FIRST GHANA HAEMOVIGILANCE REPORT 2025

National Blood Service | Food and Drugs Authority

June 2025

Privacy statement

This report does not aim to identify individual patients, clinicians, blood establishments or healthcare institutions. Every reasonable effort has been made to ensure their anonymity.

Comments and questions should be referred to the National Blood Service on 0302 663 701, 0302 663 702 or at info@nbs.gov.gh or the Food and Drugs Authority on +233 (0)3022 35100 or at fda@fda.gov.gh.

Disclaimer

This document is a general report designed to provide healthcare professionals and the public with an overview of blood donation- and transfusion-related adverse events in Ghana.

The information, data, and analysis presented offer a snapshot of currently available resources. However, the data are derived from limited sources, are neither comprehensive nor complete in many cases, and may not have undergone validation.

Contents

Abbreviations & Acronyms

ABRs	Adverse Blood Reactions
AEs	Adverse Events
ARs	Adverse Reactions
BCI	Blood Collection Index
BCUs	Blood Collection Units
BSIS	Blood Safety Information System
DARs	Donor Adverse Reactions
DHIMS2	District Health Information Management System II
FDA	Food and Drugs Authority
FFP	Fresh Frozen Plasma
GARBC	Greater Accra Regional Blood Centre
GDP	Good Distribution Practice
GMP	Good Manufacturing Practice
GPP	Good Preparation Practice
GSP	Good Storage Practice
HBBs	Hospital Blood Banks
HBV	Hepatitis B Virus
HCPs	Healthcare Professionals
HCV	Hepatitis C Virus
HIV 1 & 2	Human Immunodeficiency Virus
ICP	Institutional Contact Person
NBS	National Blood Service
NBS-HQ	NBS Headquarters
NHO	National Haemovigilance Office
PEI	Paul-Ehrlich-Institut
PDMPs	Plasma-Derived Medicinal Products
PTP	Post-Transfusion Purpura
RAS	Rapid Alert System
RBC	Red Blood Cells
RBCs	Regional Blood Centres
SABRs	Severe ABRs
SAEs	Serious Adverse Events
SARs	Serious Adverse Reactions
SOPs	Standard Operating Procedures
TAC-VBP	Technical Advisory Committee on Safety of Vaccines and Biological Products
TAD	Transfusion-Associated Dyspnea
TRALI	Transfusion-Related Acute Lung Injury
TTIs	Transfusion-Transmissible Infections
WHO	World Health Organization

Definitions

(AE) reporting	Sending information on adverse events to the haemovigilance system for further investigation, analysis and feedback.
Adverse event (AE)	Any undesirable or unintended occurrence associated with transfusion or donation. It includes all adverse reactions, incidents, near misses, errors, deviations from standard operating procedures and accidents.
Adverse reaction (AR)	Any unintended response in donor or patient associated with the collection or transfusion of blood or blood products.
Blood collection	The procedure whereby a single donation of blood is collected in an anticoagulant and/or stabilizing solution, under conditions designed to minimize microbial contamination, cellular damage and/or coagulation activation of the resulting blood donation.
Blood component	A constituent of blood (erythrocytes, leukocytes, platelets, cryoprecipitate and plasma) that can be prepared by various separation methods and under such conditions that it can be used either directly for therapeutic purposes or for further processing/manufacturing.
Blood establishment (BE)	Any structure, facility or body that is responsible for any aspect of the collection, testing, processing, storage, release and/or distribution of human blood or blood products when intended for transfusion or further industrial manufacturing.
Regional Blood Centre	The main operational wing of the NBS responsible for blood donor education and management, collection of blood, donation and confirmatory testing, processing, storage and issue to hospital blood banks, blood banks, blood collection units, other blood centres or for further manufacture.
Blood collection Unit	A hospital unit that is under the supervision of the NBS responsible for blood donor education and management, the collection of blood from donors and any other function authorised by the NBS.
Blood products	Any therapeutic substances derived from human blood, including whole blood and blood components.
Blood Related Adverse Event	A blood related adverse event is an incident and/or reaction in which harm resulted, or potentially could have resulted, from the transfusion/administration of a blood product.
Corrective action	Action taken to eliminate the cause of a detected nonconformity or other undesirable situation.
Blood Donor	A person in defined good health conditions who donates blood or blood components, including plasma for fractionation.

Haemovigilance	Haemovigilance is a set of surveillance procedures covering the entire transfusion chain, from the donation and processing of blood and its components, to their provision and transfusion to patients and their follow-up. It includes the monitoring, reporting, investigation and analysis of adverse events related to the donation, processing and transfusion of blood, and taking actions to prevent their occurrence or recurrence.
Haemovigilance feedback report	Report of aggregated analysed data from the haemovigilance system.
Imputability	The likelihood that a serious adverse reaction in a recipient can be attributed to the blood or blood component transfused or that a serious adverse reaction in a donor can be attributed to the donation process.
Incident	Any untoward occurrence associated with an activity or process, such as the collection, testing, processing, storage and distribution of blood and blood products, or in the transfusion or administration.
Incorrect blood component transfused (IBCT)	All events related to IBCT must be included in haemovigilance reporting, even if the event did not result in injury or damage.
Look-back	The process of investigation on the fate of recipients of previously donated blood or blood products resulting from a report that the donation may have presented a risk of transmission of infection (donor to receiver).
Manufacture	All operational processes or steps — including purchase or selection of materials and products, production, quality control, release, storage and distribution of products and the related controls — used to produce a blood product. This includes also the donation process.
Near miss	An error or deviation from standard procedures or policies which, if undetected, could result in the determination of a wrong blood group or issue, collection or administration of an incorrect, inappropriate or unsuitable component, but which was recognized before the transfusion took place.
Notification	Mandatory information on a notifiable event to the regulatory authority.
Preventive action	Action taken to eliminate the cause of a potential nonconformity or other potential undesirable situation.
Quality management system	A management system that directs and controls an organisation with respect to quality and that ensures that steps, processes, procedures and policies related to quality activities are being followed
Serious Adverse Event	Serious adverse events are those that might have led to death or life-threatening, disabling or incapacitating conditions for recipients or

	donors, or which might have resulted in prolonged hospitalization or morbidity.
Serious Adverse Reaction	Unintended response in donor or in recipient associated with the collection or transfusion of blood or blood products that is fatal, life-threatening, disabling, incapacitating, or which results in, or prolongs hospitalization or morbidity.
Traceability	The ability to reliably follow the information trail from donor to recipient and vice versa in a timely manner. Traceability is essential to ensure the ability to recall at-risk products, to identify recipients of non-conforming products that may require additional follow-up, and to fully investigate adverse events.
Trace-back	The process of investigating a report of a suspected transfusion-associated adverse reaction in a recipient to identify a potentially implicated donor (receiver to donor).
Transfusing facility	Healthcare facilities where blood and blood products are transfused to patients.
Transfusion reaction	A transfusion reaction refers to an undesirable response to a transfusion, which may or may not be a result of a clinical incident depending on the nature of the event.

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Message from the Chief Executive Officer of the National Blood Service - Dr. Shirley Owusu-Ofori

The transfusion of blood and blood products remain an essential, life-saving intervention in the health sector. However, as with all medical interventions, transfusion comes with inherent risks to both donors and recipients. As the National Blood Service (NBS), our mandate goes beyond simply collecting and supplying blood products. We are committed to ensuring that every unit of blood collected, processed, and issued meets the highest standards of safety and quality. Haemovigilance is at the heart of this commitment.

The role of the NBS in haemovigilance is therefore key and central. In collaboration with the Food and Drugs Authority (FDA), we have embraced haemovigilance as a critical component of transfusion safety, an essential system that allows us to monitor, detect, analyze, and respond to adverse events and near misses, with the ultimate goal of protecting both blood donors and recipients.

The joint efforts between NBS, FDA, and our partners, especially the Paul-Ehrlich-Institut (PEI), led to the successful launch of Ghana's Haemovigilance Guidelines and Framework in 2022. This landmark achievement provides structured pathways for incident reporting and encourages a culture of safety and accountability within the health system.

Despite this progress, we recognize the challenges we continue to face, including underreporting of adverse events, inconsistent documentation, and limited technical capacity for healthcare workers involved in blood donation and transfusion processes. Moving forward, we are committed to deepening collaboration with the FDA and other key stakeholders to strengthen Ghana's haemovigilance system. We are working to enhance awareness among health professionals at all levels, integrate digital systems to simplify and standardize haemovigilance reporting, foster a non-punitive culture that encourages transparent reporting and learning from every event and improve our data systems to allow for timely analysis, feedback, and quality improvements across the transfusion chain.

Together, we envision a robust, responsive, and transparent haemovigilance system that protects the safety of every blood donor and every patient who relies on blood transfusion in Ghana. Let us continue to work collaboratively, innovatively, and with unwavering commitment to ensure that our nation's blood supply remains safe, effective, and trusted by all who depend on it.

Thank you.

Message from the Chief Executive Officer of the Food and Drugs Authority - Dr. Delese Mimi Darko

Blood transfusion and the use of blood and blood products are essential, life-saving medical interventions, especially during emergencies. However, just like all medical interventions, it comes with some level of risks to donors and recipients.

The Food and Drugs Authority (FDA) and the National Blood Service (NBS) have recognized that ensuring the safety, quality, and efficacy of blood and blood products is not just a medical necessity but a national health priority.

The two agencies, over the years, have collaborated to develop regulatory guidelines for registering Plasma-Derived Medicinal Products (PDMPs), for licensing of blood facilities and the listing of blood and blood components in Ghana. Guidelines have also been developed for inspection and compliance monitoring of blood facilities and other facilities in the blood supply chain. These guidance documents are being implemented to ensure that good quality, efficacious and safe blood and blood products are available to Ghanaians.

Haemovigilance is a necessary component of the blood transfusion service to reduce potential adverse events in donors and recipients of blood and blood components. Ghana is proud to be one of the few African countries with a comprehensive regulatory framework covering all aspects of blood regulation.

We are especially grateful for the continued support from the Paul-Ehrlich-Institut (PEI), which has worked with us over the years, leading the launch of the Guidelines for Haemovigilance and the Framework in 2022. These documents were aimed at establishing the framework for haemovigilance and enhanced patient safety and promoting a culture of vigilance within the Ghanaian healthcare settings.

Nonetheless, challenges persist, including underreporting, incomplete documentation, and limited training. Moving forward, the FDA will continue to work with the NBS and other partners to strengthen the reporting systems, improve training at all levels of the blood transfusion chain and use technology for reporting and management of donor and recipient reactions.

We remain committed to fostering a culture of safety, collaboration, and continuous improvement. By working together, we can ensure that every unit of blood collected and transfused in Ghana meets the highest standards of safety and quality.

Executive Summary

The ***First Ghana Haemovigilance Report 2025*** marks a pivotal step in strengthening blood transfusion safety and accountability across Ghana's health systems. Jointly produced by the National Blood Service (NBS) and the Food and Drugs Authority (FDA), this report documents adverse events (AEs) and adverse reactions (ARs) in blood donation and transfusion and assesses the performance of Ghana's haemovigilance system from 2022 to 2024.

The report highlights substantial progress, including the establishment of a national haemovigilance system, the introduction of key regulatory frameworks in 2022, and the rollout of capacity-building programs. Yet, critical challenges remain. These setbacks include persistent under-reporting, poor documentation, low voluntary blood donation rates (~30%), and suboptimal separation of whole blood into components (26.7% vs. 70% target). Ghana's blood collection index (BCI) remains below WHO's threshold of 10 units per 1,000 population, reaching 6.0 in 2024.

Nearly 4,000 donor adverse reactions were reported over the period, with higher rates at hospital-based collection sites. Only 101 transfusion-related reactions were properly documented with case reports over the three years; likely due to lack of awareness and knowledge of the reporting requirements and system and limited reporting infrastructure. Discard rates due to TTIs, expiry, and quality concerns also highlight gaps in inventory and quality management.

To address these challenges, the report calls for practical, evidence-based reforms: mandating AE/AR reporting, expanding digital systems, enhancing donor recruitment and retention strategies, institutionalizing hospital transfusion committees, and scaling staff training. Strategic investment in technology, infrastructure, and data systems is critical to building a safe, sustainable, and trusted blood supply.

This first report offers a blueprint for operational excellence, improved patient safety, and a resilient national blood system rooted in transparency, traceability, and continuous quality improvement.

1 Introduction

Haemovigilance is a critical component of quality management in the blood transfusion process and is essential for continually improving the safety and quality of blood products. The haemovigilance system in Ghana is a collaborative effort between the National Blood Service (NBS) and the Food and Drugs Authority (FDA), both institutions of the Ministry of Health. This system aims to monitor, collect, and analyze data on adverse events and reactions related to blood donation and transfusion. This data is used to improve transfusion practices, inform health policies, and ultimately enhance patient safety in Ghana.

1.1 Scope of Haemovigilance

The scope of haemovigilance in Ghana encompasses all adverse events (AE) and adverse reactions (AR) that occur throughout the blood value chain for blood and blood products. This includes events related to blood donation and transfusion, from donor syncopal events to transfusion-transmitted infections, immunological complications, non-immunological transfusion reactions, near-misses, and other incidents. Specifically, the haemovigilance system in Ghana covers:

- Blood donors, including adverse donor reactions, look-back, and trace-back procedures.
- Processes including manufacturing, collection, handling, processing, storage, distribution, and transport.
- Blood products such as red blood cells (RBC), platelets, fresh frozen plasma (FFP), whole blood, and cryoprecipitate.
- Blood recipient adverse reactions of all severities, incidents, and near misses related to transfusions.

The haemovigilance system does not cover adverse reactions to Plasma-Derived Medicinal Products (PDMPs), such as Human Immunoglobulin.

1.2 Risks of Blood Services and Transfusion Practices in Ghana

The processes within the transfusion chain carry risks for transfusion recipients, blood donors, and healthcare personnel. Some of the risks include:

- Adverse donor reactions, including vasovagal reactions, hematomas, and nerve injuries.
- Transfusion-Transmitted Infections (TTIs), such as HIV, Hepatitis B, Hepatitis C, and Syphilis.
- Errors in obtaining and labeling blood samples, requesting, storage, collection and administration of blood.

- Immunological and non-immunological transfusion reactions.

The key priority focus areas for the haemovigilance system and the broader blood programme in Ghana are to:

- ❖ Strengthen leadership and governance in safe and adequate blood supply.
- ❖ Ensure access to safe and adequate blood and blood products and related services in Ghana.
- ❖ Improve blood donation and transfusion standards and practices.
- ❖ Increase the safety and quality of the entire blood transfusion and blood donation process in Ghana.
- ❖ Inform health policy in Ghana.
- ❖ Provide training and education to healthcare professionals on transfusion safety and the importance of reporting adverse events.
- ❖ Establish a well-functioning surveillance of all processes involved in the blood transfusion chain.
- ❖ Collect data on adverse reactions and adverse events of blood transfusions and blood donations.
- ❖ Use collected data for regulatory feedback to increase the overall safety of transfusion.
- ❖ Promote extensive reporting of incidents by creating a "no blame" environment to facilitate reporting and investigation.
- ❖ Achieve a sustainable national supply of safe blood that relies on 100% voluntary unpaid blood donations.

1.3 Key Players in the Blood Transfusion Chain

Several key players contribute to the standards of blood transfusion services in Ghana. Ghana's Ministry of Health holds ultimate responsibility for ensuring blood safety and sufficiency in Ghana. It secures government support for the national blood programme, provides policy direction, and ensures adequate human and financial resources for a sustainable and safe blood supply system. The NBS, an agency under the Ministry, coordinates efforts to provide safe and adequate blood and blood products while designing and maintaining the national haemovigilance system in collaboration with the FDA. The FDA, as the national blood regulatory authority, oversees the regulation of blood and blood products, ensuring their manufacture, supply, and use meet safety standards while collaborating with the NBS on haemovigilance.

At the operational level, Regional Blood Centres (RBCs) report directly to the National Haemovigilance Office (NHO) which is located at the NBS. The RBCs also forward reports received from blood establishments and transfusing facilities to the NHO. The NHO then forwards these reports to the FDA within 24 hours of receipt.

Blood Collection Units (BCUs) and transfusing facilities are mandated to report serious adverse events (SAEs) and serious adverse reactions (SARs) promptly, with healthcare professionals (HCPs) playing a critical role in identifying and reporting these occurrences. These layers of collaboration ensure an effective haemovigilance programme, enabling a coordinated national approach to blood safety and quality.

The haemovigilance system in Ghana aims to provide a framework for the delivery of blood services and to promote the rational use of safe blood and blood components in all healthcare facilities nationwide. Through continuous monitoring, analysis, and feedback, the system seeks to enhance blood safety and ultimately contribute to a healthier Ghanaian population.

2 Background to Blood Supply Safety and Quality in Ghana

Haemovigilance is a critical component of quality management in the blood transfusion process and is essential for continually improving the safety and quality of blood products. The haemovigilance system in Ghana is a collaborative effort between the NBS and the FDA. This system aims to monitor, collect, and analyze data on adverse events and reactions related to blood donation and transfusion. This data is used to improve transfusion practices, inform health policies, and ultimately enhance patient safety in Ghana.

2.1 Blood Supply Safety and Quality in Ghana

The NBS is dedicated to ensuring access to safe and adequate blood and blood products in Ghana. Its mission is to provide a reliable and efficient supply of blood while prioritizing the well-being of both blood donors and recipients. Recognizing the importance of voluntary unpaid blood donations, as recommended by the World Health Organization (WHO), the NBSG is actively working to transition Ghana's reliance on family replacement donations, which accounted for approximately 70% of donors in 2024, toward a system founded on voluntary unpaid blood donations from low-risk populations.

Ghana's blood collection index (BCI) remains below the WHO-recommended threshold of 10 units per 1,000 population to meet basic transfusion needs, with a BCI of 5.9 in 2023 and 6.0 in 2024. Currently, only about 48% of donated blood are processed into blood components at the three Blood Centres of the NBSG in Accra, Kumasi and Tamale. The NBS aims to increase this to 70% in the near future. To ensure safety, all donated blood undergoes mandatory testing for HIV, Hepatitis B, Hepatitis C, and Syphilis, in line with WHO guidelines.

The NBS works in close collaboration with the FDA. The FDA regulates blood establishments, blood and blood products by inspecting and licensing all blood establishments and listing of blood/blood components as well as granting marketing authorization of blood products. The NBS is the agency mandated for collection of blood from voluntary unpaid blood donors, ensuring that donated blood is tested and processed, stored, distributed and transported appropriately. The NBSG is responsible for inspecting and accrediting HBBs to receive, store, and conduct compatibility testing on blood and blood components. To further enhance safety and efficiency, a Blood Safety Information System (BSIS) has been implemented at the Greater Accra Regional Blood Centre (GARBC), enabling improved traceability and oversight of blood supplies. Through

these efforts, the NBS is committed to building a more robust and sustainable blood supply system in Ghana.

2.2 Relationships, Roles and Responsibilities in Ghana's Blood Programme

The **Ministry of Health** is ultimately responsible for blood services in Ghana. It is responsible for the quality, safety, and sufficiency of the supply of blood and blood products and for securing government commitment and support for the National Blood Programme. The Ministry also provides policy direction towards the attainment of a sustainable supply of safe and adequate blood and blood components.

The **National Blood Service Ghana** is an agency of the Ministry of Health and is tasked with ensuring an effective and coordinated national approach to the provision of safe, adequate, and efficacious blood and blood products. The NBS comprises a Headquarters and three RBCs located in Accra, Kumasi and Tamale. The NBS operates a near-nationally coordinated program to improve access to safe and adequate blood and blood products. The NBS also designs, maintains and reviews the national haemovigilance system in collaboration with the FDA.

The **Food and Drugs Authority** is the national blood regulatory authority that regulates the manufacture, importation, exportation, supply, and possession of blood and blood products. The FDA also collaborates with the NBS to establish and maintain the national haemovigilance system. The FDA is responsible for amending and updating the imputability, outcome severity scoring system and list of reportable additional data to align with changes at the national level.

Regional Blood Centres collect and distribute blood and blood components to Hospital Blood Banks (HBBs) to ensure the timely accessibility of blood. RBCs report donor adverse events directly to the NHO at the NBS Headquarters (NBS-HQ) and forward reports received from blood establishments and transfusing facilities.

Blood Collection Units are required to report all SAEs and serious adverse reactions (SARs) to their Regional Blood Centres within 24 hours. They must also report all other adverse events (AEs) and adverse reactions (ARs) to the NBS via their RBCs within a month.

Transfusing facilities and hospitals are encouraged to participate in haemovigilance activities by reporting all AEs and ARs. They are also responsible for reporting all suspected SAEs and SARs to the Blood Establishment that the transfused unit originated from in real-time and all other AEs and ARs to the NBS via their RBCs within a month.

Healthcare Professionals in transfusing facilities and HBBs are responsible for stopping blood transfusion in the case of a suspected adverse reaction and ensuring same is investigated. They must also report AEs/ARs occurring in a blood recipient or post-transfusion information without delay to the designated Institutional Contact Person (ICP). At the RBC, Healthcare Professionals are responsible for stopping blood collection in the case of suspected donor reaction and reporting all adverse donor events to the haemovigilance officer.

2.3 Governance and Regulatory Environment

Blood services in Ghana operate under the National Blood Service Act, 2020 (Act 1042), which provides the legislative foundation for blood safety and management. Additionally, the regulation of medicinal products, including blood and blood products, is governed by the Public Health Act of 2012 (Act 851). The regulatory framework for blood, blood components, and blood products establishes guidelines for the licensing of blood facilities and mandates the reporting of all SAEs and SARs to ensure accountability and safety.

The National Haemovigilance Framework outlines the organization and management of haemovigilance activities related to blood and blood products in Ghana. While reporting haemovigilance data to the NHO/NBS and the FDA is voluntary for transfusing facilities and HBBs, all such entities, including RBCs, are strongly encouraged to participate. This includes reporting all adverse events and reactions to strengthen the haemovigilance system and improve patient safety.

2.4 Blood Collection and Transfusion Risks in Ghana

Blood collection in Ghana faces several risks that can impact the safety and adequacy of the blood supply, as well as the well-being of blood donors. One major challenge is the reliance on family replacement donations, which accounted for about 70% of donations in 2024. This practice is associated with higher risks of TTIs compared to voluntary unpaid donations and could underreport health risks to meet the immediate need. Despite efforts by the NBS to transition to a safer system of voluntary unpaid donations, this shift remains a work in progress.

Another risk stems from logistical and resource limitations in blood collection processes. Many RBCs and BCUs face inadequate infrastructure, equipment shortages, and limited access to modern technologies for donor screening and blood testing. These limitations increase the likelihood of errors in donor eligibility assessments and the processing of donated blood.

Additionally, the blood collection index in Ghana remains below the WHO recommendation of 10 units per 1000 population, creating a risk of shortages and an inability to meet basic transfusion needs.

These challenges are compounded by the voluntary nature of donor vigilance reporting in some facilities, which may lead to underreporting of adverse events and hinder efforts to improve the safety and efficiency of blood collection processes. Addressing these risks requires enhanced donor recruitment strategies, investment in infrastructure and technologies, and a stronger culture of haemovigilance and quality assurance across the blood value chain.

Blood donation, while generally safe, carries potential risks and adverse reactions for blood donors. One common reaction is a vasovagal response, which may cause discomfort, weakness, light-headedness, nausea, or even loss of consciousness. These reactions can occur before, during, or after phlebotomy, with delayed vasovagal reactions sometimes arising after the donor has left the collection site. Proper donor care, including hydration, monitoring, and supportive measures, is essential to minimize the likelihood of these reactions.

Other potential complications include physical issues such as re-bleeding from the venipuncture site, arteriovenous fistula (an acquired connection between a vein and artery), or brachial artery pseudoaneurysm (blood pooling outside an artery). Donors may also experience thrombophlebitis (inflammation of the vein), cellulitis (infection of the soft tissues), or nerve injuries, which can lead to pain, swelling, tingling sensations, or even partial paralysis in the affected arm.

Blood transfusions in Ghana are associated with several risks, particularly due to errors in the transfusion process, TTIs, and adverse transfusion reactions. Process errors, such as incorrect labelling of blood samples, mistakes in requesting or storing blood, and the administration of ABO-incompatible red cells, pose significant risks to patients and are among the leading causes of fatal transfusion reactions. These errors underscore the need for robust systems to improve accuracy and prevent mishandling of blood products during collection, storage, and administration.

Transfusion-transmissible infections remain a concern, as up to 5% or more of blood and blood components may be infected with agents such as HIV, Hepatitis B and C viruses, and Syphilis[1].

[1] Gebreyes DS, Kifetew K, Gizaw A, Abebe TA, Shenkutie TT, Genetu D, Yitayew B, Hailu A. Prevalence and Risk Factors of Transfusion-Transmissible Infections Among Voluntary Blood Donors in North Shoa, Amhara Region, Ethiopia: A Cross-Sectional Study. Health Sci Rep. 2025 May 5;8(5):e70769. doi: 10.1002/hsr2.70769. PMID: 40330765; PMCID: PMC12051436.

Although all donated blood in Ghana is tested for these infections, the risk persists, highlighting the importance of strengthening donor screening processes. Additionally, recipients face the risk of adverse transfusion reactions, both immunological and non-immunological, such as transfusion-related acute lung injury (TRALI), post-transfusion purpura (PTP), and bacterial infections. Other complications include hemolysis, generalized allergic reactions, and transfusion-associated dyspnea (TAD). These risks emphasize the importance of adherence to haemovigilance protocols, proper testing, and comprehensive monitoring to ensure transfusion safety.

2.5 Impact of Blood-Related Adverse Events

Blood transfusion is a vital therapeutic intervention that saves lives during acute emergencies, enhances the quality of life for patients with chronic conditions, and enables the success of complex medical and surgical procedures. However, adverse events and reactions within the blood transfusion chain pose significant risks to transfusion recipients, blood donors, and healthcare personnel. Addressing these risks is essential for ensuring the safety and efficacy of blood and blood products.

Haemovigilance plays a critical role in quality management across the blood value chain, serving as a cornerstone for the continual improvement of blood product safety and the transfusion process. In Ghana, the goal of haemovigilance is to establish a robust surveillance system that monitors all processes within the blood transfusion chain. This involves the systematic collection and analysis of data to generate actionable insights for regulatory feedback, thereby enhancing safety standards. Central to this effort is a culture of extensive incident reporting, supported by a “no blame” or “no punishment” framework. This approach encourages open reporting, thorough analysis, and constructive feedback to strengthen the safety and reliability of blood and blood products.

3 Strengthening the Haemovigilance System in Ghana

The NBS and the FDA are the two agencies responsible for establishing and maintaining the haemovigilance system in Ghana.

3.1 Establishment of a National Haemovigilance System

A national haemovigilance system has been established in Ghana to monitor blood collection- and transfusion-related AEs and ARs, encompassing all activities of the blood transfusion chain, from blood donors to transfused patients. The establishment commenced with the development and launch of two strategic documents, the **National Haemovigilance Framework for Ghana** and **Guidelines for Haemovigilance in Ghana** in 2022. The haemovigilance system in Ghana includes a Rapid Alert System (RAS) for the dissemination of information on important events, emerging hazards or trends.

The haemovigilance system includes surveillance, feedback, and actions in response to adverse events and adverse reactions in both donors and recipients. It relies on well-organized reporting structures and defined roles and responsibilities to enable the efficient involvement of all stakeholders. The system covers the manufacturing process, from blood donation to the issue of a blood product for transfusion, as well as its transfusion. The Technical Advisory Committee on Safety of Vaccines and Biological Products (TAC-VBP), an independent committee of the FDA, carries out the imputability of selected adverse events and reaction reports received and recommends appropriate regulatory action. The NBSG collaborates with the FDA and other stakeholders to establish, maintain, and review the national haemovigilance system.

3.2 Reporting and Data Management

The provision of haemovigilance data to the NHO (NBS) and the FDA is voluntary for transfusing facilities and HBBs. Standardized reporting forms have been developed to be used by transfusing facilities and blood establishments to report AEs and ARs. The following forms have been developed:

- Ward transfusion record, initial AR record
- Ward transfusion reaction investigation record
- Suspected TTI/Trace-back
- Donor Look-back - Initial report

- Donor Look-back - Final report
- Donor reaction
- Incidents
- Rapid Alert Report
- Annual blood usage statistics – Transfusing Facilities
- Annual Activity Summary Report - Blood Establishments

The completed forms can be submitted via email, post, or online.

Furthermore, a Blood Safety Information System (BSIS) has been implemented at the GARBC for blood donor and donation management to improve blood safety and traceability. There are plans to develop and implement a national integrated system to manage information on blood donors, products, and recipients in all blood establishments in Ghana. This system will have a haemovigilance data reporting function.

3.3 Training and Capacity Building

Appropriate education, training, and competency assessment of all HCPs involved in blood collection and transfusion activities are essential. The NBS conducts regular training workshops, and webinars for HCPs on good manufacturing and laboratory practices, safe handling and administration of blood products, as well as haemovigilance (see Table 1).

Table 1: Haemovigilance-related training workshops organized and number of HCPs trained

Training	Category of HCPs Trained	Number Trained		
		2022	2023	2024
Safe blood transfusion practices	Doctors, Nurses, Physician Assistants & Laboratory Scientists	96	431	1290
Good manufacturing and laboratory practices	HBB personnel	22	38	28
Blood Centre SOPs	Blood centre staff	57	88	45

Through a collaborative Technical Working Group, the NBS and FDA have also developed a training manual and comprehensive training materials to guide the training of all stakeholders on the haemovigilance system. The training includes the general principles of haemovigilance, its

objectives and benefits, individual roles and responsibilities, reporting procedures, and national guidelines.

3.4 Future Initiatives and Projects

- Implementation of reporting tools for haemovigilance, including specific forms for reporting different types of events and reactions.
- Establishment of a haemovigilance database and implementation of electronic reporting to complement data collection at all levels.
- Regular review of haemovigilance guidelines and reporting tools.
- Standardization of forms, procedures, reports, and educational materials across Ghana.
- Development of internal haemovigilance-related SOPs, with focus on improving hospital transfusion practices.
- Implementation of corrective and preventive actions based on the analysis of incidents and reporting.
- Implementation of Look-back and Trace-back procedures to investigate and manage transfusion-transmitted infections.

4 Data on Blood Collection, Testing, Processing, Issue, Usage and Adverse Events

4.1 Data Sources and Caveats

This report provides a curated analysis of blood collection, testing, processing, issues, usage, blood donation, and transfusion-related adverse events reported in Ghana over the past three years. It exclusively includes haemovigilance data collected and collated at the national level and does not incorporate reports from individual blood centres, blood establishments, or transfusion facilities.

The data sources for this report include internal reporting systems of the NBS, such as the BSIS (used by the GARBC). This report also makes use of data from the District Health Information Management System II (DHIMS2), which is the data reporting facility for district, regional and teaching hospitals in Ghana. While every effort has been made to ensure the accuracy and quality of the information presented in this report, readers are advised to exercise caution when interpreting its contents.

The following caveats apply to the data presented in this report:

- Not all blood collection and transfusion activities are reported, limiting the ability to calculate certain rates or frequencies of adverse events.
- Variations in data definitions and collection methods across establishments make inter-facility comparisons neither feasible nor appropriate.
- Much of the data used in this report has not been validated and lacks imputability criteria, which reduces the certainty of causal links between blood donations, transfusions, and reported adverse events.
- Since adverse event reporting is voluntary, discrepancies exist between reported and actual adverse events due to differences in reporting tendencies.

4.2 Blood Collection Sessions

There are over 180 fixed blood collection sites across hospitals in the country in addition to the recognized RBCs of the NBS. These facilities organized approximately 1,000 mobile blood collection sessions to collect blood from voluntary blood donors (Table 2). These sessions are organized in collaboration with second cycle schools, tertiary institutions, faith-based organizations, corporate organizations and workplaces, organized groups and community members. Alternatively, blood centres, blood collection units and blood establishments collect

blood from both voluntary and family replacement donors throughout each year at their fixed collection sites.

Table 2: Data on blood collection in Ghana

Indicator	Values		
	2022	2023	2024
Number of voluntary mobile sessions	897	824	1,085
Number of educational talks on blood donations organized	2,015	2,129	1,414
Total number of blood collections	179,765	181,288	185,231
Percentage of blood collected from repeat blood donors	27.0%	26.9%	28.7%

4.3 Blood Donor Management

Blood donor management is a critical component of the National Blood Programme, which plays a key role in ensuring a safe and adequate blood supply. Ghana's blood donor management program encompasses essential activities such as donor recruitment, education, and retention. These efforts are fundamental in fostering a committed donor base, as every donor must undergo these processes to develop long-term engagement. Committed blood donors are not only easier to retain but also serve as a reliable and consistent resource for maintaining a safe and sufficient blood supply. In Ghana, blood donor education and recruitment are mainly done through educational talks by trained Blood Donor Recruitment Officers, who visit blood donor groups to engage existing and potential blood donors to donate blood.

Across the country, the number of educational talks on blood donation organized was 897, 824 and 1,085 for 2022, 2023 and 2024, respectively (Table 2). Additionally, the promotion of blood donation is done through television, radio and newspaper advertisements as well as digital marketing on the NBS website and social media platforms. Ghana's donor retention strategies have been marginally effective over the past three years as depicted by the three-year average proportion of donations from repeat voluntary donors currently at 27.5%. Specifically, the proportion of donations from repeat voluntary donors increased marginally from 26.9% in 2023 to 28.7% in 2024 (Table 2).

4.4 Blood Collections

Donor screening is a critical component of blood collection, ensuring the safety and efficacy of blood donations. Screening involves a thorough evaluation of prospective donors through medical history questionnaires, physical examinations, and some laboratory tests to identify any risk factors that could compromise the health of the recipient or the donor. These processes are essential for minimizing the transmission of infectious diseases, preventing adverse reactions, and maintaining the integrity of the blood supply. Effective donor screening and deferral protocols not only protect public health but also foster trust in donation systems, ensuring a safe and sustainable donor pool.

On average, about 218,000 potential blood donors are screened annually in Ghana (Table 3). Out of the total number of donors screened, the deferral rate showed a consistent declining trend from 17.5% in 2022 to 15.1% in 2024, indicating improved donor eligibility or more effective pre-screening processes. Low haemoglobin emerged as the most common reason for deferral. This increase highlights a potential area for intervention, such as providing donors with dietary guidance or iron supplements to improve eligibility. The stable number of donors screened each year against a declining deferral rate, suggests a healthy and sustainable blood donor pool. However, continued efforts to address low haemoglobin and other deferral reasons could further optimize donor eligibility.

Table 3: Donor screening and deferrals

	2022	2023	2024
Total number of donors screened	217,908	217,828	218,280
Total number of donors deferred	38143	36540	33049
Deferral rate	***17.5%***	***16.8%***	***15.1%***
Deferral reasons (% of total screened)			
High risk behaviour	*0.2%*	*0.1%*	*0.1%*
Low haemoglobin	*6.0%*	*7.0%*	*7.0%*
Low weight	*0.6%*	*0.3%*	*0.3%*
Medical condition and clinical history	*4.6%*	*3.8%*	*3.0%*
TTI test outcome	*6.1%*	*5.6%*	*4.7%*
Other reasons (clot, transfusion reactions, etc.)	*0.02%*	*0.02%*	-

Currently, the NBS collects whole blood donations from blood donors. There are plans to re-introduce apheresis donations, which was initiated in 2018 but discontinued due to logistical challenges. The total number of whole blood units collected across the country is depicted in Figure 1, showing a consistent increase in blood collections. In relation to the population, the blood collection index (BCI) per 1,000 population was 5.8 for 2022, 5.9 for 2023 and 6.1 for 2024. Even though these indices are below the WHO recommended minimum collection of 10 units per 1,000 population required to meet basic transfusion needs, they show a consistent increase in blood availability for the Ghanaian populace. The consistent increase in blood collections and BCI per 1,000 population suggest a positive trajectory in blood collection efforts. This growth reflects the effectiveness of awareness campaigns and the strengthening of blood collection systems in Ghana. Nonetheless, continued efforts are needed to maintain and further enhance this progress to meet the country's blood transfusion needs.

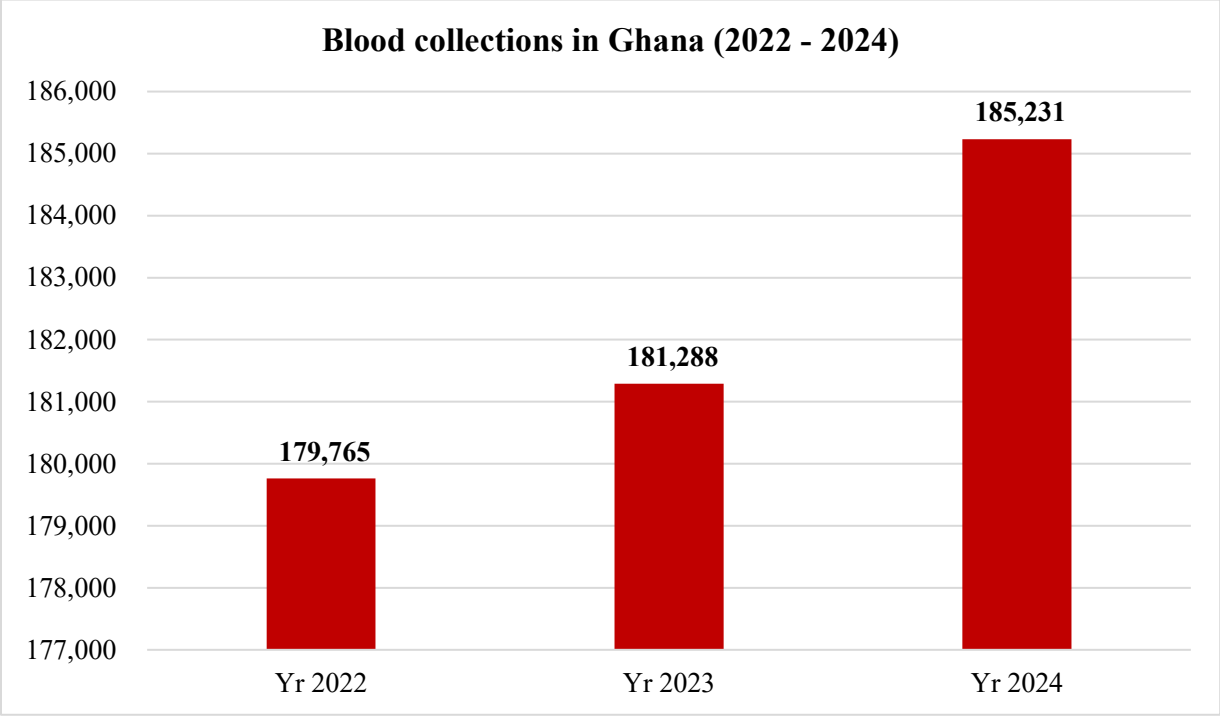

Figure 1: Total blood collections

4.5 Blood Component Preparation

Ghana is committed to providing blood components for transfusion instead of whole blood (component therapy), driven by clear safety considerations and the goal of optimizing the utilization of each whole blood donation. The NBS advocates for 70% of whole blood donations to be separated into components. However, the country is far from reaching this target due to the

low capacity of blood establishments with inadequate specialized equipment for component preparation.

Over the years, the percentage of whole blood donations separated into components across the country has been low (21.2% in 2022, 27.4% in 2023 and 26.7% in 2024). Conversely, percentages of whole blood donations separated into components by the three designated RBCs of the NBS were high i.e. 44.1% in 2022, 59.1% in 2023 and 48.2% in 2024 (Figure 2). These high proportions recorded by the RBCs can be attributed to the availability and use of specialized equipment for component preparation, mainly by the Greater Accra RBC. With the installation of two new ultracentrifuges at the RBCs in Kumasi and Tamale, it is expected that component preparation yields will significantly increase in subsequent years.

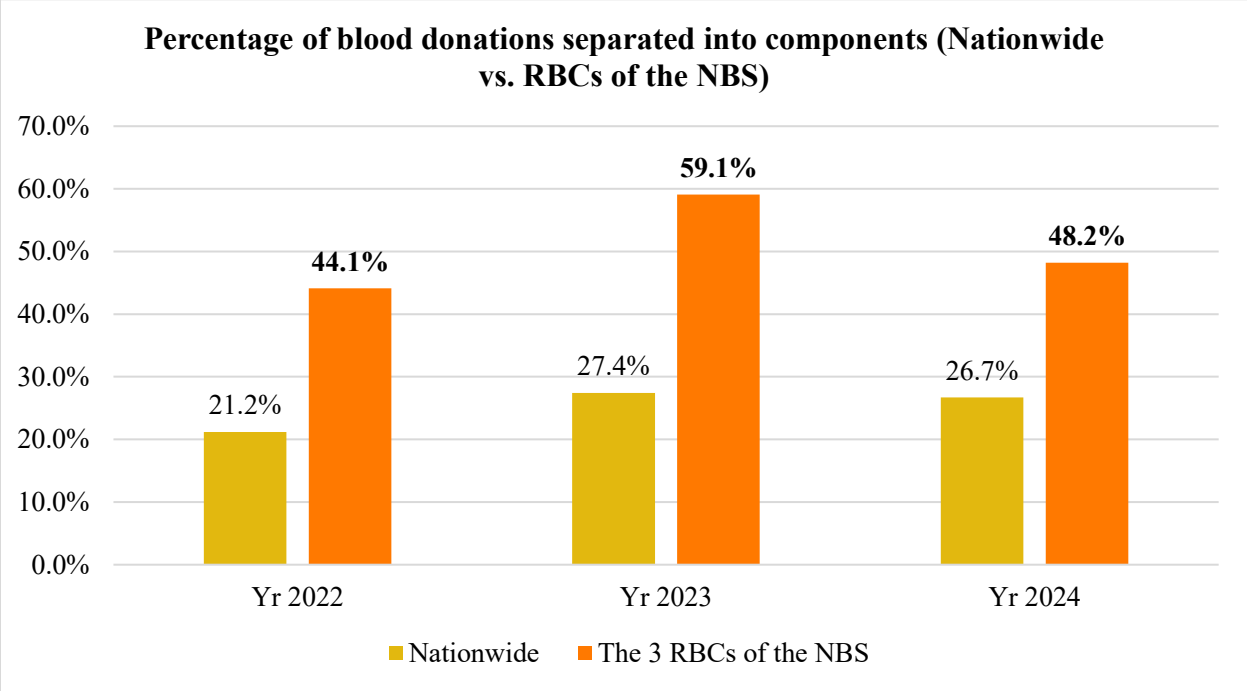

Figure 2: Percentage of blood donations separated into components

4.6 Blood Donation Testing

In Ghana, every unit of donated blood is rigorously screened for four key markers of transfusion-transmissible infections (TTIs): hepatitis B virus (HBV), hepatitis C virus (HCV), human immunodeficiency virus (HIV 1 & 2), and syphilis. There is a comprehensive testing protocol (National Strategy for Screening of Donated Blood and Immunohaematological Testing) that ensures the safety and quality of blood products for transfusion. The final determination of the usability of a blood donation or its components, as well as the appropriate management of the

blood donor, is based on the outcomes of TTI testing. Only blood products that yield negative results for all TTI markers are deemed suitable for transfusion and released for clinical use. Blood products that test positive for any TTI marker are discarded to ensure safety. The blood donor is then notified of the results, provided with counseling, and referred to healthcare providers for further evaluation and management. This post-donation care and counseling service is currently offered by only two RBCs.

Table 4: TTI results of donation samples tested

	2022	2023	2024
Total number of samples	**164,471**	**195,711**	**187,170**
Hep B			
Total number of positive samples	9,451	10,541	8,941
Prevalence	*5.7%*	*5.4%*	*4.8%*
Hep C			
Total number of positive samples	6,080	6,487	5,159
Prevalence	*3.7%*	*3.3%*	*2.8%*
HIV			
Total number of positive samples	4,290	7,174	4,839
Prevalence	*2.6%*	*3.7%*	*2.6%*
Syphilis			
Total number of positive samples	10,464	11,098	9,278
Prevalence	*5.8%*	*5.7%*	*5.0%*

Overall, the TTI results data indicates a general improvement in ensuring the safety of the blood supply in Ghana, with a general decline in prevalence among blood donors between 2022 and 2024 (Table 4). Hepatitis B, C and Syphilis showed a consistent decrease in prevalence over the three years, suggesting effective screening and possibly improved public health interventions. The HIV prevalence rate remained the same, with a notable increase in 2023 followed by a decrease in 2024. Continued efforts in testing, public health education, and treatment are essential to sustain and enhance these positive trends. The NBS seeks to strengthen the positive trend through enhanced donor screening and education, improved testing technologies, increased public awareness campaigns and targeted donor recruitment.

4.7 ABO and Rh Blood Grouping

Every blood donation, whether from a first-time or repeat blood donor, undergoes comprehensive testing for ABO and Rh grouping, as well as screening for abnormal or irregular red cell antibodies, performed mainly by the RBCs. Prior to release for transfusion, all blood components are

meticulously labeled with a blood group sticker that clearly indicates the donation's blood group, ensuring accurate and safe transfusion practices. The outcome of the testing for ABO and Rh grouping also indicates the donor's blood group. Figure 3 indicates the percentage of blood groups in the total blood collections for the period.

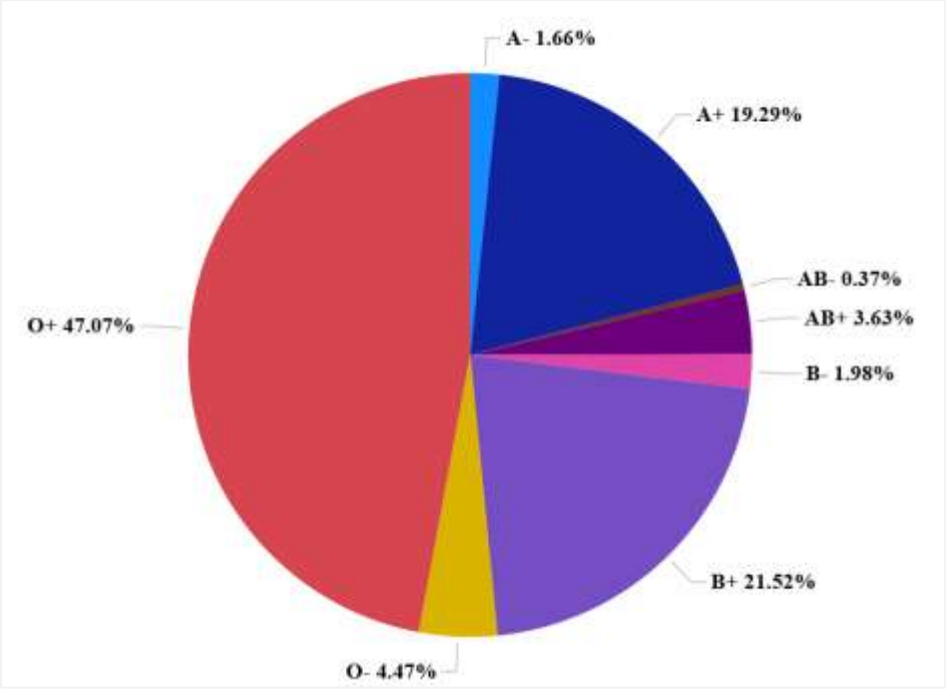

Figure 3: Percentage of ABO and RH blood groups in blood donations

4.8 Blood Product Issues

Although the NBS systematically collects data on the annual number and types of blood products issued in Ghana (as detailed in Table 5), there is currently no direct or precise data available on the actual number of blood product units transfused annually.

Table 5: Blood products issued between 2022 - 2024

Product	2022	2023	2024
Whole blood	111,128	125,128	133,109
Fresh frozen plasma	18,668	21,403	19,728
Concentrated red cells	31,261	42,844	35,758
Cryoprecipitate	605	843	625
Platelets	8,436	11,265	10,029
Total products	**172,120**	**203,506**	**201,273**

Data collated from district, regional and teaching hospitals indicate that majority (81%) of blood products are issued to children (Figure 4).

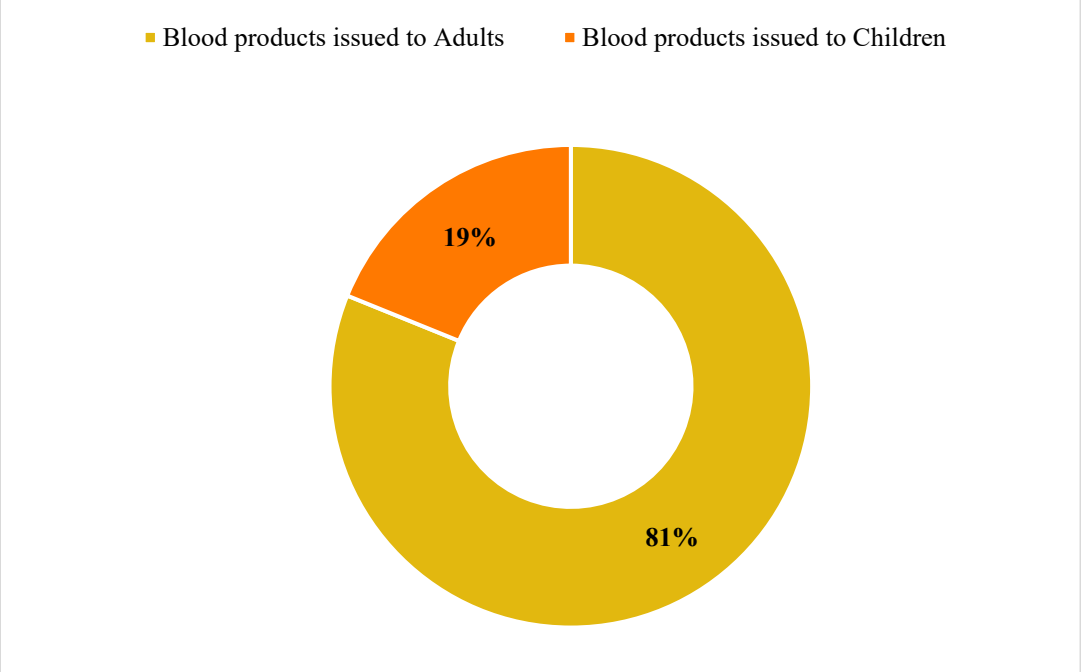

Figure 4: Blood products issued to Adults vs. Children

4.9 Blood Product Wastage

Table 6 below shows units of whole blood and red cells discarded for various reasons. The total number of units discarded and the discard rate have consistently decreased over the three years. This decrease reflects improved efficiency in blood utilization. TTI positive results remain the leading cause of discards. The percentage of units discarded due to expiration increased from 10.7% in 2022 to 11.8% in 2023, and further to 12.4% in 2024. This increase suggests a need for better inventory management to reduce wastage. The percentage of units discarded due to haemolysis decreased from 5.1% in 2022 to 3.3% in 2024. Similarly, the percentage of units discarded due to breakage during processing decreased from 1.0% in 2022 to 0.8% in 2024. These decreases indicate an overall improvement in handling and processing of blood components.

Table 6: Whole blood and concentrated red cells discarded

	2022	2023	2024
Total whole blood units collected	179,765	181,288	185,231
Number of units discarded	14,770	13,286	12,351

	2022	2023	2024
Discard rate	**8.2%**	**7.3%**	**6.7%**
Discard reasons (% of total collected)			
Expired	*10.7%*	*11.8%*	*12.4%*
TTI positive results	*80.2%*	*75.0%*	*78.4%*
Haemolysis	*5.1%*	*6.1%*	*3.3%*
Broken during processing (burst, leakage, etc.)	*1.0%*	*1.0%*	*0.8%*
Donor ineligibility issues	-	*1.6%*	-
Other reasons (clot, transfusion reactions, etc.)	*3.0%*	*4.5%*	*5.1%*

In 2023, some units were discarded for blood donor ineligibility issues, accounting for 1.6% of discards. This was recorded in one RBC where blood was collected from blood donors who were ineligible at the time of blood collection, hence resulting in discards. These discards have significant implications for the efficiency and safety of the blood supply system in Ghana, including wastage of valuable resources, such as time, effort, and materials used in the blood collection. Furthermore, the percentage of units discarded for other reasons increased from 3.0% in 2022 to 4.5% in 2023 and further to 5.1% in 2024. This rise suggests that additional, unidentified factors are contributing to discards and need to be investigated.

4.10 Adverse Reactions in Blood Donors

The NBS relies entirely on the goodwill of blood donors who give blood willingly to maintain an adequate supply of blood and blood products for patients. Ensuring donor safety throughout the donation process is, therefore, a critical priority for the NBS. Although blood donation is generally safe, recognized complications can occur, which may negatively impact donor retention and pose challenges in recruiting new donors. To address this, it is essential that all donors are fully informed about the donation process and made aware of potential adverse events before providing their consent. This transparency helps build trust, enhances donor satisfaction, and supports the sustainability of the blood donation system.

In the years under review, close to 4,000 donor adverse reactions (DARs) were reported (1,442 in 2022, 821 in 2023 and 1,725 in 2024). As observed in Table 7, the average donor reaction rate is 0.73%, which is higher than rates reported in other African countries like Namibia (0.5% in 2022 and 2021). The average reaction rates recorded in hospital-based blood collection sites were consistently higher than those recorded at RBCs (0.94% vs. 0.25%). Even though this could be

attributed to the fact that hospital-based sites deal with a larger number of donors, they may also have less controlled environments compared to the RBCs, potentially leading to more adverse events. There is the need to identify factors contributing to higher reaction rates in hospital-based blood collection sites and implement best practices to reduce adverse reactions, such as better donor screening and staff training.

Table 7: Donor adverse reactions*

	2022	2023	2024
Regional Blood Centres (RBCs)			
Blood donations	54,912	58,463	58,022
Donor adverse reactions	139	151	147
Donor reaction rate	***0.25%***	***0.26%***	***0.25%***
Hospital-based Blood Collection Sites			
Blood donations	124,853	124,233	127,209
Donor adverse reactions	1,303	670	1,578
Donor reaction rate	***1.04%***	***0.54%***	***1.24%***
Total blood donations	179,765	182,696	185,231
Total donor adverse reactions	1,442	821	1,725
Overall donor reaction rate	***0.80%***	***0.45%***	***0.93%***

Reported adverse events rarely have case report forms.

4.11 Transfusion-Related Adverse Events

Transfusion reactions are adverse events that can occur during or after a blood transfusion, ranging from mild to life-threatening, and can be either immunologic or non-immunologic.

Most commonly reported cases are mild in nature.

Records of properly documented and reported transfusion reactions for the period under review stood as 22, 24 and 55 for 2022, 2023 and 2024, respectively. Of the reported cases, 100% were acute/immediate transfusion events, 92.4% of them were immunologic and 4.2% non-immunologic. The rest (3.4%) could not be classified.

Reporting these occurrences in a timely manner helps put in place corrective and preventive measures to minimize recurrence. However, they are seldom fully documented, investigated and reported, limiting policy interventions to address systemic challenges and ensure patient safety.

4.12 Quality Management Systems

The NBS is responsible for the implementation of quality elements along the transfusion chain. To ensure consistent practice, the use of written procedures has been established alongside quality improvement plans and audits.

In the RBCs, there is a comprehensive quality system regarding blood collection, transport, storage, processing, testing and distribution to hospital blood banks. Donor vigilance is ensured with procedures for identification, management and reporting of blood donor adverse events.

The NBS encourages the establishment of hospital transfusion committees in transfusing facilities by providing guidelines on the roles and responsibilities of such committees. The hospital transfusion committees are encouraged to oversee the implementation of haemovigilance in the hospitals.

There is continuous medical education delivered quarterly to clinicians, nurses and medical laboratory scientists. These CMEs are aimed at ensuring appropriate clinical use of blood, effective training of staff, and improvement in patient management in hospitals.

4.13 Regulatory Activities – Registration of Blood and Blood Products

The FDA has a critical mandate under the Public Health Act, 2012 (Act 851) to ensure public health and safety through the regulation of biological products, including blood and blood products. The FDA has developed comprehensive regulatory guidance documents to support the implementation of quality and safety systems in the extraction, manufacturing, and control of whole blood and blood products.

In line with the FDA Guideline for Licensing Blood Facilities and Blood Products Listing, and the collective objective of efficiently regulating blood facilities in Ghana, officers of the FDA visit and inspect blood facilities on scheduled dates. The inspections are for blood facility licensure and product listing.

The inspections are conducted as extensive, verification or announced/unannounced compliance inspection. The exercise is carried out to inspect all critical operational procedures and/or systems in the blood facility required to certify a facility as Good Manufacturing Practices (GMP), Good Preparation Practice (GPP), Good Storage Practices (GSP)/Good Distribution Practices (GDP) compliant. Through these inspections, the FDA has established the capacity to regulate blood establishments and hospital blood banks across the country. The FDA sets and enforces rigorous standards of quality and safety in line with the Public Health Act 851 to govern the collection, testing, processing, storage, and distribution of human blood and blood products. These measures aim to ensure that all aspects of blood handling meet internationally recognized benchmarks for quality and safety.

The Regulatory Framework also ensure that all adverse blood reactions (ABRs) and or severe ABRs (SABRs) are documented and investigated on-site and reported to the NBSG or the FDA within specified timelines.

To ensure compliance with the requirements and ensure the safety and quality of blood and blood products, the FDA has carried out 87 inspections of blood facilities between January 2022 and December 2024. The Greater Accra Regional Blood Centre also carried out 36 inspections and accredited 90 hospital blood banks within the same reporting period (Table 8).

Table 8: Number of facilities accredited by the Greater Accra Regional Blood Centre

	2022	2023	2024
Number of facilities accredited	22	40	28
Number of inspections	7	25	4

5 Key Observations and Recommendations

5.1 Key Observations

Blood Service Operations

- Only ~30% of donations are from voluntary, unpaid donors; 70% are still from family replacement donors, increasing TTI risk vs. voluntary donors.
- National average for component separation is only 26.7% (2024) vs. the target of 70%, wasting the potential of whole blood.
- BCI was 6.1 in 2024, below the WHO target of 10/1,000 population.
- Rising blood wastage due to expiration (12.4% in 2024) and TTI-positive units (78.4% of discards).
- Only one regional blood centre (GARBC) uses a Blood Safety Information System (BSIS); national rollout is still pending.
- Hospital-based blood collection sites had 5x higher donor adverse reaction rates (up to 1.24%) compared to RBCs (0.25%).
- There is underreporting of transfusion reactions with only 101 adverse rection reports received over 3-year period (2022-2024).

Health System Performance

- Not all AEs and ARs are reported; donor adverse reactions inconsistently documented (e.g., hospital sites rarely used case report forms); lack of standardization.
- Not all transfusing facilities have trained staff for blood component AE reporting.
- 87 inspections by the FDA over 3 years are indicative of active monitoring, but system-wide coverage is unclear.
- No national data on transfused units; only on issued products; no traceability for recipient outcomes.
- No validated national database; reliance on unverified DHIMS2 data and BSIS (limited to Accra).
- Weak hospital transfusion committees and uneven quality management.

Implementation of Haemovigilance Framework and Guidelines

- Reporting AEs remains underreported by transfusing hospitals, weakening national data quality.

- Though SOPs exist, training is absent; CME activities are weak and need scale-up.

5.2 Key Recommendations

Strengthening Blood Service Operations

- Accelerate voluntary blood donation programs:
  - Expand community-based campaigns and digital outreach.
  - Introduce donor loyalty and retention programs tied to regular feedback.

- Scale component preparation infrastructure. Equip RBCs and BCUs with centrifuges and cold chain systems.

- Standardize blood donor care. Require competency certification for phlebotomists at hospital sites.

- Optimize inventory and reduce wastage:
  - Introduce a national stock management dashboard integrated with the BSIS and other information management systems.
  - Conduct regular root-cause analyses of expired and discarded units.

- Expand BSIS nationwide:
  - Include haemovigilance reporting, blood donor tracking, and traceability features.
  - Train staff on real-time digital entry to improve accuracy and coverage.

Improving Health System Performance

- Strengthen leadership and governance to ensure a safe and adequate blood supply. Secure government support, provide policy direction, and ensure adequate resources

- Make AE/AR reporting compulsory for transfusing facilities.

- Harmonize training nationally:
  - Develop tiered training for clinical and non-clinical staff using existing manuals.
  - Use micro learning and blended e-learning modules to increase access and uptake.

- Implement feedback loops:
  - Quarterly feedback reports should be shared with hospitals and blood establishments.
  - Conduct regular meetings with hospital transfusion committees to review haemovigilance data.

- Build Analytical Capability:
  - Establish a centralized data analysis unit at NHO to review trends and issue early warnings.
  - Use DHIMS2 and BSIS data for integrated performance dashboards.

Enhancing Implementation of Haemovigilance Framework

- Extensively disseminate the National Haemovigilance Guidelines and Framework across the country with standardized documentation.

- Enforce compliance with SOPs and forms. Require submission of standardized case report forms as part of licensure renewal.

- Set national benchmarks. Define KPIs for haemovigilance reporting, reaction rates, and blood product utilization.

- Operationalize rapid alert system (RAS):
  - Build alert protocols into existing information systems for real-time adverse event alerts.
  - Train regional and hospital teams on escalation procedures.

- Institutionalize hospital transfusion committees:
  - Make transfusion committees mandatory in facilities that transfuse more than 100 blood product units per year.
  - Include haemovigilance performance as a hospital quality indicator.

- Fund operational research. Study root causes of blood donor reactions and blood product expiration wastage.

Summary of critical gaps to be addressed

Gap Identified	Recommendation	Expected Impact
Under-reporting	Digital reporting + mandatory policy	↑ Reporting by 80%; accurate risk profiling
Low component preparation	Equip centers; set targets	↑ Plasma/platelet availability; ↓ wastage
Hospital donor reaction rates	Phlebotomy certification + supervision	↓ Reactions by 50%; ↑ donor retention

6 Appendices

6.1 Donor reactions reported across Ghana

Table 9: Details of donor reactions reported at blood centres and hospital-based collection sites

	2022	2023	2024
Donor reactions reported at RBCs			
Abdominal Pain	*2*	*2*	*4*
Accident	*2*	*5*	*0*
Allergy	*3*	*0*	*1*
Arterial Puncture	*3*	*0*	*0*
Convulsion	*1*	*9*	*1*
Dizziness	*50*	*67*	*65*
Ecchymosis	*1*	*0*	*0*
Headache	*12*	*22*	*46*
Hematoma	*38*	*8*	*7*
Loss of Consciousness	*5*	*5*	*1*
Nausea	*4*	*3*	*1*
Pre-syncope	*4*	*0*	*0*
Sweating	*3*	*3*	*0*
Twitching	*0*	*1*	*0*
Vasovagal	*0*	*10*	*8*
Vomiting	*10*	*16*	*13*
Weakness	*1*	*0*	*0*
Donor reactions reported at hospital-based collection sites			
Major Reactions	*248*	*59*	*450*
Minor Reactions	*606*	*463*	*635*
Moderate Reactions	*449*	*148*	*493*

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