

# A Retrospective Audit of Appropriateness and Monitoring of Fresh Frozen Plasma Transfusions in A Tertiary Care Hospital

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## ABSTRACT

**Introduction:** In spite of availability of transfusion guidelines for appropriate use of blood components, there is often unjustified and inappropriate use of blood components. The objective of the study was to audit the appropriateness and monitoring of fresh frozen plasma (FFP) transfusions in a tertiary care center.

**Material and Methods:** A retrospective audit was conducted on 204 FFP transfusion episodes. The appropriateness of transfusion indication and amount of FFP transfused were assessed based on NHMRC guidelines. The transfusion episodes were categorized as per the clinical specialty and were further divided into appropriate and inappropriate transfusion episodes depending on whether the transfusion indication and the amount transfused were as per the guidelines. Inadequately documented transfusion episodes were also considered inappropriate. Monitoring of transfusion episodes and post-transfusion assessment of the FFP recipients was also evaluated.

**Results:** The clinical specialty with the highest FFP transfusion episodes was cardiac surgery (27.9%). Out of 204, 95 episodes were appropriate (46.6%) and 105 were inappropriate (53.4%). The highest number of appropriate FFP transfusion episodes was from the specialty of General Medicine (70.5%). The most number of inappropriate transfusions were prescribed by the specialty of pediatric surgery (87.5%). Mildly elevated prothrombin time without bleeding and cardiac surgery without deranged coagulation was the most frequent inappropriate indications. Clinical monitoring of FFP recipients during the transfusion episode was performed in 15 out of 204 (7.3%) transfusion episodes. Post-transfusion follow-up of patients was performed in 29/204 (14.2%) patients from different clinical specialties.

**Conclusion:** The high rate of inappropriate FFP transfusions indicates the need for strategies to improve the transfusion practices. This can be achieved through educational interventions for the clinical specialties about the rational use of blood components and through regular transfusion audits for all blood components.

**Keywords:** Fresh Frozen Plasma, Transfusion Guidelines, Appropriateness, Audit, Documentation

satisfactory alternative therapies are available.<sup>3</sup> Inappropriate and/or excessive use of FFP is associated with transfusion hazards. Unnecessary allogeneic component exposure poses threat to transfusion transmitted infections (TTI) and allergic or serious anaphylactic reactions to plasma proteins.<sup>4</sup> The most serious immediate adverse reaction to FFP transfusions is Transfusion Related Acute Lung Injury (TRALI). The transfusions also pose a risk of volume overload and immune hemolytic transfusion reactions.<sup>5</sup> In addition, irrational use may lead to shortage of this valuable blood component.<sup>6</sup> Hence, FFP should be used only when clearly indicated as per the guidelines published by the National Health and Medical Research Council and the Australasian Society for Blood Transfusion (NHMRC/ASBT guidelines),<sup>7</sup> the College of American Pathologists (CAP),<sup>8</sup> and the British Committee for Standards in Haematology (BCSH).<sup>4,6</sup> These guidelines elaborate on dose or amount of the component to be transfused as well as the indications and contraindications for transfusion of different blood components. Furthermore, these guidelines recommend that clinical and laboratory response to transfusion of blood components should be monitored which will serve as a guide to further supportive care. It is also recommended that the recipient of blood component should be closely monitored for any adverse transfusion reaction.<sup>4</sup> Nevertheless, studies from all over the world report a high frequency of inappropriate utilization of FFP. These published reports on FFP utilization have focused predominantly on the appropriateness of FFP transfusions to improve the patient outcome.<sup>9-12</sup> Very few studies have thrown light on the monitoring of transfusion events.<sup>13,14</sup> Clinical transfusion audit helps to identify current pattern of usage and areas of improvement.<sup>4</sup> We observed an increasing trend of FFP transfusions in our institution over the past three years. Hence, a retrospective audit was conducted at the Department of Transfusion Medicine with the primary objective of assessing the appropriateness of FFP transfusion and evaluating the adequacy of monitoring of FFP transfusion events. The intermediate and long term

## INTRODUCTION

Blood components, prepared from human source, constitute a precious therapeutic modality. Fresh frozen plasma (FFP) is a component that contains plasma proteins and all the coagulations factors, including the labile factors V and VIII.<sup>1</sup> Transfusion of FFP is indicated in specific clinical situations associated with coagulation disorders.<sup>2</sup> In other situations, the use of FFP has not been shown to be of benefit; or safer and

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goals of the study were to extend the auditing process to the utilization of other blood components and to develop strategies that will result in optimal therapeutic utilization of all blood components with maximum clinical benefits.

## MATERIAL AND METHODS

The retrospective study was performed in the Department of Transfusion Medicine of a tertiary care teaching hospital with specialty and superspecialty services. Approval from the Institutional Ethics Committee was obtained for conducting the study. (Reference: IEC (II)/OUT/701/16 dated 29/07/2016).

**Study population:** The component issue records available in the Department of Transfusion Medicine were initially scrutinized to identify the patients who had received FFP transfusions in the 4 months period from August 2016 to November 2016. Although some patients had received FFP transfusions more than once during the study period, only the first transfusion episode was included in the study for each patient. Transfusion episode was defined as each transfusion event in which a patient was transfused with FFP. Thus, there were total 204 patients included in the study corresponding to the same number of transfusion episodes.

### Data collection and analysis:

**Demographic data:** The age and gender of patients and clinical specialties prescribing the FFP transfusions were recorded in the case record forms (CRF). The transfusion episodes were categorized into percentage of the total as per the gender and the age groups and the clinical specialty.

### Data for assessment of transfusion appropriateness:

Clinical diagnosis, indication for FFP transfusion, presence or absence of bleeding, history of anticoagulant therapy, invasive or surgical procedure performed or planned, pre-transfusion international normalized ratio (INR) and/or partial thromboplastin time (PTT). These were collected from the medical record department of the hospital and recorded in the CRF. The quantity or dose of FFP transfused in one transfusion episode was noted down in the CRF either directly from the medical records of the patients if documented so by the clinician or it was calculated by the following formula:

Amount of FFP transfused = (a) \* (b) where

a = number of FFP units transfused in one transfusion episode obtained from patient's medical record

b = quantity of FFP in each unit obtained from the components records maintained in the department of transfusion medicine. The data collected was tabulated and analyzed for appropriateness as per the guidelines of National Health and Medical Research Council (NHMRC) Table 1<sup>7</sup> Infusion of 10-15 ml/kg body weight of the patient was considered as optimum dose of FFP.<sup>2</sup>

The FFP transfusion episodes were divided as:

- i. Appropriate: if both the indication for transfusion and dose transfused were appropriate
- ii. Inappropriate: if the indication and/or dose were inappropriate
- iii. "Appropriateness cannot be decided": if the indoor record did not provide details required to decide appropriateness of the transfusions as per the indications and/or the transfusion dose.

Both (ii) and (iii) were added together to get total inappropriate transfusion episodes.

The specialty-wise appropriateness of transfusions was calculated as percentage out of total transfusion episodes for each specialty. The commonest indications for appropriate as well as inappropriate transfusions were evaluated and categorized as per the specialty.

### Monitoring and post-transfusion follow-up of FFP recipients:

The medical records were reviewed to assess if the following activities were carried out: (1) Clinical monitoring of patient during the transfusion episode with recording of pre-transfusion vital signs (2) Post-transfusion follow-up of the patient, including post-transfusion coagulation tests and clinical assessment. The number of transfusion episodes fulfilling each (1) and (2) of the above recorded and percentage was calculated out of total transfusion episodes.

## STATISTICAL ANALYSIS

Microsoft office 2007 was used for the statistical analysis. Descriptive statistics like mean and percentages were used for the interpretation of data.

## RESULTS

Total 627 units of FFP were transfused in 204 consecutive episodes of FFP transfusion that were included in the

While few specific indications for fresh frozen plasma exist, its use may be appropriate (level IV evidence):

- for replacement of single factor deficiencies where a specific or combined factor concentrate is not available;
- for immediate reversal of warfarin effect in the presence of potentially life-threatening bleeding when used in addition to vitamin K and possibly factor IX concentrate;
- for treatment of multiple coagulation deficiencies associated with acute disseminated intravascular coagulation;
- for treatment of thrombotic thrombocytopenic purpura;
- for treatment of inherited deficiencies of coagulation inhibitors in patients undergoing high-risk procedures where a specific factor concentrate is unavailable; or
- in the presence of bleeding or abnormal coagulation parameters following massive transfusion or cardiac bypass surgery or in patients with liver disease
- for replacement of single factor deficiencies where a specific or combined factor concentrate is not available; or

The use of fresh frozen plasma is generally not considered appropriate in cases of hypovolaemia, plasma exchange procedures or treatment of immunodeficiency states (level IV evidence).

**Table-1:** Guidelines for FFP transfusion<sup>7</sup>

study. The most transfusion episodes (59/204) occurred in pediatric patients (0-12 years of age) amounting to 29% of transfusion episodes across different specialties, followed by the age group of 21-30 years (34/204 transfusion episodes, 16.7%). There were 115 /204 (56.4%) males and 89/204 (43.6%).females who received FFP transfusions. The clinical specialty with the highest FFP transfusion episodes was cardiac surgery (27.9%) followed by general medicine (Table 2).

Out of 204 transfusion episodes, 95 (46.6%) episodes were appropriate in terms of indications and the dose transfused. The median dose in appropriate transfusions was 12 ml/kg (Dose of 10-15 ml/kg considered optimum. The most number of appropriate FFP transfusion episodes were prescribed by the specialty of General Medicine (70.5%) followed by cardiac surgery (57.9%).

Specialty	Number of patients receiving FFP transfusions (% of total)
Cardiac surgery	57 (27.9%)
General medicine	44 (21.7%)
General surgery	32(15.7%)
Pediatrics	27 (13.2%)
Pediatric Surgery	08 (3.9%)
Gynecology	08 (3.9%)
Hematology	07 (3.4%)
Neonatology	06 (2.9%)
Others	15 (7.4%)
Total	204 (100%)

**Table-2:** Specialty wise usage of FFP

In 79/204 (38.7%) of patients, the dose and/or indication were inappropriate. In 58 out of these 79 episodes, only the indication of FFP transfusion was inappropriate, while in 10/79 transfusion episodes both the transfusion indication and dose were inappropriate and in 11/79 episodes, only the amount of FFP transfused was suboptimal. The median suboptimal volume transfused was 8 ml/kg. There was no overdose of FFP transfusions. In 30/204 (14.7%), appropriateness could not be decided because either the amount transfused was not documented or clinical or laboratory information was inadequate. Thus, 109/204 (53.4%) of transfusions were inappropriate. The most number of inappropriate transfusions were prescribed by the specialty of pediatric surgery (87.5%) followed by general surgery (78.2%). Table 3 shows the specialty –wise categorization of transfusion episodes.

The most common indications for appropriate as well as inappropriate transfusions for the main user specialties have been shown in Table 4.

Considering the other specialties with lesser use, the most common indication for appropriate transfusions was disseminated intravascular coagulation with bleeding. FFP was transfused inappropriately in cases of hypoalbuminemia and in acute leukemias with no evidence of bleeding and/or deranged coagulation parameters.

**Clinical monitoring and post-transfusion follow-up of FFP recipients:**

Clinical monitoring of FFP recipients during the transfusion episode was performed in 15 out of 204 (7.3%) transfusion episodes. These 15 recipients included 11 patients from

Clinical specialty	Total transfusion episodes in the specialty	Total appropriate transfusion episodes per specialty (%age)	Episodes with inappropriate dose or indications (i)	Episodes where appropriateness could not be decided (ii)
			Total inappropriate transfusion episodes per specialty (%age)= (i)+(ii)	
Cardiac surgery	57	33 (57.9%)	04 (7%)	20 (35.1%)
			24(42.1%)	
General medicine	44	31 (70.5%)	10 (22.7%)	03 (6.8%)
			13 (29.5%)	
General surgery	32	07 (21.8%)	24 (75%)	1 (3.1%)
			25 (78.2%)	
Pediatric medicine	27	08 (29.6%)	16 (59.3%)	03 (11.1%)
			19 (70.4%)	
Pediatric surgery	08	01 (12.5%)	06 (75%)	01 (12.5%)
			07(87.5%)	
Gynecology	08	03 (37.5%)	04 (50%)	01 (12.5%)
			05 (62.5%)	
Hematology	07	02 (28.6%)	05 (71.4%)	00 (0%)
			05(71.4%)	
Neonatology	06	02 (33.3%)	04 (66.7%)	00 (0%)
			04 (66.7%)	
Others	15	08 (53.3%)	06 (40%)	01(6.7%)
			07 (46.70%)	
Total	204	95/204 (46.6%)	79/204 (38.7%)	30/204 (14.7%)
			109 (53.4%)	

**Table-3:** Specialty-wise categorization of transfusion appropriateness

Speciality	Commonest indication of appropriate transfusion	Commonest indication of inappropriate transfusion
Cardiac surgery	Warfarin reversal before emergency valve replacement surgery for rheumatic heart disease and raised PT/INR value, along with vitamin K	Coronary artery bypass graft surgery with normal INR and no evidence of bleeding
General medicine	Decompensated liver disease with bleeding and deranged coagulation parameters	Mildly elevated prothrombin time with no evidence of bleeding in various disorders
General surgery	Disseminated intravascular coagulation with bleeding in postoperative period	Preoperative correction of mildly elevated prothrombin time
Pediatrics	Plasma exchange for thrombotic thrombocytopenic purpura	Dengue fever Protein energy malnutrition

**Table-4:** The most common indications for appropriate and inappropriate transfusions for major user specialties.

pediatric medicine and four patients from neonatology. The monitoring included assessment of vital parameters before, during and at the end of the transfusion and documentation that the transfusion was uneventful. Only five out of these 15 transfusion episodes were appropriate.

Post-transfusion follow-up of patients was performed in 29/204 (14.2%) patients from different clinical specialties. Out of these, 17 transfusion episodes were appropriate. In all 29 patients, only the post-transfusion coagulation tests were performed between 1 to 12 hours after the transfusion was complete. None of the record documented post-transfusion clinical assessment of bleeding or other parameters which were expected to be affected by FFP transfusions. Post-transfusion prothrombin time was available in all 6 patients with warfarin toxicity.

## DISCUSSION

Transfusion audits are important tools that form basis for developing strategies to reduce inappropriate transfusions and identifying areas of further improvement. In our study, the transfusion audit of 627 FFP units in 204 patients identified 109 (53.4%) transfusion episodes to be inappropriate in terms of indication and amount transfused. These included inadequately documented transfusion episodes as well as documented inappropriate indications and/or dose. Other studies have also reported high rates of inappropriate transfusions (39.4% to 73%).<sup>3,9,12,13,15-17</sup> Thus, there continues to be general but unfounded enthusiasm for FFP usage across a range of clinical specialties leading to shortage of the component as well as posing the patients to the risks of adverse effects of transfusion.<sup>18</sup>

The highest number of transfusion episodes occurred in the clinical specialty of cardiac surgery. FFP substitution is currently a standard practice in cardiac surgery. However, it should be used only with proven coagulation abnormality. In our study, patients undergoing coronary artery bypass graft were transfused with FFP despite normal coagulation parameters and absence of bleeding. Earlier reports provide no evidence to support the prophylactic administration of FFP to patients without coagulopathy undergoing elective cardiac surgery.<sup>6,19-21</sup> Moreover, patients on cardiopulmonary bypass may bleed postoperatively due to surgical causes, platelet dysfunction or residual effects of heparin.<sup>21</sup> Another common inappropriate indication of transfusion in our

study was correction of mildly elevated INR (1.4-1.6) either preoperatively or in various medical disorders without evidence of bleeding. There is little evidence in the current literature to suggest that mild to moderate abnormalities of the INR and PTT are predictive of hemorrhagic risks, or that these patients will benefit from pre-procedure FFP transfusions.<sup>22</sup> Minimally prolonged INRs decrease with treatment of underlying disease alone. A significant amount of change in INR following FFP transfusion is expected at an INR of more than 1.7.<sup>14</sup> Protein energy malnutrition, dengue fever and acute leukemias were the other inappropriate indications for transfusion. In addition to these, we also came across transfusion episodes where indications and/or amount transfused were not documented. This was observed in 30 out of 204 transfusion episodes (14.7%). Suboptimal transfusion documentation remains problematic and is highly correlated with non-justifiable transfusions.<sup>23</sup> Appropriate documentation is beneficial in assessing transfusion justification within established guidelines.<sup>24</sup> Hence, inadequately documented transfusion episodes were considered inappropriate in terms of dose and/or indications. Monitoring of transfusions ensures safety of transfusion episodes. Moreover, follow up of clinical and laboratory parameters following transfusions indicates degree of effectiveness, serves as a guide to further supportive care and may help in refining the existing guidelines of transfusion.<sup>4,13</sup> We could not assess the effectiveness of transfusion due to inadequate number of patients in whom post-transfusion assessment was done (14.2%). Monitoring was performed in 7.3% of episodes. Lack of documentation, in spite of performing the activities, could have been one of the contributory factors resulting in lesser number. Earlier studies have shown positive correlation between the lack of clear documentation regarding rationale of transfusion with the lack of follow up after transfusion and ability to justify such transfusions during retrospective audits of transfusion.<sup>23,24</sup> We could not assess this correlation due to insufficient number.

The findings of FFP transfusion audit indicate need for further analysis and implementation of changes in transfusion practices. Lack of awareness of transfusion guidelines for component usage has been reported to be the most common reason for inappropriate FFP transfusions in previous studies.<sup>13,14,18,25,26</sup> Educational interventions in

the form of regular seminars, discussions in the hospital transfusion committee; and training programs for clinicians and postgraduate students can have positive impact on transfusion practices and optimal use of blood components. The use of a self-educating transfusion request form was found to be beneficial in improving the pattern the FFP usage.<sup>27</sup>

A research has reported a 5.2% decrease in inappropriate FFP usage following an educational program.<sup>28</sup> Thus, regular routine audits and outcome audits after educational intervention will provide necessary information required to improve transfusion practices.<sup>29,30</sup> The transfusion audits should also aim at educating the clinicians to improve transfusion documentation which in turn will increase the effectiveness of the audit.<sup>23,24</sup>

The strength of our research is that we audited the adequacy of monitoring and follow up of FFP recipients as well as indications and amount transfused. Majority of the other studies have emphasized upon the appropriateness of FFP transfusions.<sup>9,16-18,31</sup> Moreover, the data indicates that most of the published audits of FFP usage in India are from the northern part of the country.<sup>16,29,31-33</sup> The present research was performed in a medical college hospital in western India. However, the major hindrance to the transfusion audit was poor documentation, which is a known limitation of retrospective audits.<sup>24</sup> We could not assess the actual effectiveness of FFP transfusions due to inadequacy of data because of insufficient documentation. Hence, we plan to perform prospective and concurrent audits of usage of all the blood components in future to overcome this limitation.

## CONCLUSION

The study identified a high rate of irrational FFP transfusions and inadequacy of transfusion documentation. Regular transfusion audits and implementation of educational programs on rational use of blood components for the clinicians are recommended based on the findings of this study.

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