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Fresh Frozen Plasma Quality Control at the Al Marj Central Blood Bank, Libya

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A B S T R A C T

Background:

Fresh frozen plasma (FFP) is a vital blood component used to treat coagulation disorders, and ensuring its quality is essential to prevent transfusion-related complications.

Objectives:

This study aimed to evaluate the quality of FFP prepared at the Al Marj Central Blood Bank, Libya, and to compare the findings with the international standards established by the American Association of Blood Banks (AABB).

Methods:

A cross-sectional study was conducted on 100 FFP bags. Each unit was analyzed for volume, pH, prothrombin time (PT), partial thromboplastin time (PTT), and residual cell counts after thawing, according to AABB procedures.

Results:

The mean FFP volume (193 ± 28 ml) was significantly below the AABB standard of 200–400 ml ($p < 0.001$). The mean pH (6.9 ± 0.45) and PT (13.7 ± 1.43 s) were within acceptable limits, while the mean PTT (35.6 ± 2.04 s) was slightly above the upper limit of the standard range (25–35 s), suggesting borderline prolongation. Importantly, the mean platelet count (31.1 ± 38.4 $\times 10^9$/L) exceeded the AABB limit (<5$\times 10^9$/L).

Conclusion:

Although most parameters met AABB standards, the FFP units demonstrated reduced volume and elevated platelet counts, indicating possible inefficiencies in centrifugation and plasma separation processes. Optimization of preparation procedures is recommended to enhance FFP quality and ensure compliance with international standards.

Keywords: *Fresh Frozen Plasma, AABB standards, Quality control, Platelet residues, Libya, Blood component quality.*

1. Introduction

Ensuring the safety and quality of blood products is a fundamental objective of transfusion medicine. The primary goal of blood transfusion services is to maintain an adequate supply of high-quality blood components that provide maximum therapeutic benefit with minimal risk to patients and donors. A failure in the quality of collected or screened blood units can lead to catastrophic and potentially fatal outcomes. Therefore, a comprehensive quality management system must integrate good manufacturing, medical, and laboratory practices, all of which are interrelated and essential to guarantee patient safety and product reliability **[1, 7]**.

FFP is a blood component obtained from whole blood by high-speed centrifugation and rapidly frozen to preserve labile coagulation factors. It is typically prepared from triple or quadruple plastic blood bags and stored at –25 °C or lower to maintain stability. FFP contains all coagulation factors (except platelets), including both labile and stable factors, as well as albumin, fibrinogen, antithrombin, protein C, protein S, tissue factor pathway inhibitor, fibrinolytic and complement proteins **[2, 3]**. Clinically, FFP is widely used to treat coagulation factor deficiencies, liver disease, disseminated intravascular coagulation (DIC), and to reverse the effects of vitamin K antagonists **[4]**.

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The quality of FFP is critical for ensuring patient safety and effective transfusion outcomes. According to international quality principles, FFP should remain free from contamination by other blood elements, including red blood cells (RBCs) and white blood cells (WBCs), and should not show any leakage, clot formation, or discoloration **[5]**. The presence of residual cellular elements, particularly RBCs, may lead to alloimmunization, while elevated residual platelet counts—a frequent issue in FFP production—may increase the risk of transfusion-related acute lung injury (TRALI) and allergic or inflammatory reactions in recipients. These potential hazards underscore the importance of strict adherence to quality standards during plasma processing.

To address these risks, the American Association of Blood Banks (AABB) has established international standards defining acceptable ranges for FFP characteristics, including volume, pH, prothrombin time (PT), partial thromboplastin time (PTT), and residual cellular content. These parameters are used globally to monitor production consistency and ensure that each plasma unit meets clinical safety requirements **[6]**.

While these international standards and best practices are well established, local data on FFP quality in Libya remain limited. Published studies assessing the compliance of locally prepared plasma with AABB quality benchmarks are scarce, leaving a gap in regional transfusion quality monitoring.

Accordingly, the aim of the current study was to assess the quality of FFP produced at the Al Marj Central Blood Bank, Libya, and to compare the results with the international quality standards set by the AABB.

2. Materials and methods

A cross-sectional study was conducted on 100 FFP units collected at the Al Marj Central Blood Bank, Libya. Each FFP unit was prepared from fresh whole blood (450 ± 50 ml) collected in triple bags containing 63 ml of *Citrate Phosphate Dextrose Adenine-1 (CPDA-1)* anticoagulant. All collected units were screened and confirmed negative for Hepatitis B virus (HBV), Hepatitis C virus (HCV), and Human Immunodeficiency Virus (HIV) prior to processing.

Plasma Separation

Plasma was separated by centrifugation for 14 minutes at approximately 2900 × g (equivalent to 4158 rpm), producing PPP. The separated plasma was immediately frozen at –22°C or lower to preserve the stability of coagulation factors.

FFP Thawing Procedure

In accordance with the AABB guidelines, all FFP units were thawed before testing using the following standardized procedure:

1. Verify the unit identity against the transfusion request.
2. Confirm proper storage conditions, including temperature and expiration date.
3. Submerge the FFP bag in a water bath maintained between 30°C and 37°C for 15–30 minutes.
4. Ensure complete thawing and gentle mixing of the plasma within the bag.
5. Visually inspect the plasma for acceptable color and odor prior to testing.

Testing and Analysis

All quality control tests were performed on samples taken after the FFP units were fully thawed.

The volume of each FFP unit was measured directly.

From each unit, 5 ml of plasma was collected and divided into two plain containers:

One portion was used for counting residual cells (RBCs, WBCs, and platelets) using a *Nihon Kohden hematology analyzer*.

The second portion was used to determine PT and PTT using the *Technoclon (TC) kit* and a *Dia Lab Coagulometer Analyzer™*.

The pH of each plasma unit was measured using a calibrated pH meter.

Data Analysis

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All data were analyzed using SPSS software (version 27). Results were compared with AABB international reference standards using a one-sample t-test with 95% confidence intervals (CI). Statistical significance was set at $p < 0.05$.

3. Results

A total of 100 FFP units collected from the Al Marj Central Blood Bank, Libya, were analyzed. The evaluated parameters included total plasma volume, pH, PT, PTT, and residual cell counts (RBCs, WBCs, and platelets) to assess compliance with AABB quality standards.

1. Volume and pH

The mean FFP volume (193 ± 28 ml) was significantly lower than the AABB reference range (200–400 ml, $p < 0.001$). The mean pH (6.9 ± 0.45) showed no statistically significant difference from the acceptable range (7.0–7.4, $p = 0.123$).

These results indicate a notable reduction in plasma volume, while pH levels remained within acceptable limits.

(Table 1)

Table 1. Volume and pH levels of fresh frozen plasma units compared with AABB standards

Parameter	AABB Reference Range*	Measured Values (Mean ± SD)	Range	p-value
Volume (ml)	200–400	193 ± 28	135–208	< 0.001
pH	7.0–7.4	6.9 ± 0.45	6.0–7.5	0.123

* According to AABB guidelines.

2. Coagulation Profiles (PT and PTT)

The mean PT (13.7 ± 1.43 s) was within the acceptable range (11–15 s, $p = 0.46$).

Although PTT (35.6 ± 2.04 s) showed no statistically significant difference ($p = 0.67$), its mean value was slightly above the upper limit (25–35 s), suggesting a potential borderline prolongation that may be clinically relevant.

(Table 2)

Table 2. Coagulation profiles of fresh frozen plasma units compared with AABB standards

Parameter	AABB Reference Range*	Measured Values (Mean ± SD)	Range	p-value
PT (s)	11–15	13.7 ± 1.43	12–16	0.46
PTT (s)	25–35	35.6 ± 2.04	30–40	0.67

* According to AABB guidelines.

3. Residual Cellular Content

The mean RBC and WBC counts were within AABB standards and showed no statistically significant difference ($p > 0.05$).

However, the platelet count was markedly elevated compared with the AABB limit, indicating incomplete removal of platelets during centrifugation.

Given that WBC and platelet counts displayed non-normal distributions (with large variability and skewed data), results for these parameters were reanalyzed using median and interquartile range (IQR), and the Wilcoxon signed-rank test was applied instead of the *t*-test.

Table 3. Residual cellular content of fresh frozen plasma units compared with AABB standards (median and IQR used for non-normal data)

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Cell Type	AABB Reference Range*	Measured Values	Range	Statistical Test	p-value
RBCs (×10⁶/unit)	< 0.1	0.006 (0.00–0.02)	0.00–0.20	One-sample *t*-test	0.778
WBCs (×10⁶/unit)	< 0.1	0.05 (0.01–0.32) †	0.01–29	Wilcoxon signed-rank	0.212
Platelets (×10⁹/unit)	< 5	18.0 (6.0–52.0) †	0.00–175	Wilcoxon signed-rank	< 0.001

* According to AABB guidelines.
† Reported as median (IQR) due to non-normal data distribution.

4. Discussion

The present study evaluated the quality of FFP produced at the Al Marj Central Blood Bank, Libya, by comparing key physical and biochemical parameters with the international quality standards established by the American Association of Blood Banks (AABB). The findings revealed that while most parameters—including pH, PT, RBCs, and WBCs—were within the acceptable range, the mean plasma volume (193 ± 28 ml) was significantly lower than the AABB reference (200–400 ml). The mean PTT (35.6 ± 2.04 s) was slightly above the upper limit of the standard range, indicating a borderline prolongation, whereas the median platelet count (18 × 10⁹/unit) was markedly elevated compared with the AABB threshold (<5 × 10⁹/unit).

Plasma Volume and Coagulation Parameters

The reduced FFP volume observed in this study contradicts findings from previous reports by Uwamungu et al. (2014) [10] and Gunjan Bala et al. (2019) [11], where FFP volumes were consistent with international standards. Several operational factors may account for this discrepancy. The collection volume of whole blood (450 ± 50 ml) may not have been precisely standardized, or the expression of plasma into the satellite bag may have been incomplete, leading to suboptimal plasma yield. Additionally, minor evaporation losses or improper sealing during freezing could contribute to the reduced volume.

The measured pH values (6.9 ± 0.45) were consistent with AABB recommendations and with earlier studies (Uwamungu et al., 2014 [10]; Pták et al., 2000 [12]), confirming the adequacy of storage and freezing conditions. The mean PT (13.7 ± 1.43 s) was within the expected range, reflecting proper preservation of stable coagulation factors [6]. However, the PTT (35.6 ± 2.04 s), although not statistically different from AABB standards, exceeded the upper limit clinically, suggesting a possible borderline prolongation. This mild prolongation could indicate partial loss or instability of labile coagulation factors, particularly Factor VIII, during freezing or thawing, which may slightly reduce the hemostatic efficacy of transfused plasma.

Platelet Contamination and Centrifugation Efficiency

The most critical finding in this study was the significantly elevated residual platelet count, with a median value of 18 × 10⁹/unit, well above the AABB standard of <5 × 10⁹/unit. This clearly indicates a methodological issue in plasma preparation. The current centrifugation protocol approximately 2900 × g for 14 minutes appears insufficient to produce platelet-poor plasma (PPP) as required by AABB specifications [13]. Incomplete platelet removal during centrifugation can lead to higher residual counts in the plasma fraction.

From a clinical perspective, such elevated platelet levels in transfused FFP may increase the risk of transfusion-related acute lung injury (TRALI), allergic reactions, and inflammatory complications. These findings underscore the need for a review and optimization of the centrifugation process, possibly by increasing the relative centrifugal force or extending centrifugation time to ensure more efficient separation of plasma from platelets.

Limitations

This study has several limitations. It was conducted at a single blood bank, which may limit the generalizability of the results. The sample size (n=100), while adequate for initial evaluation, may not fully capture inter-batch variability in FFP production. In addition, some parameters—such as PT and PTT—showed wide variability that could mask subtle differences due to the use of parametric statistical tests.

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Future studies should include larger sample sizes and biochemical analyses of specific coagulation factors (e.g., Factor VIII and fibrinogen) to provide a more comprehensive assessment of plasma quality.

5. Conclusion

This study assessed the quality of FFP prepared at the Al Marj Central Blood Bank, Libya, in comparison with international standards set by the AABB. The findings demonstrated that most parameters—pH, PT, RBCs, and WBCs—were within the acceptable limits, reflecting satisfactory control of basic production and storage conditions.

However, two significant quality deviations were identified:

The mean plasma volume (193 ± 28 ml) was significantly below the AABB standard (200–400 ml).

The median residual platelet count (18 × 10^9/unit) was markedly higher than the recommended limit (<5 × 10^9/unit).

Additionally, the PTT value (35.6 ± 2.04 s) was slightly above the upper reference range, indicating a possible borderline prolongation that may be linked to minor degradation of labile coagulation factors during processing.

These results indicate that, although the overall FFP quality is acceptable, the centrifugation and plasma separation procedures require optimization to meet international standards consistently and ensure patient safety.

Practical Recommendations

Optimize Centrifugation Protocol:

Increase the relative centrifugal force (RCF) and/or extend centrifugation time beyond 14 minutes to achieve more effective platelet separation and ensure the production of platelet-poor plasma (PPP).

Standardize Blood Collection Volume:

Ensure that all whole blood donations consistently meet the target volume (450 ± 50 ml) to maintain adequate FFP yield.

Enhance Staff Training:

Provide periodic technical training for laboratory and transfusion staff on plasma preparation, separation, and freezing procedures according to AABB guidelines.

Implement Continuous Quality Control:

Conduct routine internal audits and quality checks for FFP units, focusing on volume, platelet contamination, and coagulation parameters to detect process deviations early.

Review Equipment Calibration and Maintenance:

Regularly verify the calibration of centrifuges, coagulometers, and pH meters to ensure consistent accuracy in analytical and preparation steps.

Future Research:

Future studies should include multi-center evaluations across Libyan blood banks and incorporate biochemical assays of coagulation factors (e.g., Factor VIII, fibrinogen) to provide a more comprehensive understanding of FFP quality.

ETHICAL STATEMENT

Not Applicable

CONFLICT OF INTEREST

No conflict of interest.

AUTHORS' CONTRIBUTIONS

All authors contributed equally.

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