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Midwives Study Day
27th Jan 2016
South West Regional Transfusion Committee
Obstetric Cell Salvage

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Patient Blood Management Manager
Royal Cornwall Hospital

Outcome from today's presentation

1. Key Points of intraoperative cell salvage
2. How does Cell Salvage work?
3. Perceived Risks and Benefits
4. Patient information

Key points when introducing Intra Operative Cell Salvage

1. Intra Operative Cell Salvage (ICS) is an efficacious technique for blood replacement.
2. Patients should be informed of theoretical issues around ICS prior to surgery.
3. ICS should be undertaken regularly in obstetrics, allowing teams to gain ICS experience.
4. ICS should be seen as part of a Blood Conservation program.
5. Teams should consider following up patients, to evaluate the risk of alloimmunisation.
6. Teams should consider implementing a Quality Control program, when offering an ICS service.

Demographics

Population 450,000 -almost doubles in summer

County delivery rate of 4,000 deliveries per annum

C/S rate <20% currently approx 18% equiv 70-80 C/S per month

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The Principles of Intra Operative Cell salvage

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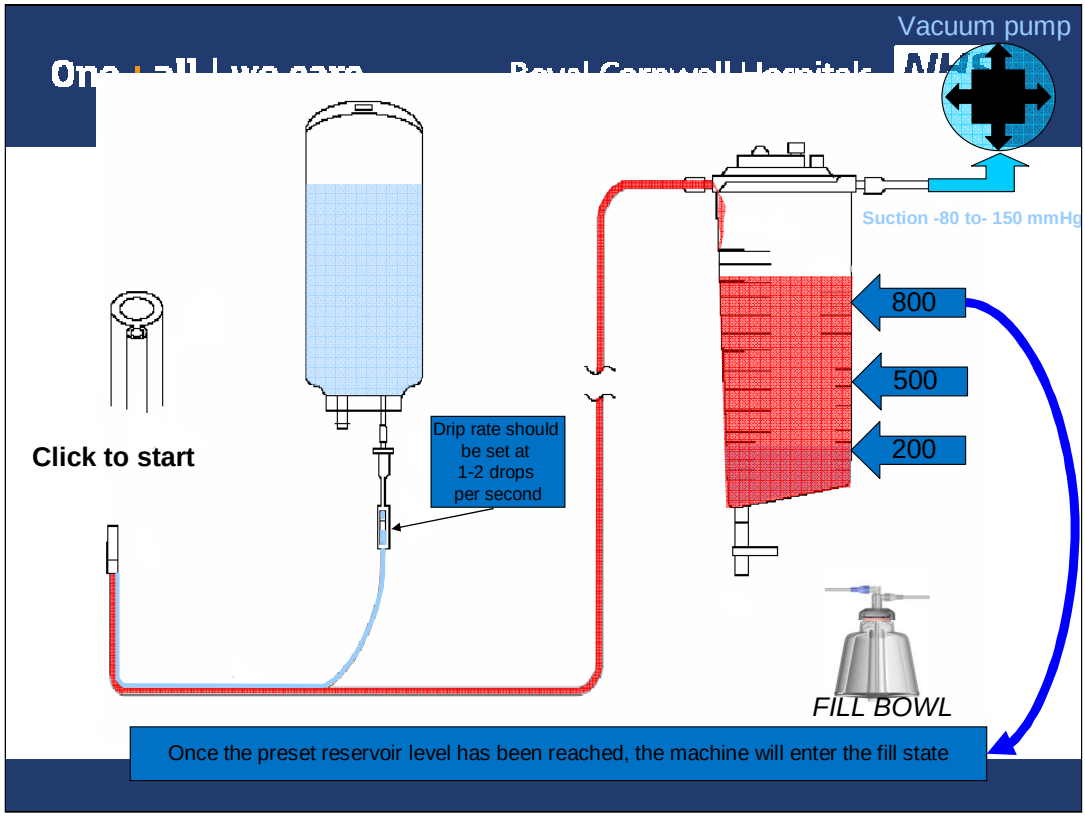
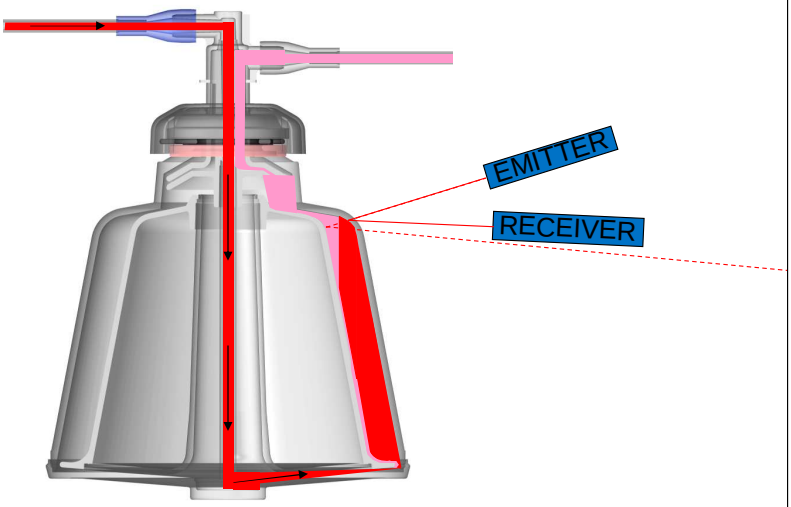
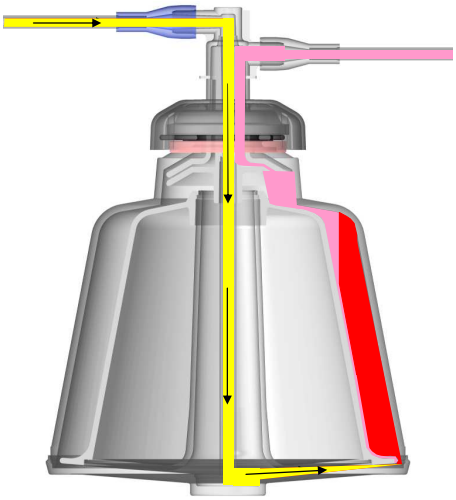
Haemonetics Cell Saver 5+ - Intra Operative Cell Sa


Vacuum pump
Suction -80 to- 150 mmHg
800
500
200
Click to start
Drip rate should be set at 1-2 drops per second
FILL BOWL
Once the preset reservoir level has been reached, the machine will enter the fill state

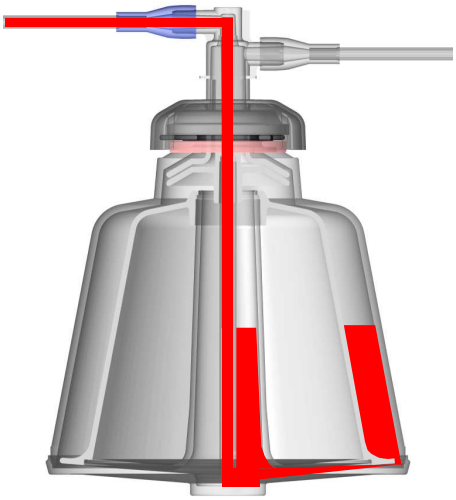
Fill Cycle



Washing Cycle



Empty Cycle



Reinfusion using a Leucodepletion Filter

ICS setting the scene!

When used in unfamiliar / emergency situations, cell salvage may lead to a poor outcome! Resulting from lack of knowledge and confidence in the equipment, therefore producing a reduced quality end product?

Patients should be informed of theoretical issues and benefits around ICS prior to surgery?

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ICS Risks in Obs

Two main concerns

- Amniotic fluid embolism.
- Fetal red cell contamination and risk of alloimmunisation

Perceived risk of AFE

Amniotic fluid is removed through the washing process regardless of use of 1 or 2 suction devices.

Fetal squames are present in post wash samples but almost completely removed post filtration. We use a leucodepletion filter (Pall Leuko Guard RS filter, Pall Europe Europa house Portsmouth.). The significance of fetal squames in the circulation is unknown

No cases have been reported of AFE following ICS

Entirely theoretical

Fetal red cell contamination. Fetal RBC s are present in the re-infusion and may result in red cell antigen incompatabilities between mother and baby – will discuss further

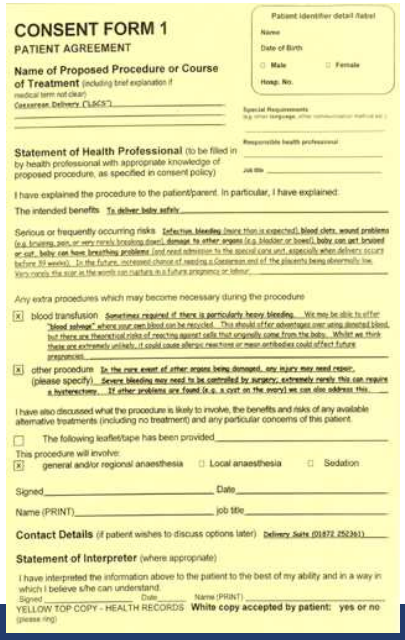
BENEFITS

Autologous blood- No incompatability, warm, maintain 2,3 DPG levels

Avoid allogeneic blood - expensive limited resource.(£140 = $221)Caries potential risk of infection and incompatability reactions and associated with increase in post-op wound infections and LO Hosp stay.

DoH Better blood transfusion health circular suggests to consider use of alternatives- .

salvaged blood is a suitable alternative to allogeneic blood



CONSENT FORM 1

PATIENT AGREEMENT

Patient identifier detail /label

Name

Date of Birth

☐ Male ☐ Female

Hosp. No.

Name of Proposed Procedure or Course of Treatment (including brief explanation if medical term not clear)

Caesarean Delivery ("LSCS")

Special Requirements (e.g. other language, other communication method etc.)

Statement of Health Professional (to be filled in by health professional with appropriate knowledge of proposed procedure, as specified in consent policy)

Responsible health professional

Job title

I have explained the procedure to the patient/parent. In particular, I have explained:

The intended benefits To deliver baby safely

Serious or frequently occurring risks Defective bleeding (more than is expected), blood clots, wound problems (e.g. bruising, pain, or very rarely breaking down), damage to other organs (e.g. bladder or bowel), baby can get bruised or cut , baby can have breathing problems (and need admission to the special care unit, especially when delivery occurs before 39 weeks). In the future, increased chance of needing a Caesarean and of the placenta being abnormally low. Very rarely the scar in the womb can rupture in a future pregnancy or labour.

Any extra procedures which may become necessary during the procedure

☒ blood transfusion Sometimes required if there is particularly heavy bleeding. We may be able to offer "blood salvage" where your own blood can be recycled. This should offer advantages over using donated blood, but there are theoretical risks of reacting against cells that originally come from the baby. Whilst we think these are extremely unlikely, it could cause allergic reactions or mean antibodies could affect future pregnancies.

☒ other procedure (please specify) In the rare event of other organs being damaged, any injury may need repair. Severe bleeding may need to be controlled by surgery, extremely rarely this can require a hysterectomy. If other problems are found (e.g. a cyst on the ovary) we can also address this.

I have also discussed what the procedure is likely to involve, the benefits and risks of any available alternative treatments (including no treatment) and any particular concerns of this patient.

☐ The following leaflet/tape has been provided

This procedure will involve:

☒ general and/or regional anaesthesia ☐ Local anaesthesia ☐ Sedation

Signed Date

Name (PRINT) job title

Contact Details (if patient wishes to discuss options later) Delivery Suite (01872 252361)

Statement of Interpreter (where appropriate)

I have interpreted the information above to the patient to the best of my ability and in a way in which I believe s/he can understand.

Signed Date Name (PRINT)

YELLOW TOP COPY - HEALTH RECORDS **White copy accepted by patient: yes or no** (please ring)

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Consent

Any extra procedures which may become necessary during the procedure

[X] blood transfusion Sometimes required if there is particularly heavy bleeding. We may be able to offer "blood salvage" where your own blood can be recycled. This should offer advantages over using donated blood, but there are theoretical risks of reacting against cells that originally come from the baby. Whilst we think these are extremely unlikely, it could cause allergic reactions or mean antibodies could affect future pregnancies.

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Within our trust we are working towards making Cell Salvage the norm and not the exception! and hope to introduce it fully into the consent form where patients will have to opt out of not having cell salvage? **CONTRAVERSIAL**

Risks of Red Cell Transfusion

- Acute Haemolytic Reactions 1 in 250,000 to 1 in 1,000,000
- Hepatitis B 1 in 450,000
- Hepatitis C 1 in 32,000,000
- HIV 1 in 5,000,000
- HTLV 1 in 12,500,000
- Bacterial Contamination of Red Cell Concentrates 1 in 500,000

Amniotic Fluid Embolus

- Also known as anaphylactoid syndrome of pregnancy
- Possibly caused by Amniotic Fluid (AF) entering the maternal circulation, and so could be initiated by re-infusing any AF aspirated by the cell salvage machine?

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Alloimmunisation

- Fetal red cell contamination in cell salvage blood is comparable to that found in maternal circulation following delivery.
- Trans placental haemorrhages result in maternal contamination
- Clinically significant antibodies other than anti-D
- Incidence of antibody formation unknown
- Follow up 4-6 months post re-infusion

Fetal red cell contamination. Fetal RBC s are present in the re-infusion in volumes comparable to that found in the maternal circulation after delivery.(0.2mls-12.9mls- our study 2010).

TPH more likely in 3rd trimester and on delivery.

We do not know the critical volume vol required to provoke an Ab response

Rh D negative women routinely receiving AntiD prophylaxis throughout pregnancy which has reduced the formation of anti-D immunization BUT there are other clinically significant. Abs .include anti-K, anti-C c, anti-E , anti-S These too have been implicated in heamolytic disease of the newborn

Data from 2007 at RCHT indicates incidence of other significant Abs in maternal pop =0.4% - origin pregnancy or allogeneic blood Tx

Before women receive a reinfusion we take a sample to test for fetal red cells contamination(using the Kleihaur –Betke technique).

We invite all women for a follow up test of Ab formation to attempt to test for Abs. If antibodies are found in the f/u sample and the pre-infusion sample did not detect fetal cells than we can conclude the cell salvage blood caused the immunisation. As the incidence is low we are currently unable to assess if incidence of Ab formaiton is increased or the same as that which occurs in pregnancy and during delivery.

ICS benefits in Obs

- Autologous blood
- Avoid or reduce allogeneic blood consumption

Nice Guidelines

1. Intraoperative blood cell salvage is an efficacious technique for blood replacement and its use is well established in other areas of medicine, but there are theoretical safety concerns when it is used in obstetric practice. Data collection is therefore important and clinicians should report all complications to the Medicines and Healthcare products Regulatory Agency.

1.2 Whenever possible, patients should be fully informed of the potential complications

1.3 This procedure should only be performed by multidisciplinary teams who develop regular experience of intraoperative blood cell salvage.

https://www.nice.org.uk/guidance/IPG144/chapter/1-Guidance

Teams should consider following up patients, to evaluate the risk of alloimmunisation

Patient Follow up's

- Re infusion data entered into data base
- Letter to GP and patient
- Patient asked to make appointment for follow up bloods.
- Full antibody screen
- Outcome data entered onto database

Current data shows approx **50%** follow up!

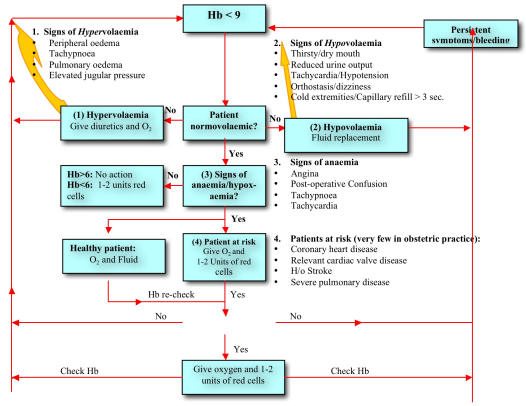
ICS in obstetrics should be seen as part of a PBM Programme

Key benefits of Introducing a PBM service

- Reduced risk for patients and improved patient care
- Reduced demand on blood banks and associated costs
- Reduced risk of peri-operative operative complications leading to reduce length of stay
- Reduction in last minute cancelled operations

Guidelines for blood transfusions in pregnancy.

- Ante-,peri and post partum management of fluid and blood status includes careful consideration of the need for red cells **and** other fluid replacement
- The patient's **volume status** needs careful assessment with special attention in pre-eclampsia.
- **Asymptomatic patients** with normo-volaemic anaemia **do not need blood transfusion** if the haemoglobin level is above 6 g/100ml
- All Hb levels referred to below are in gram per 100 mls



Note: High risk patients need special thresholds for red cell transfusion

Not an indication for transfusion:

- Anaemia with patient **feeling well.**
- Prophylactic substitution
- Top up of HB in **asymptomatic** anaemia
- Hypovolaemia, i.e. use as plasma expander.

HTT August 2004.
Blood transfusion and the Anaesthetist 2
AAGBI June 08

Teams should consider implementing a Quality Control program, when offering an ICS service?

QA Samples

Full Blood Count (Hb/Hct)

- Marker of quality of blood returned to patient

Micro-albumin

- Marker of washing efficiency

Heparin testing

- Marker of washing efficiency and to ensure blood returned to patient is not grossly contaminated with heparin

Plasma free Hb

- Not compulsory if equipment not available

ICS Obstetrics at RCHT

- Routinely used for all sections – elective and emergency
- Dedicated machine
- Tx rates decreasing
- Patients have to opt out not in – IOCS built into consent form
- Further research?