National Comparative Audit of the use of Fresh Frozen Plasma

North West RTC

Prepared by John Grant-Casey on behalf of the NCA FFP Project Group

April 2009
The National Comparative Audit Programme

Background information

- A series of audits designed to look at the use and administration of blood and blood components
- Open to all NHS Trusts and Independent hospitals in the UK
- Collaborative programme between NHS Blood and Transplant & Royal College of Physicians
Use of FFP

Why was this audit necessary?

• FFP may be associated with high rates of inappropriate transfusion.

• FFP is not without risk
  – may be amongst the most ‘high risk’ of all blood components in relation to transfusion reactions.

• Health Service Circular Better Blood Transfusion (HSC 2007/001)
  – promotes the appropriate use of all blood components with avoidance of unnecessary transfusion.
Use of FFP

What were the aims of this audit?

- To audit the clinical use of FFP against BCSH guidelines
  - Dosage of FFP used.
  - Coagulation testing is performed pre and post administration of FFP.
  - Recording changes in standard coagulation testing after administration of FFP.
  - Clinical use of FFP in infants and children.
Use of FFP
Participation

Who took part
- Of 248 NHS hospitals 186 (75%) participated
- Of 61 Independent hospitals 10 (16%) participated

Number of patients audited
- Nationally = 4969  North West RTC = 736

And how?
- Hospitals asked to audit 40 FFP transfusions or all in 3 month period
- Hospitals also asked to send in completed organisational questionnaire
## Use of FFP
### Number of cases audited

<table>
<thead>
<tr>
<th>Hospital</th>
<th>Number of cases audited</th>
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<tbody>
<tr>
<td>A</td>
<td>40</td>
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182 centres responded to organisational audit

- 80% (145/182) had guidelines for FFP use in adults
- 16% (29/182) did not have guidelines
- 3% (6/182) were specialist children’s hospitals
- 1% (2/182) stated ‘not known’

- 57% (104/182) had local guidelines for paediatric use
- 39% (70/182) did not have guidelines (7 centres stated ‘not known’).
RESULTS – Guidelines for Use of FFP

Plasma product used for children <16yrs

- 88% (160/182) used methylene blue FFP
- 3% (6/182) used solvent detergent treated plasma
- 9% (16/182) did not treat paediatric patients or did not state clearly type of component used.
Use of FFP
Age ranges: 4635 - 16+; 114 - 1-15 years; 220 < 1 year old
In adults 14% of all FFP transfusions were given for warfarin reversal. Of these, 56% of patients were not bleeding.
Use of FFP
Main reason for transfusion in Adults

- Bleeding: National and Regional
- Before or during invasive procedure or surgery with abnormal coagulation: National and Regional
- Abnormal coagulation with no bleeding: National and Regional
- Other: National and Regional
- Not known: National and Regional
Use of FFP

Main reason for transfusion in Children (1 – 15 years of age)
Use of FFP
Main reason for transfusion in Infants (< 1 year old)

Note 42% of all FFP transfusions in <1 year olds given for abnormal coagulation without bleeding or planned procedure.
Use of FFP
INR results prior to transfusion in adult patients with & without bleeding

With bleeding

Without bleeding
### Use of FFP

#### Change in INR after FFP transfusion

<table>
<thead>
<tr>
<th>Pre-transfusion INR</th>
<th>Number of patients</th>
<th>Median value (Changes in INR post-transfusion)</th>
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<tbody>
<tr>
<td>All adults</td>
<td>2543</td>
<td>-0.2</td>
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<td>INR 1 – ≤1.5</td>
<td>985</td>
<td>0.0</td>
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<td>INR 1.6 – 2.9</td>
<td>1080</td>
<td>-0.3</td>
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<td>INR 3.0 – 4.9</td>
<td>272</td>
<td>-1.8</td>
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<td>INR ≥5</td>
<td>206</td>
<td>-5.0</td>
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Use of FFP
Other key results

Dose of FFP used
• There was wide variation in FFP dose transfused by weight.
• The median overall dose was:
  – Adults 11ml/kg.
  – Children 12ml/kg.
  – Infants 14ml/kg.
• In 40% of adults (873/2186) the dose was less than 10ml/kg.

Documentation in case notes
• The reason for transfusion was not documented in the case notes for 28% of adults, 24% of children and 17% of infants.
Use of Cryoprecipitate

- Cryo also given to 10% of adults, 13% of children and 15% of infants within 24 hours of receiving the first FFP transfusion.
- Of these, 67% of adults, 64% of children and 35% of infants had fibrinogen levels of ≥ 1.0g/l.

Reference ranges for neonatal coag results

- 32% (56/176) of centres used separate laboratory reference range for neonatal patients
Audit Recommendations

- Widespread use of FFP for prophylaxis needs careful scrutiny - audit has shown that many non-bleeding patients with normal or only minor derangements of PT or INR were given FFP.

- Much FFP use results in minimal or no improvement or correction in coagulation abnormalities.

- High quality trials are needed to address the question of efficacy of FFP use particularly in non-bleeding patients.
Audit Recommendations – Clinical use of FFP

• Trusts/ Hospitals should have local guidelines for FFP use for adult and paediatric patients based on BCSH guidelines and including indications where pathogen inactivated plasma should be used.

• The dose of FFP should be in accordance with BCSH guidelines.

• The indication for FFP use must be documented in the case notes.

• FFP use should be guided by coagulation test results – empirical use in massive haemorrhage should be confined to recommendations as stated in local guidelines.

• Appropriate reference ranges should be used when reporting coagulation results in neonatal patients.

• Trusts / Hospitals should empower transfusion laboratory staff to challenge medical staff about the issue of FFP where no clear clinical indication as defined by local guidelines.

• Prothrombin Concentrate Complex (PCC) should be the treatment of choice for the reversal of warfarin overanticoagulation.
**Use of FFP**

**Implementation – sample checklist**

<table>
<thead>
<tr>
<th>Recommendation: Use of Guidelines and Implementation</th>
<th>Compliance</th>
<th>Who?</th>
<th>Action Required</th>
<th>Progress</th>
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<tbody>
<tr>
<td>Every Trust / Hospital must have guidelines for use of FFP or cryoprecipitate relevant to adult and paediatric patients</td>
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<td>These guidelines should also indicate where pathogen inactivated plasma (e.g. methylene blue FFP, solvent detergent treated FFP) should be used instead of FFP</td>
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<td>Trusts / Hospitals should empower transfusion laboratory staff to challenge medical staff about the issue of FFP where there is no clear clinical indication as defined by local guidelines.</td>
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Use of FFP
Acknowledgements

- Project team:
- Report written by: Dr. Shubha Allard, Dr. Simon Stanworth, John Grant-Casey & Derek Lowe
- Advised by: Prof Mike Laffan, Dr. Helen New, Helen Nulty, Carol Cantwell, David Dalton, Sylvia Hennem, Jane Jones, Emily Okukenu, Elaine Parris, Dr. Miriam Tecle, and Katharine Young.

- Hospital staff who collected the audit data
Additional slides on paediatric data
Use of FFP

Underlying medical or surgical conditions in Children (1 – 15 years of age)