Audit of the Use of Fresh Frozen Plasma in the East Midlands Region 2013
Audit Sub Group

Dr Hafiz Qureshi
Consultant Haematologist
NHSBT/Leicester Royal Infirmary

Dr Robert Webster
Consultant Haematologist
NHSBT

Ms Kath Hearnshaw*
Patient Blood Management Practitioner
East Midlands Regional Transfusion Committee (EMRTC)

Ms Hayley Bond
Lead Transfusion Practitioner
Blood Transfusion Department
NUH NHS Trust

Ms Marie Browett
Lead Transfusion Practitioner
Leicester Royal Infirmary

Ms Joanne Shorthouse
Patient Blood Management Practitioner
East Midlands Regional Transfusion Committee (EMRTC)

Ms Odette Colgrave
East Midlands RTC Administrator

Hospital Transfusion Practitioners, EM RTC Region
(Appendix 4&5 list of contributors and participating sites)

* Ms Kath Hearnshaw has retired
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Glossary

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Meaning</th>
</tr>
</thead>
<tbody>
<tr>
<td>APPT</td>
<td>Activated Partial Thromboplastin Time</td>
</tr>
<tr>
<td>APPTR</td>
<td>Activated Partial Thromboplastin Time Ratio</td>
</tr>
<tr>
<td>ATR</td>
<td>Acute Transfusion Reaction</td>
</tr>
<tr>
<td>BCSH</td>
<td>British Committee for Standards in Haematology</td>
</tr>
<tr>
<td>DIC</td>
<td>Disseminated Intravascular Coagulopathy</td>
</tr>
<tr>
<td>ECMO</td>
<td>Extra Corporeal Membrane Oxygenation</td>
</tr>
<tr>
<td>EMRTC</td>
<td>East Midlands Regional Transfusion Committee</td>
</tr>
<tr>
<td>FFP</td>
<td>Fresh Frozen Plasma</td>
</tr>
<tr>
<td>g</td>
<td>Grams</td>
</tr>
<tr>
<td>HTC</td>
<td>Hospital Transfusion Committee</td>
</tr>
<tr>
<td>INR</td>
<td>International Normalised Ratio</td>
</tr>
<tr>
<td>MBFFP</td>
<td>Methylene Blue Fresh Frozen Plasma</td>
</tr>
<tr>
<td>mg</td>
<td>Milligrams</td>
</tr>
<tr>
<td>NHSBT</td>
<td>National Health Service Blood and Transplant</td>
</tr>
<tr>
<td>RBCs</td>
<td>Red blood cells</td>
</tr>
<tr>
<td>SDFFP</td>
<td>Solvent Detergent Fresh Frozen Plasma</td>
</tr>
<tr>
<td>TTP</td>
<td>Thrombotic Thrombocytopenic Purpura</td>
</tr>
</tbody>
</table>
Executive Summary

A previous audit in the East Midlands region into FFP use demonstrated that there was continued use of FFP for warfarin reversal, under dosing with poor weight recording and transfusion of FFP with normal pre-transfusion coagulation continued (8). Following a meeting of the East Midlands regional transfusion committee, it was decided to repeat an audit of FFP use across all hospitals in the region.

An online survey to elicit information regarding the use of FFP in the region was constructed. Local governance arrangements were adhered to.

Main findings

- The NCA 2009 reported that FFP was used to reverse warfarin in 14% of cases audited. In our audit this figure was 3%, indicating a significant improvement in this region.

- This audit also shows a significant variation in the dose of FFP transfused. There was evidence of both under- and over-transfusion based on the dosage recommended in the BCSH guideline.

- Pre transfusion coagulation parameters were reported for the vast majority (98%) of cases. However post-transfusion coagulation parameters were reported for 62% of cases, and of these only 37% had coagulation checked within 3 hours following the completion of FFP transfusion.

Recommendations

- Hospitals should have locally agreed, specialty specific, guidelines for the use of FFP. As a minimum, specific local guidelines should address the use of FFP in liver patients, cardiac surgery, trauma, Intensive Care Units and Neonatal units.

- These guidelines should define appropriate dose (mls /Kg) of FFP.

- Hospitals should have local guidelines on the reversal of anticoagulation with warfarin and other vitamin K antagonists. This guideline should clearly define exceptions where the use of FFP may be appropriate in addition to vitamin K, when Prothrombin Complex Concentrates (PCCs) are contra-indicated.

- Clinicians who prescribe FFP should be familiar with the guidelines for their specialty.

- Each high user clinical specialty should perform regular (annual) audits of compliance with local guidelines. The audits findings and action plans should be disseminated to all clinicians within the specialty, and presented to the Hospital Transfusion Committee.

- Use of FFP for the treatment of bleeding should be guided, wherever possible, by appropriate laboratory or point of care tests of coagulation before and after transfusing FFP.
• The East Midlands Regional Transfusion Committee, in collaboration with HTTs, should organise regional and local educational events on evidence based use of FFP.

Introduction

Earlier investigations have indicated that that Fresh Frozen Plasma (FFP) may be associated with high rates of inappropriate transfusion with some studies indicating rates of up to 50% non compliance with established guidelines (1). The current British Committee for Standards in Haematology (BCSH) guidelines on the use of FFP aim to reinforce the message regarding avoidance of its inappropriate use (2).

A systematic review of published randomised clinical trials involving FFP found an overall lack of evidence to support benefit in all clinical areas apart from TTP (3).

FFP is not without risk and indeed may be amongst the most ‘high risk’ of all blood components in relation to transfusion reactions (the 2012 SHOT report indicates FFP in 29/372, 8% of ATRs)

The Health Service Circular Better Blood Transfusion: Safe and Appropriate Use of Blood (HSC 2007/001) promotes the appropriate use of all blood components including FFP with avoidance of unnecessary transfusion (5).

In addition, increasing use of solvent detergent FFP and methylene blue treated FFP for specific groups of patients and children introduce new areas for vigilance.

There have been several previous audits into the use of this product. An audit of FFP use in 2007 in the South Central region revealed that FFP was used for warfarin reversal in 26% of the cases audited (6). FFP weight related dosage was poorly implemented with weight being recorded in only 32% of cases. A large scale audit of FFP use undertaken in 2009 as part of the National Comparative Audit programme indicated that FFP continued to be used for warfarin reversal and was frequently given where there was no evidence of actual bleeding. Liver disease also accounted for a significant degree of FFP use. An audit of FFP use in the South West in one large hospital found that following a period of intensive educational measures, appropriate use of FFP improved dramatically particularly with respect to use for warfarin reversal (7).

A previous audit in the East Midlands region into FFP use demonstrated that there was continued use of FFP for warfarin reversal, under dosing with poor weight recording and transfusion of FFP with normal pre-transfusion coagulation continued (8). Following a meeting of the East Midlands regional transfusion committee, it was decided to repeat an audit of FFP use across all hospitals in the region.

Methods

A consensus approach was adopted to conduct the audit. The regional transfusion practitioners elected to undertake the data collection using a hard copy data collection form. The form was a modification of a developed audit form used by Leicester Royal Infirmary. In addition, an organisational audit was undertaken and issued once to each site. Copies are given as appendices XXXXX and XXXX.
Appropriate governance arrangements were implemented and approval to participate in the audit obtained. Caldicott Guardians in each participating site were also informed.

Each site that elected to participate in the audit was asked to collect information on FFP use for a total of 20 cases per site. A pragmatic time frame was adopted which was later extended. Data collection was undertaken by local transfusion practitioners and took place during the summer of 2013 until November of the same year. Completed forms were returned to the RTC data analyst and audit facilitator. Information was manually entered into an Excel spreadsheet and analysed proportionately (n, %). Data anomalies were discussed at a subsequent RTC meeting before final analysis. No overt identifying patient details were taken and hospitals have been anonymised in this report.

Results

Organisational Survey

14 hospitals (8 Trusts) make up East Midlands RTC with 1 independent site. 9 sites responded to the organisational questionnaire. Of these:-

- 8/9 had an FFP use policy for all areas (paediatrics). 1 site had a policy for adults only
- 9/9 had a policy for over coagulation with Warfarin

8 organisations who responded used FFP variants for children under the age of 16 years. Table 1 indicates the type of product that is used.

Table 1

<table>
<thead>
<tr>
<th>Organisation</th>
<th>What plasma do you use for children &lt; 16 years?</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>MB FFP</td>
</tr>
<tr>
<td>B</td>
<td>Paediatric MB FFP or Octaplas</td>
</tr>
<tr>
<td>C</td>
<td>Octaplas</td>
</tr>
<tr>
<td>D</td>
<td>MB FFP</td>
</tr>
<tr>
<td>E</td>
<td>Octaplas</td>
</tr>
<tr>
<td>F</td>
<td>MB FFP</td>
</tr>
<tr>
<td>G</td>
<td>Octaplas</td>
</tr>
<tr>
<td>H</td>
<td>Octaplas</td>
</tr>
</tbody>
</table>

Results - Case Audit

Standards

1. FFP should be used in appropriate situations as defined by BCSH guidelines
2. FFP dosage should be based on the weight of the patient
3. Coagulation screening should be performed pre and post transfusion
Demographics

Individual case data was submitted by transfusion staff working in each hospital. One hospital trust was unable to participate in the audit. In total, 12 hospitals from all remaining NHS Trusts contributed data.

177 datasets were completed on 167 patients (multiple submissions on one case of thrombotic thrombocytopenic purpura). 2 sites submitted a full compliment of 20 cases with 8 contributing 15 or more cases. The dataset indicated a mean age of 52 years (1 – 99 years), 85 (48%) female, 90 (51%) male, 2 no gender submitted.

Type of FFP used was documented in 166/167 (99%) cases. Methylene blue FFP was used in all cases where infants were involved and solvent detergent used in cases of TTP and Plasma Exchange.

Reasons for FFP Transfusion

Details of admission were provided in 166/167 (99%) of cases. As in previous audits, the principle reasons for FFP use were massive bleeding, cardiac surgery and liver disease. In some cases, massive bleeding was also indicated in conjunction with gastrointestinal bleeds and liver disease so cases directly attributable to liver disease may be an underestimate. Details are provided in table 2.

Table 2

<table>
<thead>
<tr>
<th>Principle Reasons for FFP Use</th>
<th>Numbers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Massive Bleeding*</td>
<td>49</td>
</tr>
<tr>
<td>Pre Procedure/Surgery plus Abnormal Coagulation No Bleeding</td>
<td>29</td>
</tr>
<tr>
<td>Liver Disease plus Abnormal Coagulation</td>
<td>21</td>
</tr>
<tr>
<td>Abnormal Coagulation No Bleeding No Procedure</td>
<td>12</td>
</tr>
<tr>
<td>Cardiac Surgery</td>
<td>11</td>
</tr>
<tr>
<td>TTP (see glossary)</td>
<td>1</td>
</tr>
<tr>
<td>Pre Procedure Surgery plus Abnormal Coagulation with Bleeding</td>
<td>9</td>
</tr>
<tr>
<td>Plasma Exchange</td>
<td>6</td>
</tr>
<tr>
<td>Warfarin/Heparin Reversal</td>
<td>5</td>
</tr>
<tr>
<td>DIC (see glossary)</td>
<td>2</td>
</tr>
<tr>
<td>Factor Deficiency</td>
<td>2</td>
</tr>
<tr>
<td>Post Op Bleed</td>
<td>2</td>
</tr>
<tr>
<td>Deranged TEG results</td>
<td>1</td>
</tr>
<tr>
<td>ECMO (see glossary)</td>
<td>1</td>
</tr>
<tr>
<td>Melena</td>
<td>1</td>
</tr>
<tr>
<td>No details given (not in notes)</td>
<td>1</td>
</tr>
<tr>
<td>Plasminogen Deficiency</td>
<td>1</td>
</tr>
<tr>
<td>Vascular surgery with surgical bleed</td>
<td>1</td>
</tr>
<tr>
<td>Total</td>
<td>155</td>
</tr>
</tbody>
</table>

*Other Reasons

| Unknown                                                           | 5       |
| Deranged TEG Results                                             | 1       |
| Blank                                                             | 6       |
| Final Total                                                       | 167     |

*15% cases of FFP use in massive bleeding associated with gastrointestinal bleeding
Table 3 indicates the principle process aspects of documentation unrelated to laboratory information.

Table 3 – Documentation of FFP Transfusion

<table>
<thead>
<tr>
<th>Audit Question</th>
<th>Field Completed N, (%)</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date of First Transfusion episode Recorded</td>
<td>162/167 (97)</td>
<td></td>
</tr>
<tr>
<td>Time of 1st Unit Transfusion Recorded</td>
<td>163/167 (98)</td>
<td></td>
</tr>
<tr>
<td>Weight of Patient Recorded</td>
<td>142/167 (85)</td>
<td></td>
</tr>
<tr>
<td>Total Volume of FFP Transfused Recorded</td>
<td>131/167 (78)</td>
<td></td>
</tr>
<tr>
<td>Type of FFP Used Recorded</td>
<td>166/167 (99)</td>
<td></td>
</tr>
<tr>
<td>Reason for FFP Transfusion Documented</td>
<td>161/167 (96)</td>
<td></td>
</tr>
<tr>
<td>Bleeding/Not Bleeding Documented</td>
<td>167/167 (100)</td>
<td></td>
</tr>
<tr>
<td>Bleeding Features Documented</td>
<td>90/90 (100)</td>
<td>Denominator = bleeding (n)</td>
</tr>
<tr>
<td>Appropriate Vit K Use Documented</td>
<td>21/21 (100)</td>
<td>Denominator = 21 (group designated for Vit K)</td>
</tr>
<tr>
<td>Dose Vit K Documented</td>
<td>34/38 (89)</td>
<td>Denominator = total receiving Vit K</td>
</tr>
<tr>
<td>Route Administered Documented</td>
<td>36/38 (95)</td>
<td>Denominator = total receiving Vit K</td>
</tr>
<tr>
<td>Date Procedure Documented</td>
<td>63/67 (94)</td>
<td>Denominator = those having a procedure (n)</td>
</tr>
<tr>
<td>Time Procedure Documented</td>
<td>44/67 (66)</td>
<td>Denominator = those having a procedure (n)</td>
</tr>
<tr>
<td>Consent to Transfusion Documented</td>
<td>41/167 (26)</td>
<td></td>
</tr>
<tr>
<td>Date of Consent Documented</td>
<td>32/41 (78)</td>
<td>Denominator = “yes” to consent</td>
</tr>
</tbody>
</table>

Summary Box 1
- 100% of organisations had policy documents in relation to FFP transfusion
- Age of FFP recipients may be decreasing
- Principle reasons for FFP use are massive bleeding, cardiac surgery and liver disease
- Recording of volume of FFP transfused and recording of consent to transfusion may have room for improvement
- Units recorded as “mls” and “number of units”
- Use of idiosyncratic notation (dot) to denote “unit”

The decision to use FFP should be related to coagulation data and this component should not be used for warfarin reversal although pragmatic decisions will have to be made in emergency situations.

East Midlands Regional Transfusion Committee
Table 4 indicates laboratory parameters recorded for this dataset in relation to FFP transfusion.

Table 4 – Recording of Pre and Post FFP Transfusion Laboratory Parameters

<table>
<thead>
<tr>
<th>Audit Question</th>
<th>Field Completed N, (%)</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>No of patients receiving warfarin</td>
<td>15/167 (9%)</td>
<td>5/167 (3%) stated use of FFP for warfarin reversal</td>
</tr>
<tr>
<td>No of patients receiving heparin</td>
<td>11/167 (7%)</td>
<td>3 also indicated as being on warfarin as well</td>
</tr>
<tr>
<td>Evidence of pre Tx INR or PT?</td>
<td>147/167 (88)</td>
<td></td>
</tr>
<tr>
<td>Result documented</td>
<td>147/167 (88)</td>
<td></td>
</tr>
<tr>
<td>INR &gt; 10 documented (y/n)</td>
<td>3/147 (2)</td>
<td></td>
</tr>
<tr>
<td>PT range provided where PT used</td>
<td>135/138 (98)</td>
<td></td>
</tr>
<tr>
<td>PT time documented</td>
<td>138/167 (83)</td>
<td></td>
</tr>
<tr>
<td>Evidence of APTTR</td>
<td>86/167 (51)</td>
<td></td>
</tr>
<tr>
<td>APPT documented</td>
<td>62/86 (72)</td>
<td>Denominator = APPTT documented</td>
</tr>
<tr>
<td>APPT result documented</td>
<td>132/167 (79)</td>
<td></td>
</tr>
<tr>
<td>APPT ref range given</td>
<td>129/167 (77)</td>
<td></td>
</tr>
<tr>
<td>Evidence of TEG documented (y/n)</td>
<td>9/167 (5)</td>
<td>Includes ROTEM</td>
</tr>
<tr>
<td>TEG results given</td>
<td>3/9 (33)</td>
<td>Denominator = TEG clients</td>
</tr>
<tr>
<td>Evidence of INR or PT within 3 hours</td>
<td>62/167 (37)</td>
<td>37% had post transfusion coagulation tests within or equal to 3 hours</td>
</tr>
<tr>
<td>Result INR/PT</td>
<td>104/167 (62)</td>
<td>No of results exceed 3 hour rule</td>
</tr>
<tr>
<td>APTT or APTTR documented</td>
<td>64/104 (62)</td>
<td>Denominator = results (n)</td>
</tr>
<tr>
<td>Post Tx TEG documented</td>
<td>3/167 (2)</td>
<td></td>
</tr>
<tr>
<td>Benefits of FFP documented</td>
<td>35/167 (21)</td>
<td></td>
</tr>
<tr>
<td>Adverse Effects Documented</td>
<td>0/167 (0)</td>
<td></td>
</tr>
</tbody>
</table>
Data Exploration

Laboratory Reference Ranges

Figure 1 indicates the variation in APTT laboratory reference ranges and frequency of use (hospital dependent) used in relation to client data submitted for this audit. Figure 2 shows similar information for reference ranges in relation to the prothrombin time. For this audit, the following ranges were used to define abnormal results.

- INR > 1.5 or
- APTT > 1.5 or
- Prothrombin Time > 18 seconds or
- APTT > 45 seconds or
- Prolonged “R” time >
- 9 minutes (TEG*)
- Prolonged intem or extem MCF > 72mm on ROTEM

Fig 1

11 different reference ranges are used for APTT
8 different reference ranges are used for PT.

Although caveats will apply, FFP should be used in conjunction with a review of recent coagulation results in the context of the clinical presentation.

For the purpose of this audit, abnormal coagulation is defined as an INR in excess of 1.5, and/or a prothrombin time >18 seconds or an APTT >45 seconds. Recently, the results of any thromboelastographic measurements are also taken into consideration. Not all sites measure INR and some indicate both. Pre FFP transfusion results for the whole cohort are shown in table 5.

Table 5 - FFP Use Outside Recommended Laboratory Ranges (n = 167)

<table>
<thead>
<tr>
<th>Pre Transfusion Coagulation Results (includes bleeding patients)</th>
<th>No of Cases Out of Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>INR &lt; 1.5</td>
<td>32/83 (39%)</td>
</tr>
<tr>
<td>PT &lt; 18</td>
<td>73/138 (53%)</td>
</tr>
<tr>
<td>APTT &gt;45</td>
<td>97/132 (71%)</td>
</tr>
</tbody>
</table>

The same data is indicated in table 6 but only for those patients where no bleeding was indicated.

Table 6 - FFP Use in Patients where no Bleeding Documented

<table>
<thead>
<tr>
<th>Pre Transfusion Coagulation Results</th>
<th>No of Cases Out of Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>INR &lt; 1.5</td>
<td>11/44 (25%)</td>
</tr>
<tr>
<td>PT &lt; 18</td>
<td>22/60 (37%)</td>
</tr>
<tr>
<td>APTT &lt;45</td>
<td>35/57 (61%)</td>
</tr>
</tbody>
</table>

In the NCA audit of 2009, 43% of adults audited had no evidence of bleeding. In this audit 77/167 (46%) had no evidence of bleeding. In the NCA of FFP, pre transfusion
coagulation parameters were within normal range for an average of 39% of non-bleeding patients who received FFP. In this audit, this figure was 31%.

**Vitamin K**

38/167 (23%) of patients received vitamin K intravenously. All were 10mg doses apart from a 0.6 mg given to a child. 17/38 (45%) received vitamin K where there was no stated evidence of bleeding although 31/38 (82%) mentioned abnormal coagulopathy in the presentation. 10 patients with evidence of liver disease did not receive vitamin K.

### Summary Box 3

- There is a wide range of laboratory reference ranges used across the region.
- In 46% of cases, FFP was transfused in the absence of any bleeding. The NCA in 2009 reported this figure as 43%, indicating no improvement in clinical practice.
- FFP is used where there is little or no evidence of abnormal coagulation in over 30% of cases and these figures have not changed substantially since the NCA in 2009.
- There has been a substantial reduction in the use of FFP for warfarin reversal compared to the NCA FFP audit (14% to 3%).
- 10 patients with evidence of liver disease did not receive vitamin K.

**Dosing**

FFP has optimal value when transfused at the appropriate dose; the recommended adult therapeutic dose of FFP is 12-15 ml/kg and should be at least 10 ml/kg. While it is difficult to provide an exact volume of a single unit of FFP a volume of 271ml per unit, taken from recent NHSBT recommendations, has been used to calculate the estimated correct dose of FFP from the patient weight provided in this sample (appendix 3).

Figure 3 indicates the actual dose received plotted against the recommended doses where weight data was available.
While caution is advised when using FFP in overweight patients, there is evidence of both under and overdosing in this group.

Figure 4 shows weight plotted against the volume of FFP used in bleeding patients in this group.

**Fig 4**

**Discussion**

The primary objective of this regional comparative audit was to evaluate use of FFP by comparison to current BCSH guidelines, and to evaluate current practice in our region, in comparison with the earlier, national comparative audit of the use of FFP, carried out in 2009 (NCA 2009). This audit presents analysis of data from 177 FFP transfusion episodes from 10 hospitals in the East Midlands Region of England. The audit sample is considered sufficiently representative; however audit results should be interpreted in the context of usual limitations of retrospective data collection.

The NCA 2009 showed that 43% of cases audited, FFP was transfused in the absence of bleeding. This figure in our regional audit is 46%, indicating very little or no improvement in clinical practice in our region. In these cases where FFP was transfused in the absence of bleeding, there was no evidence of a significant abnormality of coagulation in 31% of cases. This figure for the NCA 2009 was 39%.

It is therefore clear that FFP continues to be frequently transfused in the absence of bleeding or significant coagulopathy, as defined by laboratory parameters of coagulation in this audit. This audit effectively shows no improvement in this area of clinical practice since the earlier national comparative audit of 2009.

**Summary Box 4**

- FFP is under dosed and does not appear to be used in relation to the weight of the patient in a large proportion of the cases (fig 4)
- There is also evidence of overdosing in some patients
The NCA 2009 reported that FFP was used to reverse warfarin in 14% of cases audited. In our audit this figure was 3%, indicating a significant improvement in this region.

This audit also shows a significant variation in the dose of FFP transfused. There was evidence of both under- and over-transfusion based on the dosage recommended in the BCSH guideline.

Pre transfusion coagulation parameters were reported for the vast majority (98%) of cases. However post-transfusion coagulation parameters were reported for 62% of cases, and of these only 37% had coagulation checked within 3 hours following the completion of FFP transfusion.

In summary, this audit shows that FFP continues to be frequently used in the absence of bleeding and / or evidence of abnormal coagulation, and thus highlights the need for concerted efforts in the education of clinicians who prescribe FFP.

**Recommendations**

- Hospitals should have locally agreed, speciality specific, guidelines for the use of FFP. As a minimum, specific local guidelines should address the use of FFP in liver patients, cardiac surgery, trauma, Intensive Care Units and Neonatal units.

- These guidelines should define appropriate dose (mls /Kg) of FFP.

- Hospitals should have local guidelines on the reversal of anticoagulation with warfarin and other vitamin K antagonists. This guideline should clearly define exceptions where the use of FFP may be appropriate in addition to vitamin K, when Prothrombin Complex Concentrates (PCCs) are contra-indicated.

- Clinicians who prescribe FFP should be familiar with the guidelines for their specialty.

- Each high user clinical specialty should perform regular (annual) audits of compliance with local guidelines. The audits findings and action plans should be disseminated to all clinicians within the specialty, and presented to the Hospital Transfusion Committee.

- Use of FFP for the treatment of bleeding should be guided, wherever possible, by appropriate laboratory or point of care tests of coagulation before and after transfusing FFP.

- The East Midlands Regional Transfusion Committee, in collaboration with HTTs, should organise regional and local educational events on evidence based use of FFP.
References


4. SHOT 2012 annual report. www.shotuk.org

   http://www.transfusionguidelines.org.uk/uk-transfusion-committees/national-blood-transfusion-committee/better-blood-transfusion

6. South Central Regional audit of FFP.  
   http://www.transfusionguidelines.org.uk/uk-transfusion-committees/regional-transfusion-committees

7. South West Regional audit of FFP.  
   http://www.transfusionguidelines.org.uk/uk-transfusion-committees/regional-transfusion-committees

8. East Midlands regional audit of FFP.  
   http://www.transfusionguidelines.org.uk/uk-transfusion-committees/regional-transfusion-committees
Appendix 1 – Case Data Collection Form

East Midlands Regional Transfusion Committee

East Midlands FFP Audit: Data Collection Form

Please complete 1 form for each patient receiving a transfusion of FFP

Audit case number: 

Name of Hospital (where this transfusion took place):

Name of person completing this audit:

Job title:

A) Patient Demographics

Male □  Female □

Year of Birth ...../....../....

Patient weight (Kg) 

1) What was the stated reason for this admission?

B: Transfusion Episode Details

Date of transfusion of first unit for this episode ...../....../....

Time of transfusion of first unit for this episode (24 hour clock) ___ hrs ___ mins

2) What was the total volume of FFP transfused for this episode 

3) What type of FFP was given?

Standard FFP (standard UK) □

Methylene Blue Treated FFP □

Solvent detergent (Octaplas) □

Other (please state) 

Other (please state) 

Other (please state) 

1
Appendix 1 contd..

4) What was the stated indication for this FFP transfusion?
   a) Liver disease, with abnormal coagulation □
   b) Before invasive procedure or surgery, with abnormal coagulation (see definition of abnormal coagulation below) but in the absence of any bleeding □
   c) Before invasive procedure or surgery, with abnormal coagulation (see definition of abnormal coagulation below) but in the presence of bleeding □
   d) Abnormal coagulation, in the absence of bleeding and no invasive procedure planned (see definition of abnormal coagulation below) □
   e) Disseminated Intravascular Coagulation (DIC) □
   f) Thrombotic Thrombocytopenic Purpura (TTP) □
   g) Plasma exchange □
   h) Massive bleeding □
   i) Cardiac surgery □
   j) Warfarin reversal □
   h) Other, please state:

5) Was the patient bleeding?  Yes □ No □
   If Yes, please describe the features:
   Major haemorrhage □
   Surgical bleed □
   Intracranial bleeding □
   Other (please state)

6) If you ticked B1 a) or B1 g) above, did this patient receive vitamin K before FFP was transfused?  Yes □ No □
Appendix 1 contd

If yes, state the dose of vitamin administered ...............mg, and route of administration: oral □ Intravenous □

If yes, please state the date and time of administration of Vitamin K
Date ....../........./........... Time □ Hrs □ Mins (24 hour clock)

7) If FFP was given before invasive procedure or surgery, please state:
Type of procedure:

Date of Procedure: ....../........./...........

8) Was time of procedure/surgery documented? Yes □ No □
If yes please state time □ Hrs □ Mins (24 hours clock)

9) Is there evidence of written consent for blood component transfusion?
Yes □ No □
If yes, please state date consented ———/———/———

C: Pre Transfusion Laboratory Data

Please use the pre-transfusion Prothrombin time in seconds or INR value and APTT result nearest to the start of the transfusion episode being audited.

Please note that some hospitals or clinical areas may be using a point of care (or near patient) test device such as Coaguchek for checking INR and hence it is possible that an INR record cannot be found in your laboratory computer system but this result may be documented in the patient’s clinical records.

10) Was the patient receiving Warfarin at any time during the 7 days prior to transfusion? Yes □ No □

11) Was the patient on Heparin at any time during the 7 days prior to transfusion?
Yes □ No □

12) Is there evidence of a pre-transfusion INR or Prothrombin time being performed?
Yes □ No □ No result found □

13) If yes, Was Pre-transfusion INR result >10? Yes □ No □

14) If no, what was pre-transfusion INR? □□□□ (nn n)
Appendix 1 contd.....

15) If your laboratory reports Prothrombin time instead of the INR, please state the value of Prothrombin time in seconds and provide your laboratory's normal range for this test:

   Prothrombin Time in Seconds .................., your Laboratory's normal or Reference range ------ to ------ seconds

16) Is there evidence of a pre-transfusion APTT ratio being performed?
   Yes ☐ No ☐ No result found ☐

17) If yes, what was pre-transfusion APTT ratio? □□□□□□□□ (nn:n)

18) Pre-transfusion APPTR (APPT Ratio) result □□□□□□□□ (n:n)

19) If your laboratory does not report APPTR (APTT ratio), please state the APTT time in seconds and provide your laboratory's normal range for this test:

   APTT in Seconds ......................
   Your Laboratory's normal or Reference range ------ to ------ seconds

20) Was thromboelastography (TEG) performed before giving FFP?
   Yes ☐ No ☐

21) If yes, are thromboelastography results documented in notes?

22) If yes, what was the "R" time in minutes □□□□□□□□ (nn)

23) What was the Max Amplitude (MA) (mm) □□□□□□□□ (nn)

24) What was the Alpha Angle (degrees) □□□□□□□□ (nnn)

25) Was Rotem (Rotational Elastometry) performed before giving FFP?
   Yes ☐ No ☐

26) If yes, are ROTEM results documented in notes? ☐

27) If yes, what was the Intern MCF in mm □□□□□□□□ (max nnn)
   Results not documented ☐

If yes, what was the Extern MCF in mm □□□□□□□□ (max nnn)
   Results not documented ☐
Appendix 1 contd....

D: Post-transfusion Laboratory Parameters

28) Is there evidence of the following being performed within 3 hours of last unit of FFP being administered?

INR – or Prothrombin time (PT) Yes ☐ No ☐

Result: INR: _______ PT _______

APTT or APTT ratio Yes ☐ No ☐

Result: APTT Ratio: _______ or APTT in seconds _______ seconds

TEG - R time Yes ☐ No ☐ Result: _______

Rotem Intern & Extern MCF Yes ☐ No ☐ Result: _______

E: Clinical Outcome

29) Is there an outcome documented following this transfusion episode?

Benefits or efficacy of FFP documented Yes ☐ No ☐

Adverse effect documented Yes ☐ No ☐

If adverse effects were documented please specify these:

[Blank space]

Definition of abnormal coagulation for the purpose of this audit:

- INR > 1.5, or
- APPTR > 1.5, or
- Prothrombin Time >18 sec, or
- APTT > 45 sec, or
- prolonged R time > 9 min on TEG, or
- prolonged intern or extern MCF > 72 mm on Rotem analysis
Appendix 2 – Organisational Survey (taken from NCA)

Appendix 1 – Organisational Audit Questionnaire

Q1. How would you best describe your hospital?

<table>
<thead>
<tr>
<th>Independent</th>
<th>DGH</th>
<th>Teaching</th>
<th>Specialist</th>
</tr>
</thead>
</table>

Q2. Do you have a (hospial or trust) guideline for use of FFP in:

<table>
<thead>
<tr>
<th>Adults?</th>
<th>Paediatrics?</th>
</tr>
</thead>
</table>

Q3. Do you have a (hospital or trust) guideline for management of massive haemorrhage?

Yes  No

If yes, please state for which specific areas you have local guidelines

Q4. Do you have hospital or trust guideline for the management of over-anticoagulation with Warfarin?

Yes  No

Q5. Which plasma product do you use for children aged <16 years?

<table>
<thead>
<tr>
<th>MB FFP</th>
<th>Other – specify</th>
</tr>
</thead>
</table>

Q6. Do you use other pathogen inactivated plasma products?

<table>
<thead>
<tr>
<th>None</th>
<th>Octaplas</th>
<th>Other (specify)</th>
</tr>
</thead>
</table>

Q7. If you use other pathogen inactivated plasma products, please give clinical indications for use at your centre:

<table>
<thead>
<tr>
<th>Thrombotic Thrombocytopenic Purpura (TTP)</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

Other clinical indications (specify)

Q8. Do you use Prothrombin Complex Concentrate for warfarin reversal in your hospital?

Yes  No

Q9. Approximately how many times have you used PCC for warfarin reversal in your hospital over the last 6 months?

Q10. Which method does your laboratory use for measuring fibrinogen?

<table>
<thead>
<tr>
<th>Clauss</th>
<th>PT derived</th>
</tr>
</thead>
</table>
Q11. What are your current laboratory's reference ranges for prothrombin time (PT) for adults? 

PT

Q12. What is the International Sensitivity Index (ISI) of the thromboplastin used by your coagulation laboratory? 

ISI

Q13. Do you have separate laboratory reference ranges for neonatal patients? 

Yes  No

Q14. Are these ranges stated when neonatal results are reported? 

Yes  No

Q15. If you answered 'yes' to Q13, what is the source of these ranges? 

Q16. Has the hospital undertaken any specific audits in relation to use of FFP? 

Yes, within the last 2 years  Yes, within the last 5 years  No

If yes, was this a local or regional audit? Local  Regional

Other Notes
## Appendix 3 – FFP Dosage (© NHSBT)

### Fresh Frozen Plasma (FFP) Dosage

**Fresh Frozen Plasma (FFP) has optimal value when transfused at the appropriate dose. The recommended adult therapeutic dose of FFP is 15mL/kg**, and the dose of FFP should always be at least 10mL/kg; however, a smaller adult dosage is in clinical practice 40% of adults receive a FFP dose of 10mL/kg.

The prescribed dosage of FFP should be guided by clinical situation and coagulation results.

### Calculations for One Adult Therapeutic Dose FFP

<table>
<thead>
<tr>
<th>Patient Weight (kg)</th>
<th>FFP dose – Volume/Units*</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>15mL/kg</td>
</tr>
<tr>
<td>55kg</td>
<td>825mL</td>
</tr>
<tr>
<td>60kg</td>
<td>900mL</td>
</tr>
<tr>
<td>65kg</td>
<td>975mL</td>
</tr>
<tr>
<td>70kg</td>
<td>1,050mL</td>
</tr>
<tr>
<td>75kg</td>
<td>1,125mL</td>
</tr>
<tr>
<td>80kg</td>
<td>1,200mL</td>
</tr>
<tr>
<td>85kg</td>
<td>1,275mL</td>
</tr>
<tr>
<td>90kg</td>
<td>1,350mL</td>
</tr>
<tr>
<td>95kg</td>
<td>1,425mL</td>
</tr>
<tr>
<td>100kg</td>
<td>1,500mL</td>
</tr>
</tbody>
</table>

*Volume of FFP is a unit variable, mean FFP unit volume = 2.33mL/Units.

The document is intended as a guide to the appropriate adult dose of FFP, it is not a directive, and should not be used in place of clinical assessment.

Caution should be exercised using this chart for calculating FFP volume for overweight patients as the volume suggested may be an overestimation and may result in bleedback.

Guidance for the Management of Massive Haemorrhage may contain alternative strategies for the adult dose of FFP; please refer to local guidelines as appropriate.

For further information contact your Hospital Transfusion Practitioner, Consultant Haematologist for transfusion, or hospital transfusion laboratory (bloodbank).

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## Appendix 4 – Participating Trusts

### Participating Trusts

- Chesterfield Royal Hospital NHS Foundation Trust
- Derby Hospitals NHS Foundation Trust
- Kettering General Hospital NHS Foundation Trust
- Nottingham University Hospitals NHS Trust
- Sherwood Forest Hospitals NHS Foundation Trust
- United Lincolnshire Hospitals NHS Trust
- University Hospitals of Leicester NHS Trust
Appendix 5 Acknowledgements – Transfusion Practitioners

Transfusion Practitioners in the East Midlands Region without whose help this audit would not have been possible.

<table>
<thead>
<tr>
<th>Name</th>
<th>Job Title</th>
<th>Hospital</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phillipa Cheshire</td>
<td>Transfusion Practitioner</td>
<td>Nottingham University Hospitals</td>
</tr>
<tr>
<td>Ant Jackson (Scientist)</td>
<td>Transfusion Practitioner</td>
<td>Pilgrim Hospital</td>
</tr>
<tr>
<td>Carol Richardson (Nurse)</td>
<td>Transfusion Practitioner</td>
<td>Lincoln County Hospital</td>
</tr>
<tr>
<td>Debra Davis (Nurse)</td>
<td>Transfusion Practitioner</td>
<td>Royal Derby Hospital</td>
</tr>
<tr>
<td>Judy Beale (Scientist)</td>
<td>Transfusion Practitioner</td>
<td>Royal Derby Hospital</td>
</tr>
<tr>
<td>Joy Murphy (Nurse)</td>
<td>Transfusion Practitioner</td>
<td>Northampton General Hospital</td>
</tr>
<tr>
<td>Angela Houston (Nurse)</td>
<td>Transfusion Nurse Specialist</td>
<td>Kettering General Hospital</td>
</tr>
<tr>
<td>Caroline Lowe (Scientist)</td>
<td>Transfusion Practitioner</td>
<td>Kettering General Hospital</td>
</tr>
<tr>
<td>Janice Smith (Nurse)</td>
<td>Matron Transfusion Specialist</td>
<td>Chesterfield Royal Hospital</td>
</tr>
<tr>
<td>Nicky Rollings (Nurse)</td>
<td>Transfusion Competency Assessor</td>
<td>Chesterfield Royal Hospital</td>
</tr>
<tr>
<td>Virginia Pearson (Nurse)</td>
<td>Transfusion Competency Assessor</td>
<td>Chesterfield Royal Hospital</td>
</tr>
<tr>
<td>Jane Walden (Scientist)</td>
<td>Transfusion Practitioner</td>
<td>Kings Mill Hospital</td>
</tr>
<tr>
<td>Pavlina Sharp (Nurse)</td>
<td>Transfusion Practitioner</td>
<td>Glenfield General Hospital</td>
</tr>
</tbody>
</table>
Fiona Waller  
(Nurse)  
Transfusion Practitioner  
Leicester Royal Infirmary

Malcolm Chambers  
(ODP)  
Transfusion Practitioner  
Glenfield General Hospital

Lindsay Duffin  
(Nurse)  
Group Transfusion Nurse Specialist  
Nuffield Hospitals National Post  
(use home address for post)

Roz Rowe  
(Nurse)  
Transfusion Nurse  
Spire Hospital Leicester

For copies of this report or any queries concerning this audit please contact:

Brian Hockley  
Data Analyst and Audit Manager  
Sheffield Blood Centre  
Longley Lane  
Sheffield  
S5 7JN  
Brian.Hockley@nhsbt.nhs.uk  
Tel - 01143584836  
Mob - 07764280404