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Research Article

Assessment of Quality Assurance Level and Compliance of Abia State Blood Banks to National Guideline on Blood Transfusion: A Multi-Centred Study

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Received Date: August 06, 2025 | **Accepted Date:** August 18, 2025 | **Published Date:** August 28, 2025

Citation: Uche CL, Ndukwe PE, Ngwudo S, Ndukwe CO, Chikezie K, et al., (2025), Assessment of Quality Assurance Level and Compliance of Abia State Blood Banks to National Guideline on Blood Transfusion: A Multi-Centred Study, *Journal of Clinical and Laboratory Research*, 8(4); **DOI:10.31579/2768-0487/186**

Abstract

Background: Ensuring quality assurance in blood transfusion services is essential for the safety and effectiveness of blood products. This study evaluates the quality assurance practices of blood bank units in healthcare institutions in Abia State, Nigeria.

Materials and Methods: A retrospective cross-sectional six-month retrospective study was conducted from November 2023 to February 2024 across 13 health facilities in Abia State, including both public and private institutions. The study spanned the three senatorial zones of Abia State: Abia North, Abia South, and Abia Central. Data were collected using a well-semi-structured pretested interviewer-administered questionnaire adapted from the National Blood Transfusion Service (NBTS) and blood bank records. Key areas of quality assurance, including the presence of Standard Operating Procedures (SOPs), dedicated staff, quality officers, and feedback mechanisms, were evaluated.

Results: The study revealed that only 30.8% of blood bank units had SOPs for all activities and procedures, and 7.7% had a Blood Transfusion Quality Officer. Furthermore, no health institution had a haemovigilance officer or a system for feedback and complaints from blood donors and recipients. A minority of the facilities (7.7%) were linked to the NBTS centre for blood activities. Internal quality assurance mechanisms were present in 76.9% of the facilities, but external quality assurance schemes were severely lacking (7.7%).

Conclusion: The quality assurance level in blood bank units in Abia State is suboptimal, with significant gaps in the presence of essential quality assurance components. Strengthening these areas is vital to improving the safety and effectiveness of blood transfusion services in the region.

Key words: quality assurance; blood bank; health institutions; abia state; sops; blood transfusion; nigeria

Introduction

Blood transfusion is critical to modern healthcare systems, saving millions of lives each year. The availability of safe and adequate blood is essential to support treatments for various medical conditions, including surgeries, cancer treatments, childbirth complications, and trauma care. However, blood and blood products' safety and quality are paramount to successful transfusions [1]. In many low- and middle-income countries (LMICs), including Nigeria, there are significant challenges in maintaining the safety and quality of blood due to gaps in regulatory frameworks, quality assurance (QA) systems, and compliance with national guidelines. In Nigeria, the National Blood Transfusion Service (NBTS) has developed guidelines aimed at standardizing blood donation, testing, processing, and transfusion practices across the country. These guidelines, encapsulated in the National Blood Policy and National Guidelines on Blood Transfusion, are designed to ensure that all blood banks operate under stringent safety standards to prevent the transmission of infectious diseases, such as HIV, hepatitis, and malaria, and to reduce the risk of adverse transfusion reactions [1]. Despite the existence of these guidelines, the level of compliance among blood banks across Nigeria remains inconsistent. Studies have shown that a significant number of blood banks, particularly in rural and underserved areas, may lack the infrastructure, technical expertise, and financial resources to fully adhere to national standards [2]. These challenges can compromise the safety of the blood supply and increase the risk of transfusion-related complications. Quality assurance (QA) in blood banking refers to the systematic monitoring and evaluation of all aspects of the blood donation and transfusion process to ensure compliance with national and international safety standards. It encompasses a wide range of activities, including donor selection, blood testing, component separation, storage, and the distribution of blood and blood products. Effective QA systems are designed to detect and prevent errors, ensure traceability, and minimize the risk of contamination or degradation of blood products [3]. The World Health Organization (WHO) emphasizes the importance of establishing comprehensive QA programs within national blood systems, particularly in LMICs, where the prevalence of transfusion-transmissible infections (TTIs) remains high [3]. In Nigeria, the NBTS has outlined specific QA protocols that blood banks must follow, including the mandatory testing of all blood units for HIV, hepatitis B and C, syphilis, and malaria, as well as the proper labelling, storage, and transportation of blood products [1]. Blood banks are also required to maintain detailed records of all blood donations and transfusions, conduct regular audits, and ensure that their staff are adequately trained. Compliance with the National Guidelines on Blood Transfusion is crucial to ensuring the safety and efficacy of blood transfusion services. In Nigeria, these guidelines are based on internationally accepted standards and cover a wide range of procedures, including donor recruitment and retention, blood collection, testing, processing, and transfusion practices [4]. However, the degree of compliance among blood banks in different states varies significantly. In Abia State, the performance of blood banks has come under increasing scrutiny, particularly concerning their adherence to national guidelines. Abia State, located in southeastern Nigeria, is home to a mix of public and private healthcare facilities, many of which operate blood banks. The effectiveness of these blood banks in ensuring the safety of blood products has been a matter of concern, as several reports suggest that compliance with the national guidelines is inconsistent [5]. Key areas where compliance has been problematic include the screening of blood for TTIs, proper storage and handling of blood products, and the implementation of QA protocols. A multi-centred study conducted in Lagos, Nigeria, revealed that while some blood banks adhered to the national guidelines, many private and smaller facilities failed to meet basic safety standards due to a lack of resources and trained personnel [6]. These findings raise concerns about the safety of blood transfusion services in other states, such as Abia, where similar systemic challenges are likely to exist. Given the critical role that blood banks play in public health, assessing the level of QA and compliance with national guidelines in Abia State is essential. This study aims to fill the gap in the literature by providing a comprehensive evaluation of blood banks across multiple centres in the state. By examining the extent to which these blood banks adhere to national guidelines, the study will provide valuable insights into the factors influencing compliance and the barriers that need to be addressed to improve blood safety. The findings of this study are expected to contribute to the ongoing efforts to strengthen Nigeria's blood transfusion system, particularly in regions with significant public health challenges. It will also provide evidence-based recommendations for policymakers, healthcare providers, and stakeholders on how to improve QA systems and ensure that all blood banks in Abia State meet national and international safety standards. The significance of this study lies in its potential to improve public health outcomes by enhancing the safety and quality of blood transfusions in Abia State. By identifying gaps in compliance and QA practices, the study will help to inform interventions aimed at strengthening the regulatory oversight of blood banks and improving the quality of care for patients requiring transfusions. Furthermore, the study's findings could serve as a benchmark for assessing blood bank performance in other regions of Nigeria and contribute to the broader discourse on healthcare quality improvement in the country.

Materials and methods

Study design

A cross-sectional six-month retrospective study was conducted in both Abia state public and private health institutions. Health facilities that met the inclusion and exclusion criteria were recruited in the study. The three Senatorial zones in Abia state were involved: Abia North, Abia South and Abia Central. Four to five health institutions that met the inclusion and exclusion criteria were recruited from each of the three senatorial zones respectively.

Study Area

Abia State is a state in the Southeast geopolitical zone of Nigeria, it is bordered to the north and northeast by the states of Enugu, and Ebonyi, Imo State to the west, Cross River State to the east, Akwa Ibom State to the southeast, and Rivers State to the south. Abia State occupies about 6,320 square kilometres of land with an estimated population of over 3,720,000 as of 2016. It has three Senatorial zones: Abia North, Abia South and Abia Central as shown in Appendix 2. Each senatorial zone consists of 6, 6, and 5 LGAs respectively. On the whole Abia state has a total of 17 Local govt. area (LGA). Abia state has about 200 registered hospitals and clinics.

Ethical Consideration

The ethical clearance for this study was obtained from the Health Research Ethics Committee (HREC) of the Federal Medical Centre Umuahia, Abia State with reference number FMC/QEH/.596./Vol.10/690.

Data Collection

A well-semi-structured pretested interviewer-administered questionnaire (adapted from the National Blood Transfusion, Ministry of Health) was used for the study. Blood bank records were used where necessary. Information was obtained from data covering January to June 2022. The data was collected between November 2023 and February 2024 in Health facilities in Abia State and a total of 13 health facilities were used.

i. Demographic data: The following information was collected under demographic data: Senatorial zone made up of Abia North, Abia South and Abia. Type of the Institutions (Secondary and tertiary), Specialty (multispecialty), Number of dedicated staff in the blood transfusion unit and presence of active blood transfusion committee. Sex and age distribution of donors were collected from all facilities.

ii. Quality assurance assessment: This was done using the following; the Presence of available SOPs for activities and procedures done in the blood, the presence of a blood transfusion quality officer, haemovigilance officer, a channel for feedback or complaints of blood donors and recipients, presence of standard monitoring and evaluation system in place, internal/ external quality assurance mechanism in place, if the hospital is linked to any NBTS centre for blood activities etc. (Table 2a, 2b, 2c). A total of 15 questions were obtained from each question. Each question attracted 0.66 point making a total of approximately 10 points. Score of 1-3points = poor, 4-6points = fair while >6points = good

iii. National Guideline on Blood Transfusion Services: Parameters used were: Voluntary non-remunerated donors, PCV screening, screening for Transfusion transmissible infection (TTI), Use of blood components, blood transfusion committee, haemovigilance officer, use of SOP, medically qualified Coordinator, Staff training, documentation of adverse transfusion reactions, storage of blood in the blood bank and records of deferrals. Total of thirteen parameters were used, and each parameter has a total of 10%. Hundred percent of the total scores from the 13 health Institutions numbered HI—H13 were calculated. The percentage scores gotten from table 3a. were used to assess the compliance level into as: very poor, poor, fair and good as shown in table 3b.

Statistical Analysis

Data was analyzed using the SPSS version 23 statistical package. Continuous variables were analyzed using descriptive (means, standard deviation, median) while categorical variables were analyzed in frequency and proportions.

Results

The sociodemographic distribution and institutional characteristics, as presented in Table 1, show a balanced distribution of healthcare institutions across the three senatorial zones in Abia State, with Abia Central slightly leading at 38.5%, followed by Abia North and Abia South, each at 30.8%. The majority of institutions surveyed are secondary healthcare facilities (77%), with a smaller proportion being tertiary institutions (23%). Regarding the blood transfusion units' staffing, only 23% of institutions have two or more dedicated staff members, indicating a potential understaffing issue in many units. Additionally, none of the institutions surveyed has an active blood transfusion committee, nor do they have a quality officer specifically assigned to blood issues. The absence of these critical components suggests a significant gap in ensuring quality and safety in blood transfusion practices across these institutions. Notably, 69.23% of institutions have a record-keeping system that can identify blood donors, although all records are maintained manually, with no computerized systems reported. Table 2 focuses on the quality assurance level within blood bank units. It highlights severe deficiencies, with 69.2% of institutions lacking Standard Operating Procedures (SOPs) for blood bank activities. A staggering 92.3% of institutions lack a Blood Transfusion Quality Officer, and none have a Haemovigilance Officer or a system for donor feedback and complaints, reflecting a lack of oversight and accountability in blood transfusion practices. While 76.9% of institutions report having an internal quality assurance mechanism, only 7.7% participate in an external quality assurance scheme. This lack of external validation further underscores the vulnerability of the current quality assurance practices. Additionally, only one institution (7.7%) is linked to the National Blood Transfusion Service (NBTS) for blood activities, which could limit the quality and safety of blood transfusion services across the state.

Senatorial Zone	Frequency	Percentage
Abia North	4	30.8
Abia South	4	30.8
Abia Central	5	38.4
Type of Institution		
Secondary	10	76.9
Tertiary	3	23.1
Specialty		
Monospecialty	0	0.0
Multispecialty	13	100.0
Number of dedicated staff per blood Bank		
One staff	7	53.8
Two staff	3	23.1
≥ 3 staff	3	23.1
Voluntary Blood Recruitment unit		
Yes	1	7.7
No	12	92.3

Blood bank record keeping technique		
Manual	9 or 13	100.0
Computerized	0 or 3	0.0

Table 1: Sociodemographic distribution and Institutional Characteristics.

Personnel/ Committee	Frequency	Percentage
Hospital Transfusion Committee		
Yes	1	7.7
No	13	92.3
Blood Transfusion Quality Officer		
Yes	1	7.7
No	12	92.3
Haemovigilance officer		
Yes	0	0
No	13	100
Do blood bank Personnels receive any training?		
Yes	6	46.2
No	7	53.8

Table 2a: Quality assurance: Key personnel.

	Frequency	Percentage
Existing quality management policy		
Yes	2	15.4
No	11	84.6
Existing quality assurance manual		
Yes		
No		
Availability of Standard Operating Procedures		
Yes	4	30.8
No	9	69.2
Blood Donor traceability record		
Yes	9	69.2
No	4	30.8
Are incident reports available?	0 13	0 100
Yes		
No		
Documentation of adverse effect		
Yes	0	0.0
No	13	100.0

Table 2b: Quality assurance: Documentation.

	Frequency	Percentage
Is there a channel for feedback or complaints from blood donors/recipents in Place?		
Yes	0	0
No	13	100.0
Is there a standard monitoring and evaluation system in place?		
Yes	0	0
No	13	100.0
Is there a quality assurance mechanism in place?		
Yes	10	76.9
No	3	23.1
Is there an external quality assurance programme in place?		

Yes	1	7.7
No	12	92.3
Is the hospital linked to any NBTS center for blood activities?		
Yes	1	7.7
No	12	92.3

Table 2C: Quality assurance: other processes.

Fifteen variables were used to assess Quality assurance levels in the Abia state health institution's blood bank. The majority of the health institutions had good internal quality assurance in place. However other aspects of the quality management system were suboptimal or nonexistent.

Variables	Frequency n= 13	Percentage (%)
Quality assurance level		
Poor (Score: 1 – 3 points)	12	92.3
Fair (Score: 4 – 6 points)	1	7.7
Good (Score: >6 points)	0	0

Table 2d: Quality Assurance Level.

Quality assurance levels in the Abia State Health Institution's blood bank are poor.

Variables	**Health Institutions (H)**												
	H1	**H2**	**H3**	**H4**	**H5**	**H6**	**H7**	**H8**	**H9**	**H10**	**H11**	**H12**	**H13**
Voluntary non-remunerated	0	5	0	10	0	5	0	0	0	0	0	0	0
PCV SCREENING	10	10	10	10	10	10	10	10	10	10	10	10	10
Screening for TTI with ELISA	0	0	0	0	0	0	0	0	0	0	0	0	0
Use of blood component	0	0	0	0	0	0	0	0	0	0	0	0	0
Blood transfusion committee	0	0	0	10	0	0	0	0	0	0	0	0	0
Haemovigilance Officer	0	0	0	0	0	0	0	0	0	0	0	0	0
Use of SOP	0	10	0	10	0	10	0	10	10	10	0	10	10
Medically qualified coordinator	0	0	0	0	0	0	0	0	0	0	0	0	0
Staff training	0	5	5	10	0	5	5	0	5	0	0	0	0
Documented adverse effect	0	0	0	0	0	0	0	0	0	0	0	0	0
Storage of blood in the standard blood bank	0	10	0	10	10	10	0	0	10	0	0	10	0
Deferrals	0	5	0	10	0	0	0	0	5	0	0	0	0
Total	10	45	15	70	20	35	15	20	40	20	10	30	20
Total (100%)	8.3	37.5	12.5	58.3	16.7	29.1	12.5	16.7	33.3	16.7	8.3	25	16.7

Table 3a: Compliance of Health Institutions to National Guideline on Blood Transfusion Services.

H= Health institution

Only one health institution had a total of 58.3%. None of the health Institutions used ELISA for screening. Two health institutions Practiced voluntary non-remunerated donation. Half of the health institutions did not use blood banks. None had medically qualified as a coordinator, none produced blood components, and no documented adverse blood transfusion reaction. Adherence concerning PCV screening and the use of SOP is good.

Variable	Score (%)	Frequency (n= 13)	Percentage (%)
Compliance level			
Very Poor	0-29.9	8	61.5
Poor	30- 49.9	4	30.7
Fair	50-69.9	1	7.7
Good	≥70	0	0

Table 3b: Compliance Level of the Health Facilities.

The table showed a very poor compliance level of the majority (61.5%) of health facilities in Abia state to National guidelines on blood transfusion services.

Discussion

A quality assurance (QA) programme is the sum of all activities and procedures undertaken by medical laboratories to improve the quality and

clinical usefulness of laboratory test results. Quality assurance includes training of personnel, purchase and maintenance of equipment and reagents, the analytical process itself, and reporting and interpretation of results. The present study discovered that non-availability of standard operating procedure (SOP) for all activities in the blood bank was found in about 69% of the health Institutions. A multi-centred study conducted in south-south Nigeria amongst 80 medical laboratories showed that only 45% of medical laboratories used SOP [7]. However, a study done in Kenya listed workload, inadequate number of staff and long working hours as determinants of adherence to standard operating procedure among laboratory personnel and adduced that factors that promote adherence to SOPs are professional education, leadership factors, and work environment and suggested professional education and leadership for the sustenance of intervention [8]. SOPs are written step-by-step instructions on how to carry out procedures correctly. SOPs are meant to ensure consistency, accuracy, and quality of data. SOPs harmonize laboratory practices, reduce user errors, and can be used as training tools. Moreover, they help ensure compliance with the study protocol, regulations, and international standards. SOPs are the main building blocks of a laboratory quality assurance framework and as such, failure to use it is a recipe for unreliable and poor-quality results that may lead to wrong diagnoses and treatment. Surprisingly, this study revealed that no health institution had a Haemovigilant officer, no standard monitoring and Evaluation system in place and only one health Institution had a quality officer, the same health institution participated in the external quality assurance process and also received blood from the regional branch of National blood transfusion service (NBTS) and had blood transfusion committee (7.7%) in place. Haemovigilance is defined as the surveillance of adverse reactions occurring in donors and in recipients of blood components and as epidemiological surveillance of donors. The ultimate purpose of haemovigilance is to prevent the repetition of adverse events and reactions [9]. The practice of haemovigilance in this country has been a concern, Aneke et al [10] study showed that the practice of key elements of haemovigilance was suboptimal among health professionals. The lack of well-coordinated haemovigilance practices in the whole state even in the country at large is very worrisome, there is therefore need for a state and national level of registration of severe adverse reactions connected with the collection, processing and storage of blood and blood components, hence the need for well-coordinated hemovigilance office A Hospital Blood Transfusion Committee (HBTC) is a governance body established within the hospital to ensure appropriate blood product use, audit blood use, and monitor and prevent adverse events by developing local policies and educating clinicians [11]. World Health Organization recommends “Blood transfusion committee should be established in each hospital to implement the national policy and guidelines and monitor the use of blood and blood product at the local level” [12]. The primary goal of HBTC is to promote the safe and effective use of blood and blood components. Only one health institution in Abia state had a blood transfusion committee. This is glossily unacceptable as quality is sacrificed. To buttress the importance of blood transfusion, a multicentered study done in South-South Nigeria showed that established transfusion committees were present in 63.4% of the services visited and transfusion incidents were reported by 53 (36.8%) transfusion services with transfusion committees and eight (9.6%) without transfusion. The study revealed that the incidence of notification and investigation of the causes of transfusion reactions was higher in transfusion services where a transfusion committee was present [7]. This is an eye-opener that the lack of a blood transfusion committee in Abia state must have hidden a lot of data that should have served as a recipe for change. There is therefore a need for a clarion call for complete overhauling of Abia state blood transfusion practices, the need for the establishment of a hospital blood transfusion committee followed by intensive training and monitoring through the process of monitoring and evaluation. Participation in external quality assurance (EQA) is quite low as only one health institution participated. A similar scenario was seen with regard to participation in external quality assessment (EQA) schemes where 9 out of 88 laboratories were under study. This state of practice is not consistent with international quality management best practices and is certainly undesirable for blood transfusion practices this 21st century. However, 76.9% of the Health Institutions practice internal quality assurance mechanisms. This is similar to a multi-centred study where 88% of laboratories adhered to quality control even though they could not show a quality control chart [7]. The National blood policy, for ease of availability, accessibility and affordability, structured blood transfusion services in Nigeria under the following strata: (i) the national blood transfusion service (NBTS), (ii) the zonal blood service centres, (iii) state and local government areas blood service centres, (iv) the armed forces blood service, and (v) private and other nongovernmental health establishments. The above stratification aimed to ensure universal coverage of the country, from National to local government councils [13]. This present study showed that only 7.7% (1) of the health institutions had a link with the National Blood Transfusion Service (NBTS). This finding had totally defeated the aim of this establishment. The reason given by some health Institutions during the Interview includes poor accessibility because of the distance, not being sure of the availability of blood and lack of awareness. The regional or zonal arm of National Blood Transfusion Services resides at Owerri (Imo State) which is very far from the majority of Health Institutions in Abia State. The need for the establishment of a state arm of the National blood transfusion service is inevitable. This will enhance easier coordination. Holistically, the quality assurance level in Abia state blood transfusion services was found to be poor. The importance of quality assurance in the blood bank cannot be over-emphasized as without a good quality management system in place in the blood bank all the results emanating from it cannot be guaranteed.

Conclusion

The assessment of the quality assurance level of blood bank units in health institutions across Abia State, Nigeria, reveals significant deficiencies in adherence to standard quality practices. The study highlights that the majority of institutions, particularly secondary health facilities, lack the necessary infrastructure, personnel, and standard operating procedures (SOPs) to ensure high-quality blood transfusion services. Key findings include the absence of dedicated blood transfusion quality officers, haemovigilance officers, and effective monitoring and evaluation systems across all surveyed institutions. Additionally, the lack of external quality assurance schemes and the absence of hospital transfusion committees further underscore the challenges faced by these institutions in maintaining optimal blood transfusion practices. The overall quality assurance level in the majority of the blood bank units was found to be poor, posing potential risks to patient safety and the efficacy of blood transfusion services in the state.

Recommendations

1. **Implementation of Standard Operating Procedures (SOPs**): Health institutions in Abia State should prioritize the development and implementation of comprehensive SOPs for all activities and procedures in blood bank units. This will ensure consistency, safety, and compliance with best practices.
2. **Appointment of Dedicated Quality Officers:** The state health authorities should mandate the appointment of blood transfusion

quality officers and haemovigilance officers in all health institutions to oversee and ensure the quality and safety of blood transfusion services.

3. **Establishment of Active Blood Transfusion Committees:** Health institutions should establish and maintain active blood transfusion committees to provide oversight, ensure adherence to protocols, and address issues related to blood transfusion practices.
4. **Strengthening Internal and External Quality Assurance Mechanisms:** Health facilities should be linked to external quality assurance schemes, and robust internal quality assurance mechanisms should be developed and regularly reviewed to enhance the reliability and safety of blood transfusion services.
5. **Enhancing Training and Capacity Building:** Continuous training programs should be conducted for all staff involved in blood transfusion services to enhance their knowledge and skills in quality assurance and patient safety.
6. **Integration with the National Blood Transfusion Service (NBTS):** Efforts should be made to link more hospitals with the National Blood Transfusion Service to improve the quality of blood products and ensure compliance with national standards.
7. **Development of Feedback and Monitoring Systems:** Health institutions should develop and implement channels for feedback and complaints from blood donors and recipients, along with standard monitoring and evaluation systems to continuously improve blood transfusion practices.

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DOI:10.31579/2768-0487/186