal visit. Further copies of the information leaflet can be given to non-elective cases if time permits (these can be found on Delivery Suite).

- Verbal consent and why blood is required (both salvaged/donor), should be documented in the patient's notes.
- IV Iron therapy may also be considered alone or in conjunction with salvaged/donor blood.
- The blood bag **must** show the patient's full name, date of birth, hospital number and a clear date and time of expiry before it can be administered.
- Salvaged blood must be prescribed on the patient's drug chart and treated exactly the same as donor blood regarding patient identification and observational checks. (please refer to the Trust's Transfusion policy)
- Any suspected transfusion reactions with salvaged blood should be treated exactly the same as a donor transfusion reaction. This includes testing of the remaining blood and completion of a Datix incident report form with attention to blood transfusion. This report will then automatically be forwarded to SHOT (Serious Hazards of Transfusion).
- Salvaged blood should be re-infused within 6 hours from the start of collection with or without a leuco-depletion filter (LDF). It must never be pressurised or forced through the giving set. the pressure can damage the RBCs, cause an air embolus or cause the blood bag to explode.
- If the salvaged blood is required for resuscitation, or the re-infusion is about to expire, the clinician will need to remove the filter (if used) and suspend the bag higher on the drip stand to speed up the re-infusion. The use, or not, of the LDF should be documented and the blood administered via a standard blood giving set.
- The blood should stay with the patient at all times and must **NEVER** be refrigerated.
- Salvaged blood does not contain clotting factors or preservatives – so FFP, platelets and cryoprecipitate may still be required
- Whenever blood is re-infused, the ICS data sheet (yellow) must be completed by the Anaesthetist. This is especially important in Obstetrics, where patients who have received a re-infusion are invited to have a follow-up blood test at three months, to check for antibodies. (The yellow data sheets are kept on the ICS machines.)
- Salvaged blood that has not been re-infused should be discarded before the patient is transferred from the Delivery Suite, even if this is before the 6-hour timeframe. (Disposal should be in the yellow waste bin in the sluice for IV fluids.)

LEUCO-DEPLETION FILTER USE

- There is little or no evidence for the use of leucodepletion filters (LDF) for reinfusion of blood at caesarean section.[12,13]
- A LDF may reduce reinfusion flow rate causing delay in re-infusion during major haemorrhage
- LDFs have the potential to cause bradykinin mediated hypotension. Twenty hypotensive episodes associated with using a LDF were reported to SHOT 2010-2017
- LDFs are not routinely used in obstetrics at RCHT. A standard blood giving set is used.
- They may be used at the discretion of the clinician. If this occurs they must **not** be primed with saline as they work on ionic charge as well as pore size. To increase infusion rate, use a large bore cannula and raise the height or the infusion.

CONTACT DETAILS: ext 3577 or via Net page