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Appropriateness of transfusions of red cells, platelets and fresh frozen plasma: An audit in referral hospitals in Tanzania

Pertinence des transfusions de globules rouges, de plaquettes et de plasma frais congelé : un audit dans les hôpitaux de référence en Tanzanie

Bhombo AJ[1], Mwashiuya O[1], Mauka WI[1], Mgasa A[1], Ngerageza IM[1], Mogella D[1], Lyimo MA[1]

1. National Blood Transfusion Services, Dar Es Salaam, Tanzania

Corresponding author:
Dr Abdu Juma Bhombo
National Blood Transfusion Services, Dar Es Salaam, Tanzania
Email address: abduj2010@gmail.com
Mobile Phone: +255 713 446 522

ABSTRACT

Background: The global scarcity of blood with imbalanced level of safety is not an exception in Tanzania. This necessitates rational use of blood components to optimise the usage of the available blood components to save lives while instituting safety measures to ensure that blood transfusion is safe. This audit aimed to determine current hospital practices about the appropriateness of transfusions of red cells, platelet and fresh-frozen plasma (FFP) in referral hospitals.

Methods: This was a retrospective cross-sectional study involving secondary data of 1,150 index transfusions from twelve referral hospitals. Multistage cluster and random sampling procedures were used to obtain referral hospitals and index transfusions from blood bank registers respectively. Data were analysed using Stata version 14.1. The categorical variables were summarised into frequency and percentages, while continuous variables were summarised into median with their interquartile range.

Results: In the present audit, 1 150 index blood transfusion episodes were recorded, with only (n=468; 40.7%) indicating the type of blood component in the request form. Among blood component indicated by type, 460 whole blood/red cells units were requested and transfused. Out of 460 blood units, less than one third (n=151; 32.8%) were appropriately transfused. The rest of the blood components FFP (n=3) and platelet concentrate (n=5) were inappropriately transfused.

Conclusions: The study highlighted a low proportion of appropriate usage of blood and blood component. Educational efforts addressing appropriate use of blood component should be strengthened in transfusing hospitals with emphasis on proper documentation along with scale-up blood component production in the country.

RÉSUMÉ

Contexte : La pénurie mondiale de sang avec un niveau de sécurité déséquilibré n'est pas une exception en Tanzanie. Cela nécessite une utilisation rationnelle des composants sanguins pour optimiser l'utilisation des composants sanguins disponibles pour sauver des vies tout en instituant des mesures de sécurité pour garantir la sécurité de la transfusion sanguine. Cet audit visait à déterminer les pratiques hospitalières actuelles quant à la pertinence des transfusions de globules rouges, de plaquettes et de plasma frais congelé (PFC) dans les hôpitaux de référence.

Méthodes : Il s'agissait d'une étude transversale rétrospective impliquant des données secondaires de 1 150 transfusions index de douze hôpitaux de référence. Des procédures d'échantillonnage en grappes et aléatoires à plusieurs étapes ont été utilisées pour obtenir les hôpitaux de référence et les transfusions d'index à partir des registres des banques de sang, respectivement. Les données ont été analysées à l'aide de la version 14.1 de Stata. Les variables catégorielles ont été résumées en fréquence et en pourcentage, tandis que les variables continues ont été résumées en médiane avec leur intervalle interquartile.

Résultats : Dans le cadre du présent audit, 1 150 épisodes de transfusion sanguine index ont été enregistrés, avec seulement (n=468 ; 40,7 %) indiquant le type de composant sanguin dans le formulaire de demande. Parmi les composants sanguins indiqués par type, 460 unités de sang

total/globules rouges ont été demandées et transfusées. Sur 460 unités de sang, moins d'un tiers (n=151 ; 32,8 %) ont été correctement transfusés. Le reste des composants sanguins PFC (n = 3) et le concentré plaquettaire (n = 5) ont été transfusés de manière inappropriée.

Conclusions : L'étude a mis en évidence une faible proportion d'utilisation appropriée du sang et des composants sanguins. Les efforts éducatifs portant sur l'utilisation appropriée des composants sanguins doivent être renforcés dans les hôpitaux de transfusion en mettant l'accent sur une documentation appropriée ainsi que sur l'intensification de la production de composants sanguins dans le pays.

INTRODUCTION

At the global level, blood is still a scarce resource with imbalanced availability and safety of the products between income clusters of high-Income countries and low and middle-income countries, including Tanzania. With this picture in mind, rational and appropriate use of blood and blood components and safety measures that are well coordinated are needed in all countries to foster blood availability.[1]

The audits defined as a quality improvement process that seeks to improve patient care and outcome through a systematic review of care against published criteria.[2] It is part of a continuous quality improvement process and an essential element of clinical governance. Clinical audit in blood transfusion services is a management tool for the appraisal and justification of appropriateness and efficiency of transfusion therapy and an essential part of the quality assurance programme, providing necessary information for improving transfusion medicine practice.[3] Furthermore, the audit is intended to discover snags in the implementation of blood utilization strategy, paving for more improvements. Yet, there is a paucity of information regarding audit on the appropriate use of blood and blood products in East Africa and Tanzania general.[4]

Tanzania recently developed and adopted various WHO strategies for promoting the rational use of blood and blood components. The strategy included, among other measures, the development of national guidelines to guide clinicians on indications for transfusion and formulation of hospital blood transfusion committees for monitoring blood utilization. This study aimed to audit the appropriateness of transfusion of blood components such as red cells, platelets, and fresh frozen plasma (FFP) in alignment with published guidelines in Tanzania.

METHODS

Study design, setting and population

The study was a retrospective cross-sectional survey involving a review of blood transfusion records covering all blood and blood components transfused within a period of three months from 1st January to 31st March 2020. The study involved all patients who received a blood transfusion during the study period.

Sample size, sampling and power

The present study involved 1 150 index transfusions in estimating the overall proportion of appropriate transfusion with 95% confidence, margin error of ±5% and design effect of 2 to account for the multistage sampling. The sample size had more than 99% power to detect a 5% difference in the proportion of appropriate transfusions among hospitals. The study used a multistage cluster sampling procedure wherebytwelve (12) referral hospitals were sampled from thirty-six (36) referral hospitals in Tanzania. These twelve (12) hospitals, one (1) National Hospital, two (2) ultra-specialised hospitals, three (3) zonal referral hospitals, and six (6)regional referral hospitals.

Data source and processing method

This study involved 1 206 consecutive blood requests obtained from medical case notes randomly selected from the available transfusion registers in twelve (12) referral hospitals that met the current study inclusion criteria in three months starting from January to March 2020. A review of the patient's medical history was done on each blood request by two research assistants (Medical Officer and Laboratory Technologist). A total of 1 479 blood units transfused from the index request were recorded. After data cleaning and removing duplicate records, the final data set of 1 150 index transfusions were available for audit and analysis on the appropriateness of transfusion (Figure 1).

Data collection

A review of transfusion records from each blood request was conducted thoroughly with the Medical Officer and Laboratory Technologist, and for each transfusion episode, a single questionnaire was completed. The type and number of blood component requested, issued and transfused to the patient were recorded together with age, gender, blood group, patient's ward/department, current clinical diagnosis and reason or stated indication. From the patient medical case notes and blood request, the study reviewed the record regarding clinical features such as pulse rate, respiratory rate, characteristics of respiratory distress (grunting, nasal flaring), pallor, capillary refill, blood pressure, bleeding status was reviewed at the time of blood requisition. This was followed by identifying diagnoses for each patient, which was then grouped into broad categories according to the International Classification of Diseases (ICD-10). Additionally, from the patient case note, hospital information system and blood

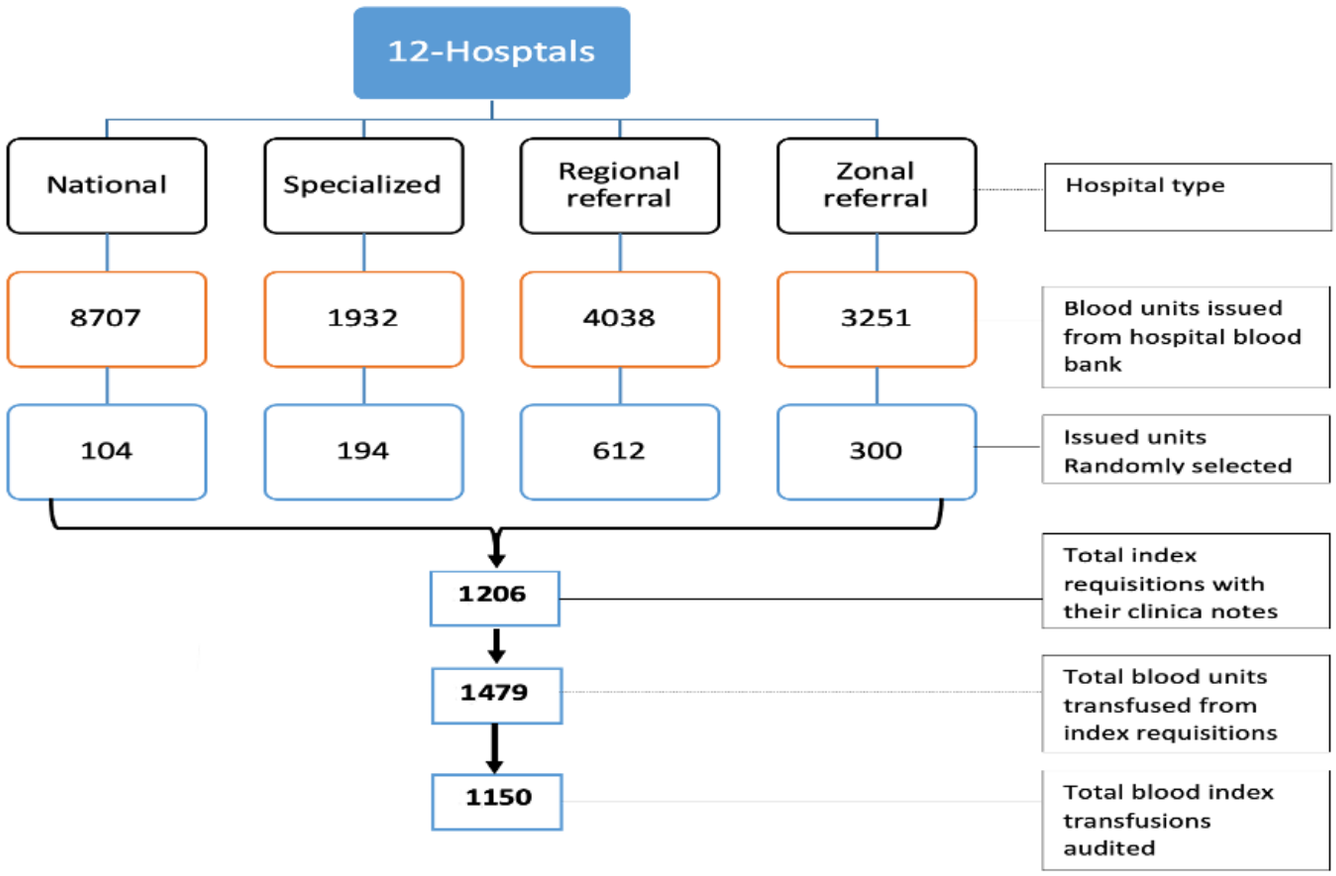

Figure 1: Data management process from selection of patients' files to the final dataset

transfusion registers, various laboratory investigations requested at the time of blood requisition were identified and reviewed, such as compatibility test, red cell mass, haemoglobin level, coagulation tests (Prothrombin time (PT), activated partial thromboplastin time (aPTT) and International normalized ration (INR)). Data were collected into a modified excel sheet which was verified and compiled into a single excel database.

Study Variables

The dependent variables in this audit were appropriateness of blood transfusion and all binary response (yes/no) determined through relevant criteria.

Independent variables were

- Socio-demographic characteristics (age, sex, department and level of the hospital)
- Transfusion information such as
  - ◊ Patient pre-transfusion signs and symptoms [active bleeding, consciousness, cardiac failure, cold extremities, decreased capillary refill, respiratory distress, large liver or spleen, pallor and tachycardia) and vital signs (blood pressure, pulse rate, respiratory rate].
  - ◊ Number of units requested, cross-matched, issued
  - ◊ Number of blood units transfused and not transfused
- Pre-transfusion laboratory test (pre-transfusion haemoglobin level (Hb), compatibility test, red cell mass, coagulation tests (Prothrombin time-PT, activated partial thromboplastin time-aPTT and International normalized ration-INR and diagnosis-underlying cause of anaemia, low platelet count or abnormal coagulopathy.

Criteria for assessment of appropriate transfusion of blood and blood components

Assessment of appropriate transfusion of the packed red cell (RBCs)/Whole blood (WB): appropriate transfusion was based on the criteria below.[5-7]

Paediatric

- Blood was transfused to the patient with
- [Age 0–4-month, Neonates] Hb below 8.5 g/dL with/without any (respiratory support hypoxia, shock, heart failure)
- [For those aged <5 years] Hb below 4 g/dL with/without cardiac/respiratory distress clinical features present.
- [For those aged <5 years] Hb above 4 g/dL with cardiac/ respiratory distress features

Adult [age 5 and above]:

- Blood was transfused with Hb below 5 g/dL in the presence/ absence of any cardiac or respiratory distress or prior surgery.
- Blood was transfused with Hb 5-7 g/dL in presence of cardiac/ respiratory distress, bleeding or severe sepsis, or any stage of Pregnancy and not in labour
- Blood was transfused with Hb 7-8g/dL with bleeding postoperative or under critical care
- Blood was transfused with Hb below 9 g/dL with chemotherapy or radiotherapy or sickle cell disease patient as top up prophylaxis transfusion.

Assessment of appropriate transfusion of platelet concentrate: Transfusion of platelet concentrate was considered appropriate if transfused as:[7-10]

- Prophylaxis in patient with platelet count <100 x 10^9/L and planned for brain or eye surgery.
- Prophylaxis in a patient with a platelet count below 50 x 10^9/L and planned for lumbar puncture, epidural anesthesia, liver biopsy or laparotomy surgery.
- Prophylaxis inpatient with platelet counts below 50 x 10^9/L and has massive hemorrhage/transfusion or disseminated coagulopathy (DIC).
- Prophylaxis in patient with platelet count below 20 x 10^9/L and has bone marrow failures with additional risk factors: fever, sepsis, DIC or severe anaemia massive haemorrhage/transfusion
- Prophylaxis in patient with platelet count below 10 x 10^9/L with or without bleeding
- Therapeutic in a patient with any level of platelet count and patient presented with active bleeding, petechiae, mucosal bleeding or ecchymoses.

Assessment for appropriate transfusion of Fresh Frozen Plasma (FFP): Transfusion of FFP was considered to be appropriate if FFP was transfused in a patient with coagulation test of [INR: $\geq$ 1.5, PT: $\geq$ 18 sec or aPTT: $\geq$ 60sec] and either of the following disease conditions.[7,11-13]

- Liver disease or failure with bleeding
- Acute disseminated intravascular coagulopathy
- Excessive bleeding such as postpartum haemorrhage (PPH)/ antepartum haemorrhage (APH)
- Invasive procedure
- Before major surgery
- 24 hours after major surgery

Statistical analysis

Data were collected through an excel spreadsheet and then entered, cleaned and analysed using Stata version 14.1 Stata Corp LP® [StataCorp. 2015] and presented in narration, figures, and tables. The categorical variables were summarized into frequency and percentages, while continuous variables were summarised into median with their interquartile range.

Ethical considerations

Ethical clearance was obtained from the Ethics Committee of the National Institute for Medical Research (NIMR) and permission to use data was sought from the Medical Officer In-charge (MOI) and Executive Directors (ED) of the respective hospitals. The code number was used instead of names to keep the anonymity of the patients.

RESULTS

Socio-demographic characteristics

A total of 1 150 index blood transfusion episodes were recorded, whereby almost half (n=567; 49.3%) were from regional referral hospitals. The hospital departments recorded 1,148 index transfusion episodes, the most (n=242; 21.1%) were from adult medical wards, and the least (n=6; 0.5%) were from an emergency department. Out of 1,133 index transfusion episodes with recorded age, the majority (n=210; 18.5%) were between 25 and 34 years, and their median age was 28 (IQR: 12-45) years.

Out of 1 135 index transfusion episodes recorded by the sex of the recipient, more than half (n=691; 60.6%) were female patients. The obstetric wards had most (n=148; 21.2%) of female patients transfused (Table 1).

Disease conditions

Out of 951 recorded disease conditions related to anaemia, more than one third (n=354; 37.2%) were due to anaemia of chronic disease followed by continuing active bleeding (n=133; 14.0%) and the least (n=3; 0.3%) were due to Disseminated Intravascular Coagulation (DIC) (Table 2).

Pre-Transfusion Haemoglobin levels

The pre-transfusion median haemoglobin level among males was 6.2 g/dL (IQR=4.5-8.6) g/dL with a minimum of 1.6 and a maximum of 16.3 g/dL. Among females, 5.9 g/dL (IQR=4.5-8.2) g/dL, while minimum and maximum were 1.6 and 19.6 g/dL respectively (Figure 2).

Table 1: Socio-demographic characteristics

Characteristics	Overall		Female		Male	
	n	%	n	%	n	%
Hospital level	**(n=1 150)**		**(n=697)**		**(n=438)**	
National Referral Hospital	104	9	74	10.6	30	6.8
Regional Referral Hospitals	567	49.3	385	55.2	182	41.6
Specialized Hospital s	191	16.6	103	14.8	87	19.9
Zonal Referral Hospitals	288	25.0	135	19.4	139	31.7
Admitted hospital wards	**(n=1 148)**		**(n=697)**		**(n=438)**	
Adult Medical wards	242	21.1	122	16.1	120	27.5
Medical Oncology	112	9.8	82	11.8	30	6.9
General Surgical wards	132	11.5	61	8.7	71	16.3
Emergency department	6	0.5	2	0.3	4	0.9
Gynaecological ward	139	12.1	139	19.9	0	0.0
ICU	13	1.1	7	1.0	6	1.4
Obstetrics	148	12.9	148	21.2	0	0.0
Orthopedics ward	93	8.1	32	4.6	60	13.8
Paediatric medical	233	20.3	106	15.2	123	28.2
Others	30	2.6	8	1.2	22	5.0
Age group (Years)	**(n=1 133)**		**(n=688)**		**(n=430)**	
0-4	177	15.6	78	11.3	98	22.8
5-14	128	11.3	55	8.0	72	16.7
15-24	170	15.0	131	19.0	36	8.4
25-34	210	18.5	153	22.2	55	12.8
35-44	155	13.7	120	17.4	35	8.1
45-54	116	10.2	69	10.0	44	10.2
55-64	78	7.0	38	5.5	39	9.1
65+	99	8.7	44	6.4	51	11.9
Median age (IQR) years	**28**	**(12-45)**	**29**	**(19-42)**	**27**	**(5-50)**

Table 2: Distribution of Disease condition recorded related to reported anaemia

Disease condition (n=951)	n (%)
Active continuing bleeding (Trauma)	133 (14.0)
Anaemia of chronic disease	354 (37.2)
Disseminated Intravascular Coagulation (DIC)	3 (0.3)
Haematemesis (Liver disease & PUD)	24 (2.5)
Malaria infection	139 (14.6)
Maternal hemorrhage (PPH, APH)	74 (7.8)
No disease condition recorded	63 (6.6)
Post-operative bleeding	46 (4.8)
Others	115 (12.1)

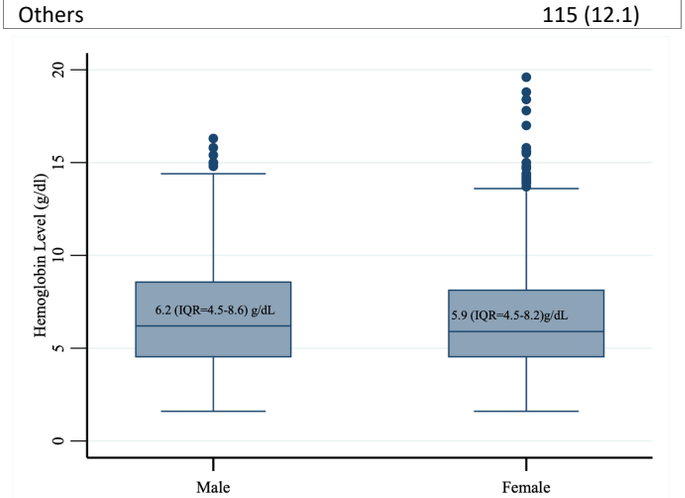

Figure 2: Patient's pre-transfusion median haemoglobin by sex

The overall pre-transfusion average mean haemoglobin levels across hospitals among females and males were 6.7 (SD=3.1) g/dL and 6.8 (SD=3.0) g/dL. Furthermore, the difference between pre-transfusion haemoglobin and the overall average mean *between* hospitals among females and males was ±0.5 g/dL and ±0.4 g/dL, respectively. Meanwhile, the difference of patient pre-transfusion haemoglobin level and overall pre-transfusion average mean haemoglobin levels *within* the hospitals among females and males was (SD=3.1) g/dL and (SD=3.0) g/dL, respectively (Figure 3).

Clinical transfusion features

A total of 945 clinical features were documented in the files during index blood request, whereby the most (n=757; 80.1%) indicated clinical sign was the presence of pallor among patients, followed by active bleeding (n=71; 7.5%) and the least (n=2; 0.2%) were splenomegaly and cold extremities (Table 3).

Type of blood components transfused

Out of 1 150 index blood transfusion episodes recorded in the index request, less than half (n=468; 40.7%) indicated the type of blood component requested and transfused (Table 4).

Out of 468 blood units identified by type of component, whole blood (WB) was requested and transfused in more than two thirds (n=300;

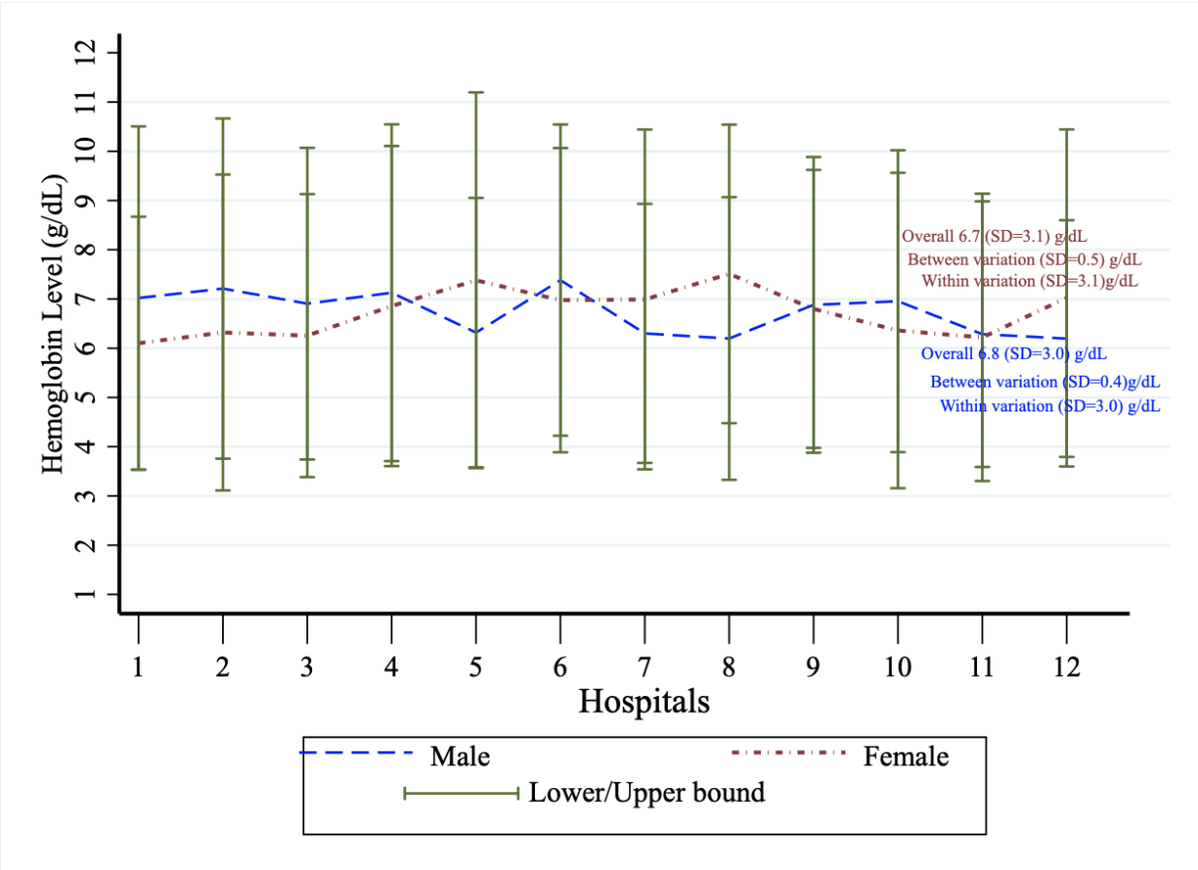

Figure 3: The variations of average means of haemoglobin levels between and within 12 hospitals by sex

Table 3: Clinical signs and symptoms recorded during index blood requisition

Clinical signs and symptoms (n=945)	n (%)
Active bleeding	71 (7.5)
Cardiac failure	7 (0.7)
Cold extremities	2 (0.2)
Decreased capillary refill	4 (0.4)
Hypotension	11 (1.2)
Pallor	757 (80.1)
Shortness of breath	28 (3)
Splenomegaly	2 (0.2)
Tachycardia	20 (2.1)
Others	43 (4.6)

Table 4: Distribution of Blood Components Transfused

Blood components requested and transfused in index requisition (n=1 150)	n (%)
Identified by type	468 (40.7)
Not identified by type	682 (59.3)
Total	**1 150**

Table 5: Distribution of blood components identified by type

Blood components requested and transfused in index requisition (n=468)	n (%)
Fresh Frozen Plasma (FFP)	3 (0.6)
Packed Red Blood Cell-RBC (Paediatric)	56 (12.0)
Packed Red Blood Cell-RBC (Adult)	104 (22.2)
Single unit Platelet concentrates	5 (1.1)
Whole blood (WB)	300 (64.1)

64.1%), and the least was FFP (n=3; 0.6%) (Table 5).

Appropriateness of transfused blood components

Audit on the appropriateness of transfusion was conducted only for 468 blood units identified by blood component type. A total of 460 units of blood (WB and RBC) recorded to be transfused, less than one third (n=151; 32.8%) were appropriately transfused. The rest of blood components; FFP (n=3) and platelet concentrate (n=5) were inappropriately transfused based on the set criteria (Figure 3).

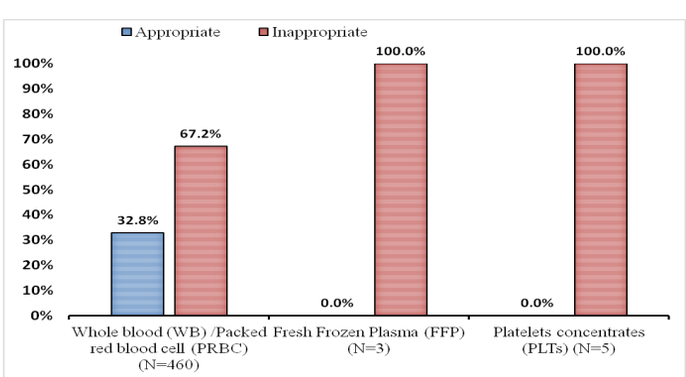

Figure 3: Appropriateness use of blood components by blood components

Appropriate transfusion by hospital wards

More than 40% of blood transfusion episodes in Oncology and Orthopedics were appropriate (41.3% and 41.2%, respectively) (Figure 4).

Appropriate transfusion by facility level

Among 76 transfusion episodes occurred in specialized hospitals, more than forty percent (42.1%) were appropriately transfused and among regional hospitals, less than one third (Figure 5).

Causes of inappropriate transfusion

The inappropriate transfusions were considered for all 682 transfused units which lacked information on the type of blood component. Among 309 inappropriate transfusions which were recorded, 24 (7.8%) were due to missing information on the haemoglobin level, while 285 (92.2%) patients whose haemoglobin level was reported, transfusions were considered inappropriate due to insufficient information to determine appropriateness.

Among 214 inappropriate transfusions, 28 (13.1%) had normal haemoglobin level and there was no any other justification for transfusion, while 186 (86.9%) a low haemoglobin level, transfusion was inappropriate due to missing clinical features to support the transfusion (Figure 6).

A total of 305 inappropriate transfusion were recorded by the hospital departments, the most (n=71; 23.3%) were from paediatric medical wards, followed by medical wards (n=66; 21.6%), and the least (n=3; 1.0%) were from intensive care unit (ICU) (Table 6).

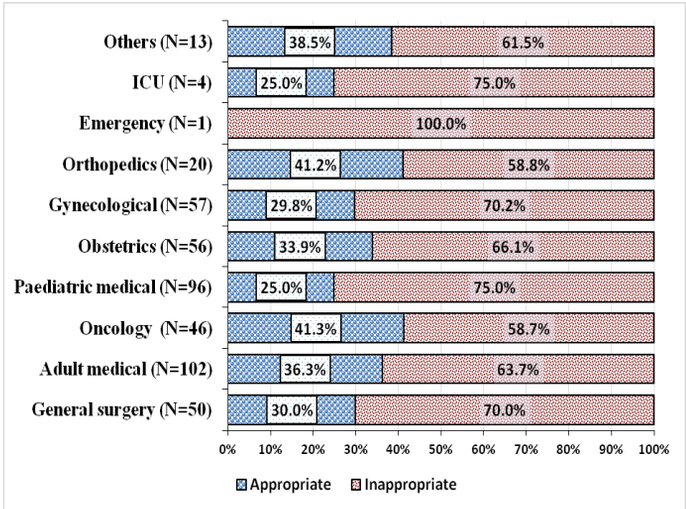

Figure 4: Appropriateness use of blood components by departments

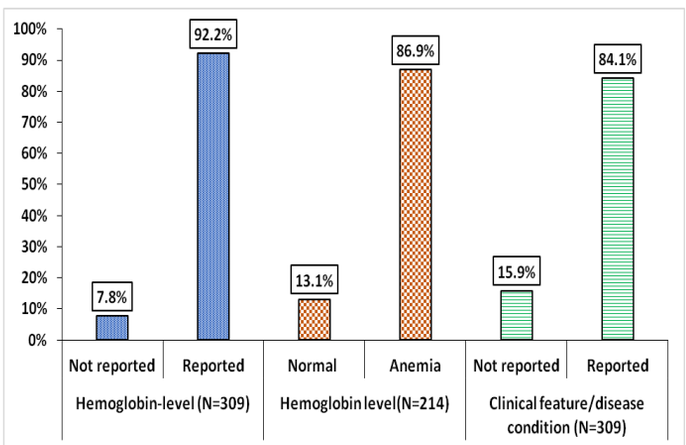

Figure 6: Main causes of inappropriateness

Table 6: Inappropriate transfusion by ward (n=305)

Type of ward	n (%)
Medical	66 (21.6)
Oncology	26 (8.5)
Surgical	34 (11.1)
Emergency	1 (0.3)
Gynaecological	40 (13.1)
ICU	3 (1.0)
Obstetrics	36 (11.8)
Orthopedics	20 (6.6)
Paediatric Medical	71 (23.3)
Others	8 (2.6)

DISCUSSION

This study included 1 150 index transfusion episodes during the defined study period of three months from January-March 2020. More than half of the audited patients were female (n=691; 60.6%) from 1 135 transfusion episodes recorded by sex.

Of the 1 150 blood units ordered, issued and transfused across various departments in 12 referral hospitals, 40.7% (468/1 150) were indicated by their type of blood component by the clinicians and thus were audited for appropriateness of transfusion. The remaining unclassified blood units, 59.3% (682/1 150), were not audited for transfusion appropriateness.

Out of 468 indicated type by clinicians and transfused units, whole blood (WB) was requested in more than two thirds 64.1% (300/468) of cases, followed by packed red blood cells (RBC) 34.2% (160/468), platelets 1.1% (5/468) and the least 0.6% (3/468) was fresh frozen plasma (FFP). A similar finding on the reliance of whole blood by 60% has been reported from the five-year audit of blood transfusion practice conducted at Ilorin, Kwara State North central Nigeria.[14] There is little justification for the use of whole blood transfusion, except for managing trauma patients with massive bleeding Lack of knowledge among clinicians regarding indications of blood components and the limited capacity for component production in the country could be the major factors contributing to this over-reliance on the use of whole blood (WB) as NBTS annual reports (2020) indicates that of 312 714 blood units collected, only 17% (925/312 714) were processed into the blood components.

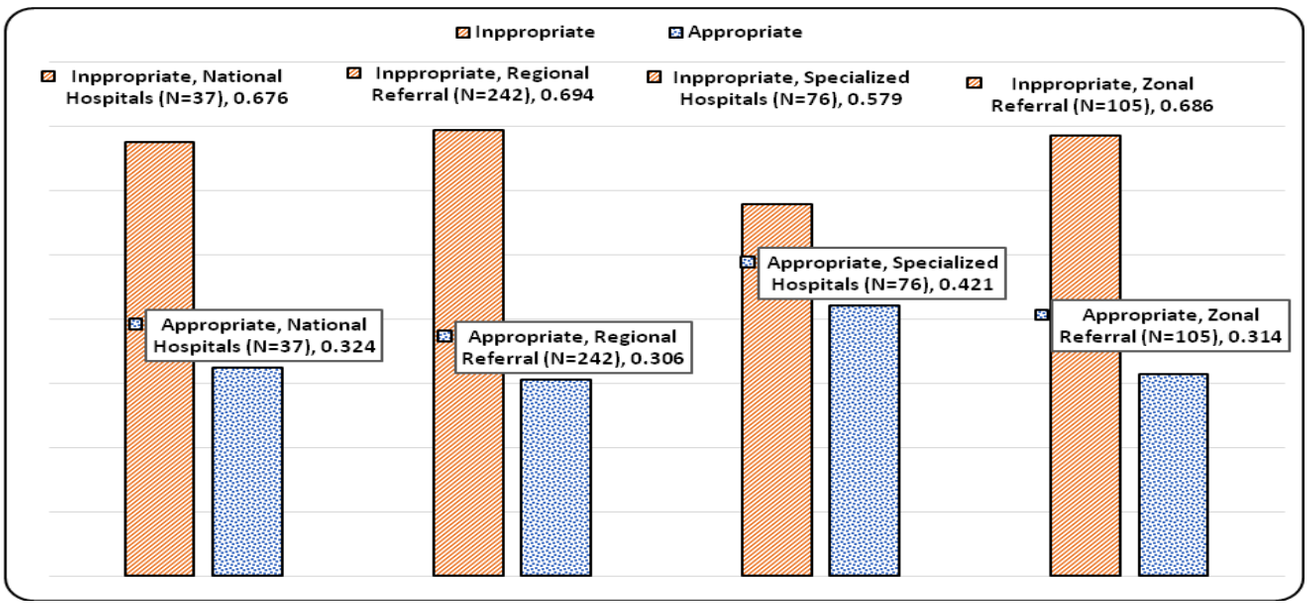

Figure 5: Appropriateness of blood components transfusion by hospital level

Whole blood/Packed red cell transfusions

A total of 460 units of blood (WB and RBC) were recorded. Of these, less than one third, 32.8% (151/460), were deemed appropriate transfusions while 67.2% (149/309) were inappropriate transfusions according to the set criteria. The same finding on appropriate transfusion has been noted in other studies by Marti-Carvajal et al. from Venezuela 39% (64/164).[15] However, regarding appropriate transfusion, the results are much lower, contrary to other published reports from India, Iran and Nigeria by 90.2% (924/1 024), 84.3% (503/596) and 96.8% (481/497), respectively.[15-17]

The present study criteria for WB/RBC transfusions included both laboratory and clinical data, with the need to document both the haemoglobin levels and the clinical criteria. This approach may have increased the inappropriateness rate as opposed to when clinical or haemoglobin trigger criteria alone are used to indicate appropriateness of transfusion. Overall inappropriate transfusion occurred in 309 blood units transfused. Out of 309 inappropriate transfusions, 24 (7.8%) were due to missing information (Hb) while 285 (92.2%) were inappropriate based on lack of clinical information to support the need for transfusion, despite provision of the Hb.

Among 214 inappropriate transfusions, 28 (13.1%) had a normal Hb and there was no any other justification for transfusion, while 186 (86.9%) who had anaemia due to low Hb, transfusion was inappropriate due to missing clinical features to support the transfusion they had.

The explanation for such limited appropriate use of WB/RBCs seems to be using the laboratory criterion alone. In many instances, low Hb above the set threshold of $\leq$5 g/dL is used to determine the request for transfusion of WB/RBC. In this study, the average mean Hb was 6.7 g/dL. At the same time, the correct approach is to combine both the laboratory criteria with the symptoms of the patients. In the present study, clinical features of anaemia were rarely used as essential criteria to determining the request for blood transfusion whereby only 15% (170/1 150) of the index transfusion request did document the clinical features of anaemia before blood requisition.

We also postulate that the appropriate use of blood may be influenced by the level of hospital and training level of the physicians. In the present audit, appropriate transfusion was recorded higher among specialised hospital (42.1%) compared to regional referral hospitals (30.6%). This result suggests that physicians working in specialised hospitals are well trained and informed more about the appropriate use of blood and blood products.

Platelets concentrate and Fresh Frozen Plasma transfusions

Platelet transfusions comprised of 5 platelet concentrates units (Table 3). In this audit, the common indication for platelet transfusion was bleeding prophylaxis in marrow failure related to acute leukaemia, HELLP syndrome, and chronic renal failure (CKD) with uraemia. In these patients, almost all five (5) of the platelet transfusions were inappropriate due to a lack of clinical features such as abnormal bleeding to support the laboratory assessment on platelet count. In the five patients in whom the use of platelets for bleeding was inappropriate, the trigger platelet counts ranged from 11-138 x 10^9/L.

The rest of the blood component transfused in this present audit was three (3) units of FFP. These components were transfused in a patient with HELLP syndrome. Massive haemorrhage and all transfusions were considered inappropriate due to lack of either risk factor or coagulation profile recorded at the time of audit.

CONCLUSION

The study highlighted a low proportion of appropriate usage of blood and blood components. Educational efforts addressing the appropriate use of blood and blood components should be strengthened in all hospitals with an emphasis on proper documentation on type of the blood components transfused, clinical features, disease conditions and pre-transfusions triggers such as haemoglobin level, platelet count and coagulation profiles.

STUDY INFORMATION

Limitation of the study

A major limitation of this study is the retrospective study design

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None

Conflicts of interest

The authors have no conflict of interest to declare

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