Joint trust guideline for the Management of Intraoperative cell salvage in obstetrics

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Version	Date	Author	Reason/Change
V1.0	September 2014	THCGAP	Change of header & footer to joint hospital version. JPUH Minor changes pg4 sentence 1. Pg 5 change of ward.
V2.0	March 2017	Dr Jeremy Corfe	Minor amendment to clarify where the cell savers are in each hospital.
V2.1	February 2019	Dr Jeremy Corfe	Addition of disclaimer to front page.
V2.2	March 2020	Dr Jeremy Corfe	No time for review due to Covid -19 a one year review date given to allow for thorough review at a later stage.
V3.0	April 2021	Dr Jeremy Corfe	Updated references and inclusion of SALVO trial and AAGBI recommendations.
V4.0	March 2024	Dr Jeremy Corfe	Updated costs of components.

			Change to audit requirements. Document transferred to new guideline template.

Previous Titles for this Document:

Previous Title/Amalgamated Titles	Date Revised
None	Not applicable

Distribution Control

Printed copies of this document should be considered out of date. The most up to date version is available from the Trust Intranet.

Consultation

The following were consulted during the development of this document:

- Mr Charlie Bircher, (NNUH), Lead Obstetrician for Delivery Floor
- Dr Lindsay Barker, Consultant Anaesthetist (NNUH)
- Dr R Dumpala, Consultant Anaesthetist (JPUH)
- Miss Daisy Nirmal (Consultant Obstetrician)
- Dr Gill Turner (Consultant Haematologist and Trust Lead for Transfusion),
- Mrs Carole Winstanley (Senior Operating Department Practitioner, Obstetric theatres)
- Miss Jan Perkins (Litigation and Complaints Manager).

Monitoring and Review of Procedural Document

The document owner is responsible for monitoring and reviewing the effectiveness of this Procedural Document. This review is continuous however as a minimum will be achieved at the point this procedural document requires a review e.g., changes in legislation, findings from incidents or document expiry.

Relationship of this document to other procedural documents

This document is a joint clinical guideline applicable to NNUH an JPUH; please refer to local Trust's procedural documents for further guidance, as noted in Section 5.

Joint trust guideline for the management of intraoperative cell salvage in Obstetrics.

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Joint trust guideline for the management of intraoperative cell salvage in Obstetrics.

1. Introduction

1.1. Rationale

Obstetric haemorrhage is major cause of maternal morbidity and mortality. In the 2016 – 2018 MMBRACE report[1] 14 women died from haemorrhage. Based on UKOSS data[2] with 6000 deliveries per year we would expect to see 2-3 peripartum hysterectomies due to massive haemorrhage each year. The incidence of Massive Obstetric Haemorrhage (MOH) has increased in developed countries over the last few decades[24]. Data from the 2014 Scottish Confidential Audit of Severe Maternal Morbidity 10th Annual Report gives a rate of 5.8 per 1000 births of major obstetric haemorrhage (≥2500ml)[20]. At the Norfolk and Norwich this would equate to approximately 35 cases of MOH per annum. Lesser degrees of blood loss occur more frequently. In 2023 there were 548 incidents of post-partum haemorrhage ≥1000mL at the Norfolk and Norwich; 34 of these were ≥ 2500ml.

Blood transfusion can be lifesaving in severe haemorrhage, but it is not without its own risks[3]. The use of intraoperative cell salvage in Obstetrics has increased over the last twenty years. Until recently, only case series totalling approximately 400 cases had been published with few reported complications[14] and it has been shown to be safe[5-12], clinically effective[5,6,11] and cost effective[13]. More recently the SALVO Trial[25] was published in 2019 which looked at its cost effectiveness and safety. The trial randomised 3028 women at risk of haemorrhage to receive routine care or cell salvage. They found that it was not cost effective to use cell salvage routinely and that there was a high incidence of feto-maternal haemorrhage in the intervention group. Only 2 serious adverse events (severe hypotension and tachycardia with difficulty breathing) were reported in the intervention group and these were considered to be secondary to the use of the Leucocyte Depleting Filters. In light of these findings, **this guideline recommends a cautious approach to its use.**

Cell salvage avoids the risks of infection and incompatibility reactions that can be associated with allogeneic blood transfusion. Salvaged blood is superior to banked blood as pH, potassium levels and 2,3 DPG levels are normal[15]. Cell salvage is acceptable to some people who would otherwise decline blood transfusion.

Previously there have been concerns over the possibility of amniotic fluid embolism (AFE) with cell salvage in obstetrics. These concerns have not been borne out in clinical practice. The pathophysiology of AFE is unclear. Previously thought to be an embolic phenomenon, it is now considered to be immune mediated and has been described as an anaphylactoid reaction[16]. It has been shown that amniotic fluid is frequently present in the maternal circulation at the time of delivery[17] but the incidence of AFE is extremely rare.

The use of the Haemonetics 5 Cell Saver with the Pall RS leucocyte depletion filter (LDF) has been shown to effectively remove all elements of amniotic fluid[17,18]. To date there have been no proven cases of AFE in the literature caused by the reinfusion of salvaged blood[12] including in the SALVO trial. Previously there had been two recent case reports of hypotension associated with reinfusion of salvaged blood. These were thought to be due to the passage of blood through the leukocyte depletion filter causing the release of vasoactive substances; the hypotension resolved when the transfusion was stopped. There were 2 occurrences of LDF

related severe adverse events in the SALVO study that both resolved when the transfusion was stopped.

The 2018 Association of Anaesthetists guideline: cell salvage for peri-operative blood conservation[26] questioned the use of LDFs because of their slow infusion rates, potential to become saturated needing replacement and their potential to cause bradykinin-mediated hypotension. Because of this, the Working Party decided not to recommend routine use of double suction or LDFs in obstetric practice.

Contamination of salvaged blood with fetal red blood cells can occur[8,17,18] and could cause maternal Rhesus or other red blood cell antigen immunisation. Higher rates of fetomaternal haemorrhage in patients receiving cell salvage were confirmed by the SALVO study. Therefore, all Rhesus negative women who receive salvaged blood must have an assessment of the degree of fetomaternal haemorrhage and appropriate administration of Anti-D.

The Obstetric Anaesthetists Association[19], the Association of Anaesthetists of Great Britain and Ireland12,26, The Royal College of Obstetricians and Gynaecologists[10], The National Institute for Health and Clinical Excellence (NICE)[11], and the Centre for Maternal and Child Enquiries[1] have all published material that endorses the use of cell salvage in obstetrics.

1.2. Objective

To facilitate the effective and safe use of cell salvage in obstetric theatres. This guideline will describe the indications for its use, the process of collecting and re-infusing blood and the required follow up.

1.3. Scope

This guideline has been approved by the Trust's Clinical Guidelines Assessment Panel as an aid to the diagnosis and management of relevant patients and clinical circumstances. Not every patient or situation fits neatly into a standard guideline scenario and the guideline must be interpreted and applied in practice in the light of prevailing clinical circumstances, the diagnostic and treatment options available and the professional judgement, knowledge and expertise of relevant clinicians. It is advised that the rationale for any departure from relevant guidance should be documented in the patient's case notes.

The Trust's guidelines are made publicly available as part of the collective endeavour to continuously improve the quality of healthcare through sharing medical experience and knowledge. The Trust accepts no responsibility for any misunderstanding or misapplication of this document.

1.4. Glossary

The following terms and abbreviations have been used within this document:

Term	Definition
NNUHFT	Norfolk and Norwich University Hospital Foundation Trust
JPUH	James Paget University Hospital
CGAP	Clinical Guidelines
MOH	Massive Obstetric Haemorrhage
AFE	Amniotic Fluid embolism
LDF	Leucocyte depletion filter
AAGBI	Association of anaesthetist of Great Britain and Ireland
FACS	Flourescence activated cell sorting
SHOT	Serious hazards of transfusion
SABRE	Serious adverse blood reactions and events
MHRA	Medicines and Healthcare products regulatory agency

2. Responsibilities

All anaesthetic and obstetric staff who provide care in a setting which may require the use of intraoperative cell salvage should ensure they remain up to date with this clinical guideline. Please see section 3.3.

3. Policy Principles.

3.1. Broad Recommendations

3.1.1. Intraoperative Cell salvage in obstetrics should be considered for the following situations:

1. Caesarean section at increased risk of significant bleeding:
    - Grade 4 placenta praevia.
    - Placental abruption.
    - Suspected placenta accreta or percreta.
    - Maternal bleeding disorders.
2. Caesarean section for women who refuse transfusion of allogeneic blood.
3. Laparotomy following postpartum haemorrhage.
4. In an emergency situation when there is difficulty with crossmatching.

3.1.2. Contraindications to the use of cell salvage:

1. Contamination of surgical field with:
    a) Bowel contents.
    b) Substances not licensed for intravenous use.
2. Malignancy.
3. Homozygous Sickle Cell Disease.

3.2. Procedure

The decision to use the cell saver should be made by a senior clinician only (Consultant or ST 6 and above). All anaesthetists and obstetricians should understand the indications, contraindications, benefits and risks of cell salvage. Theatre staff should only set up and use the cell saver if appropriately trained and competent to do so. Training for theatre staff is provided during governance sessions 2-3 times per year. An E-Learning module for cell salvage is available at www.transfusionguidelines.org.uk.

In the James Paget Hospital there is one CATS cell saver in main theatres which can be found in old ITU. At the Norfolk and Norwich there are Haemonetics cell savers available in Obstetric theatres, Theatre 2 (Orthopaedics), Theatre 6 (Emergencies) and Theatre 18 (Vascular).

Disposables for the Haemonetics cell savers come in two parts: collection and processing. The collection reservoir costs £50.83 and the sucker costs £17.80 giving a total cost of £68.63 for the collection kit. The processing unit costs £85.23 and a leukocyte depleting filter costs £6.29. The total cost for collection, processing and re-transfusion of blood is £160.15. A unit of allogeneic blood costs £158.18[28]; blood bank, staff and disposable costs[27]add additional cost.

It is not necessary to open both parts initially. The cell saver should initially be set up in 'collect only' mode. Only if sufficient blood is collected should the processing part be opened and used. Even when massive blood loss is expected it is more economical to initially set up only the collection part of the cell salvage disposables.

In situations when increased risk of bleeding is predicted, the collection part of the cell saver should be set up before the start of surgery. This allows maximal collection of blood. Waiting for haemorrhage to occur before setting up the cell saver results in blood being lost and the member of the theatre team setting up the cell saver will be temporarily unavailable during the haemorrhage situation.

Informed patient consent should be obtained prior to its use but this may not be possible in all emergency situations.

3.3. Collection

A two sucker technique should be used to try and reduce contamination by amniotic fluid. Initially the standard theatre suction should be used to clear amniotic fluid from the surgical field. Cell salvage suction should then be started as soon as possible after delivery of the baby. In some circumstances (e.g. anterior placenta praevia) it may be appropriate to commence cell salvage before delivery of the baby as significant blood loss may occur before. The AAGBI Working Party decided not to recommend routine use of double suction or LDFs because "in-vitro evidence consistently demonstrates that the cell salvage/filtration process can effectively remove plasma phase elements of amniotic fluid whatever the initial load[26]." However, this guideline recommends a cautious approach, and this practice will continue locally.

To optimise the yield and quality of salvaged blood a large bore sucker should be used in conjunction with a low vacuum pressure. Significant blood may be lost on

swabs. By gently washing the swabs in isotonic saline in a sterile bowl and then processing the fluid some of this blood may be retained.

Cell salvage should be discontinued when substances not licensed for intravenous use are present within the surgical field. The standard theatre suction should be used, and the wound irrigated with copious 0.9% sodium chloride before resuming cell salvage. Contamination of the field with urine is not a contraindication to cell salvage as it is widely used in urological surgery. However, the presence of bowel contents should be considered a contraindication unless there is catastrophic haemorrhage. Obvious meconium should be removed from the surgical field prior to collection. The risk of infection also exists if cell salvage is used for vaginal bleeding. Blood loss from vaginal wounds should not be suctioned unless there is catastrophic haemorrhage.

If enough blood is collected and it is thought necessary to reinfuse the blood, then the processing part of the kit should be set up and the collected blood processed. The collected blood is washed in saline and centrifuged which removes any debris, fibrin, plasma, platelets, complement, free haemoglobin, microaggregates, and most of the heparin. **Salvaged blood contains no platelets or clotting factors.** The packed red cells are re-suspended in saline (haematocrit 50 – 80) before being pumped up to the re-transfusion bag. A leucocyte depletion filter and a standard blood giving set should be connected to the transfusion bag and primed before being connected to the patient.

3.4. Reinfusion

Salvaged blood may contain fetal red blood cells. This not only puts the mother at risk of Rhesus immunisation (if Rhesus negative) but also at risk of immunisation and formation of other clinically significant antibodies. The degree of risk of non-Rhesus antigen immunisation from salvaged blood in respect to pregnancy itself is not known. It cannot be attenuated by administration of a similar product to anti-D. This is in conjunction with the very low and theoretical risk of AFE means that salvaged blood should only be re-infused if clinically indicated. **The decision to re-infuse should be guided by the pre-operative haemoglobin, estimated blood loss, the clinical situation and, ideally, a HemoCue.**

Reinfusion of salvaged blood should be via a dedicated cannula. A leukocyte depletion filter should be used unless there are special circumstances. The Pall LeukoGuard® RS Leukocyte Reduction Filter is the only filter proven to eliminate residual elements of amniotic fluid. Product information states that the filter has a maximum capacity of 450mL and should therefore be changed after this much has been transfused. Flow rates through these filters are slow and may not be fast enough in situations of rapid blood loss. The use of a pressure bag is not recommended due to the risk of air embolism and its potential impact on the retention of amniotic fluid components within the filter. To increase the flow rate a second filter may be connected to each port on the reinfusion bag and connected to the same giving set via a 3-way tap.

In life threatening haemorrhage when allogeneic blood is not available or is declined, flow rates through the filter may not be fast enough. In this situation careful consideration should be given to removing the filter altogether. If hypotension occurs

on infusion of salvaged blood the infusion should be stopped until the blood pressure normalises. It can then be carefully restarted. If hypotension recurs, then the infusion should be stopped and consideration should be given to removing the filter.

Salvaged blood should immediately be labelled with a patient identity sticker and the time of the start of transfusion. To avoid "wrong blood, wrong patient" errors reinfusion must always begin before the patient leaves theatre. Ideally reinfusion should be completed before the patient leaves Recovery but may be continued if the patient is to remain on Delivery Suite. It should be discontinued before the patient is transferred to the postnatal ward. **Salvaged blood must be kept with the patient at all times and must never be stored. In all circumstances reinfusion of salvaged blood should be completed within 4 hours of collection.**

3.5. Follow Up

Transfusion of salvaged blood exposes Rhesus negative mothers to the risk of Rhesus immunisation. Trust Guideline on the use of Anti-D immunoglobulin for Rhesus Prophylaxis in RhD-negative women Trustdocs Id: 827 must be followed. A sample of maternal blood should be taken after the transfusion of salvaged blood has been completed. This should be sent for Fluorescence-activated cell sorting (FACS) measurement of the degree of fetomaternal haemorrhage. Anti-D can then be given as required to mothers of Rhesus positive infants. This applies to all Rhesus negative women, even those who have had a caesarean-hysterectomy.

3.6. Special Circumstances:

3.6.1. Jehovah's Witnesses:

Due to religious beliefs Jehovah's Witnesses may refuse allogenic blood transfusion (red cells, platelets, fresh frozen plasma and cryoprecipitate). Some will accept autologous salvaged blood if the system is set up as a continuous circuit. This is an individual decision for each person. Please refer to the trust guideline on the Management of Obstetric Haemorrhage in Women who refuse Blood Transfusion Trustdocs Id: 851. If there is no advance decision in the notes detailing refusal of cell salvage or if there has not been the opportunity to discuss the use of cell salvage (i.e., an unconscious patient) then it can be used in the best interests of the patient. For further information on the Treatment of Patients who lack Mental Capacity, Advance Decisions and Achieving Resolution in Difficult Cases please refer to the Consent to Examination or Treatment Policy, Appendices 4, 8 and 9.

The continuous circuit must be set up before any blood is collected. To set up the circuit in continuity both parts of the set (collection and processing) must be opened and primed with saline ensuring that the saline enters the reinfusion bag. An appropriate giving set with a leukocyte depleting filter should be primed and attached to the reinfusion bag. The giving set should be attached to a dedicated cannula and the saline administered at the slowest rate possible to maintain the patency of the cannula. A 3 way tap inserted between the filter and giving set will allow the filter to be changed after 450mL of blood has been infused whilst maintaining continuity of the circuit.

3.6.2. Sickle Cell Disease:

Homozygous Sickle-Cell disease is a contraindication to the use of cell salvage. Heterozygous disease (sickle cell carrier or trait) is a relative contraindication. Studies[22,23] looking at the occurrence of sickling in processed blood from sickle cell carriers have shown results ranging from altered cells with no sickling to as much as 50% sickled cells. In one of these studies blood with 20% sickled cells was transfused to the patient who made an uneventful recovery. Current national guidance does not cover this situation.

Because of the associated risks it should only be used in a lifesaving situation when other options have failed or are unavailable. The decision to use cell salvage in the presence of sickle cell carrier status should be made on an individual patient basis and where possible appropriate informed consent should be taken before its use. If salvaged blood from a sickle cell carrier is to be re-infused, then a blood film from the processed blood should be performed urgently to ascertain the degree of sickling. Advice should be sought from Haematology.

3.6.3. Critical Incidents:

Any adverse incident associated with intraoperative cell salvage must be reported to Transfusion Services. They in turn will submit a report to SHOT (Serious Hazards of Transfusion) and SABRE (Serious Adverse Blood Reactions and Events) which is part of the Medicines and Healthcare products Regulatory Agency (MHRA). **This is a legal requirement**. Incidents that should be reported include any operator error (e.g. incorrect equipment assembly, aspiration of contraindicated substances, time exceeded for transfusion, reinfusion bag not labeled, etc), machine failure, clinical events (e.g. hypotension, air embolus, coagulopathy, etc). More information can be found at www.shotuk.org.

4. Training & Competencies

All anaesthetists and obstetricians should understand the indications, contraindications, benefits and risks of cell salvage. Theatre staff should only set up and use the cell saver if appropriately trained and competent to do so. Training for theatre staff is provided during governance sessions 2-3 times per year. An E-Learning module for cell salvage is available at www.transfusionguidelines.org.uk.

5. Related Documents

Anti D Immunoglobulin for RH prophylaxis in RhD-negative women (Trust Docs ID 827)

Obstetric haemorrhage in women who decline blood and blood products (Trust Docs ID: 851)

Cell salvage elearning module. Transfusion guidelines.org - https://www.transfusionguidelines.org/document-library/documents/the-learn-blood-transfusion-elearning-package
Serious Hazards of Transfusion - https://www.shotuk.org/

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7. Monitoring Compliance

Compliance with the process will be monitored through the following:

Key elements	Process for Monitoring	By Whom (Individual / group /committee)	Responsible Governance Committee /dept	Frequency of monitoring
Adverse incidents	Monitoring of incident reports via DATIX	Women's and Childrens Risk and Governance	Women's and Childrens Risk and Governance	Case by Case

Adverse incidents will be reports and investigated via Datix. Key learning will be shared via Maternity Clinical Governance to review the results and recommendations for further action. Maternity Clinical Governance will ensure that the actions and recommendations are suitable and sufficient.

8. Appendices

There are no appendices for this document.

9. Equality Impact Assessment (EIA)

Type of function or policy	Existing

Division	Women and Childrens	**Department**	Obstetrics
Name of person completing form	Nikki Hill	**Date**	07/03/24

Equality Area	Potential Negative Impact	Impact Positive Impact	Which groups are affected	Full Impact Assessment Required YES/NO
Race	No	No	None	No
Pregnancy & Maternity	No	No	None	No
Disability	No	No	None	No
Religion and beliefs	Yes	Yes	Jehovah's Witnesses	Yes
Sex	No	No	None	No
Gender reassignment	No	No	None	No
Sexual Orientation	No	No	None	No
Age	No	No	None	No
Marriage & Civil Partnership	No	No	None	No
EDS2 – How does this change impact the Equality and Diversity Strategic plan (contact HR or see EDS2 plan)?				

- **A full assessment will only be required if: The impact is potentially discriminatory under the general equality duty**
- **Any groups of patients/staff/visitors or communities could be potentially disadvantaged by the policy or function/service**
- **The policy or function/service is assessed to be of high significance**

IF IN DOUBT A FULL IMPACT ASSESSMENT FORM IS REQUIRED

The review of the existing policy re-affirms the rights of all groups and clarifies the individual, managerial and organisational responsibilities in line with statutory and best practice guidance.