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Intraoperative Cell Salvage Procedure

Introduction and Aim

This procedure is supporting the Intraoperative Cell Salvage Policy.

The Welsh Health Circular (WHC), "Better Blood Transfusion: Appropriate Use of blood", recommends that in order to make transfusion safer, to provide better information for patients relating to transfusion and to avoid the unnecessary use of blood in clinical practice, blood transfusion must be an integral part of care and clinical governance responsibilities. The WHC further recommended that effective alternatives to allogeneic blood transfusion be explored, including the appropriate use of autologous blood transfusion techniques such as Intraoperative Cell Salvage (ICS).

The aim of this procedure is to support a safe, effective, efficient, lawful, timely, equitable, patient centred and prudent approach to using ICS.

Objectives

- To promote safer transfusion as part of clinical governance responsibilities
- To ensure that ICS is used by adequately trained staff, is simple, safe and cost effective method of reducing allogeneic transfusion.
- To assist clinical staff in the identification of patients and procedures considered suitable for ICS and outlining the indications and contraindications.
- To assist clinical staff to provide appropriate advice on options for treatment, particularly where patients are anxious about risks associated with, or prefer not to receive, allogeneic blood.
- To provide clear written information about the risks and benefits of autologous transfusions from blood salvaged intraoperatively.
- To assist clinical staff to minimise avoidable / potential risks of autologous transfusions from blood salvaged intraoperatively.
- To ensure that any treatment is given lawfully

Scope

This procedure has been written to support the implementation and use of intraoperative cell salvage in the intraoperative / surgical setting within the Cardiff and Vale University Health Board (UHB). It may also be applicable when intraoperative cell salvage devices are used in the pre and /or postoperative environment (e.g. Emergency Unit, recovery, ward etc.) and for devices specifically designed for Intra and Post-operative Cell Salvage.

Equality and Health	An Equality and Health Impact Assessment (EHIA) has been

Impact Assessment	complete and this found there to be a positive impact. Key actions have been identified and these can be found within this procedure.
Documents to read alongside this Procedure	UHB 030 - Cell Salvage Policy UHB 068 - Blood Component Policy UHB 348 - Blood Component Procedure UHB 282 - Decontamination of Reusable Medical Devices Policy and Procedure UHB 100 - Consent to Examination or Treatment Policy UHB 186 - Independent Mental Capacity Advocacy Procedure (Mental Capacity Act 2005), UHB 113 - Lasting Power of Attorney and Court Appointed Deputy Procedure (Mental Capacity Act 2005), Welsh Government Guide to Consent for Examination or Treatment (July 2017) Mental Capacity Act 2005 Code of Practice ANTT all- Wales policy http://www.gpone.wales.nhs.uk/sitesplus/documents/1000/ANTT%20IPC%20Policy%20FINAL%20May%202017%20V1pdf.pdf UHB 138 – Incident, Hazard and near miss reporting policy and procedure
Approved by	Quality, Safety and Experience Committee

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Disclaimer

If the review date of this document has passed please ensure that the version you are using is the most up to date either by contacting the document author or the Governance Directorate.

Summary of reviews/amendments			
Version Number	**Date of Review Approved**	**Date Published**	**Summary of Amendments**
1	12/06/18	13/06/18	Previous policy is now split into a policy and procedure. Welsh Government Guide to Consent for Examination or Treatment (July 2017) and Mental Capacity Act Code of Practice 2005 referred to.

Contents

ROLES AND RESPONSIBILITIES

The UHB

The UHB is responsible for

- Ensuring that there is a Clinical Lead for Cell Salvage. The organisation's Clinical Lead for ICS is currently a Consultant Anaesthetist.
- Providing a member of the theatre management team to be the Operational Manager, responsible for ensuring overall management and facilitation of the ICS service. The Senior Nurse for Theatres is currently in this role. The Operational Manager will be supported by a number of Cell Salvage Coordinators.
- Ensuring that all cell salvage operators have been trained and achieved their cell salvage competencies.
- Ensuring that competent personnel in sufficient numbers are available to provide the ICS service, including for out of hours cases if applicable.

The Clinical Lead

The Clinical Lead is responsible for

- Identifying members of staff who will take on the role of coordinating the cell salvage service.
- Being involved in the purchase of equipment and service contracts.
- Liaising with the Lead ICS clinician to produce and implement local protocols and guidelines.

The Cell Salvage Co-ordinators

The Cell Salvage Co-ordinators are responsible for

- Delivering and recording of training and competency assessment.
- Arranging for cell salvage to be available at the clinician's request.

If the service is not available this should be reported to the lead ICS Manager and Clinician

- Ensuring audit is complete
- Regular Quality Control of machines

These roles are carried out as extended roles by named theatre staff.

Prescribing Responsibilities

Salvaged blood for reinfusion will be appropriately prescribed by the responsible clinician on the designated documentation. The responsible

clinician must also ensure that valid consent for transfusion is obtained, or where there is reason to doubt a patient's mental capacity to provide consent, the Mental Capacity Act 2005 is followed.

Labelling Responsibilities

The reinfusion bag must be labelled as soon as is reasonably practical (i.e. When the patient is in theatre or as soon as the processing set is loaded if a "collect only" system has been used initially). The patient details should be handwritten and include the following:

- Full name
- Date of birth
- Hospital number
- Collection start date and time
- Expiry date and time

Addressograph labels **should not** be used because of the known associated risks.

Individual Responsibilities

The cell salvage Operators will ensure that they are adequately trained and competent in the safe use of the ICS system in each of the specialities they work in. All individuals involved in the care of patients undergoing cell salvage will ensure that they are adequately trained in the safe use, including the indications and contraindications, of cell salvage i.e. operator, anaesthetic, surgical, scrub, recovery and ward staff.

Documentation responsibilities

Staff must ensure that documentation (including all appropriate labelling) accurately reflect the ICS process, the documentation record should include:

- The ICS audit form (Appendix 1). Audit of use enables future service planning and quality assurance.
- The autologous transfusion label which must be fully completed and attached to the reinfusion bag.
- At the time of reinfusion of the salvaged blood, the peel out section on the autologous transfusion label must be completed and attached in the appropriate place in the patients' clinical records or equivalent as specified in the Blood Component Transfusion Procedure
- There must be appropriate labelling of anticoagulant used e.g. Heparin Saline with confirmation of appropriate dose by lead Anaesthetist at the start of the procedure. (See appendix 10). Guidance on prescribing will be attached to each of the machines.
- Bedside pre-transfusion checks and patient observations should be performed and recorded during the autologous blood reinfusion in the

same way as for the transfusion of allogeneic blood. Refer to the UHB 068 Blood Component transfusion policy and UHB 348 Blood component transfusion procedure. The minimum observations required are pre-transfusion, 15 minutes into the transfusion and on completion of the transfusion. Additional observations are at the discretion of the clinical staff based on an individual patient assessment.

- Adverse incidents should be documented in the patients' clinical records

TRAINING

Training is provided in accordance with the Joint United Kingdom Blood Transfusion and Tissue Transplantation Services Professional Advisory Committee (JPAC). A UK Cell Salvage Action Group was established in 2006 to help support wider implementation of cell salvage as an alternative to donor blood https://www.transfusionguidelines.org/transfusion-practice/uk-cell-salvage-action-group

Individual staff must receive training in the indications, contraindications and technical differences specific to their speciality /specialties. If a member of staff moves from one speciality to another, it is essential that training needs are identified and addressed prior to the staff member using ICS in their new clinical environment.

Theoretical and practical training must be undertaken and staff must be competency assessed before they set up or operate ICS equipment without supervision. This must include Aseptic Non Touch Technique (ANTT) training and assessment

Staff carrying out ICS for patients with particular religious or other requirements must have received training and have been competency assessed in preparing the equipment and blood for reinfusion in accordance with the patients' requirements prior to carrying out the procedure.

An ICS Competency Assessment Workbook is available via the Better Blood Transfusion Toolkit https://www.transfusionguidelines.org/transfusion-practice/uk-cell-salvage-action-group/cell-salvage-competency-workbooks . All members of staff carrying out ICS will hold this workbook and once assessed as competent will keep an ongoing log (as in the ICS Competency Assessment Workbook) of all the ICS procedures they carry out.

Update training is recommended under the following circumstances:

- Any reasonable length of time without practical use of the ICS device
- A learning need is identified by an individual member of staff or supervisor
- Changes in the product from the manufacturer or a change in the product due to the organisation trialling/purchasing new products
- Changes to national and/or local guidelines relating to any aspect of autologous transfusion (which could include changes to the Blood Component Transfusion policy

To ensure that trained personnel are available to operate the cell saver, for elective cases the Consultant Surgeon must give at least two weeks' notice to the Clinical Lead in anaesthesia.

INDICATIONS AND PATIENT SELECTION

ICS systems may be used in elective and/or emergency surgical procedures where the surgical field is not contaminated by faecal or infective matter and where no other contraindications exist (see next section).

Patient selection for ICS is considered via the clinical decision making processes of the surgeon and anaesthetist responsible for the patient. Providing that none of the contraindication listed in the next section exist, patients to be considered for ICS include

- Adult and paediatric patients undergoing elective or emergency surgical procedures where the anticipated blood loss in greater than 20% of the patient's estimated blood volume
- Cases fitting the criteria that are undertaken locally regularly include:
    - Cardiac surgery
    - Scoliosis surgery
    - Revision hip replacements
    - Major gynaecological surgery
    - Abdominal Aortic Aneurysm
    - Cystectomy
    - Nephrectomy
    - Liver resection
    - Pancreatic transplantations
    - Caesarian sections at high risk of bleeding greater than 20% total blood volume
    - Postpartum haemorrhage
    - Meningioma

- Major trauma where blood loss likely to be greater than 20% total blood volume
- Any procedure where blood loss is higher than expected and likely to exceed 20% total blood volume
- Adult and paediatric patients undergoing elective or emergency surgical procedures who have risk factors for bleeding or low preoperative Haemoglobin levels
- Patients who have rare blood groups or multiple antibodies for whom it may be difficult to obtain allogeneic blood

CONTRAINDICATION AND WARNINGS

The risk benefit ratio of ICS should be assessed for each individual patient by the surgeon and anaesthetist responsible for the patient's care.

Contraindications

ICS should not be used in the following situations:

- Bowel contents in the surgical field
- Heparin induced thrombocytopenia or Antithrombin III Deficiency when heparin is the anticoagulant of choice (a citrate containing anticoagulant solution may be used instead) See appendix 10)

Warnings

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

Examples of non-IV materials that should not be aspirated into the ICS system include:

- Antibiotics not licensed for IV use
- Iodine
- Topical Clotting Agents
- Orthopaedic cement of debris
- The use of ICS in the presence of **infection** may result in bacterial contamination of the salvaged blood. The aspiration of blood from an infected site should be avoided and antibiotics should be given as appropriate.

- **Gastric/pancreatic** secretions should not be aspirated into the system as they may cause enzymatic haemolysis and are not reliably removed by the washing procedure.
- **Pleural effusions** should not be aspirated and should be drained prior to cell salvage. However, blood which subsequently accumulates in the pleural space may be aspirated.
- There are concerns relating to the use of ICS in patients with **sickle cell disease**. The use of ICS in patients with abnormal red cell disorders should be made on a clinical, individual patient basis.
- **Amniotic fluid** shouldn't be aspirated into the system due to theoretical concerns related to Amniotic Fluid Embolism. See Appendix III for obstetric ICS usage.
- The use of ICS in patients undergoing surgery for **malignant disease** is not recommended by the manufacturers of ICS devices. This is due to concern about the possibility of malignant cells being reinfused and giving rise to metastases. It is vital that the clinicians remain up to date with the latest evidence relating to this. However, there are now a number of reports in the literature of the use of ICS in cancer surgery without obviously leading to early metastasis and some hospitals now use ICS routinely during surgery for malignant disease. Aspiration of blood from around the tumour site should be avoided to minimise decontamination of salvaged blood with malignant cells and the salvaged blood should be reinfused through a leucocyte reduction filter to minimise the reinfusion of any malignant cells which may have been aspirated into the collection reservoir. The decision to use ICS in the presence of malignant disease should be made by the surgeon and anaesthetist in consultation with the patient and duly documented in the medical records
- As there is no evidence to support the use of cell salvage in **paediatric malignancy** surgery the local paediatric oncologists have advised against its use. In cases where it is felt that benefit may outweigh the risk. Obtain the agreement of the paediatric oncologist prior to proceeding

Cautions

- The use of Hartmann's Solution will inhibit the action of citrate based anticoagulants (e.g. ACD) if used as an irrigant or wash solutions.
- Air will be present in the primary reinfusion bag when it is still connected to the cell saver or when it has been disconnected but air has not been evacuated. Where possible, all air should be evacuated from the primary reinfusion bag prior to reinfusion. Manufacturers advise not to use a pressure cuff as there is a risk of air embolus and

some devices may also detect a back pressure if the reinfusion line is open.

- Manual node – it is recommended the ICS devices are not run in manual mode as this may lead to reduced quality, insufficient washing of the final red blood cell product and the possible reinfusion of potentially harmful contaminants e.g. heparin. Machines should be run in automatic mode and manual mode should only be used when the benefits of doing so outweigh the risks e.g. emergency situations where the need to reinfuse the red cells quickly outweighs the risks associated with running the machine in manual mode.

PATIENT INFORMATION AND CONSENT ISSUES

Patients considered likely to have ICS during planned surgery must receive information about ICS before their operation. The process must be discussed with the patient pre-operatively whenever possible. Written information should be given to the patient wherever possible – for example the Patient Information Leaflet "Cell Salvage" (Appendix 5.1).

The patient must be given comprehensive information, in a format that they are likely to be able to understand, about ICS. They must also be advised of any specific risks peculiar to them that this procedure might involve. They must also be told of any alternatives to ICS (i.e allogeneic blood). The patient's consent must be obtained and documented.

Where the patient is aged under 16 years, a person with parental responsibility must give consent if the patient is not *Gillick* competent.

If there is reason to doubt the patient's mental capacity to consent to ICS and the patient is aged 16 years and over, then the Mental Capacity Act 2005 must be followed.

In an emergency, in the absence of a valid Advance Decision to Refuse Treatment or an attorney of a personal welfare Lasting Power of Attorney, the clinician should decide how to proceed using the information they have available and their clinical experience.

For further information about consent and capacity issues, please see the UHB's Consent to Examination or Treatment Policy

CONDITIONS FOR USING ICS

Use of ICS Equipment

- The ICS system should be used in accordance with the manufacturer's guidelines (Appendix 5).
- All procedures should be carried out in accordance with this and other relevant policy /procedural documents including infection control, management of sharps, decontamination and blood components transfusion.
- The ICS system should be routinely run in automatic mode (see Cautions in the precious section).
- Contraindications should be considered as identified in the previous section
- All staff who set up or operate ICS systems should receive theoretical and practical training and should have completed the ICS Competency Assessment Workbook (Appendix 2).
- Aseptic non-touch technique (ANTT) should be used as appropriate, to reduce the risk of infection.

Anticoagulant

- The type of anticoagulant and dose used should be documented on the cell salvage record and anaesthetic chart for each case (Appendix 1 and Appendix 10).
- Anticoagulant prepared by the operator (e.g. heparin saline) **must** be labelled clearly to avoid error

Wash Solution

- 0.9% IV Grade Saline should be used as the wash solution.
- The minimum wash volume, as outlined in the manufacturer's guidelines (Appendix 5) for the size of the centrifuge bowl in use and the type of surgical procedure should be used in all but the most urgent situations.

Labelling

- All salvaged blood **must** be labelled.
- Labels should be hand written. Pre-printed "addressograph" labels **should not** be used.
- Labelling information should include
    - full name
    - date of birth
    - hospital number
    - collection start date and time
    - expiry date and time

  - the statement “Untested Blood – For Autologous Use Only”
- To avoid errors in patient identification an autologous transfusion label such as that in appendix 6 should be completed at the patient’s side, when the patient has arrived in theatre i.e. the reinfusion bag should not be pre-labelled prior to the patent’s arrival in theatre or labelled after the patient has left theatre. The patient details should be taken from their identification band and not from any clinical records or charts that may be present in the operating theatre. All fields on the label should be completed in full.
- If the system has been set up as a “collect only” system (collection reservoir and aspiration and anticoagulant line only), the collection reservoir should be labelled in accordance with the above instruction for labelling a reinfusion bag. If a processing set is subsequently loaded into the machine, the autologous label on the collection reservoir should be transferred onto the reinfusion bag immediately or a new label completed (as above).

Re-infusion

Prescribing responsibilities: Salvaged blood reinfusion should be prescribed by the responsible clinician on the blood transfusion documentation record.

- ICS may be set up as a “closed-circuit” system. Blood is aspirated from the surgical field, processed and transferred to a reinfusion bag. The reinfusion bag is simultaneously connected to the patient’s IV cannula via an appropriate filter (see below). The person administering the reinfusion adjusts the rate at which the red cells are reinfused using a clamp on the administration set and by adjusting the height of the reinfusion bag. A pressure cuff **should not** be applied to increase the flow rate because of the risk of air embolism. The same reinfusion bag may fill and empty many times during an operation.
- Alternatively, ICS mat be set up without simultaneous connection of the reinfusion bag to the patient (as above). In this case, the reinfusion bag is disconnected from the ICS device when it is full or at the end of the surgical procedure and is subsequently connected and reinfused to the patient as in the “closed-circuit” system.
- A filter, appropriate to the type of surgery, should be used for reinfusion. In most cases this will be a 200 micron filter found in a standard blood administration set. In certain circumstances (e.g. obstetrics and malignancy) a leukocyte depletion filter may be indicated. A 40 micron microaggregate filter or a 40 micron lipid depleting filter is suggested for orthopaedic surgery where there is a risk of contamination of fat embolism respectively.
- The reinfusion bag should be kept beside the patient at all times.

- The reinfusion bag **should not** be placed into a refrigerator.
- Reinfusion of the salvaged blood should follow standard blood transfusion practice as described in the Blood Components Transfusion Policy.
- The responsible clinician should prescribe salvaged blood for reinfusion in the same manner as for 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.
- The reinfusion of salvaged blood should be documented appropriately on the blood transfusion documentation record. The autologous transfusion label, as in Appendix 6, contains a peel out section which should be completed at the time of reinfusion and can be used for this purpose.

Expiry

- The collection, processing and reinfusion of salvaged blood should be completed within the timeframes as recommended by the manufacturer. This should be in accordance with guidance from the American Association of Blood Banks (AABB) and the Blood Components Transfusion Policy and Procedure.

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

- Intraoperative Cell Salvage: 4 hours from the completion of processing.
- Postoperative Cell Salvage: 6 hours from the start of collection (applicable when Intra-operative Cell Salvage devices are used to salvage blood postoperatively).

Any blood that has not been transfused within the timeframe specified in the guidelines must be disposed of in accordance with local policy for dealing with liquid bio hazardous waste (see Disposal below).

Documentation

- The collection and reinfusion of salvaged blood should be accurately documented on an appropriate form such as the in Appendix 1.
- The use of a generic autologous transfusion label is recommended (Appendix 6) – the peel out section of the label is completed and attached to the patient's clinical record upon reinfusion of the salvaged blood.
- Adverse incidents, near misses and hazards should be documented and reported according to the Adverse Event section of this procedure

and in accordance with the Incident, hazard and near miss reporting policy and procedure

- Bedside pre-transfusion checks and patients' observations should be performed and recorded during autologous blood reinfusion in the same way as transfusion of allogeneic blood – in accordance with the Blood Components Procedure. Additional observations are at the discretion of the clinical staff based on an individual patient assessment.
- The organisation should ensure that adequate records are retained in all cases where ICS is used.

Disposal of used ICS equipment

- Following use, all ICS disposable equipment should be disposed of in accordance with local requirements. The UHB Waste Management Department requires cell salvage associated waste to be disposed of in containers appropriate for incineration.

Cleaning and Disinfection of ICS Machines

- Following use, the cell salvage machine should be cleaned in accordance with the manufacturer's guidance and the Decontamination of reusable medical devises policy and procedure including procedures for cleaning equipment following high risk cases.
- Following contamination of the equipment internally, the equipment should be removed from use, identified as a potential biohazard and referred to the manufacturer.

Maintenance of Equipment

- All ICS equipment should be serviced regularly in accordance with the manufacturers' recommendations. A maintenance record and fault log (Appendix 7) should be kept for each machine.

MANAGEMENT OF MASSIVE REINFUSION

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

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

Staff should be alert to a large blood loss into the collection reservoir and report the to the surgeon and/or anaesthetist.

Quality Assurance

It is necessary to maintain a comprehensive quality assurance system to ensure the provision of a safe, high quality ICS service.

Personnel

The UHB has identified a single individual responsible for ensuring that a safe and effective ICS service is provided. The organisation's Clinical Lead for ICS is currently a Consultant Anaesthetist. The Lead is responsible for ensuring that quality assurance systems are fully implemented.

The organisation will ensure that competent personnel in sufficient numbers are available to provide the ICS serviced, including for out of hours cases if applicable. Personnel involved in ICS will have undergone appropriated training (see section 6) and competency assessment (Appendix 2). Training Records will be maintained for all staff involved in the ICS process and it is highly recommended that individuals maintain a case log of all procedures in their own portfolios.

Equipment

All ICS equipment must be appropriately maintained. Maintenance should include both an operator maintenance programme and regular manufacturer maintenance visits. Operator maintenance programmes should include the implementation of a documented cleaning and minor checking system and the use of a machine specific fault log (Appendix 7). Manufacturer maintenance visits must be carried out by an authorised service engineer who will perform a series of documented maintenance controls and fine tune the device for maximum performance.

Product Quality

A Quality Control procedure will be performed on each machine every 2 months at both UHL and UHW sites. The QC log is to be checked by the operator prior to each case, and samples taken if the last QC was performed more than two months ago. This involves taking 2 samples from salvaged blood prior to return to the patients.

A full blood count is requested on 1 sample to assess Haematocrit. An acceptable level to be obtained is above 45%.

An anti-factor Xa assay is requested on the 2nd sample to assess heparin contamination. A result of (less than) <0.05U/ml is reported as the lower limit of detection of the anti-factor Xa assay.

The QC results will be returned to the clinical lead who will record this data in the QC logbook for each machine.

If results are outside the acceptable range further management will be discussed with haematology, and the manufacturers.

ADVERSE EVENT REPORTING

- Technical problems with ICS should be reported to the manufacture. It is advisable to discuss any action suggested by the manufacturer with Clinical Engineering.
- Serious Adverse Events must be reported to the Clinical Lead for ICS and the Transfusion Practitioner. Any adverse events relating to the ICS device must be reported in accordance with the UHB Incident, hazard and near miss reporting policy and procedure. Additionally, where appropriate reporting to the relevant external bodies should be undertaken e.g. Serious Hazards of Transfusion (SHOT), Medicine and Healthcare products Regulatory Agency (MHRA), especially if the incident has led to or, were it to occur again, could lead to death, life-threatening illness or injury.
- Other minor safety or quality incidents should also be reported as these can help demonstrate trends or highlight inadequate manufacturing or supply systems, or inadequate instructions and / or training.
- Adverse incidents, near misses and hazards should be documented and reported in accordance with the Incident, hazard and near miss reporting policy and procedure.

Examples of Adverse Events include:

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

AUDIT

Appropriate audit activity will be co-ordinated via the Cell Salvage Working Group Refer also to Appendix 1.

RESOURCES

The UHB will ensure adequate resources for the formal, documented training of all staff who set up of operate the equipment and for the regular maintenance and prompt repair of all ICS equipment.

Welsh Blood Service provides a substantial amount of funding for Intra-operative and Postoperative Cell Salvage, however, funding is capped and the UHB makes up the shortfall. In order to recue costs, the reservoir for collection only is set up in the first instance. Processing is only to occur if adequate volumes are obtained and a decision is made to process and reinfuse collected blood to the patient.

Evidence of cell salvage activity and consumable use must be provided to the WBS to enable reimbursement to the organisation.

EQUALITY

The UHB is committed to ensuring that, as far as is reasonably practicable, the way it provides services to the public and the way it treats its staff reflects their individual needs and does not discriminate against individuals or groups. An Equality and Health Impact Assessment has been undertaken for this policy and procedure. The assessment found that ICS has a positive impact.

IMPLEMENTATION

This procedure document will be circulated to all relevant personnel and implemented in all areas which may be involved in ICS. This will include:

- Consultant Lead for Transfusion
- Clinical Lead for ICS
- Manager for Theatres
- Transfusion Practitioner
- Jehovah's Witness Hospital Liaison Committee
- Senior Nurse / Theatre Managers
- Relevant surgical specialities
- Obstetrics and Gynaecology

It will also be available via the UHB Intranet. Members of the public will be able to access it via the website of the UHB with hard copies being provided on request.

Guidance on and queries relating to the procedure should be addressed to the organisation's Clinical Lead for ICS.

REVIEW

The procedure will be reviewed at timely intervals when new information becomes available that needs to be incorporated or every 3 years.

APPENDIX 1 – Intra-operative Cell Salvage Competency Assessment Workbook

The intraoperative Cell Salvage Competency Assessment Workbook is available through the Better Blood Transfusion Toolkit website at:

https://www.transfusionguidelines.org/transfusion-practice/uk-cell-salvage-action-group/cell-salvage-competency-workbooks

APPENDIX 2 – Intraoperative Cell Salvage in Obstetrics

ICS is being increasingly used in the UK in obstetrics for women at risk from post-Partum haemorrhage during caesarean section as evidence grows in support of it.
The use of ICS in obstetrics has been endorsed by:

- The Confidential Enquiry into Maternal and Child Health
- Joint Association of Anaesthetists of Great Britain and Ireland/Obstetric Anaesthetists Association Guidelines

- National Institute Health and Care Excellence

Any healthcare professional involved with obstetric ICS should be familiar with these guidelines.

Patient Selection and Preparation
Wherever possible, the advantages and risks of ICS and allogeneic blood transfusion should be discussed with the patient prior to undergoing an obstetric surgical procedure. In a pre-planned case this can be during the pregnancy. It is recommended that patients receive the NHS Blood and Transplant information leaflet entitled "Will I need a blood transfusion?" (Appendix VIII) which contains an "Alternatives to blood transfusion" section in the Intraoperative Cell Salvage Patient Information Leaflet (Appendix IV).

The NICE guidance "Intraoperative blood cell salvage in obstetrics recommends that whenever possible, the woman understands what is involved and the theoretical risks, and agrees (consents) to have the procedure. When obtaining formal consent for a caesarean section, the obstetrician or anaesthetist should discuss the advantages and risks of ICS with the patient and document clearly the agreement of the patient to undertake the procedure. Such detailed consent may not be practicable in an emergency, as for allogeneic transfusion.

Indications for ICS
Patient selection for ICS is at the discretion of the obstetrician and anaesthetist caring for the patient who should be involved in the decision. The type of obstetric cases that should be considered for selection include:

- Emergency situations
  - Ruptured ectopic pregnancy
  - Post –partum haemorrhage

- Elective situations
  - Patient with an anticipated blood loss of (more than) >1000 mls e.g. placenta accrete, large uterine fibroids, and other predictable causes of MOH.

- Other situations
  - Patients who for religious or other reasons refuse allogeneic blood and have consented to the use of ICS in elective or emergency bleeding situations of in significant anaemia.

Additional measures necessary in obstetrics ICS:

Amniotic fluid and use of Leukocyte Depletion Filter
Amniotic fluid should ideally not be aspirated into the ICS collection reservoir, but should be removed by separate suction prior to starting cell salvage. This recommendation will reduce the initial contamination, but it should be noted that the *in vitro* evidence is that the ICS process can effectively remove plasma phase elements of amniotic fluid whatever the initial load, therefore, in life-threatening haemorrhage, a clinical decision to use ICS from the start of the procedure could be carefully considered.

After processing, a Pall RS filter (LeucoGuard® RS Leukocyte Reduction Filter, Pall Biomedical Products Co., East Hills, NY) should be used to reinfuse ICS blood. This is the only filter proved to effectively eliminate residual particulate elements of amniotic fluid. It should be remembered that prior to 2000 this filter was not available, over 250 obstetric cases worldwide safely received ICS blood without a problem prior to the availability of the filter. Therefore, in life-threatening haemorrhage a clinical decision to reinfuse ICS blood without this filter could be carefully considered.

8 Rh immunisation and Kleihauer testing
In any pregnancy involving an Rh negative mother and Rh positive foetus there's a danger of Rh immunisation of the maternal circulation is exposed to foetal red cells.

Kleihauer testing is required to establish the amount of foetal red cell exposure and ensures that the mother receives and appropriate dose of Anti-D immunoglobulin (usually 125 iu/ml of foetal blood). Depending on the results of the Kleihauer, a minimum of 500 is Anti-D will be offered in the post-partum period to Rh negative mothers with Rh positive babies.

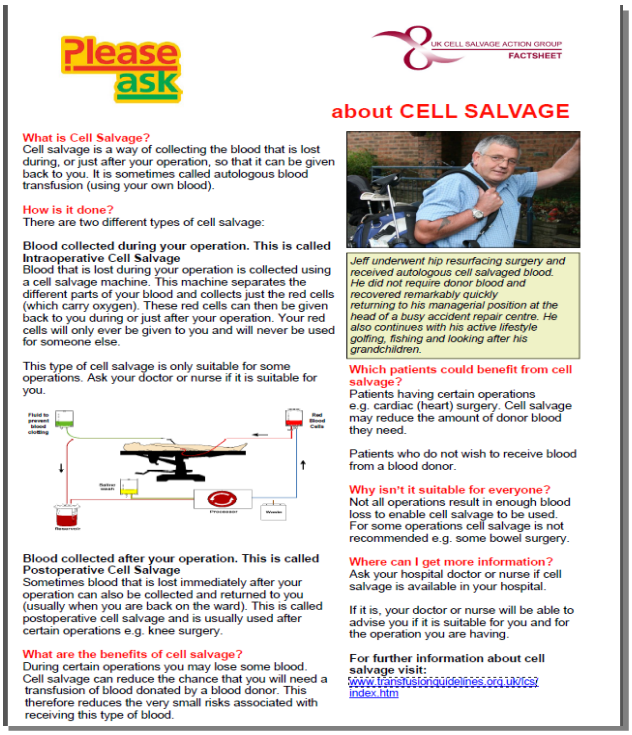
The same protocol should be followed for Rh negative mothers who have undergone reinfusion of ICS blood. The presence of foetal red cells in the ICS blood is likely because the ICS device cannot distinguish foetal from maternal red cells. Depending on the test results it may b that higher doses of Anti-D will need to be administered.

The sample for Kleihauer testing should be taken after the reinfusion of ICS blood and administration of Anti-D should occur within 48-72 hours of delivery.

Patient factsheets – Information about Cell Salvage when you have your baby is available here https://www.transfusionguidelines.org/transfusion-practice/uk-cell-salvage-action-group/patient-factsheet

APPENDIX 3 – Cell Salvage Patient Information Leaflet

The Cell Salvage patient information leaflet can be downloaded from http://www.npsa.nhs.uk/EasySiteWeb/GatewayLink.aspx?alId=28445



Please ask

UK CELL SALVAGE ACTION GROUP
FACTSHEET

about CELL SALVAGE

What is Cell Salvage?
Cell salvage is a way of collecting the blood that is lost during, or just after your operation, so that it can be given back to you. It is sometimes called autologous blood transfusion (using your own blood).

How is it done?
There are two different types of cell salvage:

Blood collected during your operation. This is called Intraoperative Cell Salvage
Blood that is lost during your operation is collected using a cell salvage machine. This machine separates the different parts of your blood and collects just the red cells (which carry oxygen). These red cells can then be given back to you during or just after your operation. Your red cells will only ever be given to you and will never be used for someone else.

This type of cell salvage is only suitable for some operations. Ask your doctor or nurse if it is suitable for you.

Blood collected after your operation. This is called Postoperative Cell Salvage
Sometimes blood that is lost immediately after your operation can also be collected and returned to you (usually when you are back on the ward). This is called postoperative cell salvage and is usually used after certain operations e.g. knee surgery.

What are the benefits of cell salvage?
During certain operations you may lose some blood. Cell salvage can reduce the chance that you will need a transfusion of blood donated by a blood donor. This therefore reduces the very small risks associated with receiving this type of blood.

Jeff underwent hip resurfacing surgery and received autologous cell salvaged blood. He did not require donor blood and recovered remarkably quickly returning to his managerial position at the head of a busy accident repair centre. He also continues with his active lifestyle golfing, fishing and looking after his grandchildren.

Which patients could benefit from cell salvage?
Patients having certain operations e.g. cardiac (heart) surgery. Cell salvage may reduce the amount of donor blood they need.

Patients who do not wish to receive blood from a blood donor.

Why isn't it suitable for everyone?
Not all operations result in enough blood loss to enable cell salvage to be used. For some operations cell salvage is not recommended e.g. some bowel surgery.

Where can I get more information?
Ask your hospital doctor or nurse if cell salvage is available in your hospital.

If it is, your doctor or nurse will be able to advise you if it is suitable for you and for the operation you are having.

For further information about cell salvage visit:
www.transfusionguidelines.org.uk/ics/index.htm

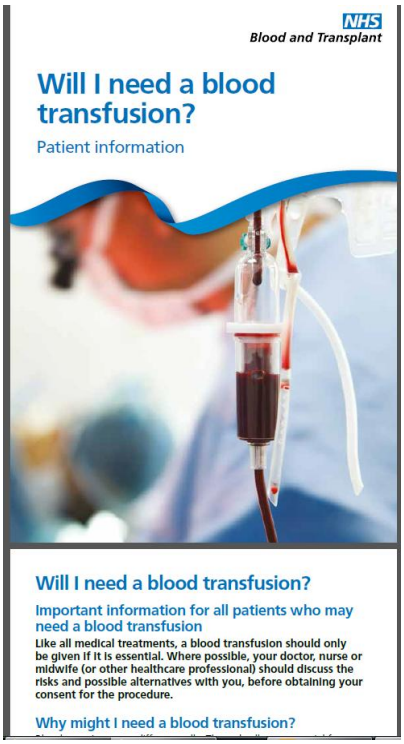
APPENDIX 4 – Manufacturers' Guidelines

These are held centrally by the Clinical Lead for ICS

APPENDIX 5 – Autologous Transfusion Label

These are held centrally by the Clinical Lead for ICS

APPENDIX 6 – NHS Blood and transplant information leaflet entitle "Will I need a blood transfusion"



An order form for the NHS Blood and Transplant information leaflet “Will I need a blood transfusion” can be downloaded at:

https://hospital.nhsbtleaflets.co.uk/Home.html

Alternatively the leaflet can be downloaded at:
http://hospital.blood.co.uk/media/28307/160511-27360-will-i-need-a-blood-transfusion-final.pdf

The leaflet is available in a number of other languages (Welsh, Albanian, Arabic, Bengali, Chinese, Croatian, Farsi, French, Greek, Gujarati, Pashto, Polish, Punjabi, Serbian, Somali, Sorani, Turkish, Urdu, and Vietnamese) at:

http://hospital.blood.co.uk/library/patient_information_leaflets/leaflets/index.asp

APPENDIX 7 – Blood loss calculation

At the end of the procedure, when all of the blood from the collection reservoir has been processed, an estimate of the volume of blood the patient has lost during procedure can be made using a simple calculation.

The information required is:

Fluid in volume (Machine read out) – Total volume of fluid processed by machine, includes: blood aspirated from surgical field, anticoagulant and irrigation frim surgical field.

Irrigation fluid – Volume of sterile irrigation fluid used within surgical field and aspirated into the ICS collection reservoir.

Anticoagulant used – An estimate of volume used

Swab wash – Volume of IV normal saline (0.9% NaCl) or equivalent used to wash swabs

Theatre suction

Wet-dry weight of swabs – compensates for blood and saline swab wash retained on swabs and allows them to be weighed outside of the sterile field after washing.

Blood Loss Calculation:

Blood loss = fluid in volume plus theatre suction plus (wet-dry weight of swabs) minus irrigation fluid minus anticoagulant used minus swab wash

APPENDIX 8 - Heparin Concentration

Heparin Saline

In usual circumstances, 30,000 iu of Heparin is added to 1,000ml of intravenous (IV) normal saline (0.9% NaCl) and labelled clearly with an appropriate “drugs added label”.

Some manufacturers recommend that 60,000 iu of Heparin should be added to 1,000ml of IV normal saline for **neurosurgical** procedures. This should be confirmed with the manufacturer.

The Heparin Saline anticoagulant concentration should be checked by the Lead Anaesthetist at the start of the procedure and documented on the Welsh Blood Service audit form. **Under no circumstances** should the heparin used for preparation of anticoagulant for cell salvage purposes be prescribed on an inpatient drug chart. This is to reduce the risk of inappropriate administration of heparin saline outside of the theatre environment.

A pre prepared citrate based anticoagulant should be used for patients with antithrombin III deficiency.

Equality & Health Impact Assessment for

Intraoperative Cell Salvage Policy and Procedure

Please note:

- The completed Equality & Health Impact Assessment (EHIA) must be
  - Included as an appendix with the cover report when the strategy, policy, plan, procedure and/or service change is submitted for approval
  - Published on the UHB intranet and internet pages as part of the consultation (if applicable) and once agreed.
- Formal consultation must be undertaken, as required[1]
- Appendices 1-3 must be deleted prior to submission for approval

Please answer all questions:-

1.	For service change, provide the title of the Project Outline Document or Business Case and Reference Number	Intraoperative Cell Salvage Procedure
2.	Name of Clinical Board / Corporate Directorate and title of lead member of staff, including contact	Surgery Clinical Board

[1] http://nww.cardiffandvale.wales.nhs.uk/portal/page?_pageid=253,73860407,253_73860411&_dad=portal&_schema=PORTAL

	details	
3.	Objectives of strategy/ policy/ plan/ procedure/ service	• To promote safer transfusion as part of clinical governance responsibilities • To ensure that ICS is used by adequately trained staff, is simple, safe and cost effective method of reducing allogeneic transfusion. • To assist clinical staff in the identification of patients and procedures considered suitable for ICS and outlining the indications and contraindications. • To assist clinical staff to provide appropriate advice on options for treatment, particularly where patients are anxious about risks associated with, or prefer not to receive, allogeneic blood. • To provide clear written information about the risks and benefits of autologous transfusions from blood salvaged intraoperatively. • To assist clinical staff to minimise avoidable / potential risks of autologous transfusions from blood salvaged intraoperatively. • To ensure that patients are treated lawfully
4.	Evidence and background information considered. For example • population data • staff and service users data, as applicable • needs assessment • engagement and involvement findings	**REFERENCES** 1. Serious Hazards of Transfusion (SHOT) Report 2005. http://www.shotuk.org/SHOT%20report%202005.pdf 2. Better Blood Transfusion: The Appropriate Use of Blood (2002) HSC 2002/009 3. Murphy GJ, Rogers CS, Lansdowne WB, Channon I, Alwair H, Cohen A, Caputo M and Angelini GD (2005) Safety, efficacy, and cost of intraoperative cell salvage and autotransfusion after off-pump coronary artery bypass surgery: a randomized trial. *J Thorac Cardiovasc*

	• research • good practice guidelines • participant knowledge • list of stakeholders and how stakeholders have engaged in the development stages • comments from those involved in the designing and development stages Population pyramids are available from Public Health Wales Observatory[2] and the UHB's 'Shaping Our Future Wellbeing' Strategy provides an overview of health need[3].	*Surg*; 130(1); 20-8 4. James V (2004) A National Blood Conservation Strategy for the NBTC and NBS http://www.dh.gov.uk/prod_consum_dh/idcplg?IdcService =GET_FILE&dID=26734&Rendition=Web 5. Policy for the provision of Intraoperative Cell Salvage. http://www.transfusionguidelines.org.uk/docs/misc/bbt-03_icsag-policy-v11.doc 6. British Committee for Standards in Haematology Blood Transfusion Task Force (1999). The administration of blood and blood components and the management of transfused patients. *Transfusion Medicine*; 9; 227-238. British Committee for Standards in Haematology Blood Transfusion Task Force (1997) Guidelines for Autologous Transfusion II. Perioperative Haemodilution and Cell Salvage. *British Journal for Anaesthesia*; 78; 768-771. 8. Gray CL, Amling CL, Polston GR, Powell CR and Kane CJ (2001) Intraoperative cell salvage in radical retropubic prostatectomy. *Urology*; 58(5); 740-5. 9. Nieder AM, Carmack AJ, Sved PD, Kimm SS, Manoharan M and Soloway MS (2005) Intraoperative cell salvage during radical prostatectomy is not associated with greater biochemical recurrence rate. *Urology*; 65(4); 730-4. 10. Nieder AM, Manoharan M, Yang Y and Soloway MS (2007) Intraoperative Cell Salvage during radical cystectomy does not affect long term survival. *Urology*; 69(5); 881-4.

[2] http://nww2.nphs.wales.nhs.uk:8080/PubHObservatoryProjDocs.nsf
[3] http://www.cardiffandvaleuhb.wales.nhs.uk/the-challenges-we-face

		11. American Association of Blood Banks (AABB) (2005) Standards for Perioperative Autologous Blood Collection and Administration (2nd Edition) 12. Cardiff and Vale NHS Trust Incident Reporting and Investigation Procedure, May 2007 13. http://nww.cardiffandvale.wales.nhs.uk/pls/portal/docs/PAGE/POLICY_PAGEGROUP/LIBRARY/RISK%20MANAGEMENT%20POLICY.PDFMedicines and Healthcare products Regulatory Authority (MHRA) (2007) Device Bulletin: Reporting adverse incidents and disseminating medical device alerts. http://www.mhra.gov.uk/home/idcplg?IdcService=GET_FILE&dDocName=CON2025834&RevisionSelectionMethod=LatestReleased Roberts, M.M. (2006) Procedure for Post-operative Autologous Blood Transfusion Drainage Systems in Adult and Paediatric Patients. *Cardiff and Vale NHS Trust*. 15. Kelleher, A.A. (2004) Policy for the Provision of Perioperative Red Cell Salvage. *Royal Bromptonand Harefield NHS Trust*. 16. Obstetric Intra-operative Cell Salvage Guidelines (Draft 1). *St Mary's NHS Trust* 2006.
5.	Who will be affected by the strategy/ policy/ plan/ procedure/ service	Patients who for clinical and/or personal reasons would benefit from the appropriate use of autologous blood transfusion techniques such as Intraoperative Cell Salvage (ICS). Staff who must be adequately trained to undertake the procedure.

6. EQIA / how will the strategy, policy, plan, procedure and/or service impact on people?

Questions in this section relate to the impact on people on the basis of their 'protected characteristics'. Specific alignment with the 7 goals of the Well-being of Future Generations (Wales) Act 2015 is included against the relevant sections.

How will the strategy, policy, plan, procedure and/or service impact on:-	**Potential positive and/or negative impacts**	**Recommendations for improvement/ mitigation**	**Action taken by Clinical Board / Corporate Directorate.** Make reference to where the mitigation is included in the document, as appropriate
6.1 Age For most purposes, the main categories are: • under 18; • between 18 and 65; and • over 65	Where the patient is aged under 16 years, a person with parental responsibility must give consent if the patient is not *Gillick* competent. If there is reason to doubt the patient's mental capacity to consent to ICS and the patient is aged 16 years and over, then the Mental Capacity Act 2005 must be followed.	N/A	N/A
6.2 Persons with a disability as defined in the Equality Act 2010	The policy and procedure lists supporting documents to ensure appropriate consent	Staff must be familiar with the list of documents associated with informed	Mandatory training compliance. Evidence of clinical audit.

How will the strategy, policy, plan, procedure and/or service impact on:-	**Potential positive and/or negative impacts**	**Recommendations for improvement/ mitigation**	**Action taken by Clinical Board / Corporate Directorate.** Make reference to where the mitigation is included in the document, as appropriate
Those with physical impairments, learning disability, sensory loss or impairment, mental health conditions, long-term medical conditions such as diabetes	to treatment and to affirm the rights of patients and their autonomy without discrimination. The UHB is aware from its demographic information that it employs staff who have disabilities as defined within the Act. As such, the Policy would be made accessible to staff in alternative formats on request or via usual good management practice. **Note -** the Arial font size 14 recommendation is aimed at communication and information needs for patients. We are aware that	consent.	

How will the strategy, policy, plan, procedure and/or service impact on:-	Potential positive and/or negative impacts	Recommendations for improvement/ mitigation	Action taken by Clinical Board / Corporate Directorate. Make reference to where the mitigation is included in the document, as appropriate
	we may need to amend/provide the format of our communication in line with the appropriate All Wales Sensory Loss Standards and legislation.		

7. EQIA / how will the strategy, policy, plan, procedure and/or service impact on people?

Questions in this section relate to the impact on people on the basis of their 'protected characteristics'. Specific alignment with the 7 goals of the Well-being of Future Generations (Wales) Act 2015 is included against the relevant sections.

How will the strategy, policy, plan, procedure and/or service impact on:-	**Potential positive and/or negative impacts**	**Recommendations for improvement/ mitigation**	**Action taken by Clinical Board / Corporate Directorate.** Make reference to where the mitigation is included in the document, as appropriate
6.1 Age For most purposes, the main categories are: • under 18; • between 18 and 65; and • over 65	Where the patient is aged under 16 years, a person with parental responsibility must give consent if the patient is not *Gillick* competent. If there is reason to doubt the patient's mental capacity to consent to ICS and the patient is aged 16 years and over, then the Mental Capacity Act 2005 must be followed.	N/A	N/A
6.2 Persons with a disability as defined in the	The policy and procedure lists supporting documents to	Staff must be familiar with the list of documents	Mandatory training compliance. Evidence of clinical audit.

How will the strategy, policy, plan, procedure and/or service impact on:-	Potential positive and/or negative impacts	Recommendations for improvement/ mitigation	Action taken by Clinical Board / Corporate Directorate. Make reference to where the mitigation is included in the document, as appropriate
Equality Act 2010 Those with physical impairments, learning disability, sensory loss or impairment, mental health conditions, long-term medical conditions such as diabetes	ensure appropriate consent to treatment and to affirm the rights of patients and their autonomy without discrimination. The UHB is aware from its demographic information that it employs staff who have disabilities as defined within the Act. As such, the Policy would be made accessible to staff in alternative formats on request or via usual good management practice. **Note -** the Arial font size 14 recommendation is aimed at communication and information needs for	associated with informed consent.	

How will the strategy, policy, plan, procedure and/or service impact on:-	Potential positive and/or negative impacts	Recommendations for improvement/ mitigation	Action taken by Clinical Board / Corporate Directorate. Make reference to where the mitigation is included in the document, as appropriate
	patients. We are aware that we may need to amend/provide the format of our communication in line with the appropriate All Wales Sensory Loss Standards and legislation.		

8. EQIA / how will the strategy, policy, plan, procedure and/or service impact on people?

Questions in this section relate to the impact on people on the basis of their 'protected characteristics'. Specific alignment with the 7 goals of the Well-being of Future Generations (Wales) Act 2015 is included against the relevant sections.

How will the strategy, policy, plan, procedure and/or service impact on:-	**Potential positive and/or negative impacts**	**Recommendations for improvement/ mitigation**	**Action taken by Clinical Board / Corporate Directorate.** Make reference to where the mitigation is included in the document, as appropriate
6.1 Age For most purposes, the main categories are: • under 18; • between 18 and 65; and • over 65	Where the patient is aged under 16 years, a person with parental responsibility must give consent if the patient is not *Gillick* competent. If there is reason to doubt the patient's mental capacity to consent to ICS and the patient is aged 16 years and over, then the Mental Capacity Act 2005 must be followed.	N/A	N/A
6.2 Persons with a disability as defined in the Equality Act 2010	The policy and procedure lists supporting documents to ensure appropriate consent	Staff must be familiar with the list of documents associated with informed	Mandatory training compliance. Evidence of clinical audit.

How will the strategy, policy, plan, procedure and/or service impact on:-	**Potential positive and/or negative impacts**	**Recommendations for improvement/ mitigation**	**Action taken by Clinical Board / Corporate Directorate.** Make reference to where the mitigation is included in the document, as appropriate
Those with physical impairments, learning disability, sensory loss or impairment, mental health conditions, long-term medical conditions such as diabetes	to treatment and to affirm the rights of patients and their autonomy without discrimination. The UHB is aware from its demographic information that it employs staff who have disabilities as defined within the Act. As such, the Policy would be made accessible to staff in alternative formats on request or via usual good management practice. **Note -** the Arial font size 14 recommendation is aimed at communication and information needs for patients. We are aware that	consent.	

How will the strategy, policy, plan, procedure and/or service impact on:-	Potential positive and/or negative impacts	Recommendations for improvement/ mitigation	Action taken by Clinical Board / Corporate Directorate. Make reference to where the mitigation is included in the document, as appropriate
	we may need to amend/provide the format of our communication in line with the appropriate All Wales Sensory Loss Standards and legislation.		
6.3 People of different genders: Consider men, women, people undergoing gender reassignment **NB Gender-reassignment is anyone who proposes to, starts, is going through or who has completed a process to change his or**	There is no current evidence of positive or negative impact on staff or patients associated with gender though we are aware that it is widely known that there are differences between men and women in the incidence and prevalence of most health conditions. .	N/A	N/A

How will the strategy, policy, plan, procedure and/or service impact on:-	Potential positive and/or negative impacts	Recommendations for improvement/ mitigation	Action taken by Clinical Board / Corporate Directorate. Make reference to where the mitigation is included in the document, as appropriate
her gender with or without going through any medical procedures. Sometimes referred to as Trans or Transgender			
6.4 People who are married or who have a civil partner.	There is no current evidence of positive or negative impact on staff or patients associated with this protected characteristic	N/A	N/A
6.5 Women who are expecting a baby, who are on a break from work after having a baby, or who are breastfeeding. They are protected for 26 weeks after having a baby	There is a specific section for obstetric patients who may be considered for Intraoperative Cell Salvage	Staff must be familiar with specific section.	N/A

How will the strategy, policy, plan, procedure and/or service impact on:-	Potential positive and/or negative impacts	Recommendations for improvement/ mitigation	Action taken by Clinical Board / Corporate Directorate. Make reference to where the mitigation is included in the document, as appropriate
whether or not they are on maternity leave.			
6.6 People of a different race, nationality, colour, culture or ethnic origin including non-English speakers, gypsies/travellers, migrant workers	Patient information leaflets are available in multiple languages from the NHS Blood and Transplant site. Elective surgery patients being considered for Intraoperative Cell Salvage will have access to an interpreter where appropriate	Staff to be familiar with interpreter booking system	Support interpreter service.
6.7 People with a religion or belief or with no religion	This is a positive impact for patients for who, for moral,	Staff to be familiar with aspects of the policy and	Provide training where appropriate.

How will the strategy, policy, plan, procedure and/or service impact on:-	Potential positive and/or negative impacts	Recommendations for improvement/ mitigation	Action taken by Clinical Board / Corporate Directorate. Make reference to where the mitigation is included in the document, as appropriate
or belief. **The term 'religion' includes a religious or philosophical belief**	religious or other reasons, are unwilling to receive allogeneic blood and have given their consent to receiving autologous blood collected using ICS (all such decisions should be documented).	procedure and receive regular updates and training	
6.8 People who are attracted to other people of: • **the opposite sex (heterosexual);** • **the same sex (lesbian or gay);** • **both sexes (bisexual**	There appears not to be any impact on staff or patients in terms of sexual orientation.	N/A	N/A
6.9 People who	Bilingual information leaflets	Staff to be familiar on how	Provide welsh language

How will the strategy, policy, plan, procedure and/or service impact on:-	**Potential positive and/or negative impacts**	**Recommendations for improvement/ mitigation**	**Action taken by Clinical Board / Corporate Directorate.** Make reference to where the mitigation is included in the document, as appropriate
communicate using the Welsh language in terms of correspondence, information leaflets, or service plans and design **Well-being Goal – A Wales of vibrant culture and thriving Welsh language**	are available for patients. This is in line with our current Welsh Language Scheme and the future Welsh Language Standards.	to access welsh speaking colleagues to support the patient. Information should be available in Welsh. Service to encourage Welsh language 'active offer' to those receiving the procedure.	training
6.10 People according to their income related group: Consider people on low income, economically inactive, unemployed/workless, people who are unable to work due to ill-health	Minimal Impact is anticipated The procedure aims to deliver an achievable equitable service regardless of an individual's income. Any decisions are clinically made.	N/A	N/A

How will the strategy, policy, plan, procedure and/or service impact on:-	**Potential positive and/or negative impacts**	**Recommendations for improvement/ mitigation**	**Action taken by Clinical Board / Corporate Directorate.** Make reference to where the mitigation is included in the document, as appropriate

6.11 People according to where they live: Consider people living in areas known to exhibit poor economic and/or health indicators, people unable to access services and facilities	Minimal Impact is anticipated The procedure aims to deliver an achievable equitable service regardless of an individual's income. Any decisions are clinically made.	N/A	N/A
6.12 Consider any other groups and risk factors relevant to this strategy, policy, plan, procedure and/or service	There are anticipated positive impacts for adult and paediatric patients undergoing elective or emergency surgical procedures who have risk factors for bleeding or low preoperative Haemoglobin levels; patients who have rare blood groups or multiple antibodies for whom it may be difficult to obtain allogeneic blood and adult and paediatric patients undergoing elective or emergency surgical procedures where the anticipated blood loss in greater than 20% of the	Staff to be familiar with aspects of the policy and procedure and receive regular updates and training	Provide training where appropriate.

	patient's estimated blood volume. The procedure lists contraindications		

9. HIA / How will the strategy, policy, plan, procedure and/or service impact on the health and well-being of our population and help address inequalities in health?

Questions in this section relate to the impact on the overall health of individual people and on the impact on our population. Specific alignment with the 7 goals of the Well-being of Future Generations (Wales) Act 2015 is included against the relevant sections.

How will the strategy, policy, plan, procedure and/or service impact on:-	**Potential positive and/or negative impacts and any particular groups affected**	**Recommendations for improvement/ mitigation**	**Action taken by Clinical Board / Corporate Directorate** Make reference to where the mitigation is included in the document, as appropriate
7.1 People being able to access the service offered: Consider access for those living in areas of deprivation and/or those experiencing health inequalities	People will be consulted regarding ICS dependent on the surgical procedure being undertaken and their own preferences. Geographical location will have no impact on the decision.	N/A	N/A

How will the strategy, policy, plan, procedure and/or service impact on:-	Potential positive and/or negative impacts and any particular groups affected	Recommendations for improvement/ mitigation	Action taken by Clinical Board / Corporate Directorate Make reference to where the mitigation is included in the document, as appropriate
Well-being Goal - A more equal Wales			
7.2 People being able to improve /maintain healthy lifestyles: Consider the impact on healthy lifestyles, including healthy eating, being active, no smoking /smoking cessation, reducing the harm caused by alcohol and /or non-prescribed drugs plus access to services that support disease prevention (eg immunisation and vaccination, falls prevention). Also consider impact on access to supportive services including smoking cessation services, weight management services etc Well-being Goal – A healthier Wales	Indirectly associated with this procedure – patients listed for elective surgery will have the opportunity to improve their wellbeing with healthcare professional support pre-operatively.	N/A	N/A
7.3 People in terms of their	Positive impact by ensuring	Ensure all staff involved with	Enable the trained ANTT

How will the strategy, policy, plan, procedure and/or service impact on:-	Potential positive and/or negative impacts and any particular groups affected	Recommendations for improvement/ mitigation	Action taken by Clinical Board / Corporate Directorate Make reference to where the mitigation is included in the document, as appropriate
income and employment status: Consider the impact on the availability and accessibility of work, paid/ unpaid employment, wage levels, job security, working conditions Well-being Goal – A prosperous Wales	staff are appropriately trained for their roles associated with cell salvage in order to maintain safe practice and thus job security. Aseptic Non Touch Technique processes (ANTT) has been introduced as an all-Wales approach to reducing healthcare associated infection. The PADR process supports further development appropriate to role and future employment ambitions.	aseptic techniques associated with ICS are trained and assessed in ANTT	facilitators to continue rolling out ANTT in accordance with the all-Wales approach
7.4 People in terms of their use of the physical environment: Consider the impact on the availability and accessibility of transport, healthy food, leisure activities, green spaces; of the design of the built environment on the physical and mental health of patients, staff and visitors; on air quality,	N/A	N/A	N/A

How will the strategy, policy, plan, procedure and/or service impact on:-	Potential positive and/or negative impacts and any particular groups affected	Recommendations for improvement/ mitigation	Action taken by Clinical Board / Corporate Directorate Make reference to where the mitigation is included in the document, as appropriate
exposure to pollutants; safety of neighbourhoods, exposure to crime; road safety and preventing injuries/accidents; quality and safety of play areas and open spaces Well-being Goal – A resilient Wales			
7.5 People in terms of social and community influences on their health: Consider the impact on family organisation and roles; social support and social networks; neighbourliness and sense of belonging; social isolation; peer pressure; community identity; cultural and spiritual ethos Well-being Goal – A Wales of cohesive communities	If a patient has a carer or parent/guardian we will ensure they receive the appropriate information.	N/A	N/A

How will the strategy, policy, plan, procedure and/or service impact on:-	Potential positive and/or negative impacts and any particular groups affected	Recommendations for improvement/ mitigation	Action taken by Clinical Board / Corporate Directorate Make reference to where the mitigation is included in the document, as appropriate
7.6 People in terms of macro-economic, environmental and sustainability factors: Consider the impact of government policies; gross domestic product; economic development; biological diversity; climate Well-being Goal – A globally responsible Wales	Intraoperative Cell Salvage has the potential for a positive impact in terms of supporting the prudent use of donated blood in accordance with the Welsh Health Circular (WHC), “Better Blood Transfusion: Appropriate Use of blood”.	N/A	N/A

Please answer question 8.1 following the completion of the EHIA and complete the action plan

8.1 Please summarise the potential positive and/or negative impacts of the strategy, policy, plan or service	Intraoperative cell salvage has a positive impact by providing an alternative to allogeneic blood transfusion in accordance with the Welsh Health Circular (WHC), "Better Blood Transfusion: Appropriate Use of blood". The policy and procedure promotes safe and effective practice that is consistent with people's beliefs and values.

Action Plan for Mitigation / Improvement and Implementation

	Action	**Lead**	**Timescale**	**Action taken by Clinical Board / Corporate Directorate**
8.2 What are the key actions identified as a result of completing the EHIA?	All staff should be trained and assessed in line with the all-Wales use of ANTT. This should be embedded in ongoing training for ICS. http://howis.wales.nhs.uk/sitesplus/888/page/64404 There are no additional new actions identified as a result of updating the policy and procedure.	Lead Nurse and Education Lead for the directorate.	Immediate and ongoing	Enable relevant staff to access the e-learning and have a practical assessment by a trained ANTT facilitator within the UHB

	Action	Lead	Timescale	Action taken by Clinical Board / Corporate Directorate
8.3 Is a more comprehensive Equalities Impact Assessment or Health Impact Assessment required? This means thinking about relevance and proportionality to the Equality Act and asking: is the impact significant enough that a more formal and full consultation is required?	As part of its implementation this procedure document will be circulated to all relevant personnel and implemented in all areas which may be involved in ICS. This will include: • Consultant Lead for Transfusion • Clinical Lead for ICS • Manager for Theatres • Transfusion Practitioner • Jehovah's Witness Hospital Liaison Committee • Senior Nurse / Theatre Managers • Relevant surgical specialities • Obstetrics and Gynaecology It will also be available via the UHB Intranet. Members of the public will be able to access it via the website of the UHB with hard copies being provided on request. Guidance on and queries relating to the procedu should be addressed to the organisation's Clinica Lead for ICS.	N/A	N/A	N/A

	Action	Lead	Timescale	Action taken by Clinical Board / Corporate Directorate
8.4 What are the next steps? Some suggestions:- • Decide whether the strategy, policy, plan, procedure and/or service proposal: ○ continues unchanged as there are no significant negative impacts ○ adjusts to account for the negative impacts ○ continues despite potential for adverse impact or missed opportunities to advance equality (set out the justifications for doing so) • Have your strategy, policy, plan, procedure and/or service proposal approved • Publish your report of	Continue unchanged as there are no significant negative impacts. EHIA will be placed on the intranet once approve Adherence to the policy will be monitored throug the Perioperative Care Directorate governance forums When this policy is reviewed, this EHIA will form part of that consultation exercise and publication This EHIA will be reviewed three years after approval unless changes to terms and conditions legislation or best practice determine that an ear review is required. The UHB standard is that all policies are reviewed within 3 years (1 year if a statutory requirement).	Lead Nurse and Education Lead for the directorate.	Ongoing	