Mother, Babies and Blood
South West Regional Study Day
25th Jan 2017

*Obstetric Cell Salvage*

Mr John Faulds
Patient Blood Management Manager
Royal Cornwall Hospital
What is Patient Blood Management?

Patient blood management (PBM) views a patient’s own blood as a valuable and unique natural resource that should be conserved and managed appropriately.

PBM is a multidisciplinary, multimodal, evidence based, patient centred approach to optimising, conserving and managing the patient’s own blood.

PBM puts the patient at the centre of decisions made about transfusion.
RCHT - Three “A” Principal (PBM)

Alternatives – Algorithms supporting transfusion, Intravenous Iron, erythropoietin

Autologous – Intra/post operative Cell Salvage

Allogeneic - Appropriate transfusion
NICE Statement on Cell Salvage

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.

National Institute for Clinical Excellence
Blood transfusion

NICE guideline [NG24] Published date: November 2015

Cell salvage and tranexamic acid

1.1.5
Offer tranexamic acid to adults undergoing surgery who are expected to have at least moderate blood loss (greater than 500 ml).

1.1.6
Consider tranexamic acid for children undergoing surgery who are expected to have at least moderate blood loss (greater than 10% blood volume).

1.1.7
Do not routinely use cell salvage without tranexamic acid.

1.1.8
Consider intra-operative cell salvage with tranexamic acid for patients who are expected to lose a very high volume of blood (for example in cardiac and complex vascular surgery, major obstetric procedures, and pelvic reconstruction and scoliosis surgery).
Blood Conservation Service Pledge
Royal Cornwall Hospital

The Royal Cornwall Hospital employs and supports a patient blood management programme.

Background
Since 2003 Blood Conservation strategies have been implemented within the Royal Cornwall Hospital to support the reduction of allogeneic (donor) blood transfusion peri-operatively. Initially focussed on conserving blood during orthopaedic surgery, the service has since expanded to include all surgical specialities, and evolved into a Patient Blood Management Programme.

The current blood management programme aims to reduce the consumption of allogeneic blood in the surgical setting, in the following ways

1. Optimise patients’ Hb (blood count) levels before surgery.
2. Use appropriate cell salvage techniques to collect patients’ own blood for re-infusion peri-operatively.
3. Implement a comprehensive blood conservation, competency based training program for all staff involved in cell salvage and blood conservation.
4. When indicated, support the use of blood transfusions, ensuring that updated and current practice is employed and patient consent is sought whenever possible.
5. Educate staff to always consider the use of alternatives to blood transfusion when appropriate.
6. Monitor the use of cell salvage, audit interventions, collect and disseminate data relating to blood conservation.
7. Undertake research and publish outcomes in relevant areas of blood conservation.
“Washed” Cell Salvage

The collection of intraoperative/postoperative surgical blood loss, using a dedicated suction device, that collects, filters, centrifuges, and washes salvaged blood, producing a unique end product of Red Cells suspended in saline, individulised to the patient.
ICS Obstetrics – Theoretical Risks

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

Alloimmunisation
Fetal RBCs cannot be distinguished from maternal RBCs by cell salvage machines. Could theoretically cause haemolytic disease of the newborn and fetal hyperbilirubinemia and anaemia
Intraoperative Cell Salvage in the Emergency Situation

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?
Intra Operative Cell Salvage
1. Recommendations

- The use of intra-operative Cell Salvage (ICS) reduces the demand on allogeneic (donor) red cells and is a cost-effective measure.
- Trusts should provide the necessary resources to set up and maintain an ICS service in a safe, appropriate and cost-effective manner.
- Each Trust needs to ensure there is a clinical lead for ICS.
- A member of the theatre management team is responsible for ensuring overall management and facilitation of the ICS service.
- All personnel using ICS must be adequately trained and competent in its use.
- Pre-operative assessment clinics should provide information on ICS to patients.
- All ICS cases undergoing require documentation and audit of use to enable future service planning and quality assurance.

Implementing a Cell Salvage Programme

Prescribing/Labelling Responsibilities – who prescribes the blood? Partial or full bowels? What labels? Checking of blood

Individual Responsibilities – User records? Maintaining competency

Training – Competency based training? Maintaining training records? Staff training – What grade

Indications and Patient Selection – What groups of patients will receive ICS? How will they be flagged up
OrthoPat

Common ICS machines

Electa

CATS

Cell Saver 5+
CONSENT FORM 1
PATIENT AGREEMENT

Name of Proposed Procedure or Course of Treatment

General Statement

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

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

The intended benefit to the patient:

Any other procedures which may become necessary during the procedure:

1. Blood transfusion: Sometimes you may be given blood during surgery. In case of an emergency, we may give you or a member of your family blood from a known non-related donor. This is done to save your life. If the donor does not have an infectious disease, the blood is considered safe.

2. Other procedures: In case of an emergency, we may give you or a member of your family blood from a known non-related donor. This is done to save your life. If the donor does not have an infectious disease, the blood is considered safe.

3. The following extends the patient to the patient

Context Details

Statement of Interpreter (where appropriate)

I have explained the information above to the patient in such a way that I can understand the patient's ability to

Signed:

Date:

Name (print):

For patient's use in discussing options below:

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Patients have to Opt out not in!

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
Next step

Intraoperative Cell Salvage Disposable set

- Reinfusion Bag
- Reservoir with Level Sensor
- Control Panel
- Fluid Deck (with valves, air detectors and pump)
- Effluent Line Sensor
- Waste Bag Weight Hook
- Waste Bag
- Reservoir Line
- Saline Line
- Centrifuge Bowl
- Centrifuge Bowl Weigh Hook
- Tubing Manifold
Once the preset reservoir level has been reached, the machine will enter the fill state.
Washing Cycle
Empty Cycle
Salvaged Blood

Red Cells suspended in Saline
Risks and benefits

**RISKS**

Amniotic fluid embolism
Fetal red cell contamination and risk of alloimmunisation

**Use 1 suction device**

**BENEFITS**

Autologous blood
Avoid or reduce allogeneic blood consumption

Perceived risk of AFE
Amniotic fluid is removed through the washing process regardless of use of 1 or 2 suction devices.
Take home message 1
Fetal squames are present in post wash samples but almost completely removed post filtration. We currently are discussing the recommendation to 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 incompatibilities between mother and baby – will discuss further

**BENEFITS**

Autologous blood- No incompatibility, warm, maintain 2,3 DPG levels maintained (takes 1-2 days for levels to return to normal in stored blood and therefore immediate benefit unlikely to be better oxygen delivery).

Avoid allogeneic blood - expensive limited resource.(£125 = $221)Caries potential risk of infection with unknown emerging pathogens . ATRs and incompatibility reactions can be significant. Blood 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
Things to Consider?

Patient Information – What, how and where do you tell patients about ICS?
Quality Assurance – How, when and why?

Clinical Coding - OPCS-4 (The classification is mandatory for use by healthcare providers to support various forms of data collections for operational and secondary uses.)
  • X36.4 Autologous blood salvage – use if ICS is set up for the patient
  • X33.7 Autologous transfusion of red blood cells – use if blood is actually returned to the patient.

Adverse Event Reporting

Alloimmunisation

- Fetal red cell contamination in cell salvage blood
- Transplacental 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 RBCs 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 antibodies such as anti-K, anti-c, anti-Fy(a) and anti-Jk(a) These too have been implicated in haemolytic 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
Women who have a sample of blood taken prior to re-infusion will be tested for fetal contamination (using the Kleihaur–Betke technique).
We invite all women for a follow up test of Ab formation. 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 formation is increased or the same as that which occurs in pregnancy and during delivery.
Follow up of cases improving 2013 currently 48%. 2012 achieved 62% including incidental
RCHT ICS - Results 2014

- Service established as routine
- 853/869 = 98% of cases had blood collected
- 30% processed (226 cases)
- 146 women were re-infused (64% of processed collections)
- Average volume reinfused - 221 mls
- Follow up cases 2014 - >50%
- New Abs detected?

2014 Service now established as routine although on going training of anaesthetic assistants
Mean vol re-infused 260mls range 111mls-1066mls

4 women had allogeneic blood in addition to cell saver blood- 1 had 1 unit and 2 had 2 units, 1 had 3 units + FFP
Note need for FFP etc and fibrinogen – Removed FFP from 1st Pack MOH

F/U so far — no new Abs detected =F/U improving 62% for 2012, 2013 48% so far y
Reasons salvaged blood is not reinfused back?

Two main Reasons

- Partial Bowls
- Patients decline – WHY?

- Misunderstanding?
Allogeneic and autologous transfusions
Benefit of ICS in Obs

- Reduction in Tx rate seen from 2008.
- Cost consumables (processing)
- Partial bowls – use of LDF – reduce costs further
- Reduction in costs of producing blood and treatment ATR
- Reduction in post operative infections, readmissions and potentially LOS
- Future….less risk of exposure to mothers of infection from emerging pathogens

If project 2008 data of 1.8% women having a Tx of mean total 3.3 units blood would have given 83 + 83 women 548 units of blood. We gave 175 units only.

373 units costs £125 each unit = £46,600 (£23,300 pa)

Cost consumables = 226 processed per year x £50 = £11,300

67% of the cases processed were re-infused in 2013 (52% in 2012). The % re-infused will rise but unlikely to achieve 100%. So therefore will become more cost effective.

Reasons to process and not reinfuse that will reduce = training and experience in judging collected volume – should we reinfuse partial bowls. Patient refusal uncommon.

Role of LDF – get rid of.

In addition costs of producing safe unit of blood, treatment ATR s is not included in cost of a unit of blood

Reduction in infections – use OAA data and present tables
ICS - Six Key Points

1. Intra Operative Cell Salvage (ICS) is an efficacious technique for blood replacement.
2. ICS should be seen as part of a Blood Conservation program.
3. ICS should be undertaken regularly in obstetrics, allowing teams to gain ICS experience.
4. Patients should be informed of theoretical issues around ICS prior to surgery.
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.
Conclusion

The present

- The routine use of ICS in the maternity operating theatre is part of RCHT’s Patient Blood Management Programme.
- Autologous blood is a suitable and safe alternative to allogeneic blood.
- Using autologous blood has reduced the number of allogeneic units used.
- Using ICS routinely in maternity saves money

The future

- Establish the incidence of antibody formation following re-infusions from ICS.
- Salvage and re-infuse vaginal blood
ICS The Future?

Cancer surgery -

TICTOC - Feasibility study in ovarian surgery

Vaginal Cell Salvage -

Study proposal currently under way
Thank You To The Patient Blood Management Team At RCHT

- Dr C Ralph
- Mr I Sullivan
- Carol McGovern

john.faulds@rcht.cornwall.nhs.uk
Patient Blood Management –
The Future of Blood Transfusion
A joint initiative with The Department of Health and The National Blood Transfusion Committee

What is being done?
A panel of experts and influencers in the field are being invited to consider international best practice and what can be done to ensure a Patient Blood Management approach is adopted across England and North Wales

Blood Matters: doing nothing is not an option
Sir Bruce Keogh, NHS Medical Director

Sustainability of the blood supply
While the demand for red cells is stable, the demand for platelets increased by 8% in the last year. The recent increase in the use of platelets is projected to continue due to a number of factors such as medical advances and an aging population. Only 4% of the eligible population give blood, and new donors are always needed to replace regular donors who can no longer donate.

Following on from an invite meeting in London in June 2012
This meeting was supported by Govt and driven by NHSBT to show that the use of platelets was increasing at a greater rate than they had expected, and though the demand for red cells was stable, there was a feeling that they will struggle to meet the demands for Red Cells in the future.
The recent increase in the use of platelets is projected to continue due to a number of factors such as medical advances and an aging population.
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<td>Total obstetric</td>
<td>60</td>
<td>79</td>
<td>64</td>
<td>59</td>
<td>58</td>
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<td>39</td>
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<td>patients – allogeneic</td>
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<td>Del Suite patients</td>
<td>46</td>
<td>58</td>
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PBM goes beyond just the decision whether to transfuse. PBM includes considering the patient's entire (projected) course to determine whether the reason for transfusion could be avoided in the first place and/or possibly treated in another manner.

The intent of PBM is to apply transfusion as a therapeutic modality only when it is in the patient's best interest to do so.
### Number of units transfused in Obstetrics

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<tr>
<td>Total Obstetric units tx’d</td>
<td>173</td>
<td>259</td>
<td>192</td>
<td>155</td>
<td>167</td>
<td>100</td>
<td>75</td>
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<tr>
<td>Ante-natal units</td>
<td>3</td>
<td>0</td>
<td>2</td>
<td>0</td>
<td>3</td>
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<tr>
<td>Post-natal units</td>
<td>27</td>
<td>45</td>
<td>48</td>
<td>25</td>
<td>30</td>
<td>18</td>
<td>11</td>
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<tr>
<td>Delivery Suite units</td>
<td>143</td>
<td>214</td>
<td>142</td>
<td>130</td>
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Obstetric transfusion rate per delivery

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<tr>
<td>No of deliveries in Cornwall</td>
<td>4349</td>
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<td>4428</td>
<td>4688</td>
<td>4628</td>
<td>4612</td>
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<tr>
<td>Obstetric patients tx’d per delivery (%)</td>
<td>1.8</td>
<td>1.5</td>
<td>1.3</td>
<td>1.2</td>
<td>1.0</td>
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<td>Delivery Suite patients tx’d per delivery (%)</td>
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<td>0.9</td>
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SALVO -5% DROP TO 3%!!!

75% of the women who received blood 2012 did so following a vaginal bleed, 81% in 2013- see ahead
New onset sepsis symptoms – tachycardia & tachypnoea without fevers/rigors
EBL – medians
Allogeneic blood would appear to increase your risk of infection – as in other specialities
Full details to be presented by F1 trainee D Baker with Kate Teare in Dublin at OAA – e-poster
Obstetric - Intraoperative Cell Salvage
at RCHT
from 2011

- Routine collection of blood to cell saver- not targeted to high risk cases
- Usage increased to over 90% by end 2011, 95% 2012, 96% 2013 and >98% so far 2014
- Competency based training for all anaesthetic assistants
- Blood processed in 1/3rd all collections and only when adequate volumes collected
- Re-infusions offered to all women
- Invited for 4 - 6 month follow up

Haemonetics cell saver machine routinely ready to collect. If target only those women considered at risk of bleeding then will loose many cases. All have the potential to bleed more than 1L

Currently service is available for all intra-abdominal procedures that occur in maternity. Usage increased during 2011 to over 90% cases and from this year usually 98% - providing an almost 24 hour service.

We do not employ an additional person to operate machine therefore crucial to the success of this service is the training of all anaesthetic assistants who have to complete a competency based training programme

Financial considerations
Collection only costs approx £25 $39.5 and when processed this increases by an additional £50 $79 Overall $110.

Only process when adequate volumes collected and offer re-infusions to all women regardless of post-op Hb. Hb May drop further and Need to re-infuse within 6 hours of start of collection. We re-infuse 65% of all processed collections- some lost to partial bowls, training and a few patient refusal
Kept by patient and never in fridge. Discarded if unused or QC.

Follow up – letter inviting them for a check of antibody formation