Intraoperative Blood Cell Salvage for Obstetrics

1. **Aim/Purpose of this Guideline**

   1.1. This guideline applies to all health professionals involved in the collection, storage and reinfusion of blood cell salvage in maternity

2. **The Guidance**

   2.1. **Introduction**
   Intraoperative blood cell salvage is an efficacious technique for blood replacement and its use is well established in areas of medicine other than obstetrics. There is a strong case for its widespread introduction in surgery to avoid the well recognised risks, costs and increasing scarcity of homologous blood for transfusion. Theoretical safety concerns have slowed the introduction of Intraoperative blood cell salvage in Obstetric settings, despite the endorsement of the AAGBI and the OAA. The National Institute for Health and Clinical Excellence reviewed the evidence in 2005 and supported its use in Obstetrics subject to:

   1. Data collection
   2. Reporting of complications to the Medicine and Healthcare products Regulatory Agency
   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 operations in the maternity theatre is now routine at The Royal Cornwall Hospital.

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

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

   To enhance the safety of Caesarean Section (CS) for patients who decline blood products from donors

2.3. **Theoretical risks**

   - 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.\(^3\)\(^-\)\(^8\)

- Sensitisation to Fetal Red Cells

The cell salvage machine is unable to distinguish between maternal and fetal red cells. When the salvaged blood is re-infused back to the mother, fetal red cells may be present in the maternal circulation in an amount that is greater than that which may occur naturally at delivery. The critical volume for maternal sensitisation to fetal red cell antigens is unknown, but sensitisation may occur more commonly after a re-infusion of cell salvage blood. Rh(D) incompatibility sensitisation can be prevented with adequate anti-D administration after delivery.

**Rhesus negative woman:** 30-45 minutes after the re-infusion has finished, a further sample of maternal blood should be taken for fetal contamination (Kleihauer test) to assess the need for additional dose of Anti D. The request form should clearly state post reinfusion sample.

The development of antibodies to other antigens can occur and these may pose a risk of fetal anaemia and haemolytic disease of the newborn in future pregnancies. With modern management good outcomes are usually achieved in such cases but treatment is invasive and poses significant risks to the mother and baby.\(^7\)\(^-\)\(^9\)

### 2.4. Indications for OCS

All elective 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.

Procedures for which cell salvage is specifically indicated are:

- **Elective CS procedures at increased risk of bleeding. e.g:**
  - Placenta praevia
  - Suspected placenta accreta
  - Classical incision
  - Past history of uterine atony
  - Maternal bleeding disorders

- **Emergency CS at increased risk of bleeding. e.g:**
  - Placental abruption
  - Placenta praevia
  - Prolonged or obstructed labour associated with atony, head impaction or oedematous lower segment
  - Women on anticoagulants
  - Maternal bleeding disorders

- **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**
2.5. Procedure

**Anaesthetic assistant**

Never delay the start of emergency surgery to set up the cell saver. Only perform cell salvage if you are trained and competent to do so.

Prepare heparinised saline 0.9% (30,000iu Heparin in 1 litre) for collection and connect to cell saver (Cell saver 5+ -usually in obstetrics). Set to automatic mode. Use one large bore suction device and pass to scrub nurse when ready. Assist anaesthetist during induction.

Record the time the collection commences. To reduce haemolysis the vacuum pressure should be set to as low as practicable.

If possible the surgeon should attempt to minimise fetal red cell contamination of the collection by cutting the umbilical cord close to the clamp.

Even though blood can be collected from blood soiled swabs following gentle irrigation with intravenous 0.9% Saline, the aim should be to minimise the number of swabs used.

If clinically indicated or a sufficient volume of blood is collected then the blood will be processed and the processing unit can then be set up.

It is not necessary to wash the collection twice but with a bowl size of 125mls, 1500ml wash should be used and set to wash at a speed of 300mls/min. A complete bowl takes 5 minutes to wash.

Complete documentation as per proforma for every case and file in ring binder folder attached to cell saver (appendix 1).

Label the final product with maternal clinical details and time collected. The product must be used within 6 hours of the start of the collection. Keep the blood with the patient either until it is re-infused or discarded. Do not refrigerate.

2.6. Administering re-infusion

It is recommended to re-infuse the final washed product through a leucodepletion filter (Pall LeukoGuard® RS Filter).

The decision to re-infuse cell saved blood is a multidisciplinary medical decision which will be influenced by the clinical case and, if appropriate, maternal consent.

The blood must be prescribed and the time and amount of blood re-infused should be clearly documented in the patient notes.

Cell saved blood has a haematocrit of approx 50% when operated in the automatic mode. Active 2, 3-DPG (Diphosphoglycerate) is found in the end product allowing for better delivery of oxygen to the tissues. It does not require warming.

- Emergency cases with significant blood loss.

  If possible obtain verbal consent from mother to re-infuse and a full blood count sample prior to starting the re-infusion. Consideration should be given to the risks and benefits of allogeneic blood, versus cell saved blood. If the patient is under general anaesthesia the decision to re-infuse is a medical one. In cases of rapid blood loss there will be a limit to the rapidity of the re-infusion through the filter, so this may be removed if blood needs to be re-infused rapidly. The re-infusion bag can not be pressurised. Manage cases of massive obstetric haemorrhage according to local guidelines. It will sometimes be necessary to give allogeneic blood simultaneously to the re-infusion.

- Non-emergency cases.

  Obtain informed consent for the re-infusion. The decision to re-infuse should be taken jointly by the clinician and the woman and is informed by an estimate of
blood loss, a HemoCue result (taken in recovery) and the clinical situation. If the woman consents to the re-infusion, when possible, take a sample of her blood for a full blood count and request a Kleihauer test on this same sample (not just Rh D negative women), before the re-infusion. Explain to the woman she will be invited for a follow up blood sample at 3 - 6 months, post delivery, to check for antibody formation. Re-infuse blood through a leucodepletion filter. Perform regular observations as for allogeneic blood transfusion. The blood must be re-infused within 6 hours of the start of the collection. Staff must time and sign the start and completion time of the reinfusion.

The decision to re infuse the salvaged blood should be made on the delivery suite and the re-infusion commenced on delivery suite. Salvaged blood not commenced before the patient leaves delivery suite should be discarded.

2.7. Follow up
Fetal red blood cells are not washed or filtered from the final product and can therefore be re-infused into the maternal circulation. The amount of fetal red cell contamination varies. The risk of maternal immunisation and the formation of clinically significant antibodies is currently unknown, although it is uncertain if a re-infusion increases the inherent risk from pregnancy itself or from a donor blood transfusion. Rh D –ve women who have a re-infusion require a further check of fetal red blood contamination, with a blood test 30-45 minutes after the re-infusion. They may require an additional dose of Anti D. It is important to understand there are clinically significant antibodies other than Rh D.

By looking at the fetal red cell contamination prior to re-infusion and the incidence of antibody formation post delivery, the risk may be quantified. We therefore, will invite all women to have a 3 - 6 month follow up blood sample for test of antibody formation.

2.8. References
INTRA-OPERATIVE CELL SALVAGE (ICS) AND RE-INFUSION INFORMATION SHEET

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
- Currently anyone who has received one unit of donor blood can not donate blood.
- One unit of donor blood currently costs the Trust £125.
- **The Transfusion rate at RCHT (2012) is 1% for Obstetric patients (ante and post-natal combined), while 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 this unless the patient specifically requests it.
- 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 transfusion, however, if surgical intervention is attempted vaginally, ICS is only considered in life threatening circumstances.
- Currently we do not offer a 24 hour service but are working towards achieving this and use it in over 90% of open operative cases.
- The CS5+ and Electa machines are used to collect or to collect and process, during surgery. Both 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 can not differentiate between maternal and foetal red blood cells. Consequently, it is likely that there are foetal 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 can not be given to a patient intravenously should not be collected 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 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.
- Category 1 and 2 sections, re-infusions are given at the discretion of the Clinician.
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.

If possible, a FBC sample to test for Kleihauer should be taken prior to re-infusion and marked FAO Ian Sullivan.

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. This report will then automatically be forwarded to SHOT.

Salvaged blood should be re-infused within 6 hours from the start of collection and it is recommended to use a Leuco-depletion filter (LDF). It is given stat but must never be pressurised or forced through the filter. If the salvaged blood is required for resuscitation, or the re-infusion is about to expire, the clinician may decide to remove the filter (see below). This will speed up the re-infusion. If the LDF is removed, this 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.

Rh D –ve women should have a repeat Kleihauer blood test 30-45 minutes after the re-infusion has completed. This is to check they do not need a larger dose of Anti D. (See guideline “Intra-operative cell salvage in obstetrics”)

Salvaged blood does not contain clotting factors or preservatives – so these may still be required.

Pressure bags must not be used with salvaged blood as the pressure can damage the RBCs, cause an air embolus or cause the blood bag to explode. Pressure bags are also contra-indicated when a Leuco-depletion filter is being used.

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-infused 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 hr timeframe. (Disposal should be in the yellow waste bin in the sluice for IV fluids.)

LEUCO-DEPLETION FILTER USE

For Obstetric patients’ blood or blood which may contain cancer cells or bacteria, re-infusion through a Leuco-depletion filter (LDF) is recommended instead of a standard blood giving set.

Leuco-depletion filters work on ionic charge and not just on filter pore size, so must not be primed with saline. To prime, follow the instructions provided to the letter- priming may take a while.

To increase the infusion rate when using a LDF – either attach to a larger cannulae and/or increase the height of the infusion.

Whilst Leuco-depletion filters are recommended for use with the re-infusion of salvaged blood, they are NOT essential and may be omitted at the discretion of the Clinician. (However, the rationale should be documented).

BLOOD CONSERVATION CONTACT DETAILS: ext 8079 or via Net page
3. Monitoring compliance and effectiveness

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<thead>
<tr>
<th>Element to be monitored</th>
<th>The use of cell salvage</th>
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</thead>
<tbody>
<tr>
<td>Lead</td>
<td>The blood conservation lead and co-ordinator for the blood conservation team</td>
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<tr>
<td>Tool</td>
<td>Monitoring sheet attached</td>
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<tr>
<td>Frequency</td>
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<td>Reporting arrangements</td>
<td>Monthly reports to blood conservation team meetings Quarterly reports to HTC meeting- minuted</td>
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<tr>
<td>Acting on recommendations and Lead(s)</td>
<td>Blood conservation lead (Dr Catherine Ralph) and blood conservation co-ordinator (Mr John Faulds) responsible for acting on recommendations</td>
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<td>Change in practice and lessons to be shared</td>
<td>Required changes to practice will be identified and actioned as soon as possible according to clinical urgency. A lead member of the blood conservation team will be identified to take each change forward where appropriate. Lessons will be shared with all the relevant stakeholders</td>
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4. Equality and Diversity

4.1. This document complies with the Royal Cornwall Hospitals NHS Trust service Equality and Diversity statement.

4.2. Equality Impact Assessment

The Initial Equality Impact Assessment Screening Form is at Appendix 2.
Appendix 1. Governance Information

<table>
<thead>
<tr>
<th>Document Title</th>
<th>Intraoperative blood cell salvage for obstetrics</th>
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</thead>
<tbody>
<tr>
<td>Date Issued/Approved:</td>
<td>24 July 2013</td>
</tr>
<tr>
<td>Date Valid From:</td>
<td>24 July 2013</td>
</tr>
<tr>
<td>Date for Review:</td>
<td>1 July 2016</td>
</tr>
<tr>
<td>Directorate / Department responsible (author/owner):</td>
<td>Dr Catherine Ralph Consultant anaesthetist</td>
</tr>
<tr>
<td>Contact details:</td>
<td>01872 253132</td>
</tr>
<tr>
<td>Brief summary of contents</td>
<td>This guideline applies to all health professionals involved in the collection, storage and reinfusion of blood cell salvage in maternity</td>
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<tr>
<td>Suggested Keywords:</td>
<td>Cell salvage</td>
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<tr>
<td>Target Audience</td>
<td>RCHT</td>
</tr>
<tr>
<td>Executive Director responsible for Policy:</td>
<td>Medical Director</td>
</tr>
<tr>
<td>Date revised:</td>
<td>June 2013</td>
</tr>
<tr>
<td>This document replaces (exact title of previous version):</td>
<td>Intraoperative blood cell salvage</td>
</tr>
<tr>
<td>Approval route (names of committees)/consultation:</td>
<td>Maternity guideline group Obs and gynaec directorate meeting</td>
</tr>
<tr>
<td>Divisional Manager confirming approval processes</td>
<td></td>
</tr>
<tr>
<td>Name and Post Title of additional signatories</td>
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</tr>
<tr>
<td>Signature of Executive Director giving approval</td>
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</tr>
<tr>
<td>Publication Location (refer to Policy on Policies – Approvals and Ratification):</td>
<td>Internet &amp; Intranet</td>
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<tr>
<td>Document Library Folder/Sub Folder</td>
<td>Midwifery and obstetrics</td>
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<td>Links to key external standards</td>
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<td>Related Documents:</td>
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Training Need Identified? Yes

Version Control Table

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<thead>
<tr>
<th>Date</th>
<th>Version No</th>
<th>Summary of Changes</th>
<th>Changes Made by (Name and Job Title)</th>
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<td>July 2010</td>
<td>1.0</td>
<td>Initial document</td>
<td>Dr Catherine Ralph Consultant anaesthetist</td>
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<tr>
<td>July 2012</td>
<td>1.1</td>
<td>Reviewed and updated</td>
<td>Dr Catherine Ralph Consultant anaesthetist</td>
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<tr>
<td>June 2013</td>
<td>1.2</td>
<td>Addition of the requirement to take an additional sample of maternal blood post reinfusion</td>
<td>Dr Catherine Ralph Consultant anaesthetist</td>
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All or part of this document can be released under the Freedom of Information Act 2000

This document is to be retained for 10 years from the date of expiry.

This document is only valid on the day of printing

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Appendix 2. Initial Equality Impact Assessment Screening Form

| Name of service, strategy, policy or project (hereafter referred to as policy) to be assessed: Intraoperative blood cell salvage for obstetrics |
| Directorate and service area: Obs and gynae directorate |
| Is this a new or existing Procedure? Existing |
| Name of individual completing assessment: Jan Clarkson |
| Telephone: 01872 252270 |
| 1. Policy Aim* |
| This guideline applies to all health professionals involved in the collection, storage and reinfusion of blood cell salvage in maternity |
| 2. Policy Objectives* |
| Safe collection and reinfusion of cell salvage |
| 3. Policy – intended Outcomes* |
| Reinfusion of patients own blood |
| 5. How will you measure the outcome? |
| Compliance monitoring |
| 5. Who is intended to benefit from the Policy? |
| Pregnant woman |
| 6a. Is consultation required with the workforce, equality groups, local interest groups etc. around this policy? |
| b. If yes, have these groups been consulted? |
| c. Please list any groups who have been consulted about this procedure. |

*Please see Glossary

7. The Impact
Please complete the following table using ticks. You should refer to the EA guidance notes for areas of possible impact and also the Glossary if needed.

- Where you think that the policy could have a positive impact on any of the equality group(s) like promoting equality and equal opportunities or improving relations within equality groups, tick the ‘Positive impact’ box.
- Where you think that the policy could have a negative impact on any of the equality group(s) i.e. it could disadvantage them, tick the ‘Negative impact’ box.
- Where you think that the policy has no impact on any of the equality group(s) listed below i.e. it has no effect currently on equality groups, tick the ‘No impact’ box.
<table>
<thead>
<tr>
<th>Equality Group</th>
<th>Positive Impact</th>
<th>Negative Impact</th>
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<th>Reasons for decision</th>
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You will need to continue to a full Equality Impact Assessment if the following have been highlighted:

- A negative impact and
- No consultation (this excludes any policies which have been identified as not requiring consultation).

8. If there is no evidence that the policy promotes equality, equal opportunities or improved relations - could it be adapted so that it does? How? Full statement of commitment to policy of equal opportunities is included in the policy

Please sign and date this form.

Keep one copy and send a copy to Matron, Equality, Diversity and Human Rights, c/o Royal Cornwall Hospitals NHS Trust, Human Resources Department, Chyvean House, Penventinnie Lane, Truro, Cornwall, TR1 3LJ

A summary of the results will be published on the Trust’s web site.

Signed Jan Clarkson

Date 7th June 2013