

Assessment of Quality Control Procedures at the Central Blood Bank of North Kordofan State

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Abstract:

Background: Blood banks play an important role in the health care system's blood supply, and the goal of quality control methods is to ensure that patients receive safe and efficient blood transfusions while also preventing transfusion-transmitted infections. Improved quality services, leading to safer transfusion methods and fewer unfavorable consequences. Therefore, this study aimed to assess the quality control procedures at the Central Blood Bank of North Kordofan State. **Methodology:** This descriptive prospective study was conducted in the central blood bank in El-Obeid, North Kordofan State, from October 2021 to March 2022. The goal of this study is to analyze quality control measures in central blood banks and to provide potential options for improving the quality of blood transfusion services in the state. **Results:** A total of 400 units of blood components were selected by simple random method. Packed red cell units were evaluated for CBC, pH, unit volume, and blood culture. The results showed: The packed red cells had a mean HCT of 44.1 g/dl, with less than 80% HCT. The mean values for RBC, WBC, MCV, MCH, and MCHC were $5.0 \times 10^{12} /L$, $5.058 \times 10^9 /L$, 75.2 FL, 27.0 pg, and 28.6 g/dl, respectively. Random donor platelets had a mean yield of $5942.0 \times 10^9 /L$, with 73% yielding less than the necessary threshold. Only three (3%) units yielded $\geq 5.5 \times 10^9 /L$. The pH was ≥ 6.2 in 100% of units, with a mean of 7.0 ± 0.0 . All plasma units had a volume below the norm (100%). According to the study, the mean factor VIII levels for FFP were 79.3 IU/mL. (90%) of units contain factor VIII in accordance with intended levels, while only 8% have factor VIII below desired levels. The mean fibrinogen level was determined to be 364.8 IU/mL, with 24% having normal fibrinogen levels and 71% having levels higher than the usual range of ≥ 150 IU/mL. For plasma, the mean PT is 15.2s, which is 55% in agreement with the standard level and 45% higher than the standard level, and the activated prothrombin time mean is 68% in 100 units, which is in agreement with the standard level but only 21% higher. **Conclusion:** Our investigation revealed a decrease in the levels of QC out of range in the blood component. Such studies are proposed to improve quality measures in western Sudan.

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Keywords: Quality Control, Blood Bank, North Kordofan, Sudan

Introduction:

Blood banking serves as a fundamental component of healthcare services, as it is directly linked with patient safety in the field of transfusion medicine. A well-equipped blood center is the initial step towards enhancing standard quality control. Accreditation symbolizes the frame work for quality governance of a hospital and is based on optimum standard [1]. The blood transfusion is not as safe as it appears; it can also lead to many adverse reactions that may manifest later. It should only be prescribed when a patient's clinical status truly necessitates it [2]. The quality control of blood products is essential for evaluating product viability and the production chain [3].

The blood donation system relies on a manual procedure, which is based on the history of prospective donors [4]. The quality system relies on various elements, including evidence derived from established quality standards, essential components of critical quality systems, educational and training initiatives in transfusion medicine, regulatory inspections and licensing, quality audits, and accreditation processes, as well as hemovigilance [5]. This study aimed to evaluate the quality control procedures at the Central Blood Bank of North Kordofan State.

Material and method:

This descriptive prospective study was conducted at the central blood bank in El-Obeid, North Kordofan State, from October 2021 to March 2022. Comprehensive coverage sample encompassing all data pertaining to the patient's important identity information.

Statistical analysis:

All data collected were organized in an Excel sheet and subsequently entered into the statistical software package for analysis. Continuous data were described using mean $\pm$ standard deviation, while categorical data were presented in frequencies and percentages. Cross- tabulation was performed, and chi-square tests were conducted, with a P-value of less than 0.05 considered statistically significant. All data was analyzed in relation to international standards.

Methods:

Packed red cell units were evaluated for CBC, and platelets were counted using the Urit 310 hematology analyzer. Random platelet concentrates were assessed for PH, yield, and culture. PH was measured using pH-indicator strips and a universal indicator from Merck Millipore. Yield was calculated using the standard formula (platelet count $\times$ volume $\times$ 1000). Bacteriological culture analysis was performed by inoculating samples in solid culture media, including blood agar, nutrient agar, and MacConkey agar. Culture plates and whole blood. Fresh frozen plasma was incubated at 37°C (± 0.5) in a Theme Scientific incubator for a duration of 72 hours.

FFP was assessed for unit volume, factor VIII, and fibrinogen concentrations. Factor activities were determined using the Urit automated coagulation analyzer through clotting assays, including prothrombin time and activated assays. Prothrombin time is assessed using a Urit coagulator.

The criteria employed for Quality Control (QC) adhered to the standards set by the National Accreditation Board for Hospitals and Healthcare Providers (6). These are presented in Tables 3, 6, and 8.

Results:

In this study, 400 units were evaluated for IQC. The average HCT of packed red cells was 44.1 g/dl, and 200 units met the criteria with $<80\%$ HCT units. Table (1) shows the mean values for RBC, WBC, MCV, MCH, MCHC, lymphocytes, and granulocytes cells as $\pm 4.97, 5.1, 94.0, 27.0, 28.6, 19.8,$ and 47.6 . To rule out bacterial contamination of whole blood, components (PRBCs and FFP) of positive units were examined, and cultures were performed. The results were negative in 156/200 (78%) units and positive in 44/200 (22%). Blood volume was low in 151/200 (75%) and normal in 7/200 (4%), and more than the needed volume in 42/200 (21%) units, as indicated in Table (2) and Figure (1).

Table 1 displays the mean and standard deviation (SD) values for the WBC differentials in 200 apparently healthy Sudanese male donors.

Variable	Low	Normal	High	Mean	STD
Lymphocytes cell %	5	63	132	47.690	15.9188
Lymphocytes cell %	5	63	132	47.690	15.9188
Mixed cell%	0	26	174	19.854	11.3927
Granulocyte cell %	178	19	3	31.486	17.8077
WBC	73	117	9	1.73	0.917

Table 2 shows the mean and standard deviation (SD) values for the RBC indices in 200 apparently healthy Sudanese male donors.

Variable	Low	Normal	High	STD	Mean
Units volume/ml	151	7	42	135.998	325.66
RBC(C/L)	110	57	33	3.19684	4.9749
HB (G/DL)	80	37	58	28.43192	22.5852
HCT (%)	91	69	40	23.1137	44.115
MCH(PG)	72	114	14	.58961	1.7100
MCHC (%)	43	127	30	4.8126	28.613
MCV(FL)	1	32	13	6.5877	94.049

Table 3 Quality Control of Red Cell Concentrate

	RCC			RCC with Additive Solution		Frequency of control
	Quality Requirement		Frequency of control	Quality Requirement		
	450ml	350ml	1% of all units	450 ml	350ml	
Volume	225-350 ml	175-272ml	1% of all units	300-400 ml	1% of all units	1% of all units
Hematocrit (HCT)	65-75%	65-75%	1% of all units	55-65%	1% of all units	1% of all units
Sterility	By culture	By culture	1% of all units	By culture	By culture	1% of all units

Table 4 shows the culture results in platelets and RCC.

Variable	growth	Non growth
Platelets	29	71
Packed cell	44	156

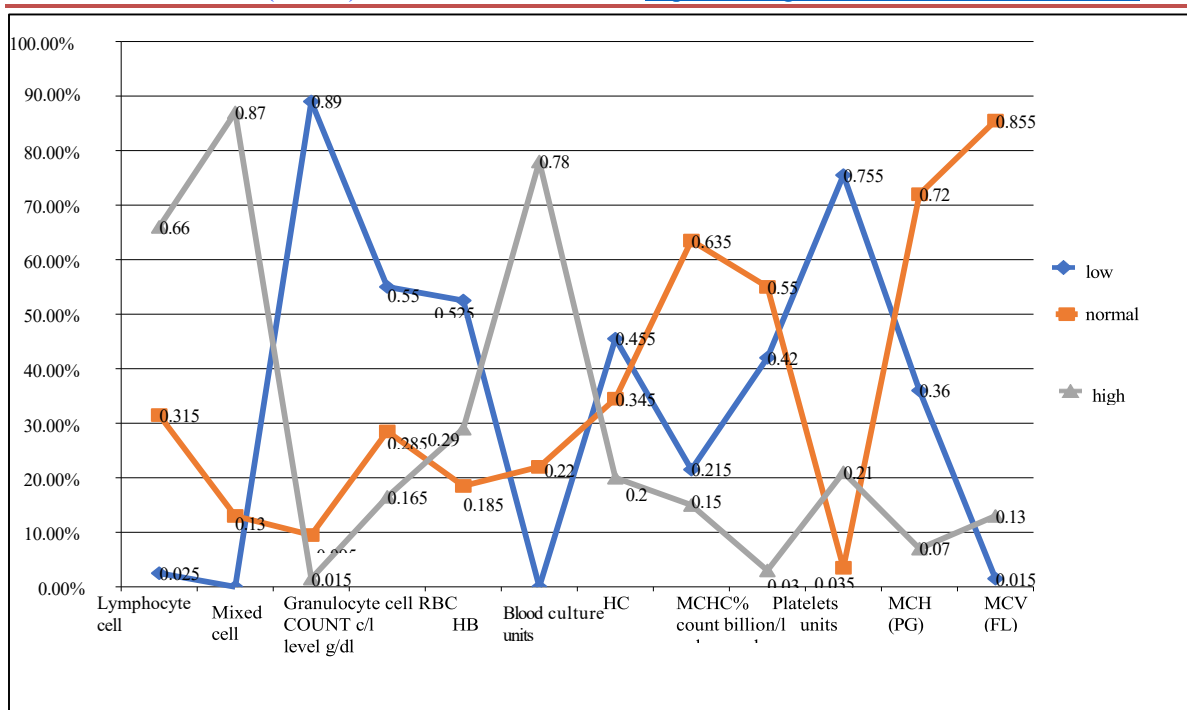


Figure 1 illustrates the explanation of CBC blood volume and blood culture

The Platelet results:

Random donor platelets yielded an average of $\pm 5942.0 \times 10^9/L$. According to AABB, the usual yield is $\geq 5.5 \times 10^9$. However, 73% of units had a yield of $\leq 5.5 \times 10^9/L$, which is considered low. 3% had a normal yield, while 24% had a high yield. The pH was ≥ 6.2 in 100% of units, with a mean of 7.0 ± 0.0 . Product cultures were negative in 71% of units tested, whereas 29% of platelet units tested were positive. Platelet volume was low in 99%, with only one unit being normal (see table 3) Figure2.

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yield is $\geq 5.5 \times 10^9$. However, 73% of units had a yield of $\leq 5.5 \times 10^9/L$, which is considered low. 3/100 (3%) was in normal yield, while 24/100 (24%) was high. The pH was ≥ 6.2 in all units, with a mean of 7.0 ± 0.0 , and product cultures were negative in 71/100. 71% of units tested, 29/100. 29% of platelet units tested positive, and platelet volume was low in 99%, with only one unit being normal.

To rule out bacterial contamination, cultures were performed on platelets from positive units, which were found to be negative in 78/100 (78%) units and positive in 22/100 (22%) units.

Table 5 shows the mean platelet levels and standard deviation (SD) in 100 apparently healthy Sudanese male donors

Variable	Low	Normal	High	STD	Mean
Platelets	99	1	0	.10000	1.0100
Platelets counts (billion/l)	88	9	3	.43519	1.1500
Platelets yield (C/L)	73	3	24	.85865	1.5100

Table 6 Quality Control of Platelet Concentrate

Parameters	Quality Requirement	Frequency of control
Volume	>200 m	1% of all units
Platelet Count	>3.0*10 ¹¹	1% of all units
pH	>6.0	1% of all units
RBC contamination	Traces to ≤ 0.5 ml	1% of all units

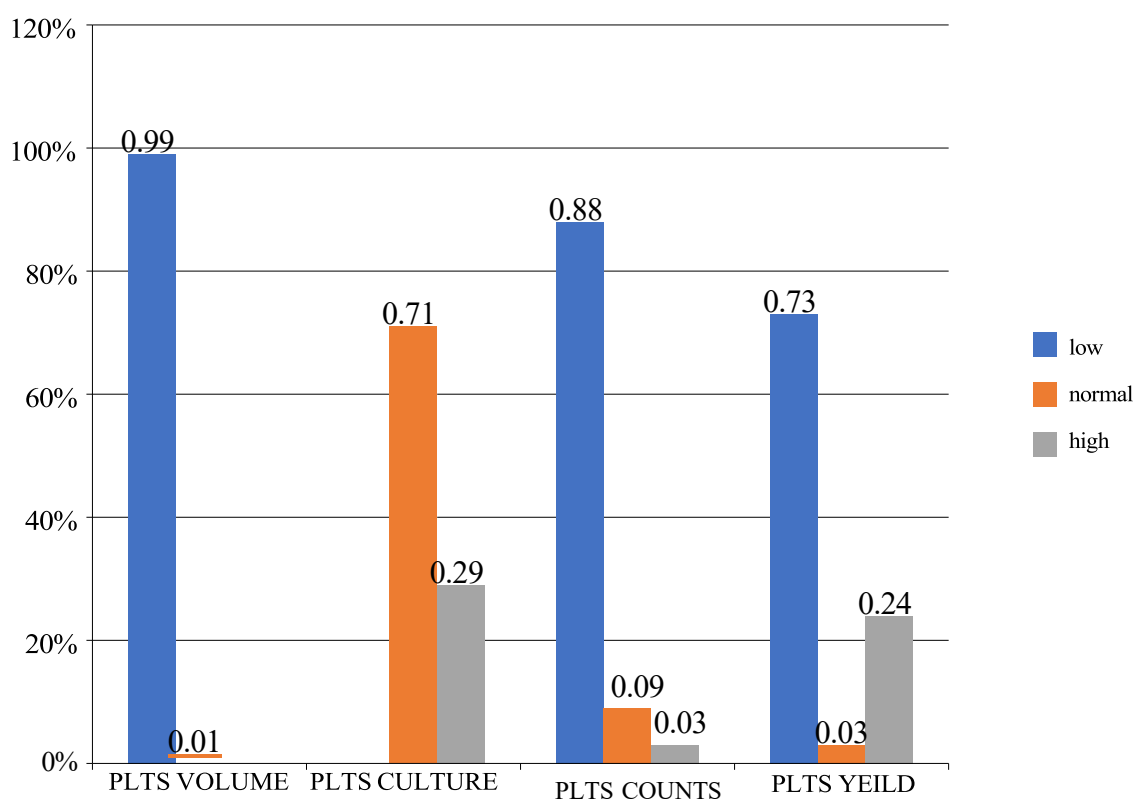


Figure 2 illustrates the relationship between platelet shelf life and platelet volume, culture, count, and yield

The plasma results:

The average factor VIII and fibrinogen levels were ± 79.3 and 315.54 for FFP, respectively. Almost all units had volume below the normal range (100%), but only eight 8/100 (8%) donors had factor VIII below the necessary levels, where the normal was 90%. For CP, the mean factor fibrinogen level was found to be 364.8; most patients had high fibrinogen levels, 71%, and 24% were higher than the acceptable limit. The mean of APTT and PT was 37.6 and 15.2,

Table 7 displays the mean and standard deviation (SD) of fresh frozen plasma values in 100 apparently healthy Sudanese male donors.

Variable	low	Normal	High	STD	Mean
Units volume /ml	100	0	0	15.990	64.18
Fibrinogen level g/L	5	24	71	315.54	98.193
Factor VIII level /ml	8	90	2	24.409	79.34
APTT Level /S	11	68	21	37.64	9.508
PT Level /S	55	0	45	15.27	6.685

respectively; 21% was prolonged (68/100) (68%) was normal in PT. 55/100 (55%) units were normal, whereas 45/100 (45%) units were extended, indicating levels below the recommendation. Among the 100 units evaluated, as shown in Table (4) and Figure 3. Table (5) shows that Group (O) positive had the highest percentage dispersion of plasma volume, fibrinogen level, factor VIII level, PT, and APTT among different blood groups.

Table 8 Quality control of fresh frozen plasma.

Variable	Quality Requirement	Frequency of control
Volume	200-220 ml (450 ml) 155-172 ml (350 ml)	1% of all units
Stable coagulation factors	PT & APTT	1% of all units
Factor VIII	0.7 units/ml	1% of all units
Fibrinogen	200-400 mg	1% of all units

Table 9 shows plasma distribution by blood group.

BLOOD GROUP	Frequency	Percent
A+ve	9	9.0
AB+ve	2	2.0
B-ve	1	1.0
B+ve	10	10.0
O-ve	4	4.0
O+ve	74	74.0
Total	100	100

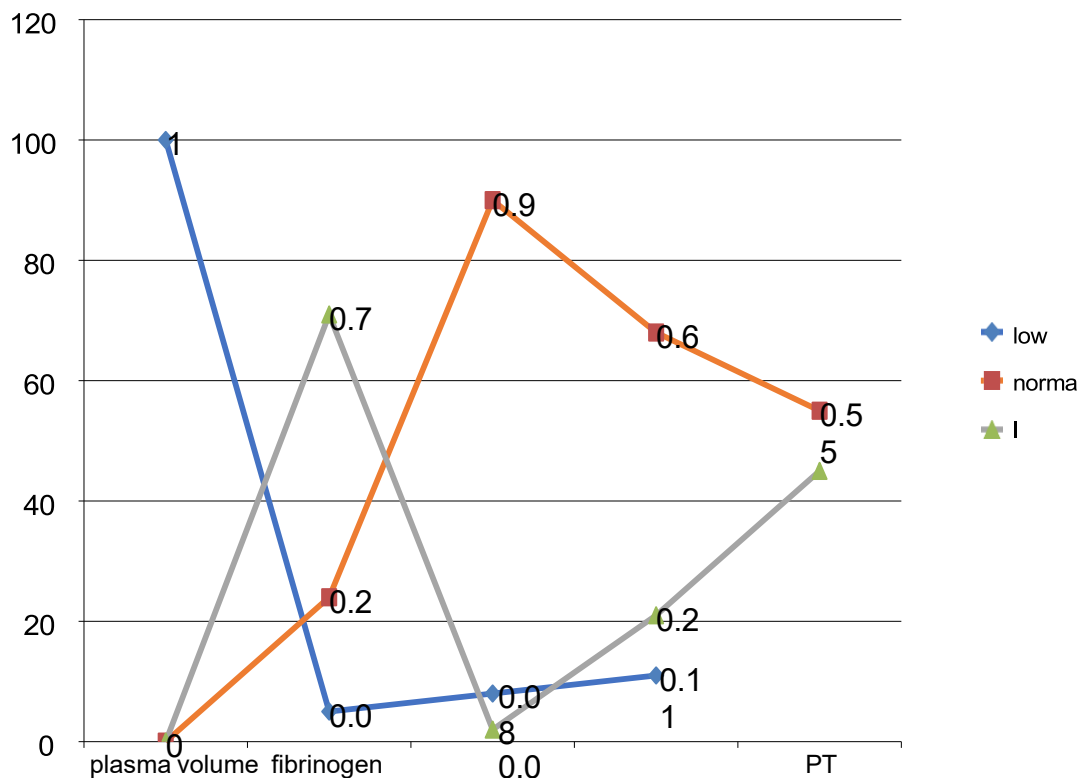


Figure 3 illustrates the relationship between plasma shelf life and plasma volume, culture, count, and yield

The mean factor VIII and fibrinogen levels were 79.3 and 315.54 for FFP, respectively. Almost all units have volume below the normal range (100%), but just eight (8) donors have factor VIII below the necessary levels (normal was 90%). For CP, the mean factor fibrinogen level was 364.8. The majority of patients had high fibrinogen levels (71% and 24% were higher than the normal range), and the mean of APTT and PT was 37.6 and 15.2, respectively. In APTT, 68% were normal, 55% were normal, and 45% were below the recommended levels. among the hundred units tested.

In red cell concentrate, the most common reason for QC failure was a high packed cell volume in the collected blood bag, accounting for 67.5% of all QC. Other factors were poor packed cell volume and a positive sterility test in blood bags, which were 25% and 7.5%, respectively. In fresh frozen plasma, the main cause of failure was a low volume of plasma, which accounted for 43% of cases. The other explanations were low

fibrinogen (33%) and low factor VIII (24%). In platelet concentrate, the most common reason for failure was low platelet count (58%), followed by RBC contamination (17%) and WBC contamination (8%). In cryoprecipitate, the most common reason for failure was a disordered factor VIII level, which occurred in 90% of cases, while low fibrinogen was responsible in 10%.

Discussion:

Blood processes are meticulously oriented towards the production of superior quality products that are both effective and safe [7].

Whole blood: quality control adhered to the standards set within permissible limits according to national guidelines. The recommended volume for whole blood was 350 ± 10 mL with a hematocrit of $>30\%$, while the recommended volume of PRBCs was 280 ± 60 mL with a hematocrit of $>55\%$, in accordance with standard guidelines.

It is mandatory for all PRBCs, must have HCT

of $\leq 80\%$ (100%), as established by the AABB, but they do not recommend or set any lower acceptable limit [8]. However, it seems to be a useful decision to set appropriate range for HCT in the tested PRBCs [9].

The mean hematocrit (HCT) of packed red cells was 69.5 ± 7.24 , with 98% of units meeting the standard of less than 80% HCT [10]. In another study, the means for red blood cells (RBC), white blood cells (WBC), mean corpuscular volume (MCV), mean corpuscular hemoglobin (MCH), and mean corpuscular hemoglobin concentration (MCHC) were 5.0, 5.08, 75.2, 27.0, and 28.6, respectively [11]. Another study indicated a mean volume of 359 mL, with a range of 345 to 375 mL. The mean hematocrit was 41.7%, with a range of 36.2% to 49.0 whereas mean hematocrit of PRBCs was 69.5% with a range of 56.3 to 80.9%. All the whole blood and PRBCs units checked had volume and hematocrit well within standard [12].

Studies in Asia also indicate the mean volume, hematocrit (HCT), platelet (PLT), and white blood cell (WBC) counts in 350 and 450 mL WB units were 394.63 mL, 39.43%, 0.93×10^{11} , and 3.12×10^9 , and 507.75 mL, 40.72%, 1.13×10^{11} , and 3.45×10^9 , respectively. The mean recovery of PLT was 95.54%, 68.63%, and 97.87%, respectively. A remarkable RBC recovery rate of 89.91% was observed in the packed red blood cell units that underwent quality control. Quality control of random donor platelets was conducted in 979 (2.36%) units, yielding acceptable results [13].

This study confirms with our results, which indicated that the mean values for RBC, WBC, MCV, MCH, MCHC, and HCT % were 5.0 c/l, 5.60 c/mm, 75.2 fl, 27.0 pg, 28.6%, and 44.1%, respectively. The averages for RBC, WBC, MCV, MCH, and MCHC were 5.0×10^{12} /l, 5.058×10^9 /l, 75.2 FL, 27.0 pg, and 28.6 g/dl, respectively. In another study, the average volume of whole blood units was 359 mL, with a range of 345-375 mL, while the average volume of PRBCs was 310 mL, with a range of 270-390 ml. The average hematocrit of whole blood units was 41.7%, ranging from 36.2% to

49%, while the average hematocrit of PRBCs was 69.5%, with a range of 56.3% to 80.9%. All the whole blood and PRBC units examined had volume and hematocrit comfortably within standard criteria. Results akin to this study have been noted in research conducted by Upadhyay, where the mean volume of whole blood units was 410 ± 8.1 mL, with a range of 391-522 mL, and the hematocrit of whole blood units was $43.7 \pm 3.2\%$, with a range of 38-52.5% [14].

Other study show low blood volume mean which opposite to our result in Sachi Sharma study which showed Mean volume was 65.5 mL with range of 50-70 mL [15]. This also confirm to other result showed Mean volume of PRBCs units was 285 ± 24.3 mL with a range of 198-350 mL and hematocrit of $54 \pm 4.2\%$ with a range of 41-69%) which is near to our hematocrit result [16]. This also confirms other results shown. The mean volume of PRBC units was 285 ± 24.3 mL, with a range of 198-350 mL, and a hematocrit of $54 \pm 4.2\%$, ranging from 41- 69%. This is comparable to our hematocrit results.

To eliminate the possibility of bacterial contamination in whole blood, components such as PRBCs and positive units were tested. Cultures were performed, and results showed that 78% of the units were negative, while 22% were positive. The possibility of bacterial contamination of units is virtually eliminated; however, positive cultures were invariably the result of faulty sampling techniques, inadequate disinfection materials, or improper storage practices.

Plasma:

Fresh frozen Plasma (FFP) is obtained by separating fresh whole blood and stored at -25°C or below, according to the European guidelines in quality control, the FFP should be checked before being transfused to patients [16]. The quality control issues and evaluation of Fresh Frozen Plasma (FFP) in the North Kordofan area reveal that the indications for transfusing FFP are restricted due to the availability of recombinant factor concentrates. Additionally, there is a misuse of plasma and transfusion of whole blood, attributed to the lack of transfusion sets

and insufficient equipment in rural blood banks. Fresh frozen plasma (FFP) is typically not utilized in developed nations; however, developing countries rely heavily on FFPs for various inherited coagulation disorders. Due to its limited application, the AABB does not provide testing standards for FFP. In contrast, our national standards and guidelines stipulate that FFPs should contain factor VIII levels exceeding 70 units in at least 75% of units. Our findings align with this requirement, showing compliance in 95% of cases. The pH exhibited an acidic average of 6.95, while the mean plasma volume was recorded at 1.0000. All units demonstrated low volume, with 100% compliance concerning the required volume (Table 7).

The mean factor VIII and fibrinogen levels, PT, and PTT were found to be ± 315.5 , 15.01, and 79.1, respectively. In our study, which indicated a factor plasma mean volume of ± 64.18 . VIII level was 79.3 (Table 7). The fibrinogen level was 364.8, the APTT was 37.6, the PT was 15.3 PT, and the PTT and fibrinogen level were within international norms. The PT was normal in 97% and prolonged in 3%. The Factor VIII level prevalence was 9% (3.3), which could be related to the plasma freezers being stored at 20 degrees Celsius. Other studies confirm our findings in Khartoum state cells, showing that RBCs and WBCs had a lower count than the international standard (P-value = 0.00), while platelets were within the reference value. The pH was slightly acidic, with an average value of 6.95, and the mean volume of the FFP bags (120 ml) was lower than the international standard range (P-value = 0.00), and PT and PTT were within the international standard [17].

Additionally, another study found the mean levels of factor VIII and fibrinogen to be $\pm 178.75 \pm 86.30$ and 420.7 ± 75.32 , respectively. Among the 100 units tested, all were found to conform to the norms regarding fibrinogen levels. The mean value was notably high at 420.7 ± 75.32 mg/unit, exceeding the minimum requirement of ≥ 150 mg/unit. The factor VIII assay conformed to the established norms for levels in 96% of units [18].

The prevalence of plasma shelf life ranging from 4 to 60 days was 68%, while the occurrence of shelf life exceeding 180 days was only 2%. This disparity may be attributed to high plasma consumption or insufficient plasma production, potentially due to limited blood resources or storage capacity (Table 4,9). Another study indicated that 95% of their FFP units complied with local guidelines [3]. Reports from other authors were also found convincing and comparable to the current study [19-21].

Group O positive exhibited the highest percentage at 74% among all FFP samples, whereas groups B, O negative, and AB positive demonstrated lower percentages of 1%, 4%, and 2%, respectively (Table 9).

Platelet:

In this study, the mean platelet count was 192.5 in a sample of 200, which is considerably lower compared to other studies that reported a mean platelet count of $215.15 \pm 68.367 \times 10^9/L$. Sixty-seven donors exhibited platelet counts below 150, representing 13.4% of the cases [22]. Possible symptomatic parasitism, such as malaria, was observed; however, no significant aggregation or giant forms were detected in all instances of thrombocytopenia. Conversely, our study indicated that 3% of participants exhibited thrombocytopenia (Figure 1, Table 2).

The mean platelet yield was $8.6 \pm 3.40 \times 10^9/L$, and the pH was ≥ 6.2 in 100% of bags. Cultures were negative in 97% of units tested, and this result conformed to local and AABB guidelines. The mean platelet yield in our study was 5942.0×10^9 , with all bags exhibiting acidity. Positive cultures were observed in 29% of the 100 units analyzed (Table 5).

The yield of PLTS is considered higher than in other studies, and they are acidic, similar to findings from studies conducted over the past 40 years. pH has been recognized as a critical factor in maintaining platelet viability and has been utilized as a quality control marker for platelet acceptability. The FDA established validation and minimum quality control requirements for platelet concentrates in 1975. Currently, FDA and AABB regulations mandate that quality

control testing of platelet components includes pH values of ≥ 6.2 , negative culture results, and platelet yields of $\geq 5.5 \times 10^9/L$ in 90% of units tested. Fifty platelet concentrates were evaluated for pH, volume, platelet count, white blood cell count, and red cell count. All concentrate preparations exhibited an acceptable pH value of 7.25. The mean volume was 18.52 mL per bag. The mean platelet count per concentrate was $41.7 \pm 39.5 \times 10^9/L$, with thirty-five percent (35%) of the platelet concentrates exceeding $55 \times 10^9/L$. White blood cell count (WBC) $< 12 \times 10^9/L$ was observed in 49% of the prepared platelet concentrates. Forty percent (40%) of the platelet concentrate exhibited a red blood cell count (RBC count) exceeding $12 \times 10^9/L$, while 30% demonstrated no red cell contamination. The swirling test yielded a positive result in 72% of the platelet samples [23].

Other studies identified quality control markers for platelet concentrate, achieving the desired criteria in 97% of units. The mean pH of platelets was 7.5 ± 0.8 , consistent with findings from other studies conducted in Western regions. Previous studies conducted in Canada and the United States have established a mean pH of 7.3 ± 0.08 , with 98.1% of units tested meeting the specified requirement for pH value [24]. Nigeria reported that all (100%) of the platelet concentrate preparations met the acceptable standard of 7.25 [25].

Our study indicates a mean volume of 1.01 ml and a platelet count of 1.15 c/l, which are considered low in volume and high in count compared to other studies. A total of 42 out of 451 (9.3%) units were tested for volume and platelet count. The mean volume was 63.7 mL, with a range of 50-70 ml. The mean platelet count was $7.4 \times 10^{10}/unit$, with a range of $5.1-12.9 \times 10^{10}/unit$ [26]. Bacterial growth prevalence was observed at 29%, while 71% exhibited no growth results. Platelet components are more prone than other blood components to being linked with sepsis, as their storage at room temperature promotes bacterial growth during various procedures. The causes of bacterial contamination may include occult bacteremia in the donor, inadequate or contaminated skin

preparation at the phlebotomy site, coring of a skin plug by the phlebotomy needle, and breaches of the closed system due to equipment defects or mishandling. All PLTS units had volumes below the intentional standard level, with a mean of 49.1. Additionally, a lack of whitening scale was observed, and group O positive exhibited a higher prevalence than other groups at 53%.

Conclusion:

In today's world, quality control is an essential step in maintaining the quality of a blood bank, so that we ensure the most efficient blood transfusion for the patient. Finally, all blood components under research met both national and international quality criteria. It is advised that all blood facilities build a thorough QC program and adhere to standard protocols and manufacturer's guidelines for its implementation and effective outcome.

Acknowledgment:

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Ethical approval:

The research committee of the faculty of medicine at the University of Kordofan approved this study protocol. Ethical clearance and national endorsement were obtained from the research directorate of the local state ministry of health.

Ethical consideration:

The protocol for this study was approved by the human ethics committee at Prof Medical Research Consultancy Center.

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