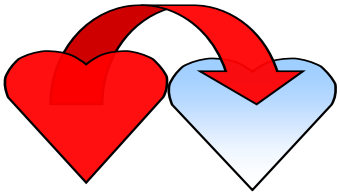
Rwanda Biomedical Centre

Healthy People, Wealthy Nation



RWANDA BIOMEDICAL CENTRE

BIOMEDICAL SERVICES DEPARTMENT

BLOOD TRANSFUSION DIVISION

HEMOVIGILANCE REPORT

2022

THE BLOOD TRANSFUSION DIVISION HEMOVIGILANCE REPORT 2022

Background of blood transfusion services in Rwanda

An effective blood transfusion service is one of the essential components of a good HCS (Health Care System). In Rwanda, Blood Transfusion Service was established in 1976 after WHO (World Health Organization) recommended that all nations should have functional blood transfusion establishment. It was known then as CNTS (Centre Nationale de Transfusion Sanguine).

In 2007, CNTS was given a semi-autonomous status by Law No: 26/2007 of 27/06/2007 and set up its mission of "Providing safe, effective and adequate blood to all patients in need" which is still inexistence even today. In 2010, CNTS was made one of the divisions of the RBC (Rwanda Biomedical Centre) under the MoH (Ministry of Health) by the Law No: 54/2010 of 25/01/2011. In 2020 Centre Nationale de Transfusion Sanguine changed its name to BTD (Blood Transfusion Division).

BTD comprises of six (units): Five (5) RCBTs (Regional Centres for Blood Transfusion) and one (1) BBU (Bio-Banking Unit). RCBTs are located in all administrative provinces and the CoK (City of Kigali) and are responsible for mobilization and recruitment of blood donors as well as blood collection, processing and distribution. BBU is a new unit in (BTD) and is responsible for CTB (Cornea Tissue Banking). BBU is located at BTD HQs in CoK.

In 2022, BTD collected blood from 5 fixed and 662 mobile collection sites countrywide and served 78 transfusing public and private health facilities.

According to WHO, countries should collect blood units equivalent to 1% of their population to satisfy their need of blood products. This means that Rwanda with about 12 million people should collect 120,000 blood units per year.

In 2022, BTD collected 78,838 blood units (6.9 donations per 1,000 populations) and hospital demands were met at the rate of 97.57%. The goal of BTD in its strategic plan 2020 - 2025 is to serve up to 100% by 2025.

Privacy Statement

This report does not identify or attempt to identify individual patients, clinicians or healthcare institutions. On the contrary, every reasonable effort has been made to prevent their identification.

Disclaimer

This document is a general report only. Its data, analysis and conclusions are intended to provide healthcare professionals and the public with general information only on adverse transfusion- related events in Rwandan hospitals. This report is a snapshot of currently available data, which have been obtained from limited resources.

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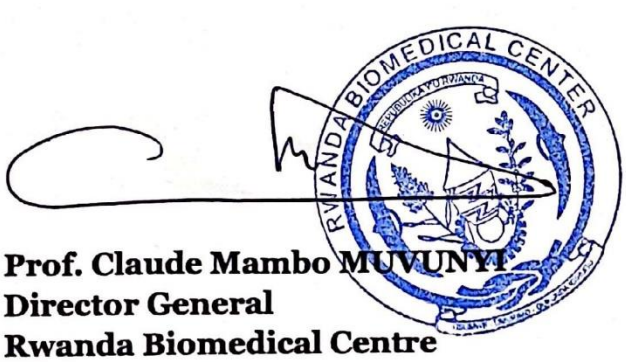
Executive summary

World Health Organization defines hemovigilance as 'the set of surveillance procedures covering the entire blood transfusion chain, from the donation and processing of blood and its components, through to their provision and transfusion to patients, and including their follow-up'.

In 2022, Rwanda Blood Transfusion Division collected 78,838 blood units which were processed into different blood products for transfusion to patients in need. A total of 118,278 units of blood and blood products were issued to transfusing facilities from 1st January to 31 December 2022. Of these, 79,583 (67.3%) were red blood cells (RBCs), 27,521(23.3%) were platelets, 8454 (7.1%) were fresh frozen plasma (FFP) and 2720 (2.3%) were Cryoprecipitate units.

Adverse donor events reported to the hemovigilance program were 24 which involved 22 mild adverse events and 2 severe ones. The adverse transfusion events were 13 and all were mild allergic transfusion reactions (ATRs).

The prevalence of HIV, HBV and HCV among the blood donors was 0.04%, 0.33% and 0.022% respectively. No cases of transfusion transmissible infection were reported.



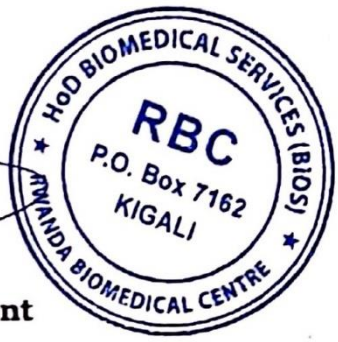
Prof. Claude Mambo MUVUNYI
Director General
Rwanda Biomedical Centre

Message of Head of Biomedical Services Department

Maintaining a supply of safe blood and blood products is our national priority, and achieving this requires the development and implementation of policies and guidelines to govern blood transfusion processes. Among these guidelines is the hemovigilance program which is geared to identify and prevent occurrence or recurrence of transfusion-related unwanted events, and to increase the safety, efficacy and efficiency of blood transfusion, covering all activities of the transfusion chain from donor to recipient.

It is in this regard that Biomedical Services Department, commits continued support to ensure availability of safe blood and blood products. We appreciate the efforts of BTD (Blood Transfusion Division) staff and their outstanding work to ensure blood is available all the time. We also thank trustworthy blood donors and partners who have tirelessly stood with us to ensure sustainability of this process.

It is important to emphasize that we are committed to achieving BTD's mission of 'Being a center of excellence in the region by conforming to international blood banking standards.



Dr Isabelle MUKAGATARE
Head of Biomedical Services Department
Rwanda Biomedical Centre

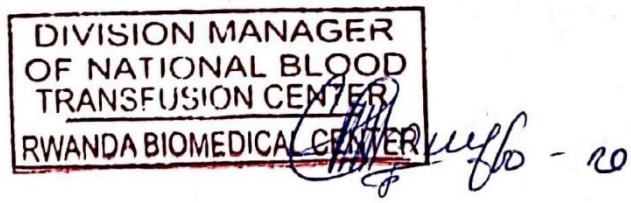
Message from Blood Transfusion Division Manager

Transfusion of blood and blood products is a life-saving intervention. However, there are risks of adverse events associated with the donation of blood and its components, and with the transfusion of blood and blood products to patients. Adverse events include all reactions, incidents, near misses, errors, deviations from standard operating procedures and accidents associated with blood donation and transfusion. Learning from adverse events and identifying system problems can drive the introduction of measures to enhance the quality, safety, efficacy and cost-effectiveness of blood and blood products as well as of the donation and transfusion processes. It is through the structured hemovigilance program in Rwanda that adverse events are reported to the blood transfusion division, investigated and published in an annual report.

Hemovigilance involves monitoring, reporting, investigation and analysis of adverse events related to the donation, processing and transfusion of blood, and taking action to prevent their occurrence or recurrence. The reporting systems play a fundamental role in enhancing patient safety by learning from failures and then putting in place system changes to prevent them in future.

In addition, the Hemovigilance Committee on Central level meets every year to analyze the trends of the transfusion-transmissible infections for which the division currently screen namely; HIV, hepatitis B and C, and syphilis. It is envisaged that the introduction of nucleic acid testing in the near future will contribute to the safety of blood products in Rwanda, to such an extent that infection transmissions will be completely rare, and the predominant complications of blood transfusion will remain allergic and febrile transfusion reactions.

This is our maiden report and we hope to continue making it an annual event. Special thanks go to all the staff of BTD who made it possible.



Dr Thomas MUYOMBO
Blood Transfusion Division Manager
Rwanda Biomedical Centre

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The key findings were

1. A total of 118,626 blood and blood components were issued in the year 2022 with red blood cells being the components transfused the most (67.3%), platelets were 23.3%. Fresh Frozen Plasma was 7.1% and Cryoprecipitate 2.3%.

2. Adverse transfusion events reported were 13 and the most frequently reported were Allergic Transfusion Reactions (ATRs).

3. A total of 24 out of 78,838 donations had adverse events in 2022.

4. The national prevalence of HIV, HBV, HCV and Syphilis among the blood donor population was 0.04%, 0.033%, 0.22% and 0.40% respectively. No case of Transfusion Transmissed Infection was reported.

Abbreviations

AHTR	Acute Haemolytic Transfusion Reaction
ARs	Anaphylactic Reactions
ATRs	Allergic Transfusion Reaction
ATRs	Anaphylactic Transfusion Reactions
BBU	Bio-Banking Unit
BTD	Blood Transfusion Division
CNTS	Centre de Transfusion Sanguine
CoK	City of Kigali
CTB	Cornea Tissue Banking)
DARs	Donor Adverse Reactions
DHTRs	Delayed Hemolytic Transfusion Reactions
DSTRs	Delayed Serological Transfusion Reactions
DTRs	Delayed Transfusion Reactions
EIDs	Emerging Infectious Disease
FNHTRs	Febrile Non- Hemolytic Reactions
HBsAg	Hepatitis B surface antigen
HBV	Hepatitis B Virus
HCS	Health Care System
HCV	Hepatitis C Virus
HIV	Human Immunodeficiency Virus
HQs	Headquarters
HRs	Hypotensive Reactions
HTLV	Human T-lymphotropic Virus
HTRs	Haemolytic Transfusion Reactions
IBCTs	Incorrect Blood Component Transfused
IHN	Hemovigilance Network
MARs	Mild Adverse Reaction
MARs	Mild Allergic Reactions
MARs	Moderate Adverse Reaction
MoH	Ministry of Health
MTs	Misdirected Transfusions
NM	Near miss
PRBCs	Packed Red Blood Cells
RBC	Rwanda Biomedical Centre
RCBTs	Regional Centres for Blood Transfusion)
RITs	Rh Incompatible Transfusions
SARs	Severe Adverse Reaction
TACO	Transfusion- Associated Circulatory Overload
TAD	Transfusion- Associated Dyspnea
TA-GvHD	Transfusion Associated Graft-versus-host Disease
THFs	Transfusing Health Facilities
TRALI	Transfusion Related Acute Lung Injury
TTIs	Transfusion- Transmissible Infections
WHO	World Health Organization

Transfusion reaction classifications and definitions

CATEGORY	DEFINITION
Acute Transfusion Reactions (ATRs)	Transfusion-related reactions that occur at any time during or up to 24 hours following a transfusion of blood or components. The most frequent reactions are, fever, chills, pruritus or urticarial, which typically resolve promptly without specific treatment or complications.
Haemolytic Transfusion Reactions (HTRs)	A reaction where there are clinical and laboratory signs of increased destruction of transfused red blood cells. Hemolysis can occur intravascularly or extra vascularly and can be immediate (acute) or delayed.
Acute Haemolytic Transfusion Reaction (AHTR)	Rapid destruction of red blood cells immediately after or within 24 hours of a transfusion. Clinical and laboratory signs of hemolysis are present. No single criterion exists to definitively diagnose this rare disorder. It is associated with fever and other symptoms/signs of hemolysis and confirmed by a fall in hemoglobin,rise in lactate dehydrogenase, positive direct ant globulin test (DAT) and positive cross match.
Allergic Transfusion Reaction (ATRs)	The result of an interaction of an allergen with preformed antibodies. In some instances, infusion of antibodies from an atopic donor may also be involved. It presents with only muco-cutaneous signs and symptoms. Minor allergic reaction: reaction limited to the skin, with or without a rash. Severe allergic reaction: reaction with risk to life occurring within 24 hours of transfusion, characterized by bronchospasm causing hypoxia or angioedema causing respiratory distress.
Transfusion Associated Dyspnoea (TAD)	Respiratory distress within 24 hours of transfusion that does not meet the criteria oftransfusion-related acute lung injury, transfusion-related circulatory overload or severe allergic reaction and is not explained by the patient's underlying condition.
Hypotensive Transfusion Reactions (HTRs)	A drop in systolic and/or diastolic pressure of >30mm Hg occurring within one hour of completing the transfusion, provided all other adverse reactions with underlying conditions that could explain hypotension have been excluded.

Transfusion Associated Circulatory Overload (TACO)	Volume infusion that cannot be effectively processed by the recipient either due to high rates and volumes of infusion or underlying cardiac or pulmonary pathologyand results in any 4 of the following occurring within 6 hours of transfusion: ▪ Acute respiratory distress; ▪ Tachycardia; ▪ Increased blood pressure; ▪ Acute or worsening pulmonary oedema; ▪ Evidence of positive fluid balance.
Transfusion Related Acute Lung Injury (TRALI)	Acute hypoxemia with PaO2 fraction of inspired oxygen [FiO2] ratio of 300mm Hgor less combined with chest x-ray showing bilateral infiltrates in the absence of leftatrial hypertension (i.e., circulatory overload). There is abrupt onset in association with transfusion.
Anaphylactic Transfusion Reactions (ATRs)	Hypotension with one or more of: urticaria, rash, dyspnea, angioedema, stridor,wheeze, pruritus, within 24 hrs of transfusion.

1. Hemovigilance in Rwanda

1.0. INTRODUCTION

According to the WHO (World Health Organization), hemovigilance is required to identify and prevent occurrence or recurrence of transfusion-related unwanted events, to increase the safety, efficacy and efficiency of blood transfusion, covering all activities of the transfusion chain, from donor to recipient. The system should include monitoring, identification, reporting, investigation and analysis of adverse events near-misses and reactions related to transfusion and manufacturing.

1.1. Introduction to Haemovigilance System

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.

The conventional systems for Haemovigilance are adverse event notification, look-back program and donor vigilance.

Haemovigilance, as part of public health surveillance, covering the donor to patient transfusion chain of processes and procedures, is a joint responsibility of BTD and Transfusing Hospitals.

Haemovigilance should be fully integrated into the quality systems of all institutions involved with the blood and blood components supply chain, including donation, testing, processing, inventory management, storage and distribution, and clinical transfusion, to ensure donor and patient safety at all levels.

Haemovigilance is therefore a quality processes with the aim to improve quality and increase the safety of blood transfusion, taking into account that it covers and surveys all activities of the blood transfusion chain from donors to recipients. It identifies factors throughout the process that may be related to risk. The system plays a critical role in ensuring that laboratory and clinical blood transfusion practice is optimal and contributes to improving the safety of blood transfusion service.

1.2. Goal and Objectives

1.2.1 Goal of Haemovigilance system

The overall goal of Haemovigilance is continuous quality improvement of the transfusion chain through corrective and preventive actions to improve donor and patient safety, improve transfusion appropriateness, and reduce wastage.

At its core, a Haemovigilance system resembles any continuous quality improvement cycle and shows the same elements and activities. As such, Haemovigilance should be embedded into every step of the transfusion chain, and into every organization that has responsibility for a part of that chain.

1.2.2. Specific objectives of haemovigilance:

- Preparation of SOPs, guidance documents & training manuals related to transfusion best practice,
- Assist in the formulation of transfusion guidelines to increase the safety and quality of the entire transfusion process,
- Identify trends, investigating underlying causes of transfusion reactions and introduce required changes in the transfusion policies,
- Mentor /Update all transfusing facilities staff about blood and blood components utilization.
- Periodic assessment, monitoring and evaluation of Blood components utilization in hospitals,
- Perform hemovigilance data quality analysis, review, validation then produce periodically and annual reports,
- Communicate recommendations of Haemovigilance to BTD management for improvement.
- Receiving adverse event reports from Transfusing hospitals, providing expert guidance to address root causes and improve safety(followup)
- Implement and maintain look-back Procedure
- To promote, maintain and improve compliance with the international standards in blood components management and utilization;
- To collect and analyze data on adverse events related to blood donation/transfusion and ensure the creation/update of the adverse reactions database and implementation of corrective actions for improvement and prevention.
- To advocate for establishment of public policy on blood transfusion safety.

1.3. Benefits of Haemovigilance system

Haemovigilance system is beneficial to all stakeholders in the blood transfusion chain.

1.3.1. Blood Donor

- Improved donor safety with a reduction in the frequency and severity of donor complications,
- Greater confidence in the blood donation process

1.3.2. Blood transfusion service :

- Improved donor retention and return,
- Early detection of deficiencies and weaknesses
- Continuous improvement in the quality of the services and products
- Improved public confidence and trust in the blood transfusion service system

1.3.4. Hospitals and health care facilities

- Reduction in errors, omissions and system failures
- Systematic and consistent reporting of all adverse events
- Development of skills and expertise in the area of total quality management
- Reduction in adverse events

- Better health care outcomes
- Less medico-legal action with an overall improvement of the community's regard of a particular facility

1.3.5. Patients receiving transfusion therapy

- Reduced risk of harm due to adverse events
- Greater confidence in the blood transfusion process

1.3.6. Physicians and other health care professionals

- Identification and mitigation of transfusion associated risks
- Identification and quantification of unavoidable complications
- Feedback leading to improved practice

1.3.7. Community

- Better care and stewardship of the gift of blood donation
- Improved donor and patient confidence and trust in the blood system

1.3.8. International bodies, societies, organizations

- Benchmarking, developing best practice and creating awareness

1.4. Characteristics of a Successful Haemovigilance System

The following are important characteristics for successful donor and patient safety reporting system:

i. Non Punitive : The most important characteristic for success of a donor and patient safety reporting system is that it must be non-punitive. Neither reporters nor others involved in the incidents can be punished as a result of reporting. It is important for facility in-charge to protect reporters from blame. The best way to do this is by keeping the reports confidential.

ii. Anonymized: identities of the individuals or institutions involved in recording and reporting adverse events are not identified in feedback reports

iii. Confidential: The donor/patient and reporter must never be revealed to any third party. At the institutional level, confidentiality also refers to not making public specific patient Information that can be used in litigation.

iv. Expert Analysis: Reports must be evaluated by experts who understand the clinical circumstances under which the incidents occur and who are trained to recognize underlying systems causes.

v. Credible: The combination of independence and the use of Content experts for analysis is necessary if recommendations are to be accepted and acted pon.

vi. Timely. Reports must be analyzed without delay, and recommendations must be promptly disseminated to those who need to know. When serious hazards are identified notification should take place rapidly.

vii. System Oriented. Recommendation should focus on changes in the systems, processes or product, rather than being targeted at individual performance. This is cardinal principle of safety that must be reinforced by the nature of recommendations that come from any reporting system. It is based on the concepts that even an apparently egregious individual error results from system defects, and will recur with another person at another time if those systems defects are not remedied.

viii. Responsive. Organization receiving reports must be capable of making and disseminating effective recommendations, and target organizations must make a commitment to implement recommendations whenever possible.
ix. Resources. Allocation of necessary resources to enable system operations

x. Voluntary: data collection and reporting will depend on the willingness of the health workers to report adverse events and there should be no any statutory requirement that must be fulfilled by health care workers and relevant stakeholders

xi. Active surveillance : Proactive and targeted search for adverse events in a systematic way

xii. Comprehensive: Include reporting of all types of adverse events and all levels of severity

1.5. Hemovigilance system in Rwanda

1.5.1. Background

The mission of (BTD) Blood Transfusion Division is to provide safe, effective and adequate blood products and other human tissues to all patients in need.

The BTD coordinates a chain of activities beginning from mobilization, recruitment and selection of voluntary non-remunerated blood donors through blood processing to its administration to recipients. The term “Safe Blood Transfusion” implies an outcome that is totally beneficent and non-maleficent to the patient. Safe blood practice is dependent on several factors including selection of voluntary blood donors with low risk for transfusion transmissible infections (TTI), aseptic collection of blood donations, use of sensitive and specific screening tests for TTI screening, appropriate cold chain maintenance, accurate cross-matching, and minimize transfusion reactions through appropriate and rational clinical use of blood and blood components. When these are not observed, the transfusion of blood and blood components can be an efficient vehicle for transmission of amongst other infections HIV, Hepatitis B & C, and Syphilis. Other than the infectious risks, transfusion may be associated with complications related to exposure to foreign antigens, altered chemical/temperature balance and anaphylaxis.

Throughout the blood transfusion chain there is a chance of occurrence errors that may lead to untoward events to both blood donors and recipients. Haemovigilance

system helps to capture these events, report, analyze, and institute corrective and preventive measures.

The Hemovigilance system in Rwanda was established in 2012. In 2016, the World Health Organization reported that Rwanda was one of 70 countries to have an established national hemovigilance system.

It is also a member of the International Hemovigilance Network (IHN) with 38 other nations and one of only 12 countries in Africa to have a formalized system for transfusion-related adverse events. The Rwandan hemovigilance system involves all relevant stakeholders and is coordinated by RBC through Blood Transfusion Division.

In future, it is envisaged that the hospital transfusion committees in collaboration with RCBTs and other stakeholders would play a more active role in the Hemovigilance system implemented by RBC through BTD.

1.5.2. Hemovigilance system reporting process

On quarterly basis, the hemovigilance teams of RCBTs receive or collect information concerning indications for blood transfusion, blood utilization and adverse transfusion reaction reports from clinicians of the hospitals within their catchment areas as well as donor adverse reactions from blood collection team. The reports are compiled and reviewed by the blood transfusion division hemovigilance team and published as annual hemovigilance report.

2. Blood components transfused in Rwanda in 2022

In 2022, Rwanda Blood Transfusion Division collected 78,838 blood units which were processed into different blood products for transfusion to patients in need. A total of 118,278 units of blood and blood products were issued to transfusing facilities from 1st January to 31 December 2022. Of these, 79,583 (67.3%) were red blood cells (RBCs), 27,521(23.3%) were platelets, 8454 (7.1%) were fresh frozen plasma (FFP) and 2720 (2.3%) were Cryoprecipitate units. As the blood components distribution was dominated by PRBCs, this made our analytical interests.

2.1. Red blood cells transfusion rates by RCBTs: 2022

A total of 79,583 units of Packed Red Blood Cells (PRBCs) were issued by the Blood Transfusion Division (BTD) in the period from 1st January to 31st December 2022.

Table 2.1 indicates that Kigali had the highest PRBCs transfusion rate, at 20.98 units per 1,000 populations, followed by Ruhengeri at 4.71, Butare at 4.08 and Rwamagana at 3.40. The lowest transfusion rate was in Karongi (2.24 per 1,000 population). The high rates of issuance in Kigali, Butare and Ruhengeri are probably justified by the huge number of healthcare facilities in their respective areas of coverage, the accessibility and other some other undescribed factors such traffic accidents incidences, etc. The predominantly rural provinces, such as Western (Karongi) and Eastern (Rwamagana), have lower transfusion rates than urbanized provinces such as City of Kigali, Northern (Ruhengeri) and Southern (Butare). Referral hospitals that use higher amounts of blood and products are mainly in Kigali, Ruhengeri and Huye cities.

AREAS	Population	PRBCs	Transfusion rate per 1,000 population
RCBT KIGALI (CoK)	1,745,555	36,629	20.98
RCBT BUTARE (SOUTHERN)	3,002,699	12,261	4.08
RCBT KARONGI (WESTERN)	2,896,484	6,485	2.24
RCBT RUHENGERI (NORTHERN)	2,038,511	9,596	4.71
RCBT RWAMAGANA (EASTERN)	3,563,145	12,113	3.40
Total	**13,246,394**	**77,084**	**5.82**

Table 2.1

3. Transfusion related adverse events in 2022

This chapter provides details on adverse transfusion reactions reported in Rwanda in 2022.

	Adverse reactions	Number	% of total reactions	Adverse effects per 100,000 units issued
Acute Transfusion Reactions (ATRs)	Acute Hemolytic Transfusion Reactions (AHTRs)	0	0.0	0
	Mild Allergic Reactions	13	100	
	Severe Allergic Reactions	0	0.0	0
	Anaphylactic Reactions	0	0.0	0
	Febrile Non-Hemolytic Reactions (FNHTRs)	0	0.0	0
	Transfusion-Associated Circulatory Overload (TACO)	0	0.0	0
	Transfusion-relatedAcute Lung Injury (TRALI)	0	0.0	0
	Transfusion-Associated Dyspnea (TAD)	0	0.0	0
	Hypotensive Reactions	0	0.0	0
	Unclassifiable (incomplete information)			
	Total (ATRs)	**13**	**100.0**	**10.9**
Delayed Transfusion Reactions (DTRs)	Delayed Hemolytic Transfusion Reactions (DHTRs)	0	0	0
	Delayed Serological Transfusion Reactions (DSTRs)	0	0	0
	Total (Delayed Reactions)	**0**	**0**	0
Incorrect Blood Component Transfused (IBCTs)	Rh Incompatible Transfusions	0	0	0
	Misdirected Transfusions (with and without ABO blood group incompatibility)	0	0	0
	Total (IBCTs)	**0**	**0**	**0**
	Near miss	0	0	

Other Reactions	Transfusion Associated Graft-versus-host Disease (TA-GvHD)	0	0	0
	Transfusion Transmitted Infections	0	0	0
	Total (other)	**0**	**0**	**0**
TOTAL (Adverse Events)		**13**	**100.0**	**10.9**

Table 2.1

Table 2.1 shows categories of adverse reactions collected by BTD hemovigilance team in 2022.

Among the 4 categories of adverse reactions, Acute Transfusion Reactions (ATRs) was the only one that was predominant as it was identified by the Blood Transfusion Division (BTD) and Transfusing Health Facilities (THFs) team. These were thirteen cases in total.

4. Transfusion transmitted infections and lookbacks

In Rwanda, all blood donations are screened for Hepatitis B surface antigen (HBsAg), anti-HCV, anti-HIV-1/2 and syphilis antibody. In 2022, the prevalence of HIV, HBV, HCV and syphilis among the blood donor population was 0.04%, 0.33%, 0.22% and 0.40% respectively. No transfusion-transmitted infection (TTI) events were reported.

4.1. Lookback

All cases of potential TTIs are investigated by the BTD quality office. Lookback cases can be either donor or recipient triggered. In a donor-triggered lookback investigation, a repeat donor would test positive for one of the screened viral infections and the recipients of the blood products associated with his or her previous donation would be traced for testing. The risk in this scenario would be potential transmission to the patient if the donation took place within the window period of these infections. Testing of patients involved in donor-triggered lookback cases should be managed by the clinician.

A recipient-triggered lookback case would be initiated when the blood service is informed that a blood product recipient has tested positive for a TTI and is requested to investigate whether this was acquired via transfusion. The implicated donors are traced and either tested for the infection, or their donation histories scrutinized for potential HIV, HBV or HCV.

There is little done in look back due to lack of legal protection. In donor triggered lookback we only collect the data.

Donor-triggered Lookback Investigations	Total Numbers
HIV	3
HBV	4
HCV	8
HIV/HCV co-infection	1
Total	**16**

(Table 3.1)

Tables 3.1 details the 16 donor-triggered lookback cases investigated in 2022. Of these, 3 cases (18.75%) were for HIV, 4 cases (25%) for HBV, 8 cases (50%) for HCV, 1 case (6.25%) for HIV/HCV co-infections.

For all those cases, no recipient was identified and tested and no recipient- triggered lookback was initiated.

5. Donor Vigilance Data 2022

Donor vigilance is the systematic monitoring of adverse reactions and incidents in blood donor care to improve quality and safety for blood donors. Donor hemovigilance systems permit monitoring of donor safety and evaluation of the impact of changes in donation procedures and of the success of interventions designed to further improve donor safety.

In BTD, there were 24 donor adverse reactions reported in 2022. The overall reported rate of donation-related adverse reactions seems to have decreased from that of 2021, which probably reflects improved donor safety, though this time there were two cases of severe adverse reactions recorded.

There were three phases of adverse reactions notably:

5.1. Mild adverse reaction

These symptoms range from a mild vasovagal reaction (VVR), nausea, vomiting, increased nervousness/anxiousness and/or hyperventilation, hypotension, cold extremities, flushing, in delayed syncope, cardiac arrest, and seizures.

5.2. Moderate adverse reaction

Pain, hyperemia and swelling may develop at the site of the extravasation. Other local events include pain due to slight trauma to the subcutaneous nerve endings and loss of consciousness >30 seconds prolonged or severe. In most cases, however, these are banal complications that do not require any treatment.

5.3. Severe adverse reaction

Symptoms are the same as Mild and Moderate plus severe tetany, convulsions, loss of consciousness with or no response, respiratory arrest, and/ or cardiac arrest. The donor may have severe bradycardia

The most frequently reported donation adverse events in 2022 were Mild adverse reaction 22 cases and 2 cases of severe adverse reactions.

Table 5.1 : Adverse réactions recorded in 2021 and 2022

DONOR ADVERSE REACTIONS (DARs)	Mild Adverse Reaction (MARs)		Moderate Adverse Reaction (MARs)		Severe Adverse Reaction (SARs)		Total	
YEARS	2021	2022	2021	2022	2021	2022	2021	2022
TOTAL	**21**	**22**	**8**	**0**	**0**	**2**	**29**	**24**

The main recommendations

From the above findings, the BTD hemovigilance team recommends the following:

1. Transfusing Health Facilities

- To Create and empower the transfusion committees
- To promote the recognition, management and reporting of transfusion-related adverse events through the implementation of specific national programs.
- Maintain and improve existing capacities for hemovigilance data reporting.
- Encourage thorough investigation of incidents to identify system-related and human factors that need to be addressed.
- Provide specific educational focus for the prevention of misdirected transfusions by encouraging hospital staff to be vigilant at each step of the transfusion process, particularly patient verification prior to transfusion.
- Encourage the use of information in the hemovigilance report by clinicians and hospital management to initiate and guide patient blood management strategies.

2. Rwanda Biomedical Centre

- To promote and empower the education sessions of clinicians on the correct management and administration of blood and blood products.
- Establish legal basis for look back procedures

Conclusion

The blood transfusion services in Rwanda continue their commitment to ensuring blood safety, supporting healthcare givers when reporting transfusion adverse events, investigating and identifying system failures, and identifying processes that will prevent recurrence.

Hospital transfusion committees should be encouraging monitoring the process and encourage staff to report accurately.

Ongoing surveillance and review of donor adverse events is vital and enables the blood services to monitor and minimize risks related to blood donation and implement corrective systems. The blood services aim for continuous improvement in an environment that is not perfect.

Haemovigilance is a continuous process of data collection and analysis of transfusion-related adverse events and reactions (AR/AE) in order to investigate their causes and outcomes, and prevent their occurrence or recurrence. A Haemovigilance system is an integral part of quality management in a blood system and is required for the continual improvement of the quality and safety of blood products and the transfusion process. Haemovigilance is essential to identify and prevent the occurrence or recurrence of adverse reactions and unwanted events, and to increase the safety, efficacy and efficiency of blood transfusion as it covers all activities of the blood chain, vein-to-vein, from donor to recipient. A system of Haemovigilance is dependent on the traceability of blood and blood products from donors to recipients and vice versa (bi-directional tracking), the monitoring, investigation and reporting of transfusion- related adverse reactions and events and the rigorous management of information related to the transfusion process. Information generated through this system is key to introduce required amendments in transfusion policies, to change processes in blood services and transfusion practices in hospitals, to improve transfusion standards, to assist in the formulation of transfusion guidelines and to increase the safety and quality of the entire transfusion process.

Rwanda Haemovigilance Programme endeavours continuously to highlight and educate healthcare providers on the importance of monitoring, evaluating and reporting of transfusion adverse events.

So far, allergic transfusion reactions remain the main concern to be addressed by all parties involved and patients who experience adverse events must be appropriately managed.

BTD is calling all the clinicians, nurses, scientists, academicians, regulatory experts, transfusion medicine experts who will receive this hemovigilance report to use it as it is and give their feedback and their valuable inputs in order to ameliorate our services. This report is the first version and has been written in simple points formats to allow for easy and quick reading. For extra information, the reader is referred to more detailed books like the BTD annual reports and guidelines.

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