

# Quality Control of Fresh Frozen Plasma using Factor VIII and Fibrinogen Levels as Measure: One Year Study in a Tertiary Care Hospital

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## ABSTRACT

**Introduction:** Quality control of blood and its components ensures the availability of high quality product with maximum efficacy and minimal risk to recipients. As per standard guidelines, for quality assurance of FFP, 1% of all the units prepared or 4 units per month are tested for stable coagulation factors: Factor VIII and Fibrinogen levels.

**Material and methods:** The retrospective data was collected from archives of blood bank from the period of 1st January 2017 to 31st December 2017 in AIMS, Bathinda. Out of total 3476 units collected, 2155 were processed for component separation. 1.9% of Fresh Frozen plasma (41/2155) were tested for total volume, fibrinogen content and factor VIII levels for quality control with the help of semi-automated coagulometer.

**Results:** 97.5% of FFP samples tested had factor VIII levels above 0.7 IU/mL and 100% of samples had fibrinogen content >200mg/dl.

**Conclusion:** It is concluded that quality of FFP being prepared at our blood bank meets the international standards. Regular quality evaluation and maintenance of records helps to keep up the working standards and any deficiency can be checked and curtailed.

**Keywords:** Components, Volume, Plasma, Quality Analysis

## INTRODUCTION

Plasma separated from whole blood, frozen within 6-8 hours of collection and stored at -20°C or below is defined as fresh frozen plasma (FFP).<sup>1</sup> Usually 175- 250 mL of FFP is separated from standard donation of whole blood (450mL), containing 70-80 units/dl of factor VIII, factor IX, von Willebrand factor and other plasma clotting factors. Transfusion of FFP is indicated to replace deficiencies of multiple coagulation factors and control protein levels in massive blood loss, liver diseases and disseminated intravascular coagulation.<sup>2</sup>

As the demand for FFP is increasing in day to day practice, its quality management is of utmost importance. Quality analysis of blood components including FFP depends on the concepts of quality control, quality assurance and quality management which aims at providing right blood to the right person at right place and time.

Quality control of blood and its components ensures the availability of high quality product with maximum efficacy and minimal risk to recipients.

As per standard guidelines, for quality assurance of FFP, 1% of all the units prepared or 4 units per month are tested for stable coagulation factors (200 Units of each factor);

Factor VIII - 0.7 Units/mL and Fibrinogen levels 200-400mg.<sup>3</sup> Factor VIII and fibrinogen levels can be measured in a standard blood bank with the help of coagulometer by clotting assay. Study and monitoring of regular monthly quality analysis of FFP is important for a tertiary care center like us so that quality product is provided to the patients in need.

## MATERIAL AND METHODS

Routine monthly quality check as per standard guidelines is carried out in our blood bank. The retrospective data was collected from archives of blood bank from the period of 1st January 2017 to 31st December 2017 in AIMS, Bathinda. During this period, total of 3476 units of blood were collected from healthy, screened donors (more than 45 kg) in sterile single, double or triple blood bags with anticoagulant CPDA 1 after taking written consent. Out of these 3476 units, 2155 units (61.99%) collected in double or triple bags from donors weighing more than 60 kg weight were processed for separation of components in a refrigerated centrifuge (Cryofuge 5500i) by Heraeus. After holding time of 2-4 hours, units were centrifuged at 4000 rpm for 10 mins at 4°C for separation into Packed red blood cells (PRBCs) and fresh frozen plasma (FFP); 2 spin centrifugation at 1500 rpm for 10 minutes at 22°C followed by 2750 rpm for 10 minutes at 22°C for separation into FFP, PRBCs and Platelet concentrate.

1.9% of Fresh Frozen plasma (41/2155) were tested for total volume, fibrinogen content and factor VIII levels for quality control as per standard guidelines given in 'Technical Manual of Transfusion Medicine', by Directorate General of Health Services Ministry of Health and Family Welfare, India.

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Volume was calculated as per formula:

FFP: 1 gm= 1.03 mL.

For measurement of weight, standard calibrated weighing scales were used.

Fibrinogen and Factor VIII levels were calculated in semi-automated coagulometer – Hemostar XF 2.0 by Tulip Diagnostic (P) Ltd. Tests were done as per manufacturer's instructions.

Statistical analysis by mean, range and standard deviation was done by SPSS version.

## RESULTS

Total of 3476 units of blood were collected from healthy, screened donors, out of which 2155 units were processed for preparation of FFP. 41 out of 2155 units (1.9%) were tested for quality analysis parameters, i.e., total volume, Factor VIII and Fibrinogen levels. Mean volume was 217±9.58 mL with range of 192- 235 mL which is well within the normal acceptable range.

Mean factor VIII levels were 0.8±0.086IU/mL with range of 0.66 – 0.98 IU/ML, the standard quality control measure being > 0.7 U/mL

Mean fibrinogen levels were 304.31±53.68 mg/dl with a range of 202.6 – 458.9 mg/dl., the standard measure being >200mg/dl.

97.5% of FFP samples tested had factor VIII levels above 0.7 IU/mL and 100% of samples had fibrinogen content between >200mg/dl.

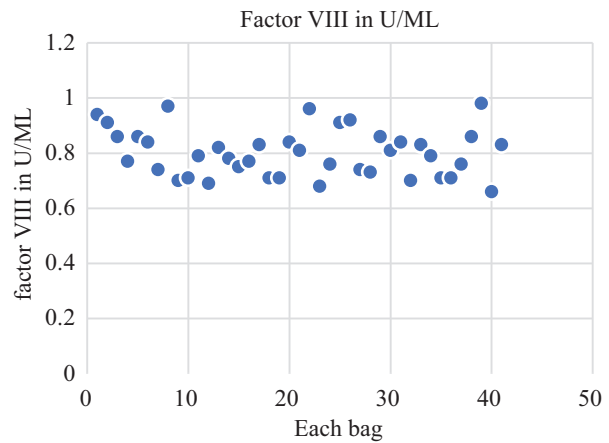
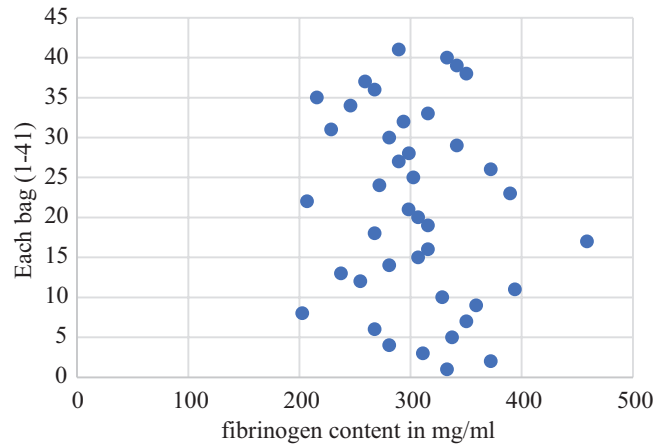
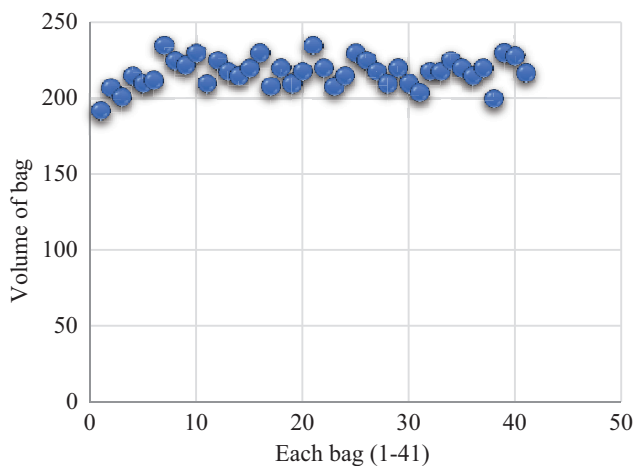
Mean volume was 217±9.58 mL with range of 192- 235 ML(figure -1).

### Fibrinogen

Mean fibrinogen content was 304.3mg/dl and range was 202.6 – 458.9 mg/dl.(figure-2)

### Factor VIII

Mean value of Factor VIII 0.8U/mL and range was 0.66 – 0.98 U/mL.(figure-3)



97.5% of our results were > 0.7 U/mL.

## DISCUSSION

Plasma is the aqueous component of blood in which many different cellular elements and macromolecules are suspended, but it is the proteins that have been the focus of interest for transfusion medicine, including specifically albumin, coagulation factors, and immunoglobulins.<sup>4</sup> Fresh frozen plasma is plasma separated from whole blood within 6-8 hours and rapidly frozen and stored at temperature below -20° C.

Utilization of fresh frozen plasma in clinical practice has been increased in recent years: Plasma for transfusion is most often used where there is abnormal coagulation screening tests, either therapeutically in the face of bleeding, or prophylactically in nonbleeding patients prior to invasive procedures or surgery.<sup>5</sup>

For safe and effective preparation of blood and its components, in house quality control plays a very important role. Quality concepts comprises of a triad of quality control, quality assurance, quality management and their maintenance.<sup>6</sup> Quality control is the backbone of all laboratory services including blood bank. Quality testing and

Parameter	Mean	Range	Normal value <sup>3</sup>	%age concordance
Volume (mL)	217±9.58	192-235	200-220	
Fibrinogen (mg/dl)	304.31±53.68	202.6-458.9	>200	100%
Factor VIII (IU/mL)	0.8±0.086	0.66-0.98	> 0.7	97.5%

monitoring of blood components have led to development of safer and more potent components for transfusion practices. Factor VIII and fibrinogen levels are internal quality control parameters required for quality analysis of fresh frozen plasma as per standard guidelines.<sup>3</sup>

Our study assessed the volume, levels of factor VIII and Fibrinogen in stored units of FFP after they were thawed for utilization. 1.9% (41/2155) of all units of FFP prepared in one year were evaluated and levels of both parameters were in concordance with standard guidelines.

Mean volume of 41 units tested was 217 mL with range of 192-235mL, mean factor VIII levels were 0.80U/mL with the range of 0.66- 0.98 U/mL and mean fibrinogen levels were 304.3mg/dl with the range of 202.6 – 458.9mg/dl. 97.5% of units tested had factor VIII levels above 0.7 U/mL and 100% units had fibrinogen levels more than 200mg/dl as per reference standards.<sup>3</sup>

Similar study was done by Sultan et al<sup>7</sup> in which 100 units were tested for internal quality control. The mean factor VIII and fibrinogen levels were found to be 84.24± 15.01 and 247.17±49.69 for FFP respectively. Almost all donors have fibrinogen ≥150 mg/dl, while only five (5%) donors had factor VIII below the desired levels.

In another study done by Agus N et al<sup>8</sup>, 30 units of FFP prepared within 8 hours of collection were tested for factor VIII levels. Mean was 1.0 IU/mL with a range of 0.66- 1.47 IU/mL.

Dogra M et al<sup>9</sup> also did a study on comparative analysis of activity of Factors V and VIII and level of fibrinogen in Fresh Frozen Plasma and Frozen Plasma. They studied 100 units of FFP in which levels of fibrinogen were 270.66 ± 69.64 mg/dl and factor VIII were 117.205±29.01%.

Thus, all the above mentioned studies have evaluated quality control parameters as done in our study and results are in concordance as per standard reference parameters.

FFP is generally not used in developed countries due to the availability of recombinant or factor concentrates, however, in developing countries like us utilization of FFP is more for various inherited coagulation disorders and diseases leading to liver dysfunctions.

Internal quality control thus enhances the quality of blood products and helps in monitoring of quality standards of blood bank. Regular quality evaluation and maintenance of records helps to keep up the working standards and any deficiency can be checked and curtailed. The results derived in our study are in concordance with the national standards<sup>3</sup> and other studies reviewed above, thus establishing the quality standards of our blood bank.

## CONCLUSION

It is concluded that quality of FFP being prepared at our blood bank meets the international standards of factor VIII > 0.7IU/mL (97.5% of units tested) and fibrinogen levels of > 200 mg/dl(100% of units tested). Regular updation of quality assessment with respect to standard guidelines is important for effective production of blood components. A study of quality parameters as done above is essential for

establishment of good transfusion practices.

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