

Quality Assurance and Blood Security in Blood Transfusion Practice in Nigeria: A Multi-Centre Study

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ABSTRACT

Introduction: Safe Blood is an indispensable resource in preventing morbidity and mortality in modern clinical practice either as supportive or as standalone therapy care. Providing safe blood requires a secured system that is standard in its operations, effectiveness and efficiency. **Aim:** This study aimed to conduct a baseline audit of the Quality Management System (QMS) and security in the provision of blood transfusion services in some government-owned Tertiary Hospitals (THs) in Nigeria. **Methodology:** This was a descriptive cross-sectional study carried out between October 2019 and June 2020. Data was collected from Haematologists or Laboratory Scientists working in the blood bank of the THs using a pretested electronic questionnaire. Data were analyzed using SPSS software (version 21.0).

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Abstract Contd.

Results: Fifty THs in Nigeria responded to the survey. Fifty two percent (26/50) of them lack blood transfusion policy. Although 54.0% have blood transfusion committee, only 18.0% have regular meetings. Fifty two percent have National Blood Service Commission (NBSC) Centres in their State and only 16.0% receive regular blood supply from NBSC. The majority (72%) have their blood bank as a separate structure, 68% have no blood component production unit, 50% have no system for validating equipment, 90% have blood inventory system and 88.0% of the THs blood bank do experience materials running out of stock. **Conclusion:** Majority of the THs lack blood transfusion management system in virtually all the components of quality assurance system.

Keywords: Blood component, Blood transfusion management system, Blood Transfusion Services, Safe Blood.

INTRODUCTION

Legal requirements for quality assurance in blood transfusion services specify best practices for blood banks. Implementation of best practices leads to the creation of a quality assurance system that guarantees transfusion safety from the structure of the blood bank through the donation of blood to blood components production and distribution. Established criteria and benchmarks must be adhered to in these processes.^{1,2,3} The main objective of a quality assurance programme in blood banks is to ensure that blood bank's processes will reliably deliver safe, efficacious blood and blood components that are collected and manufactured in a manner that causes no harm to the recipient, the donors or to the staff.³ In many countries, the implementation of a quality assurance programme has become a regulatory or government requirement.⁴ However, an effective programme can also deliver benefits to the Blood Transfusion Service beyond regulatory compliance.

The safety of Blood and/or its components or products is necessary to prevent morbidity and mortality especially in developing countries.⁴ In Nigeria, the National Blood Service Commission (NBSC) is yet to provide the desired framework and unified regulatory services on quality management system for implementation in individual hospitals to provide safe blood and blood product therapy to the

citizenry.⁵ This makes it tasking for individual tertiary healthcare facilities to provide blood therapy to ensure a steady supply of safe blood or its products.⁶ The study aimed to conduct a baseline audit of the Quality Management System (QMS) and security in the provision of blood transfusion services in all government-owned Tertiary Hospitals (THs) in Nigeria.

METHODOLOGY

A descriptive cross-sectional study involving government-owned THs in Nigeria was conducted from October, 2019 to June, 2020. Data were collected using a pretested electronic questionnaire

made up of questions covering information on hospital, blood transfusion infrastructure, blood transfusion policy, sources of blood, donor recruitment, Standard Operating Procedure (SOP), equipment validation, inventory record and blood transfusion management system. A Haematologist completed the questionnaire in each centre except in centres with no haematologist, where another physician with interest in blood transfusion or a medical laboratory scientist completed the questionnaire. The link to the questionnaire was sent to the personal email of the respondents who were randomly selected and follow-up phone calls were made every four weeks for a period of eight (8) months or until the questionnaire was thoroughly completed. Hospitals with incomplete responses and

whose response was not received within the study period were excluded from the analysis. Responses were collated directly into an Excel spreadsheet. Data was imported into and analyzed using Statistical Package for Social Sciences (SPSS) Version 21 (IBM incorporated, Armonk, NY, USA).

Quality assurance is concerned with all aspects of blood transfusion practice and applies to all activities of blood transfusion service, from identification of potential donors, blood collection and preparation of blood components/products. This is to ensure blood safety which encompasses activities intended to mitigate the risks of blood transfusion and ensure safety of the donor and the recipient.

The survey protocol and questionnaire were reviewed by the Research Ethics Committee (REC)

of the Federal Medical Centre, Birnin-Kebbi and approved with reference number FMC/BK/HP/045/P/517/VOL.III. The research did not involve information from any patients.

RESULTS

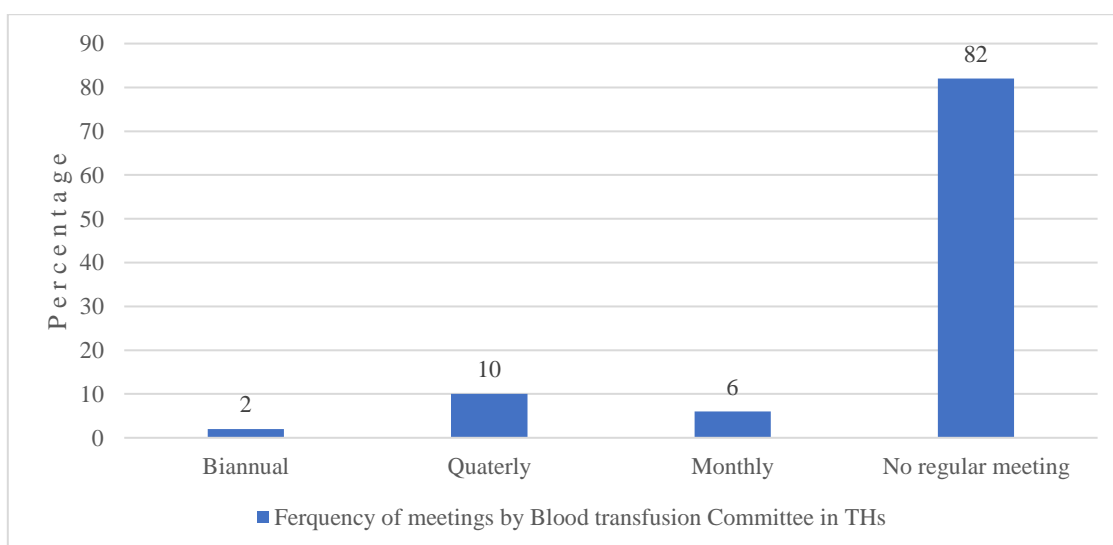
Fifty out of 103 government-owned tertiary hospitals responded to the survey. Twenty-four (48%) had hospital blood transfusion policy. Twenty-seven (54%) had a blood transfusion committee and only 9 (18.0%) of the committees had regular meetings of the stakeholders (Table 1 and Figure 1). Forty eight percent (24/50) of the THs had no National Blood Service Commission (NBSC) Centre in their respective States and only 8 (16.0%) received regular blood supply from the NBSC Centre (Table 1).

Table 1: Blood transfusion management and blood supply sources in government-owned Tertiary hospitals in Nigeria

Parameter	Yes Frequency (%)	No Frequency (%)
Blood transfusion management		
Do you have blood transfusion committee	27 (54.0)	23 (46.0)
Do you have blood transfusion policy	24 (48.0)	26 (52.0)
Do you hold regular meetings of stakeholders in BTC	9 (18.0)	41 (82.0)
Blood sources and supply		
Do you have NBSC in your State	26 (52.0)	24 (48.0)
Do you receive regular blood supply from NBSC	8 (16.0)	42 (84.0)

NBSC = National Blood Service Commission, BTC = Blood Transfusion Committee

Figure 1: Frequency of meetings by Blood Transfusion Committee in Tertiary Hospitals



Assessment of physical infrastructure in the hospitals showed that the majority, 36 (72.0%) had blood banks as separate structures in the hospital and more than 50% had different sections in their blood banks. A separate donor clinic was present in 68.0% (29/50), donor counselling section in 66.0% (33/50),

bleeding unit 96.0% (48/50), serology unit in 90% (45/50) and Transfusion Transmissible Infections (TTIs) screening unit in 86.0% (43/50) each (Table 2). A few of the hospitals 19(38.0%) had a system for external donor drives. The majority of the hospitals 34 (68.0%) had no blood components production unit (Table2).

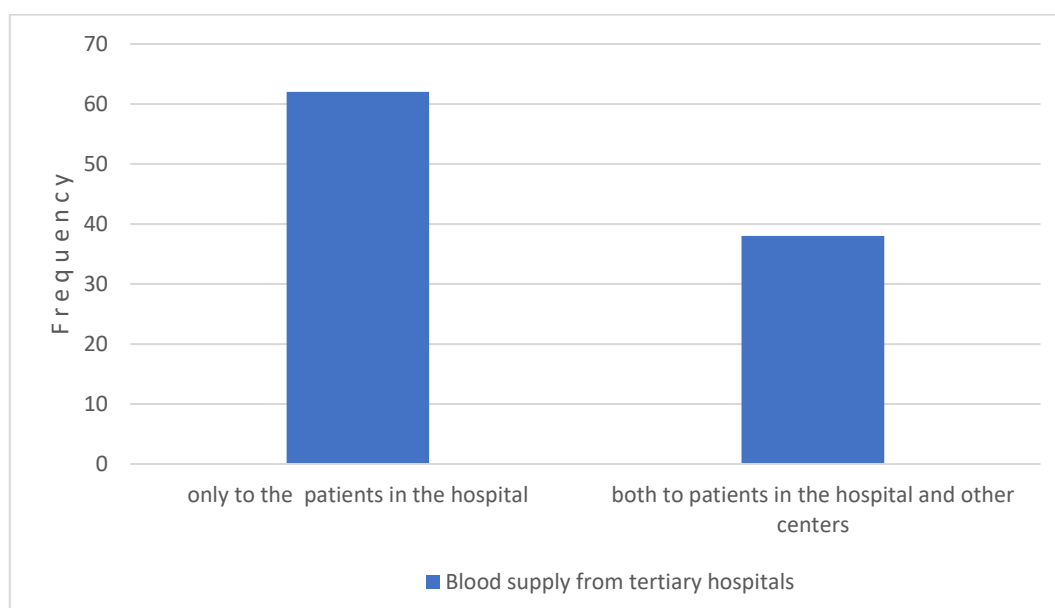
Table 2: Physical infrastructure for blood transfusion services in Nigerian Tertiary Hospitals

Physical infrastructure	Yes Frequency (%)	No Frequency (%)
Blood bank as a separate structure from main laboratory	36 (72.0)	14 (28.0)
Donor clinic as a separate unit	29 (58.0)	21 (42.0)
Donor mobilization unit for external donor drive	19 (38.0)	31 (62.0)
Donor counselling section as a separate unit	33 (66.0)	17 (34.0)
Bleeding section as a separate unit	48 (96.0)	2 (4.0)
Serology section as a separate unit	45 (90.0)	5 (10.0)
TTIs screening section as a separate unit	43 (86.0)	7 (14.0)
Component production unit	16(32.0)	34(68.0)

TTIs = Transfusion Transmissible Infections

On the issue of blood availability on demand, the majority of blood banks in the THs supplied blood only to their inpatients while only 38.0% (19/50) of them supplied to both their patients and neighbouring hospitals (both government and private facilities) (Figure 2).

Figure 2: Blood supply from the tertiary hospitals



On the issue of equipment validation, more than 50% of THs had no system for validating their blood bank equipment, although 70% (35/50) of them had SOP for all their procedures. Twenty-nine (58%) of the THs had a system in place for quality assurance, while 86.0% (43/50) were still using a manual temperature monitoring system (Table 3).

Table 3: Equipment validation

Parameter	Yes Frequency (%)	No Frequency (%)
Do you have SOP for all your procedures	35 (70.0)	15 (30.0)
Do you have a system of validating all your equipment	24 (48.0)	26 (52.0)
Do you have quality assurance system for the entire product produced	29 (58.0)	21 (42.0)
Use manual method of temperature monitoring	43 (86.0)	7 (14.0)
Use computer method in temperature monitoring	7 (14.0)	43 (86.0)

SOP = Standard Operating Procedure

Blood bank inventory and record system showed that 90% (45/50) of the THs had blood inventory system. Daily and monthly stock level each were present in 80% (40/50) of the THs (Table 4). Monthly statistics of usage and wastage was present in 76% and 70% respectively (Table 4).

The Blood Bank records in 88.0% (44/50) of the THs was manual while only 12.0% (6/50) were using both manual and computerized systems, although records could be used to trace donors from recipients in 92.0% (46/50) (Table 4).

Table 4: Blood inventory and record system

Parameter	Yes Frequency (%)	No Frequency (%)
Blood inventory		
Do you have blood inventory system	45 (90.0)	5 (10.0)
Do you do daily stock level	40 (80.0)	10 (20.0)
Do you do monthly stock level	40 (80.0)	10 (20.0)
Do you do monthly statistic of C:T ratio	20 (40.0)	30 (60.0)
Do you do monthly statistic of expiration	39 (78.0)	11 (22.0)
Do you do monthly statistic of wastage	35 (70.0)	15 (30.0)
Do you do monthly statistic of usage	38 (76.0)	12 (24.0)
Do you have blood auditing system	34 (68.0)	16 (32.0)
Method of record keeping in the blood bank		
Mainly manual record keeping	44 (88.0)	6 (12.0)
Mainly computerized record	0 (0.0)	50 (100.0)
Both manual and computerized	6 (12.0)	44 (88.0)
Based on your record can you trace donor to recipient?	46 (92.0)	4 (8.0)

C:T ratio = Cross-match to Transfusion ratio

Concerning blood security, 68% (34/50) of the THs provided blood to all patients in need irrespective of whether they had a donor or not, and 88.0% (44/50) of the THs blood banks experienced out of stock of which 42% (21/50) were rare blood groups. (Tables 5).

Table 5: Blood security in Nigeria

Parameter	Frequency (%)
Blood availability to patients in need	
To all patient	34 (68.0)
To only those who had donors	16 (32.0)
Total	50 (100.0)
Have you experienced blood components running out of stock?	
Yes	44 (88.0)
No	6 (12.0)
Total	50 (100.0)
Which type of blood group do you experience out of stock?	
All blood groups	23 (52.3)
Rare groups	21 (47.7)
Total	44 (100.0)
Cost of blood and available units of blood	
Cost of service per unit of blood (Naira)	4, 922.1 ± 2, 075.9
Average annual units of blood donation	6,338.5 ± 1,744.7

DISCUSSION

The role of blood transfusion is increasing in both medical as well as surgical practice especially in life threatening conditions. This puts the hospital blood transfusion services under greater pressure in the context of blood safety, availability and affordability.¹ The obligation of blood bank to provide safe blood for patients has currently been expanded to include the safety of the donor and their staff.⁶

The quality system in blood transfusion services covers all aspects of its activities and ensure traceability from recruitment and selection of donor to transfusing blood and blood products. It also covers the structure and capability of blood transfusion services, the needs of the hospital and the patients it serves.³ Therefore, quality systems includes organizational management, standards, documentation, training and assessment.⁷ The implementation of quality assurances programme in blood transfusion based on good manufacturing practice has played a central role in improving the safety and quality of blood and blood components.⁷ It minimizes risk to safety and quality by ensuring that blood bank processes will reliably deliver safe, efficacious blood and blood components that are collected and processed in a manner that causes no harm to the donor, recipient or staff.⁷

While implementation of quality assurance is almost certain in developed countries with regulatory agencies that ensure compliance, in developing countries such as Nigeria, the system is almost non-existent, with malfunctioning regulatory agencies and no uniformity in the quality of services. The non-availability of hospital blood transfusion policy in the majority of the hospitals in this study which is supposed to guide the entire operations of the blood transfusion system coupled with the low rate of regular meetings of Hospital Blood Transfusion Committees could greatly undermine the safety, availability and blood security. Previous studies have also reported poor implementation of quality

assurance in Nigeria and other low income countries.^{8,9}

A significant number of hospital blood banks in this study lacked separate units in their blood banks such as donor selection unit, donor counselling unit, bleeding unit, serology and Transfusion Transmissible Infections (TTIs) screening unit. This entails that the majority of services are carried out in the same areas which predisposes to many mistakes, diversion of attention with consequent effect on the donor, recipient or even accidents on the staff.¹⁰ In accordance with WHO guidelines, blood centres shall be designed in such a way that permits the movements of blood in one direction so that there is minimum retracing or crossing of paths at different sections in the handling process.¹¹

A significant number of THs do not have donor clinics and this may mean that they carry out blood donation without rigorous donor selection which is supposed to ensure the safety of both the donor and the recipient, ensure that the donor is in good health, identify medical conditions or medications that the donor is receiving which could significantly affect the recipient. Transfusion of blood from donors on some medications can adversely affect the recipients and may be mistaken for an adverse blood transfusion reaction.¹² These findings also further confirm non uniform donor selection criteria among THs in Nigeria as earlier shown in previous studies in Nigeria.^{8,13}

The timely availability of safe blood is central in blood transfusion practice. These can only be achieved through a well-coordinated system that ensures a steady supply of safe blood or its components or products either within or outside the hospital setting. As shown in this study and previous studies, blood donation within the hospital setting in a majority of cases is either from family replacement or commercial donors, dominating blood donor pool in Nigeria.^{14,15}

The finding of this study also showed a lower percentage of external donor drive among THs which is mainly Voluntary Non-remunerated Blood Donation (VNRBD). Similar finding has also been reported by previous studies.^{1,16} This situation is further worsened by the fact that the majority of THs do not have NBSC centres in their States, and only a few among those that have NBSC Centres in their state receive blood supply occasionally from NBSC centre. These further demonstrate the weakness of NBSC Centres and its failure to meeting up with the mandate of its creation which is provision of a timely and adequate blood supply to the citizenry.¹⁷ The lack of a steady supply of blood through VNRBD has a consequential effect on blood security in the country more especially during disasters, mass casualties, outbreaks and other emergency needs.¹⁸ Due to inadequate supply to the majority of THs in Nigeria as shown in this study, an insignificant number of hospitals (Government or private facilities) received blood from THs blood banks especially during emergencies. This has further demonstrated the need to have a uniform robust external blood donor system in the country that will ensure adequate blood security through a reliable steady supply of blood, blood components or products that will meet the needs of all patients.

Validation ensures the quality of any automated system which is the documented evidence that provides a high level of assurances that all parts related to the use of the automated system are working correctly and consistently. All aspects of validation (installation, operational and performance) needs to be assured for all the equipment in the blood banks. While validation is critical to the quality of services rendered in the blood transfusion services,¹⁹ findings from this study revealed no validation system in the majority of THs in Nigeria. This is further confounded by the absence of SOPs in the majority of THs blood banks with no uniformity in the operation by the users. Consequently, quality blood transfusion service may not be assured. Consistency which is the hallmark of quality can only be achieved through the use of SOP.²⁰ In this era of higher technological

advancement, the majority of THs blood banks are still using manual temperature monitoring systems. This may result in storage at inappropriate temperature range with consequent infection or haemolysis.²¹

This study also found that the method of documentation and record keeping by many THs was mainly manual method, with very few of them using a computerized system of both data record and operational system in the blood bank. The study by Pondel *et al*, also reported poor documentation / record keeping in the blood banks.²² Poor documentation/ record keeping will lead to errors and missing data, among others.

Global health initiative reveals that, Nigeria with a population of about 200 million people requires a minimum of 1.8 million units of blood annually for blood security, to take care of her people.²³ However data from NBSC showed that only about 500,000 units of blood are collected annually leaving a shortfall of about 73.3%.²³ This study further affirms the above data where the majority of THs do experience acute out-of-stock of all types of blood or its components. It also showed that a significant number of patients in the hospital who need blood will not have access to it because they do not have donors. The common practice of family replacement of blood donation in Nigeria might be contributory. This, co-existing with a high cost of service fee per unit of blood will deny the majority of the less privileged patients access to blood or blood products. Significant mortality, including maternal and childhood mortality, do occur as a results of non-availability, accessibility and affordability of blood and blood components or products.²⁴ Report by the WHO showed that Nigeria and other sub-Saharan African countries have high maternal mortality rate and the commonest cause of mortality is obstetric haemorrhage with frequency of 28.8%.²⁵ Ineffective blood transfusion services has been reported to contribute significantly to maternal mortality due to obstetric haemorrhage.²⁶

CONCLUSION

There is poor blood security and blood transfusion management in majority of the THs in Nigeria with a gross shortage of blood supply thus contributing to the morbidity and mortality in life-threatening emergencies. These might be reversed if there is a comprehensive and functional blood transfusion management system in all THs, standardized uniform quality assurance system coordinated by NBSC, creation of a uniform data collecting tools and empowerment of NBSC in each state to ensure blood security

Roles of authors: GKU, NIU and IA conceived the study. GKU, IA, NIU, and TA designed the study protocol. BN, CTU, SA, HI, AJM and SY were responsible for the analysis and interpretation of data. GKU, NIU, IA, CLU, AH, and HO drafted the manuscript. AOU, TO, TIO, AA, ICA, POO, AK, TAE, JAO, BOB, OA, OEI, EO and OEN critically revised the manuscript for intellectual content. All authors participated in data collection, read and approved the final manuscript

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