Serious Hazards of Transfusion
Paediatric Data

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SHOT
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Adverse reactions and events in adults vs children

Risk of adverse outcome of transfusion in children vs adults

Population-based epidemiological study 2004
• 4.2% red cells transfused to patients <18 yr
• 1.7% to infants <12 months

Incidence of adverse outcome of blood transfusion per 100,000 red cells issued
• Children <18 yrs 18
• Infants <12 mths 37
• Adults 13

The error rate is higher in children.
Cumulative paediatric data by age groups 2007-2011

Number of Reports

Year | ≤ 28 days | 28 days -< 1 year | 1 - <16 years | 16 - <18 years
--- | --- | --- | --- | ---
2007 | 13 | 12 | 30 | 
2008 | 20 | 11 | 43 | 
2009 | 19 | 15 | 60 | 
2010 | 15 | 20 | 68 | 
2011 | 17 | 16 | 69 |
Comparison between adults and children – reactions to different components 2011
Cumulative paediatric reports by component type 2007-2011 (excluding multiple components)

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<th>Year</th>
<th>Red Cells</th>
<th>Platelets</th>
<th>Plasma</th>
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Cumulative paediatric reports by reaction type 2007-2011

- **Febrile**
- **Allergic**
- **Anaphylaxis**
- **Mixed febrile and allergic**
- **Hypotensive**
- **Unclassified**

**Number of Reactions**

- **2007**
  - 2 Febrile
  - 5 Allergic
  - 2 Anaphylaxis
  - 1 Mixed febrile and allergic
  - 5 Hypotensive
  - Unclassified

- **2008**
  - 6 Febrile
  - 15 Allergic
  - 4 Anaphylaxis
  - 1 Mixed febrile and allergic
  - 4 Hypotensive
  - Unclassified

- **2009**
  - 14 Febrile
  - 13 Allergic
  - 2 Anaphylaxis
  - 2 Mixed febrile and allergic
  - 5 Hypotensive
  - Unclassified

- **2010**
  - 16 Febrile
  - 21 Allergic
  - 5 Anaphylaxis
  - 5 Mixed febrile and allergic
  - 5 Hypotensive
  - Unclassified

- **2011**
  - 20 Febrile
  - 16 Allergic
  - 7 Anaphylaxis
  - 2 Mixed febrile and allergic
  - 2 Hypotensive
  - Unclassified
Paediatric Reactions by component type 2011

Component type
- Febrile
- Allergic
- Anaphylaxis
- Mixed febrile and allergic
- Hypotensive
- Unclassified

Percentage of Reactions
- 0%
- 10%
- 20%
- 30%
- 40%
- 50%
- 60%
- 70%
- 80%
- 90%
- 100%

Red Cells
- 13
- Febrile: 11
- Allergic: 2
- Anaphylaxis: 0
- Mixed: 0
- Hypotensive: 0
- Unclassified: 0

Platelets
- 6
- Febrile: 2
- Allergic: 3
- Anaphylaxis: 1
- Mixed: 0
- Hypotensive: 0
- Unclassified: 0

Plasma
- 20
- Febrile: 19
- Allergic: 0
- Anaphylaxis: 1
- Mixed: 0
- Hypotensive: 0
- Unclassified: 0

Total
- 32
- Febrile: 28
- Allergic: 4
- Anaphylaxis: 2
- Mixed: 2
- Hypotensive: 2
- Unclassified: 4
Paediatric cases where the special requirements were not met 2007-2011
New observations in 2011

• Transfusion-associated circulatory overload
  – 5 cases aged from neonatal to 17yrs
• Two cases of necrotising enterocolitis possibly related to transfusion
  – 1 death
  – 1 needed surgery and survived
Some examples
Case study: Reaction to SD-FFP

• A male infant with a congenital coagulation deficiency received SD-FFP to treat a cerebral bleed, and experienced a severe anaphylactic reaction within 30 minutes of starting the transfusion, with tachycardia, hypoxia and hypotension.

• He required intubation and was given adrenaline.

• He was subsequently given MB-FFP to treat the continuing bleeding problems. On one occasion, his oxygen saturation dropped again, but otherwise he experienced no problems.

• He continues to receive MB-FFP without problems. Investigations for the cause of anaphylaxis proved negative.
Case Study: Necrotising enterocolitis post transfusion

- A clinically stable non-ventilated 6 week old preterm infant, born at 26 weeks gestation, was given a red cell transfusion for symptomatic anaemia of prematurity (Hb 9.3 g/dL).

- There were no adverse events during the transfusion, and the post Hb was 16.7 g/dL. 4.5 hrs post transfusion the baby developed tachycardia, and over the next 12 hours deteriorated and developed a distended abdomen.

- An X-ray was consistent with NEC, the baby continued to deteriorate and died at approximately 36 hrs post transfusion.
Case study

Lack of awareness of the need for irradiated blood following IUT

• A baby who had received IUT for HDN was admitted at age 7 wks with Hb 4.4 g/dL and transfused with a non-irradiated paedipack

• Neither request form or prescription indicated that irradiated blood was required

• The laboratory SOP was unclear and the BMS believed there was no need to irradiate top-ups following IUT

• Nursing staff did not notice that irradiated blood was required
Case study

Doctor unaware of neonatal specification units in satellite refrigerator

- Premature baby Hb 6.2g/dL following emergency caesarean section delivery
- Staff grade doctor borrowed midwife’s blood fridge access card
- Removed a unit of adult O RhD negative, NOT the paediatric emergency O RhD negative blood that was also present
- Baby received 100mL without any adverse reaction
Case study

Baby with HDN due to anti-c given O RhD negative blood

- Baby born by emergency caesarean section, suffering from HDN due to high titre maternal anti-c
- Removed emergency O RhD negative unit for transfusion without informing the laboratory
- Baby suffered an immediate (mild) reaction, which fully resolved
- Bilirubin climbed further, requiring exchange, and this may well have been exacerbated by the incompatible transfusion
Case studies

Clinically significant over-transfusion

• 12-month old child on PICU required 110mL red cells
• Adult unit supplied, and nursing staff transfused all 230mL
• Post-transfusion Hb was 19g/dL, requiring venesection

• 6-month old infant on ICU required 140mL red cells post-op
• Nurse asked doctor if she should give ‘1 unit’ and he verbally agreed
• Entire unit (257mL) was transfused
• No adverse outcome apart from excessive flushing
Case study

Confusion during the collection process

- A preterm baby required an emergency transfusion at 6 days of life and should have been given O RhD negative emergency blood from the satellite fridge. The nurse inadvertently collected an adult O RhD negative unit that had been issued for an obstetric patient on the delivery suite.
- The blood group and CMV status was checked with another nurse, but neither noticed that the tag on the unit had a compatibility label on as opposed to an ‘emergency blood’ label
Case study

Incorrect pre-transfusion compatibility testing procedures

• A G&S/DAT request was received in the laboratory for a newborn baby with a low Hb. Blood was requested later that day and twice more, 2 days later

• The first two requests were treated as Electronic Issue, but the third was fully crossmatched

• Mother was known to have an antibody, so ALL requests should have been crossmatched
Case study

Administration error results in over-transfusion

- A 24-day-old baby was prescribed a transfusion of 14.3mL red cells. It was noted that the baby’s Hb rose from 9.7g/dL to 20.0 g/dL
- It was noticed that the paedipack was empty, meaning that the baby had received ~50ml blood
- The roller clamp in the neonatal Y giving set had not been closed
Paediatric Commentary 2010-11

• Poor understanding by lab staff of procedures for pre-transfusion compatibility testing
• Confusion among clinical staff as to blood availability for emergency transfusion
• Over-transfusion of children – prescribing in ‘units’ rather than mL
• Ensuring giving sets are fit for purpose and transfusions are monitored throughout
• Paediatric ATR reports are increasing, particularly febrile reactions with red cells
Lessons

- Mistakes happen even in areas where there is ‘one-to-one’ care
- Specific education of staff in paediatric transfusion practice is crucial
- Wearing and checking of patient ID is essential
- Prescription - needs volume and duration of transfusion written down – no verbal instructions
Lessons (2)

- BCSH guidelines should be followed
- Closely monitor children for reactions
- Care with administration – nursing staff must be skilled and competent in the use of infusion devices, appropriate rates and volumes for transfusion, and special requirements
- Good communication is vital, between lab and clinicians and between institutions sharing care
- Avoid unnecessary transfusion – especially of FFP and platelets
Paediatric Recommendations

• Prescribing only by those with appropriate knowledge and expertise

• Particular care for special requirements, including documentation, and communication – use of specific paediatric prescription charts

• Lab BMSs must be aware of special component requirements for <16s, and routine checking for additional flags based on DOB

• Encourage clinical staff to report reactions
Paediatric Haemovigilance

• Uncertainty about the true nature and extent of adverse transfusion outcomes in children, particularly neonates and infants

• Likely to be under-reporting to SHOT
  • Signs may be more subtle due to immunological immaturity, may be masked by symptoms, or simply not recognised
  • Some reactions may not be clearly defined as relating to transfusions eg necrotising enterocolitis
  • Other complications, such as line-associated infections, problems with multiple cannulations or extravasations are not currently reported to SHOT
Neonatal transfusions

- Highly transfused, potential of long life
- Appropriate transfusion triggers not clear
- Mixed evidence on outcomes
  - Association between platelet transfusions and hepatic dysfunction
  - 9-fold increase in bacterial infection in neonates who had received >10 platelet transfusions
Audit of adverse outcomes associated with neonatal transfusion

- Many unknowns
- What are the adverse events?
- What to monitor
- Relationship to NEC
- All transfusions in NICU or NNU in participating centres
Audit Management Group

• **Neonatology**
  - Anna Curley
  - Vidheya Venkatesh
  - Rizwan Khan

• **NHSBT**
  - Helen New (Clinical Lead)
  - Simon Stanworth

• **SHOT**
  - Paula Bolton-Maggs
  - Tony Davies

• **Database**
  - Debbi Poles (SHOT)

• **Statistician**
  - Linda Hunt (NHSBT)
Objectives & Audit Plan

• Standardise a Transfusion Assessment Audit Tool (TAT) and use the TAT to;
  • Define the level of conventionally recognised acute clinical adverse outcomes
  • Define previously unrecognised adverse outcomes
  • Capture the level of additional events such as cannulation / extravasation

• Systematically record clinical information already being routinely collected during and 6 hrs post transfusion, with extra time points up to 24hrs post transfusion
Prospective Observational Survey of Clinical Adverse Outcomes related to Transfusion in Neonates version 0.15

Questionnaire for Red cell transfusions

Audit number: ________
For office use only:
Date received: ______________ Date entered: __________

PATIENT DETAILS

Date of birth in dd/mm/yy: ________ Gender (please tick): Male ________ Female ________

Gestation at birth: ________ Weeks ________ Days

Birth weight in grams: ________

TRANFUSION DETAILS

Date of transfusion in dd/mm/yy: ________

Transfusion indication:
Anaemia of prematurity ________ Pulmonary Haemorrhage ________ Suspected NEC ________ Suspected Sepsis ________

NEC requiring surgery ________ HDN ________ Acute blood loss ________ Other (please state below) ________

Transfusion of other blood product in 24 hrs prior to transfusion?: Yes ________ No ________

If yes, state which blood component(s) Platelets ________ FFP ________ Cryoprecipitate ________

RBC ________ IVIG ________ Albumin ________

RESPIRATORY STATUS AT THE START OF TRANSFUSION Please tick all that apply

Mechanical Ventilation ________ Was baby muscle relaxed? Yes ________ No ________

Non-invasive Ventilation ________ Supplementary Oxygen ________

Breathing in air without respiratory support ________

FLUID STATUS

Is infant on regular diuretics? Yes ________ No ________

Weight (Record weight closest to) Weight in grams ________ DD / MM / YY ________

Weight 72 hours pre transfusion ________

Recent Weight recorded pre transfusion ________

Weight 24 hour Post transfusion ________

MBP measured by: Indwelling arterial line ________ Peripheral cuff ________
MONITORED VITAL SIGNS DURING PACKED CELL TRANSFUSION

N.B: Please complete the 4 hours prior, 2 hours prior and 0 min as this forms the baseline. For the inotropes column Circle Y if on inotropes. Circle ↑ when dose is increased or another inotrope is added. Circle ↓ when dose decreased. If no change, do not circle either of the arrows. If ventilated record MAP (mean airway pressure). If on noninvasive ventilation record PEEP.

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<th>Time 00:00</th>
<th>Temp (°C)</th>
<th>Heart Rate (bpm)</th>
<th>Inotropes</th>
<th>Spontaneous Respiratory Rate (bpm)</th>
<th>MAP cm H20</th>
<th>PEEP cm H20</th>
<th>FiO2 (%)</th>
<th>MBP mm Hg</th>
<th>Handling</th>
<th>If other product given tick box</th>
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<td></td>
<td></td>
<td></td>
<td>Y N</td>
<td>FFP; Cryo; PLT; RBC</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Was a new cannula replacement required during the transfusion?  Yes [ ]  No [ ]

If so, was there any evidence of extravasation from the transfusion?  Yes [ ]  No [ ]

Please tick all that applies

<table>
<thead>
<tr>
<th></th>
<th>During transfusion</th>
<th>In the first 6 hours post transfusion</th>
<th>In the 6-24 hours post transfusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Increased frequency of apnea with bradycardia compared with 24 hours pretransfusion</td>
<td>Yes [ ]  No [ ]</td>
<td>Yes [ ]  No [ ]</td>
<td>Yes [ ]  No [ ]</td>
</tr>
<tr>
<td>Initiation of a new mode of ventilation</td>
<td>Yes [ ]  No [ ]</td>
<td>Yes [ ]  No [ ]</td>
<td>Yes [ ]  No [ ]</td>
</tr>
<tr>
<td>Increase in FiO2 of &gt;10% for ≥ 15 minutes compared with average 0, 2, and 4 hours pretransfusion</td>
<td>Yes [ ]  No [ ]</td>
<td>Yes [ ]  No [ ]</td>
<td>Yes [ ]  No [ ]</td>
</tr>
<tr>
<td>Increase in respiratory rate by &gt; 15 per minute for ≥ 15 minutes compared with average 0, 2, and 4 hours pre transfusion</td>
<td>Yes [ ]  No [ ]</td>
<td>Yes [ ]  No [ ]</td>
<td>Yes [ ]  No [ ]</td>
</tr>
<tr>
<td>Additional diuretic given (apart from any regular diuretics that baby was on pretransfusion)</td>
<td>Yes [ ]  No [ ]</td>
<td>Yes [ ]  No [ ]</td>
<td>Yes [ ]  No [ ]</td>
</tr>
<tr>
<td>Rise in temperature by more than 1°C</td>
<td>Yes [ ]  No [ ]</td>
<td>Yes [ ]  No [ ]</td>
<td>Yes [ ]  No [ ]</td>
</tr>
<tr>
<td>Urticaria or hive like rash.</td>
<td>Yes [ ]  No [ ]</td>
<td>Yes [ ]  No [ ]</td>
<td>Yes [ ]  No [ ]</td>
</tr>
<tr>
<td>Evidence of severe allergic reaction or anaphylaxis (hypotension with rash, dyspnoea, stridor, wheeze, angioedema)</td>
<td>Yes [ ]  No [ ]</td>
<td>Yes [ ]  No [ ]</td>
<td>Yes [ ]  No [ ]</td>
</tr>
<tr>
<td>Development of signs and symptoms of haemolysis (fall in Hb, rise in LDH, rise in bilirubin, positive DAT)</td>
<td>Yes [ ]  No [ ]</td>
<td>Yes [ ]  No [ ]</td>
<td>Yes [ ]  No [ ]</td>
</tr>
<tr>
<td>Was a Chest X ray was taken?</td>
<td>Yes [ ]  No [ ]</td>
<td>Yes [ ]  No [ ]</td>
<td>Yes [ ]  No [ ]</td>
</tr>
</tbody>
</table>

If Yes: Were there new bilateral pulmonary infiltrates on Chest X ray?

   Was there evidence of cardiomegaly (cardiac silhouette > 60%)?

   Were there any other findings on chest X ray?

   If Yes, Please describe:
Specific Measures of Outcome

- Respiratory deterioration compared to pre-transfusion average readings
  - Increase in FiO2 of >10% for >15min
  - Increase of mean airway pressure of >2cm H₂O
  - A new mode of ventilation initiated by worsening lung condition

- Temperature change >2°C

- Mean Arterial Pressure >2 cm H₂O
HV Study – the next steps

• Pilot data to be ‘cleaned’ prior to further analysis and specific outcomes refined

• Cambridge team to continue to collect data – aiming for 200 babies

• Analyse preliminary results – perhaps refine definitions of Paediatric categories

• Extend study to other UK centres

• Interest from US and Australia
BCSH guidelines for neonates and older children to be revised

Prospective study on transfusions in neonates is being carried out jointly between NHSBT Paed Group and SHOT
Conclusions 1

• Still too many errors
  – use of adult emergency O neg blood for neonates
  – laboratory errors in neonatal and maternal grouping and antibody screening,
  – failure to recognise the need for irradiated components after intrauterine transfusion
  – prescription and administration errors leading to either overtransfusion or incorrect rate of transfusion.

• Poor communication and lack of checking in I&U cases with poor clinical understanding of the transfusion process in paediatrics, including the need to administer a specific volume rather than an entire unit.
Conclusions 2

- Children developed TACO, illustrating the importance of prescribing the correct volume and rate for small infants and children.
- Two reports of NEC associated with transfusion in 2011. Prospective studies are needed to further investigate this association.
- ATRs occurred following paediatric platelet transfusion, including 4 anaphylactic reactions. As the majority of the platelet transfusions were given for prophylaxis rather than bleeding, we need to ensure that these are given according to guidelines.
SHOT Symposium 2012
The Lowry Centre, Salford Quays
Thursday 5th July £69
e-mail shot@nhsbt.nhs.uk