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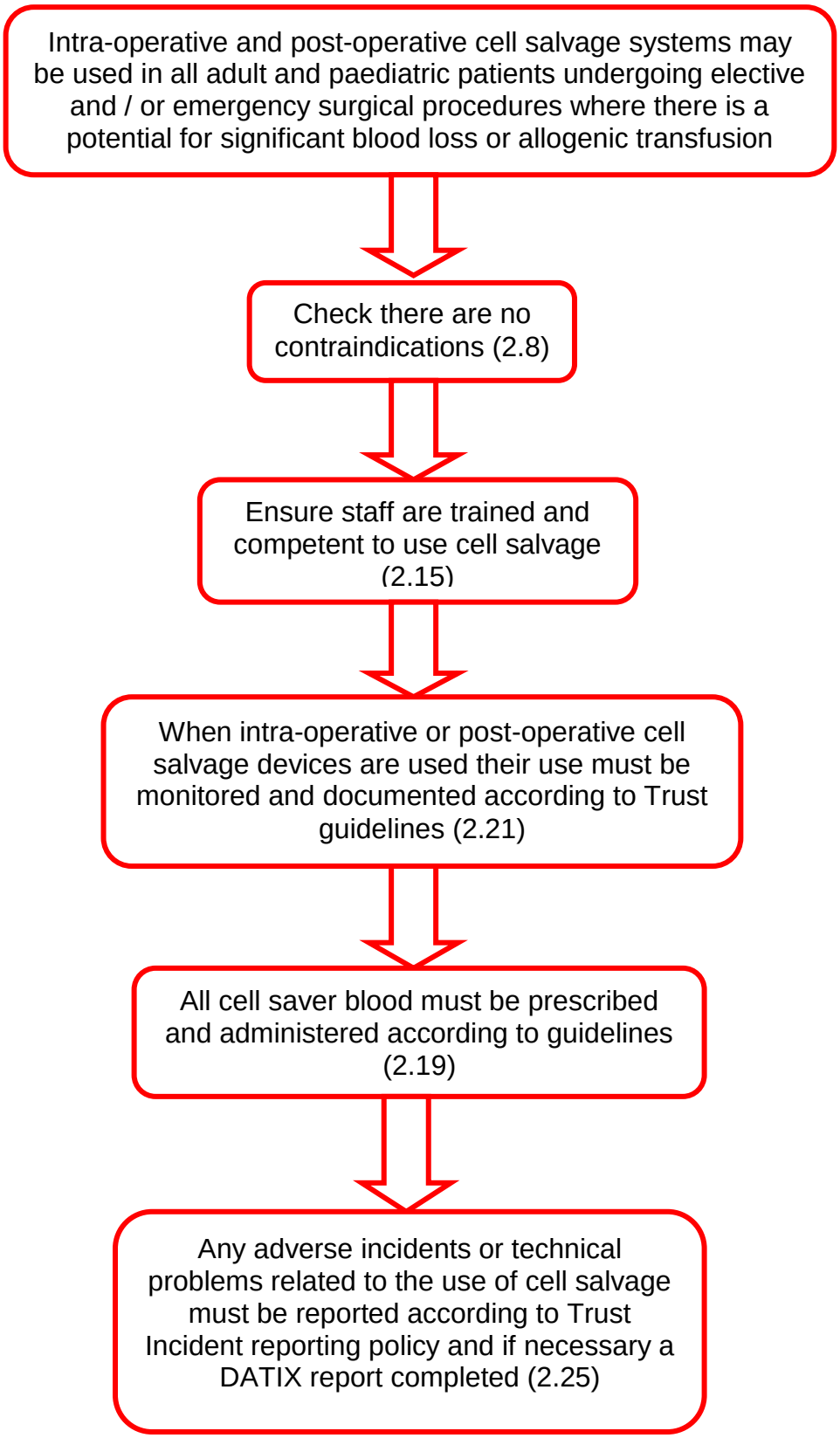
Royal Cornwall Hospitals NHS Trust

Intra-operative Cell Salvage Clinical Guideline

V3.0

October 2018

Summary intra-operative cell salvage



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

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.

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 Intra-operative (ICS) and Post-operative (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 AAGBI recommendations

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 Trusts 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.

2.9.7. Obstetric Cell Salvage. There is no evidence to support initial aspiration of amniotic fluid to waste using standard theatre suction, as amniotic fluid is removed during the ICS washing process. Use ICS suction device throughout. See separate guideline Intraoperative Blood Cell Salvage For Obstetrics V1.3

2.10. Using the Leucodepletion filter (LDF)

2.10.1. **Obstetrics & malignancy**

The use of the LeukoGuard® RS Leukocyte removal filter for Salvaged Blood is recommended in obstetrics & malignancy. The flow rate is 82(41-112)ml/min and the maximum capacity per filter is around 450ml (for washed intra-operatively 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 Hartman'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 but pressure cuffs must not be used as complete air removal is not guaranteed.

2.12. Indications and Patient Selection

Intra-operative and post-operative 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

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

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

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, some orthopaedic cases and Obstetrics (see separate guideline). However, the evidence to support these recommendations is poor and it is acceptable for the prescribing clinician to omit the leucodepletion filter in obstetrics cases and after due consideration for other indications (2.10).

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.

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

2.22. Disposal of Used Cell Salvage Equipment

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

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. References

www.transfusionguidelines www.transfusionguid.org.uk

3. Monitoring compliance and effectiveness

Element to be monitored	All cell salvage use Cell Salvage training competencies All Cell Salvage Devices
Lead	Catherine Ralph, Carol McGovern, Sean Baulch
Tool	Monitoring sheet for Cell Salvage use Training database Machine logs (Servicing, electrical safety checks and maintenance)
Frequency	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	Hospital Transfusion Team (HTT) Interrogated by members of committee and documented in minutes of HTT meeting.
Acting on recommendations	Blood Conservation team, lead or coordinator will undertake any recommendations within reasonable timeframes

and Lead(s)	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 lead 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	Intra-operative Cell Salvage Clinical Guideline V3.0			
Date Issued/Approved:	6 June 2018			
Date Valid From:	17 October 2018			
Date Valid To:	17 October 2021			
Directorate / Department responsible (author/owner):	Catherine Ralph – 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 setting.			
Suggested Keywords:	Cell salvage. Blood conservation.			
Target Audience	RCHT	CPT	KCCG	
	✓			
Executive Director responsible for Policy:	Medical Director			
Date revised:	6 June 2018			
This document replaces (exact title of previous version):	Clinical Guideline for Intra-operative Cell Salvage V2.0			
Approval route (names of committees)/consultation:	Blood Conservation Coordinator Hospital Transfusion Team Hospital Transfusion Committee			
Divisional Manager confirming approval processes	David Smith			
Name and Post Title of additional signatories	Not Required			
Name and Signature of Divisional/Directorate Governance Lead confirming approval by specialty and divisional management meetings	{Original Copy Signed}			
	Name: Suzanne Atkinson			
Signature of Executive Director giving approval	{Original Copy Signed}			
Publication Location (refer to Policy on Policies – Approvals and Ratification):	Internet & Intranet	✓	Intranet Only	
Document Library Folder/Sub Folder	Clinical / Anaesthetics			
Links to key external standards	CQC16			

Related Documents:	Intra-Operative cell salvage in obstetrics
Training Need Identified?	Yes

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

Appendix 2. Initial Equality Impact Assessment Form

Name of the strategy / policy /proposal / service function to be assessed Intra-operative Cell Salvage Clinical Guideline V3.0					
Directorate and service area: Medical			**Is this a new or existing *Policy?*** Existing		
Name of individual completing assessment: Catherine Ralph			**Telephone:** 01872 250000 (via switch) Or 01872253196		
1. *Policy* Aim* *Who is the strategy / policy / proposal / service function aimed at?*	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 ~~utilise it~~ in a safe effective manner.				
2. *Policy* Objectives*	To provide a rational and practical framework on which to maximise patient safety during Cell Salvage				
3. *Policy* – intended Outcomes*	Safe and effective use of Cell Salvage during and after surgery				
4. *How will you measure the outcome?	Monitor all episodes of Cell Salvage usage.				
5. Who is intended to benefit from the *policy*?	All patients undergoing surgical procedures for which blood loss can be collected into the cell saver				
6a Who did you consult with b). Please identify the groups who have been consulted about this procedure.	Workforce	Patients	Local groups	External organisations	Other
			√		
	Please record specific names of groups RCHT Surgical Patient Blood Management group HTT (Hospital transfusion team)				
What was the outcome of the consultation?	Endorsed and ratified				

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 differential impact on:				
Equality Strands:	Yes	No	Unsure	Rationale for Assessment / Existing Evidence
Age		**X**		
Sex (male, female, trans-gender / gender reassignment)		**X**		

Race / Ethnic communities /groups		**X**		
Disability - Learning disability, physical impairment, sensory impairment, mental health conditions 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**		

You will need to continue to a full Equality Impact Assessment if the following have been highlighted:

- You have ticked "Yes" in any column above and
- No consultation or evidence of there being consultation- this excludes any *policies* which have been identified as not requiring consultation**. or**
- Major this relates to service redesign or development

8. Please indicate if a full equality analysis is recommended.	**Yes**		**No**	

9. If you are **not** recommending a Full Impact assessment please explain why.

Signature of policy developer / lead manager / director Catherine Ralph	Date of completion and submission 6.6.18

Names and signatures of members carrying out the Screening Assessment	1. Catherine Ralph 2. Human Rights, Equality & Inclusion Lead	

Keep one copy and send a copy to the Human Rights, Equality and Inclusion Lead, c/o Royal Cornwall Hospitals NHS Trust, Human Resources Department, Knowledge Spa, Truro, Cornwall, TR1 3HD

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

Signed Catherine Ralph

Date 6.6.18