THE SOUTH AFRICAN

HAEMOVIGILANCE REPORT

2024

IHC | INDEPENDENT HAEMOVIGILANCE COMMITTEE

Haemovigilance Report 2024

The 25th South African Haemovigilance Report

Privacy Statement

Every reasonable effort has been made to not identify individual patients, clinicians or healthcare institutions in this report.

Disclaimer

This document is a general report only. Reporting of haemovigilance data to the national Haemovigilance Programme is voluntary and data validation is not performed in all instances. The report's data, analysis and conclusions are intended to provide healthcare professionals and the public with general information regarding haemovigilance surveillance in South Africa. This report is an overview of currently available data that has been obtained from limited sources from all provinces in South Africa.

List of Authors & Contributors

Compiled by:

- **Prof. Arthur Rantloane** (Member of the Independent Haemovigilance Committee)
- **Dr Patricia Knox** (Chair of the Independent Haemovigilance Committee)

Contributors:

- **Dr Caroline Hilton** (Lead Medical Consultant, WCBS)
- **Dr Solomuzi Ngcobo** (Lead Consultant, Medical Affairs, SANBS)
- **Sr Francis Ledwaba** (National Haemovigilance Officer, SANBS)
- **Mr Sydwell Mabilana** (Haemovigilance Officer, SANBS)
- **Dr Ute Jentsch** (Lead Consultant, Pathology: Specialised Services and Quality Control, SANBS)
- **Lookback Officers** (SANBS)
- **Specialised Donations, Immunohaematology and Donor Clinic Departments** (WCBS)
- **Ms Ronel Swanevelder** (Analytics Specialist, SANBS)
- **Mr Kevin de Smidt** (Manager, Information Technology Client Services, WCBS)
- **Immunohaematology: Red Cell Serology staff** (SANBS)

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A number of stakeholders provided transfusion safety and quality data to SANBS and WCBS. We encourage a higher level of reporting, which leads to proactive development of a system that identifies transfusion risks, so that appropriate measures can be taken to improve transfusion safety.

Contact Details

National Haemovigilance Offices:
South African National Blood Service
Private Bag X14
Weltevreden Park, 1715
Tel: +27 (0)11 761 9371
www.sanbs.org.za

Western Cape Blood Service
PO Box 79
Howard Place, 7450
Tel: +27 (0)21 507 6000
www.wcbs.org.za

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An electronic copy is available on **www.sanbs.org.za** and **www.wcbs.org.za**

Contents

1 Abbreviations

API	alternate products issued
ARV	antiretroviral drug
BECS	Blood Electronic Computer System
BTS	blood transfusion services
CMV	cytomegalovirus
COVID	coronavirus disease 2019 (COVID-19)
DAE	donor adverse event
DAT	direct antiglobulin test
FFP	fresh frozen plasma
FiO_2	fraction of inspired oxygen
FNHTR	febrile non-haemolytic transfusion reaction
GMP	good manufacturing practice
GP	general practitioner
Hb	haemoglobin
HBsAg	hepatitis B surface antigen
HBV	hepatitis B
HCV	hepatitis C
HIV	human immunodeficiency virus
HLA	human leukocyte antigen
HNA	human neutrophil antigen
IAT	Indirect Antiglobulin Test
IBCT	incorrect blood component transfusion
ICU	intensive care unit
ID-NAT	individual donation nucleic acid amplification test
IgG	immunoglobulin G
IHC	Independent Haemovigilance Committee
ISBT	International Society of Blood Transfusion
IVI	intravenous infusion
NAT yield	a donation which tests ID-NAT repeat reactive but serology (anti-HIV, HCV & HBsAg) negative
PaO_2	partial pressure of oxygen
PM	post mortem
RBC	red blood cell
RCC	red cell concentrate (the type of red cell product, linked to how the unit is processed)
SAE	serious adverse event
SAED	serious adverse event of donation
SANBS	South African National Blood Service
SHOT	*Serious Hazards of Transfusion* (UK Annual Report)
SOP	standard operating procedure
TACO	transfusion-associated cardiac overload
TAD	transfusion-associated dyspnoea
TIA	transient ischemic attack
TRAE	transfusion-related adverse event
TRALI	transfusion-related acute lung injury
TTI	transfusion-transmitted infection
WBIT	wrong blood in the tube
WCBS	Western Cape Blood Service

2 Definitions

Definitions Pertaining to the Haemovigilance System

The definitions aim to standardise the reporting of all haemovigilance events to improve blood safety. Definitions have been obtained from the *ISBT Working Party on Haemovigilance – Proposed Standard Definitions for Surveillance of Non-Infectious Adverse Transfusion Reactions*[1] *(2011)*, as amended (available at www.isbt.org).

Haemovigilance comprises surveillance procedures covering the whole transfusion chain, from collection of blood (components) to follow-up of its recipients. It assesses information on undesirable transfusion effects, including local venepuncture accidents, graft-versus-host disease and mild to severe transfusion reactions, to prevent their occurrence.

Donor haemovigilance is the systematic monitoring of adverse reactions and incidents in the whole chain of blood donor care, with a view to improving quality and safety for blood donors.

An **adverse event** is an undesirable and unintended occurrence before, during or after transfusion of blood or a blood component, which may be related to the administration of the blood or component. It may be the result of an error or an incident and it may or may not result in a reaction in a recipient.

An **incident** is a case where the patient is transfused with a blood component which did not meet all the requirements for a suitable transfusion for that patient, or that was intended for another patient. An incident is thus comprised of transfusion errors and deviations from standard operating procedures or hospital policies, leading to an incorrect blood component transfusion. An incident may or may not lead to an adverse reaction.

A **near miss event** refers to any error which, if undetected, could have resulted in the determination of a wrong blood group or in transfusion of an incorrect component, but which was recognised *before* the transfusion took place.

An **adverse reaction** is an undesirable response or effect in a patient, temporally associated with the administration of blood or blood components. It may, but need not, be the result of an incident.

A **serious adverse reaction** refers to an unintended response in a donor or in a patient associated with the collection or transfusion of blood or blood components that is fatal, life threatening, disabling or incapacitating, or which results in, or prolongs, hospitalisation or morbidity.

Category of Adverse Reaction	Definition
Acute transfusion reaction	Transfusion-related reaction that occurs at any time during or up to 24 hours following transfusion of blood or components. The most frequent reactions are fever, chills, pruritus or urticaria, which typically resolve promptly without specific treatment or complications.
Haemolytic transfusion reaction	Reaction where there are symptoms and clinical or laboratory signs of increased destruction of transfused red blood cells. Haemolysis can occur intravascularly or extravascularly and can be immediate (acute) or delayed.
Acute haemolytic transfusion reaction	Rapid destruction of red blood cells immediately after or within 24 hours of a transfusion. Clinical or laboratory signs of haemolysis are present. No single criterion exists to definitively diagnose this rare disorder. It is commonly associated with fever, chills/rigors and other symptoms/signs of haemolysis, and confirmed by a fall in haemoglobin, a rise in lactate dehydrogenase, a positive direct antiglobulin test (DAT) and incompatible crossmatch.
Allergic transfusion reaction	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 may present 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, characterised by bronchospasm causing hypoxia or angioedema causing respiratory distress.
Transfusion-associated dyspnoea	Respiratory distress within 24 hours of transfusion that does not meet the criteria of transfusion-related acute lung injury, transfusion-related circulatory overload or severe allergic reaction that is not explained by the patient's underlying condition. Respiratory distress is the most prominent feature.
Hypotensive transfusion reaction	Hypotension manifesting as a drop in systolic blood pressure of ≥30 mmHg occurring during or within one hour of completing transfusion **AND** a systolic blood pressure of ≤80 mmHg, provided all other adverse reactions with underlying conditions that could explain hypotension have been excluded. May be accompanied by facial flushing and gastrointestinal symptoms.

Category of Adverse Reaction	Definition
Transfusion-associated circulatory overload	The presence of acute or worsening respiratory compromise and/or evidence of pulmonary oedema during or up to 12 hours after transfusion, and a total of **THREE OR MORE** of the following: i. Acute or worsening respiratory compromise ii. Evidence of acute or worsening pulmonary oedema iii. Evidence for cardiovascular changes not explained by the patient's underlying medical condition iv. Evidence of fluid overload v. Supportive result of a relevant biomarker
Transfusion-related acute lung injury	Acute hypoxemia with PaO_2 fraction of inspired oxygen (FiO_2) ratio of 300 mmHg or less combined with chest x-ray showing bilateral infiltrates in the absence of left atrial hypertension (i.e. circulatory overload). There is abrupt onset in association with transfusion. The patient must have no evidence of acute lung injury prior to transfusion. Criteria for diagnosis include **ALL** the following: i. Acute onset ii. Hypoxaemia iii. Bilateral infiltrates on chest x-ray iv. No evidence of circulatory overload v. No temporal relationship to an alternative risk factor for acute lung injury during or within six hours of the completion of transfusion The diagnosis does not require the presence/evidence of anti-HLA (human leukocyte antigen) or anti-HNA (human neutrophil antigen) antibodies in donor(s) nor the confirmation of cognate antigens in the recipient.
Anaphylactic transfusion reaction	Presentation is usually during or shortly after transfusion, and in addition to the muco-cutaneous features such as urticaria and rash, there is airway compromise or severe hypotension requiring vasopressor treatment. The respiratory signs and symptoms may be laryngeal (stridor, hoarseness, tightness in the throat) or pulmonary (dyspnoea, cough, wheeze, hypoxaemia). Circulatory compromise may present as syncope or hypotonia.

Category of Adverse Reaction	Definition
Febrile non-haemolytic transfusion reaction	Diagnosed in the presence of **ONE OR MORE** of the following: i. Fever ≥38 °C oral or equivalent AND a change of ≥1 °C from pre-transfusion value ii. Chills/rigors Reaction occurs during or within four hours following transfusion, and without evidence of haemolysis or bacterial contamination. May be accompanied by headache and nausea. Criteria for severe febrile non-haemolytic transfusion reaction: i. Fever ≥39 °C AND a change of ≥2 °C from pre-transfusion value ii. The increase in temperature may or may not be associated with chills/rigors
Mixed febrile/ allergic reaction	Features of both allergic and febrile reactions, at least one of which is in the severe category.
Delayed haemolytic transfusion reaction	The recipient develops antibodies to red blood cell antigens. This usually manifests between 24 hours and 28 days following a transfusion, and clinical or biological signs of haemolysis are present. In practice, these are usually delayed haemolytic reactions due to the development of red cell antibodies. Simple serological reactions, such as antibody development without a positive direct antiglobulin test or evidence of haemolysis, are excluded.
Delayed serologic transfusion reaction	Demonstration of new clinically significant alloantibodies against red blood cells between 24 hours and 28 days following transfusion, despite an adequate haemoglobin response to transfusion that is maintained (i.e. no clinical or laboratory features of haemolysis).
Post-transfusion purpura	Thrombocytopenia arising five to 12 days following transfusion of cellular blood components, associated with the presence in the patient of alloantibodies directed against the human platelet antigen system.
Transfusion-associated graft-versus-host disease	The introduction of immunocompetent lymphocytes into a susceptible host. The allogeneic lymphocytes engraft, proliferate and destroy host cells. Symptoms develop within 30 days of transfusion, presenting with fever, rash, liver function abnormalities, diarrhoea, pancytopenia and bone marrow hypoplasia.

Category of Adverse Reaction	Definition
Transfusion-transmitted infection	The recipient has evidence of infection following a transfusion, but no clinical or laboratory evidence of infection prior to transfusion. Either at least one component received by the infected recipient was from a donor with evidence of the same infection or at least one component received by the infected recipient was shown to have been contaminated with the same organism.
Transfusion-transmitted viral infection	As per the definition for a transfusion-transmitted infection, but specifically related to a virus. The most common viruses associated with transfusion-transmitted viral infections are human immunodeficiency virus, hepatitis B and hepatitis C.
Transfusion-transmitted bacterial infection	Detection by approved techniques of the same bacterial strain in the recipient's blood and in the transfused blood product. Probable cases of transfusion-transmitted bacterial infection include evidence of infection in the recipient following a transfusion when there was no evidence of infection before transfusion and no evidence of an alternative source of infection.
Transfusion-transmitted parasitic infection	Detection of the parasite of infection in the recipient's blood and the same parasite or specific antibodies in the donor blood.
Incorrect blood component transfusion	All reported episodes where a patient was transfused with a blood component or plasma product that did not meet the requirements or that was intended for another patient.

Definitions Used Within This Report

Donor: A person who attends a blood donation collection site, completes a donor questionnaire and is assigned a serial number. This includes whole blood and apheresis donors.

All whole blood donations: Includes all whole blood donations (also called 'needle-in-arm events') excluding therapeutic dry pack donors and donors who present for testing purposes only (e.g. cross-reactive donors). This excludes the apheresis as this number is used for assessing red blood cell collection and usage.

All donations: The total number of donations including whole blood, apheresis and therapeutic donations, but excludes donors presenting for test purposes. This number is used for calculating the rate of donor adverse events and serious donor adverse events per 100 000 donations.

Red blood cell collections: The total number of 'valid' whole blood units available to blood banks (i.e. all donations minus insufficient units, transfusion-transmitted infection-positive units and units compromised during processing).

Red blood cell usage: The total red cell product issued.

Buffer stock: The number of units available to mitigate any shortfall between red blood cell collections and issues, thus protecting security of supply.

Cutbacks (also called restrictive issues): A mechanism used to manage limited blood supplies. The process entails issuing fewer units than have been requested and is mainly applied to Group-O patients and never to paediatric patients or emergency patients.

Transfusion rate: The total number of red blood cell units issued as a function of the size of the reference population and expressed per thousand members of said population. Thus, the national transfusion ratio is calculated as: total number of units issued x (1/population size) x 1 000. The same formula is used for determining the provincial blood transfusion ratio.

Alternate product issued (API): When the product requested is not available in the blood bank, an alternate product is issued instead and this is done in consultation with the clinician. Typical examples include standard red blood cells instead of leucodepleted red blood cells; pooled platelets instead of apheresis platelets; adult red blood cell unit for use in paediatrics.

Donor-triggered lookback investigation: A process whereby the recipient(s) of the previously negative units are identified and their treating doctors are notified that the donor has donated recently and tested positive for a viral marker. As far as possible, the patient is recalled, counselled and tested for the relevant viral marker to eliminate the possibility of a window period infection transmission and the result is reported to the blood transfusion services.

Recipient-triggered lookback investigation: Initiated when the blood transfusion services are informed that a blood recipient has tested positive for a transfusion-transmitted infection and that the infection may have been the result of a blood transfusion. The implicated donors are identified and their donation history reviewed. Where subsequent donations do not prove that the donor was not in a window period for the infection, the implicated donors are recalled for further testing.

Window period: Time between contracting a particular infection and it becoming detectable by a particular test method.

3 Foreword

> “... the importance of performing accurate and complete patient identification is under-estimated by both hospital and blood bank staff.”

This is the third edition of the annual *South African Haemovigilance Report* to be written up by an independent group. As the Independent Haemovigilance Committee (IHC), our goal is to report as accurately as possible the data provided by the hospitals and blood services of South Africa. The year 2024 has not been without challenges, such as a complete change in the blood banking computer system at SANBS and resource challenges in all our public sector hospitals.

Blood transfusion is an integral part of patient management and the impact of economic constraint in healthcare in South Africa is therefore felt both in the blood services' human resources and in decreased budgets. Doctors and nurses are at times not working in ideal circumstances and may therefore convey to blood bank staff the lack of time to complete post-transfusion monitoring and reporting of adverse events or a reluctance to report due to fear of litigation. This lack of documentation incrementally leads to a lack of accountability and, ultimately, to the inability to identify required changes to improve patient safety.

On a more positive note, we can record an increased awareness in the blood banks regarding 'near miss events' as well as several hospital staff voluntarily reporting 'near miss' misdirected units almost transfused. This is a major step in building trust in the voluntary reporting system. The Haemovigilance Officers and blood bank staff have improved in playing their part in tracing all units when an error involving more than one patient and multiple units occurs. However, the importance of performing accurate and complete patient identification is underestimated by both hospital and blood bank staff. Errors resulting in incorrect blood transfusion components being transfused, due to lack of patient identification or attention to detail when carrying out a procedure, remain a major concern.

We appreciate all the staff who have investigated cases, provided information and tirelessly answered our queries. Without identifying the risks and errors we cannot educate and forewarn our colleagues of the current risks of transfusion. Education is paramount to improve patient safety.

The IHC's goal remains to foster trust and transparency so that healthcare workers regard the annual *Haemovigilance Report* as an important source of information on the safety and sufficiency of the South African blood supply, much like a businessperson regards the annual integrated report as a source of information on a company's financial standing and governance.

Haemovigilance comprises surveillance procedures covering the whole transfusion chain, from collection of blood and blood components to follow-up of its recipients. It assesses information on undesirable transfusion effects, including local venepuncture accidents, graft-versus-host disease and mild to severe transfusion reactions, to prevent their occurrence.

4 Executive Summary

In this 25th edition of the *South African Haemovigilance Report*, we provide an overview of blood product usage and serious adverse events (SAEs) related to transfusion and blood donation in the country during the 2024 calendar year.

Of significance in this reporting period is that all three indicators of blood usage are down on the previous year. Total red blood cell (RBC) usage has decreased 1.5% from 2023 and this is associated with decreases in the use of plasma and platelet products, resulting in an overall 1.8% decrease in the issue of all products, including plasma and platelet products. These decreases in usage are underpinned by a 0.5% increase in usable RBC collections when compared to the previous year (1 078 027 vs 1 072 944). In an improvement on 2023's figures, RBC supply cutbacks were only experienced for a period of 51 days, spread between January and February, and these constitute only 0.24% of all blood-group issues for the year (target less than 1%).

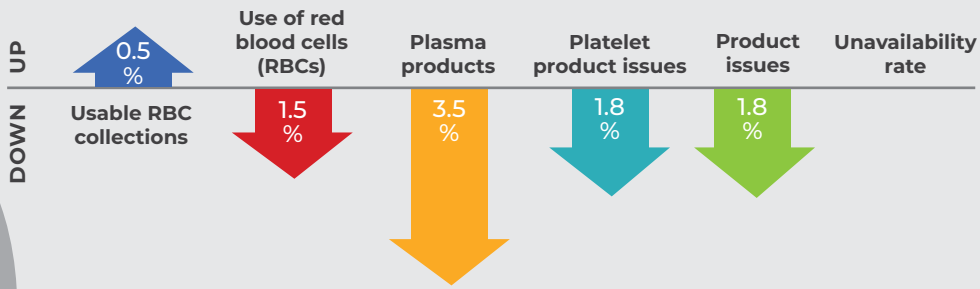
With regard to the availability of blood, the data show a positive balance between collections and issues, except in the months of May, September and October. Importantly, the negative balances have not triggered cutbacks in product issues.

> "... all three indicators of blood usage are down on the previous year."

One of the indicators of the health of the blood supply service is the transfusion rate, as it reflects availability of the product and, from it, we may also infer access to care. This rate is determined by matching the population size to the total number of blood units issued. In the year under review, the mid-year population size is estimated at 63.02 million people and a total 1 032 630 units of blood have been issued. This translates into a national blood transfusion rate of 16.4/1 000 population, which – disappointingly – is lower than the 16.9/1 000 reported in the preceding year.

A similar decline is seen in the use of blood products, with plasma and platelet products recording overall decreases of 3.5% and 1.8% respectively.

Percentage Increase of Blood Products, Usage and Availability in 2024



Transfusion rate
16.4/
1 000 population

> “… the donor pool has shown a worrying uptick in the prevalence of HIV, as well as a marginal increase in that of HBV.”

What is pleasing is that alternative products have been issued far less frequently than in the previous year (1.37% vs 1.56%) and the frequency is well within the target range of less than 2%.

The transfusion of blood and blood products is not without complications and transfusion-related adverse events (TRAEs) are therefore tracked to monitor the safety of the blood transfusion pathway.

For the year under review, the serious adverse event (SAE) rate is calculated as 14.2/100 000 transfusions, a marked improvement on the 24.8/100 000 reported in 2023. The most commonly occurring SAEs are febrile reactions and allergic-type reactions.

A worrying observation is that the number of patients receiving an incorrect blood component transfusion (IBCT) has increased from 29.5% of all SAEs reported in 2023 to 33.3% of those reported in 2024. The majority of these IBCTs have resulted from non-adherence to protocols applicable to specimen taking in the ward, crossmatching and issuing in the blood bank and/or transfusion of product in the ward. Three patients were transfused with blood that was not indicated at all.

As discussed in this report’s Foreword, near-miss reporting has improved, with a tripling of reported events in 2024 compared to the previous year. This suggests a system that has become increasingly conducive to the reporting of errors.

> … the need for actual evidence of measurably reduced clinical activity on the public health platforms cannot be overstated.

A total of 34 transfusion-associated mortalities are reported, of which only three are assessed as being likely due to the transfusion and none fulfil the criteria for a definite causal association.

Confirming the trend established many years ago, there are no reports of transfusion-related bacterial infections. Similarly, as has been the case for the past nine years, there are no reports of viral transfusion-transmitted infections. However, the donor pool has shown a worrying uptick in the prevalence of HIV, as well as a marginal increase in that of HBV.

Reporting on donor adverse events (DAEs) has unfortunately proved to be a challenge in this report, due to IT system changes at SANBS that have had an impact on the efficacy and completeness of data entry and capture. Accordingly, the DAE rate of 28.4/100 000 donations being reported for 2024 must be treated with caution as the rate has historically ranged between 37/100 000 and 44/100 000, suggesting that the current figure may be due to under-reporting. Nonetheless, as with previous reports, faints are the most common DAE reported.

In summary, the *2024 Haemovigilance Report* presents somewhat of a mixed bag in that it applies to a period when there is a 1.2% increase in population size yet collections have declined, aligning to the overall decrease in product-related issues. That being said, considering the less frequent and smaller supply cutbacks and decreased need for alternate products to be issued during the year under review, the system appears on balance to be capable of meeting patient demand.

However, the need for actual evidence of measurably reduced clinical activity on the public health platforms cannot be overstated.

Serious transfusion-related adverse events

14.2/ 100 000

transfusions

5 Blood Collections, Issues & Sufficiency

> Total red blood cell (RBC) units issued were 1.5% down on the previous year, which had in turn recorded a 0.3% decrease from 2022.

The year under review shows a decline in all the indicators considered in the determination of the adequacy of supply of blood and blood products. This is noteworthy because associated with this general decline was an increase in the population size of about 1.2% from 2023.

Total red blood cell (RBC) units issued were 1.5% down on the previous year, which had in turn recorded a 0.3% decrease from 2022. The decrease in usage was despite a net surplus of 45 397 units when comparing the number collected to the number issued.

The graph below highlights the considerable difference, or drop off, between those that present to donate (those that register and complete the questionnaire) and those who actually donate (those that have the needle inserted into the arm). This is due to the donor health check and donor questionnaire screening leading to donor deferrals. While undergoing processing and testing, an additional loss of RBC collections occurs due to:

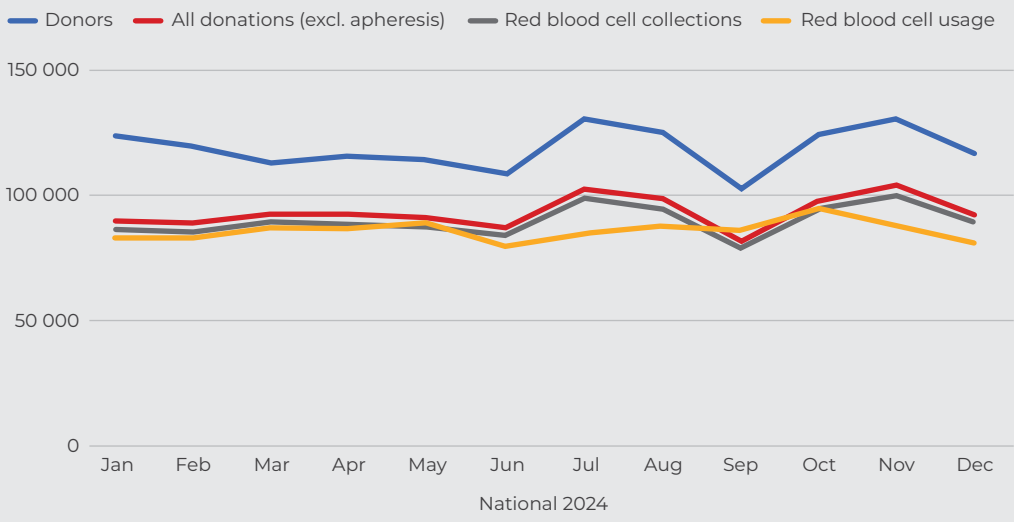
- insufficient unit volumes;
- transfusion-transmitted infection (TTI) positive units; and
- testing abnormalities.

This results in the RBC collections available to the blood banks being marginally less than donations.

> ... an average 24% of all attempted donations do not result in RBC units available for issue to patients.

RBC usage accounts for the units transfused to patients in South Africa. As can be seen in the graph below, an average 24% of all attempted donations do not result in RBC units available for issue to patients.

2024 National Donors, Whole Blood Donations vs Red Blood Cell Collections & Issues per Month



The sharp drop in donors in the month of September resulted in this being the month with the lowest donations for the year and also with by far the widest negative variance between collections and issues. However, for most of the year, RBC usage was steady and occurred within a relatively narrow band, with a significant peak in October and troughs in June and December. The latter two coincide with traditional holiday periods and the reduction in issues could be the result of reduced clinical activity.

There were critical shortages in the South African National Blood Service (SANBS) service platform during the months of January and February, resulting in supply cutbacks for four and three weeks respectively during this period. Curiously though, it was in the months of May, September and October that the number of issues exceeded the number of collections. Some of this may be explained by the fact that whole blood expires 42 days after collection.

Blood Products Issued in South Africa 2020–2024

Product	Category	2020	2021	2022	2023	2024
Plasma products	Fresh frozen plasma	139 442	142 392	153 957	152 244	140 541
	Cryoprecipitate/ cryo wet	39 239	46 776	54 804	58 456	57 999
	Cryo-poor plasma				5 373	50 001
	Total	**178 681**	**189 168**	**208 761**	**216 073**	**203 541**
Platelet products	Pooled platelets	37 755	41 943	43 909	43 689	42 380
	Apheresis platelets	39 440	41 113	43 289	44 243	44 038
	Total	**77 195**	**83 056**	**87 198**	**87 932**	**86 418**
Red cell products	**Total**	**953 760**	**993 498**	**1 050 909**	**1 047 757**	**1 032 630**
Total products		**1 209 636**	**1 265 722**	**1 346 868**	**1 346 389**	**1 322 589**

> “Total blood products issued was 1.8% down on the amount reported for 2023.”

Blood product usage was also down on the previous year, with a 3.5% decrease in total plasma products issued and a corresponding 1.8% decrease in platelet products issued. Of note, pooled platelet usage declined by some 3% and this was associated with a slight (0.5%) decrease in use of apheresis platelets.

Total blood products issued was 1.8% down on the amount reported for 2023. This is a significant jump from the 0.4% decrease reported in 2023.

It is uncertain what this all means, especially when viewed against the twin considerations of an increased population size and apparent decreased overall demand. One hypothesis is that it may signify stricter application of blood transfusion guidelines.

Red Cell Transfusion

With the total mid-year population size for 2024 estimated at 63.02 million[2], and a total RBC usage amount of 1 032 630 units, the national blood transfusion rate is calculated as 16.4/1 000 population.

This is lower than the transfusion rate of 16.9/1 000 reported for the preceding year. The reasons for the decline are not immediately apparent, especially when considering that supply cutbacks were not nearly as widespread as in the previous year and the blood services had a surplus of product in excess of 45 000 units at the end of the period under review. This decline in the national transfusion rates is further detailed in the provincial transfusion rates following hereunder.

The national blood transfusion rate is calculated as **16.4/ 1 000** population

Provincial transfusion rates

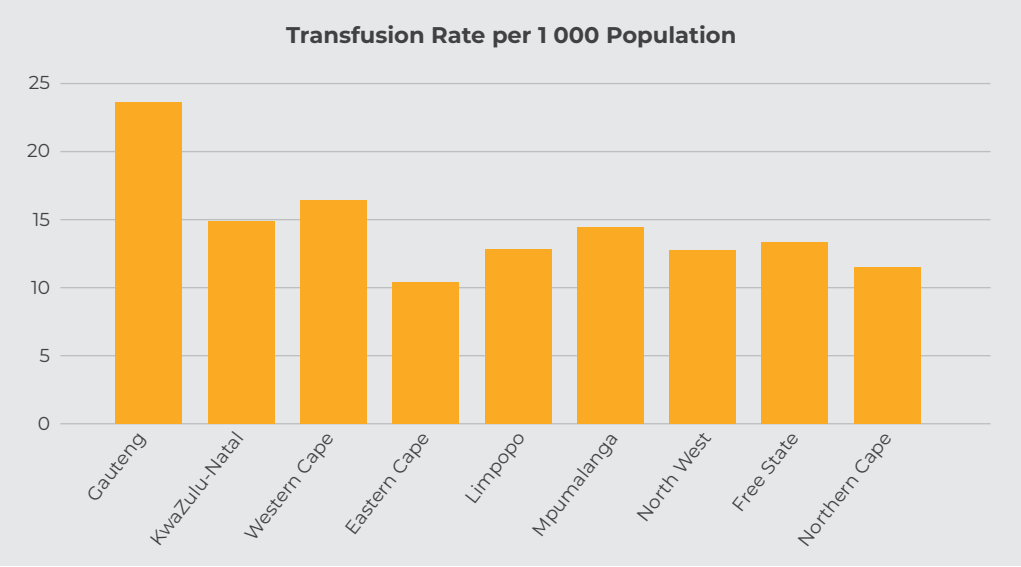
The provincial population sizes have remained relatively stable from year to year, with Gauteng, KwaZulu-Natal and Western Cape remaining the most populous provinces.

Gauteng again recorded the highest RBC transfusion rate at 23.8/1 000 population, followed by the Western Cape at 16.5/1 000 and KwaZulu-Natal at 15/1 000. This is a similar pattern to that seen in 2023, although all three provinces show a decline from the previous year.

The rest of the provinces show marginal changes in blood transfusion rates, with the three least populated provinces continuing their decreasing trend, while the rural provinces of the Eastern Cape, Limpopo and Mpumalanga recorded marginal increases from the previous reporting period.

The Western Cape has recorded the highest decrease in transfusion rate at 9.8%, followed by the North West Province at 8% and Gauteng at 6.3%. The reasons for these declines are unclear, especially in view of the very limited supply cutbacks which only affected one of the blood services.

The 8% decline in transfusion rate in the North West Province is worth a closer look, given that the rate had been increasing since 2021.



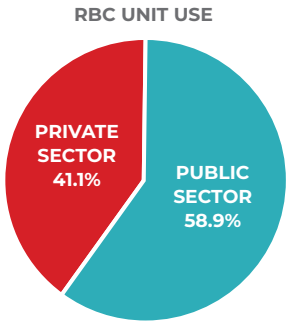
Provincial Red Cell Transfusion Rates: Comparisons Over a Five-Year Period 2019–2024

Transfusion Rate per 1 000 Population	2020	2021	2022	2023	2024
Gauteng	22.8	23.4	24.2	25.4	23.8
KwaZulu-Natal	15.0	15.6	16.5	15.1	15.0
Western Cape	17.6	17.8	18.1	18.3	16.5
Eastern Cape	9.9	11.1	11.2	10.3	10.5
Limpopo	12.6	12.2	13.4	12.7	12.9
Mpumalanga	13.7	14.1	15.0	14	14.5
North West	11.8	11.7	12.6	13.9	12.8
Free State	13.3	14.1	14.4	13.7	13.4
Northern Cape	10.2	10.6	11.9	11.8	11.6

Red blood cell transfusion in public and private sector

In the years 2020–2023, the split in RBC issues between public and private sectors has averaged 60:40 in favour of the public sector. This is unsurprising given the sheer size of the public health sector compared to private care facilities. This ratio has changed somewhat in the year 2024, with a slight uptick in the share of blood issued to the private sector. The total amount has exceeded 41% of the total for the first time in five years.

This development is probably the result of constrained clinical activity due to challenges in the public health system.



Public vs Private Red Cell Usage 2024

Red Cell Usage (Percentage)	2020	2021	2022	2023	2024
Private	38.7	40.3	39.6	39.9	41.1
Public	61.3	59.7	60.4	60.1	58.9

1 078 027
whole blood units were available for distribution

1 032 630
units were issued

Sufficiency of Blood

A total of 1 078 027 whole blood units were processed and available for distribution, and 1 032 630 units were issued over the period under review. This resulted in a net surplus of 45 397 units, or a positive variance of 4.45%, between processed units available and units issued to patients.

November had the highest positive variance of 11.75%, followed by December with 9.01% and August at 7.7%. However, a negative variance is seen in the months of May (–1.15%), September (–8.4%) and October (–0.4%). Collections during October were the fourth highest though, suggesting that the difference may be due to increased clinical activity requiring blood transfusion.

> "Overall, the data show a healthy balance between RBC collections and issues for the year..."

The difference of 8.4% in September due to a shortfall of 6 637 units did not result in supply cutbacks, presumably due to adequate stocks on hand. Neither did the shortfalls in May and October trigger the activation of restrictive measures.

The difference between collections and issues during the months of February to April ranges from 2.3% to 2.8%, with January and June occupying the middle ground at 4.0% and 5.8% respectively. With 79 075 units collected and processed, September recorded the lowest number of whole blood units available for distribution, and this was 5 001 units less than the second lowest total reported.

Overall, the data show a healthy balance between RBC collections and issues for the year, suggesting that the blood services are meeting the needs of society and demands of clinical care. Even where a negative variance is seen, these months did not experience restrictive measures to protect blood supply.

However, these data do not paint a complete picture of blood sufficiency as they only compare monthly input and output without accounting for residual stock (blood already in the inventory before new units are received from collections). A more complete assessment of the resilience of the system requires that this unknown quantity be added to the equation to give a more complete picture of the adequacy of supply.

> "... an optimally performing system requires that there be a buffer stock of product at all times to provide for routine and emergency requirements."

Nonetheless, the sum total of the net product surplus for the year and observation of product issues exceeding RBC collections in some months implies that there would have been sufficient stock on hand in the system to provide a buffer against failure to meet demand, even though that would have been variable across the blood banks. Be that as it may, an optimally performing system requires that there be a buffer stock of product at all times to provide for routine and emergency requirements. For dire emergencies, the staff can access emergency stock kept in the wards.

Product cutbacks 2024 (restrictive measures)

The two blood services were impacted differently by the unavailability of products, with the Western Cape Blood Service (WCBS) reporting minimal impact. Only two red cell concentrate (RCC) units were withheld and only six alternative products were issued instead of the product requested (non-filtered RCCs issued instead of leukocyte-reduced blood).

> The target for cutbacks is set at <1% of all issues, and the cutbacks for January and February represent 0.24% of all issues over the year. Encouragingly, this is far lower than the 1.14% reported for the previous year.

SANBS, being about six times the size of WCBS, experienced a much greater impact from product shortages. Restrictive measures were triggered and implemented for RBC during the months of January (31 days) and February (20 days), with 1 280 and 807 units held back respectively. This represents respectively 1.8% and 1.67% of all group issues during the period. The target for cutbacks is set at <1% of all issues, and the cutbacks for January and February represent 0.24% of all issues over the year. Encouragingly, this is far lower than the 1.14% reported for the previous year.

This picture does not quite correlate with the observations on RBC sufficiency because, according to that data, the months of January and February had a positive variance of 3 496 and 1 993 respectively between RBC collections and issues. The incongruence probably signifies the lag between collections and distribution to the blood banks, as a result of which restrictive measures had already been implemented when new blood stocks were received. This hypothesis notwithstanding, it is curious to note that the month of September, with a negative variance of 6 637 units, did not experience cutbacks even though it recorded the lowest collections total for the period January 2024 to December 2024.

Alternate product issued

When supplies of apheresis platelets are inadequate to meet demand, pooled platelets are issued instead, and this was true of every month of the year being reported.

With an alternate product issued (API) target of <2% of all products issued, the services achieved an average rate of 1.37% API as against the previous year's 1.56%. This implies an increased capacity to meet demand in 2024.

Interventions to protect supply

Platelet concentrate hubs were established in July 2024 and this has resulted in platelets being held in all blood banks, subject to ongoing review. The split rate is improving from a historical 1.44 in 2018 to 1.58 in 2024. The target is 1.66.

Lastly, pooled platelets are being produced in multiple zones and clinicians have been kept up to date with these developments.

> Overall, the data points to a system that is improving measurably at meeting the public's demand.

Overall, the data points to a system that is improving measurably at meeting the public's demand. The significant decrease in cutbacks of RBCs and the decrease in the frequency of issuing alternate products are good evidence of that.

The measures implemented should lead to even greater system resilience in future, which is necessary to support an ever-growing population.

6 Transfusion-Related Adverse Events

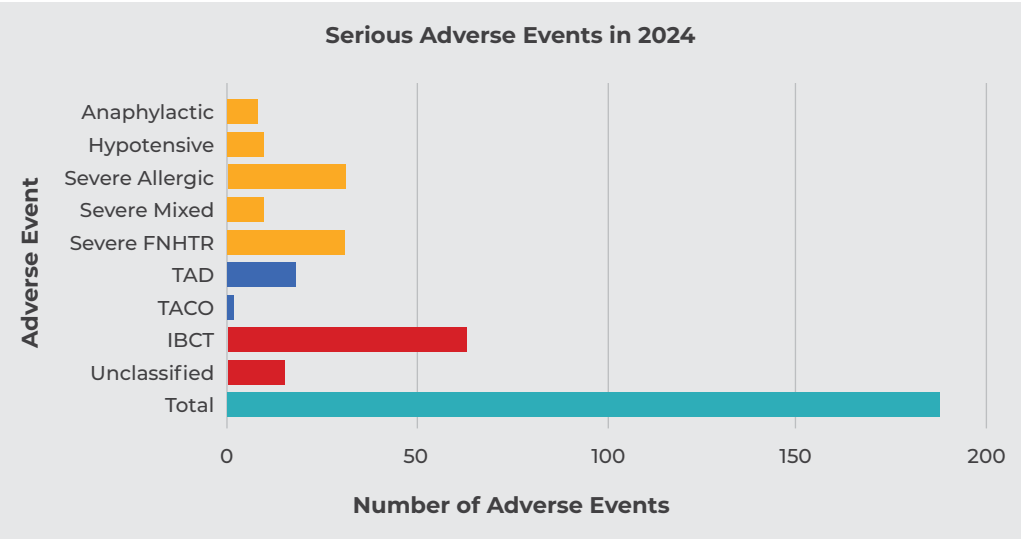
A transfusion-related adverse event (TRAE) is an undesirable and unintended occurrence before, during or after transfusion of blood or a blood component, which may be related to the administration of the blood or component. It may be the result of an error or an incident and it may or may not result in a reaction in the recipient.

1 319
adverse reactions were reported to blood bank staff in 2024, compared to
1 005
in 2023.

In 2024, a total of 1 319 adverse reactions were reported to the blood bank staff in hospitals throughout the country, compared to 1 005 in 2023. This includes mild, moderate and severe reactions and translates to a transfusion reaction rate of 99.7 per 100 000 transfusions compared to 95.9 per 100 000 transfusions in 2023. In keeping with international practice, such as described in the UK's *Annual SHOT* (*Serious Hazards of Transfusion*) Report[3], the Independent Haemovigilance Committee (IHC) does not report mild transfusion reactions. During the 12-month period under review, 188 serious adverse events (SAEs) of transfusion were reported, representing 14.3% of total adverse events associated with transfusion recipients. In comparison, a higher number of SAEs were reported to the IHC in 2023, with 261 during that 12-month period making up 25.9% of total adverse events associated with transfusion of recipients.

In 2024, with fewer total blood products (1 322 589) transfused and fewer SAEs reported (188), the SAE rate is 14.2/100 000 transfusions. This is lower than the SAE rate of 24.8/100 000 transfusions in 2023, but closer to the 2022 SAE rate of 15.2/100 000 when severe febrile non-haemolytic transfusion reactions (FNHTRs) were not included.

This considerable decrease needs further investigation as to whether it is a result of stricter categorisation of SAEs or of the single unit policy having impacted the number of units involved or some other system challenge. There have been many changes in the past three years and we look forward to observing trends in the near future, which should assist in highlighting relevant issues.



Adverse Reactions in Patients

Febrile, allergic, mixed allergic/febrile non-haemolytic transfusion reactions, anaphylactic & hypotensive reactions 2024 (*n*=90)

> This group of SAEs account for 47.7% of transfusion SAEs and are an unavoidable and unpredictable risk of transfusion.

Febrile, allergic, mixed allergic/FNHTR, hypotensive and anaphylactic reactions are an unavoidable and unpredictable risk of transfusion. This group of SAEs account for 47.7% of transfusion SAEs. Clinicians have a duty not to cause additional harm by prescribing inappropriate treatment, such as more blood or blood products than required, and to not treat all adverse reactions with a cocktail of analgesics, antihistamines and steroids.

Severe FNHTRs, which make up 16.4% of reported SAEs, were seldom treated with the treatment of choice – an antipyretic alone – but were instead treated inappropriately with antihistamine and/or steroids. South Africa is not alone in this inappropriate treatment of severe FNHTR as this has also been noted in previous UK *SHOT* Reports[3]. Concerted efforts to train UK doctors to confidently treat adverse events appropriately have resulted in improvements.

The South African criteria for the reporting of severe febrile and allergic type reactions categories have been aligned to international practice for the past two years, and can therefore be compared in the table below.

Febrile, Allergic, Mixed, Anaphylactic & Hypotensive Reactions 2023 & 2024

Category of Reaction	No. of Reactions Reported in 2023 (% of SAE)	No. of Reactions Reported in 2024 (% of SAE)
Severe FNHTRs	42 (16.1%)	31 (16.4%)
Moderate & severe allergic reactions	69 (26.4%)	31 (16.4%)
Moderate & severe mixed allergic/febrile reactions	6 (2.3%)	10 (5.3%)
Anaphylactic reactions	7 (2.7%)	8 (4.2%)
Hypotensive reactions	16 (6.1%)	10 (5.3%)

- All severe FNHTR were linked to red blood cell (RBC) products.
- 8.5% (16/188) of SAEs were related to fresh frozen plasma (FFP) or platelet product transfusions. All of these adverse reactions were allergic-type reactions, with the exception of one case where multiple products were transfused.
- 62.5% (⅝) of anaphylactic reactions were due to platelets or FFP transfusions.

KEY LEARNING Use the patient's symptoms and signs to distinguish febrile from allergic reactions and to tailor treatment appropriately.

Pulmonary adverse reactions 2024 (*n*=20)

Pulmonary complications form a significant proportion (10.6%) of the serious adverse reactions reported in South Africa. Unfortunately, the paucity of information, lack of investigations and often multiple comorbidities in these patients makes it challenging to accurately classify transfusion-associated cardiac overload (TACO) cases, with the result that most end up in the broader category of transfusion-associated dyspnoea (TAD).

Patients with respiratory complications are often elderly with multiple comorbidities which could all contribute to the clinical picture. SHOT[3] data also suggests that fluid overload contributes to most pulmonary adverse events which do not meet TACO criteria.

Transfusion-associated dyspnoea (*n*=18)

By default, all the respiratory adverse events which do not fulfil either transfusion-related acute lung injury (TRALI) or TACO criteria, and have no allergic component, end up in the TAD category. With improved reporting, many of these cases should theoretically move to the TACO category.

Transfusion-associated circulatory overload (*n*=2)

Two cases of TACO were reported. One case was a 90-year-old female who received two units of red blood cells (RCC). The other was a 30-year-old female transfused with multiple blood products after acute blood loss.

TACO may be avoided by identifying risk factors and implementing appropriate management strategies:

TACO risks:

- IV fluids in the past 24 hours
- Clinically significant positive fluid balance
- Heart failure or related cardiac disease
- Renal impairment
- Hypoalbuminaemia
- Severe anaemia
- Peripheral oedema
- Regular diuretic use
- Undiagnosed respiratory symptoms
- Pre-existing pulmonary oedema

TACO management strategies:

- Vital sign monitoring
- Single unit transfusion and review
- Fluid balance measurement
- Body weight dosing
- Prophylactic diuretic
- Use of alternatives to transfusion

Transfusion-related acute lung injury 2024 (*n*=0)

There was one case which was reported as a query TRALI, but no cases which fulfilled the criteria of TRALI.

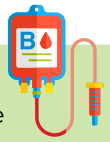
Pulmonary Adverse Reactions 2022–2024

Category	No. of Cases 2022 (% of Total)	No. of Cases 2023 (% of Total)	No. of Cases 2024 (% of Total)
TRALI	0	2 (0.8%)	0
TACO	4 (2.0%)	5 (1.9%)	2 (1.1%)
TAD	26 (12.6%)	22 (8.4%)	18 (9.6%)

From the table above it can be seen that there has been little positive change in the pulmonary categorisation. Additional effort will need to be made to improve knowledge on respiratory complications, the reporting of the adverse event and management thereof.

> There were 53 patients transfused with 63 incorrect RCC units, accounting for 33.5% of all SAEs reported to the IHC in 2024. Three patients did not require a blood transfusion at all. Fortunately all received ABO-compatible RCC ...

KEY LEARNING Identify those at risk of pulmonary adverse events. Then transfuse a single unit and review. Monitor vital signs strictly and measure fluid balance.



Unclassified adverse events 2024 (*n*=15)

We were unable to classify 8% of the adverse events into one of the International Society of Blood Transfusion (ISBT) Working Party[1] categories. There were various reasons for this, the most common being lack of information, particularly vital signs post transfusion, and lack of details about patient management and outcomes.

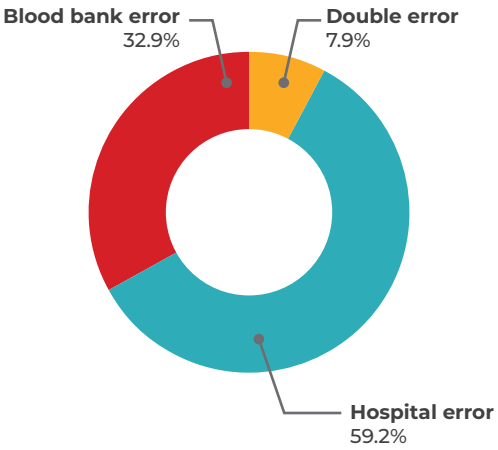
This category has increased from 5.7% in 2023 to 8% in 2024 due to fewer assumptions being made and assessors applying stricter categorisation criteria.

Incorrect Blood Component Transfusion (*n*=63 units)

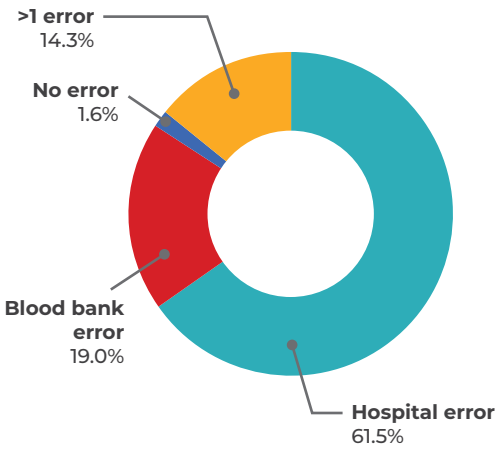
There were 53 patients transfused with 63 incorrect RCC units, accounting for 33.5% of all SAEs reported to the IHC in 2024. Three patients did not require a blood transfusion at all. Fortunately all received ABO-compatible RCC, but one of the three experienced a reaction. The post-transfusion investigation demonstrated weak serological incompatibility, with moderate Immunoglobulin G (IgG)-sensitised red cells and non-specific warm autoantibodies. It is possible that this contributed to the patient experiencing a reaction.

Patient identification errors occur at all stages of the transfusion process, particularly during sample taking, blood collection and administration. At each of these stages it is essential that staff focus on the accuracy of patient identifiers, i.e. name, date of birth, ID number, gender, etc. and – where possible – actively engage with the patient. Staff need to be extra vigilant during emergency situations, when additional pressure and distractions are likely.

Service Provider Responsible for Incorrect Blood Component Transfusion 2023



Service Provider Responsible for Incorrect Blood Component Transfusion 2024



Service Provider Responsible for Errors 2024	Units
Single blood bank error	12
Blood transfusion services >1 error (blood bank double error; blood bank & donor division)	2
Hospital & blood bank error	5
Hospital >1 error (collection from ward fridge & administration)	2
Single hospital error	41
No error (emergency crossmatch*)	1
Total	**63 units**

*The standard operating procedure (SOP) was followed correctly, see example 4 below

> In 2024, 65.1% of incorrect blood component transfusions (IBCTs) were the result of a single error by hospital staff and 19% were due to a single error by blood bank staff. More than one error occurred in the remaining 14% ...

In 2024, 65.1% of incorrect blood component transfusions (IBCTs) were the result of a single error by hospital staff and 19% were due to a single error by blood bank staff. More than one error occurred in the remaining 14% (i.e. >1 error by blood bank or >1 error by hospital staff or error by both hospital and blood bank staff).

Although there has been a concerted effort to educate doctors, nurses and technicians, the IBCT rate remains high. Of even greater concern is the increase in the number of cases that involve more than one error. A few examples illustrate the poor attention to detail which results in many of these cases:

EXAMPLES

1	In the donor division, two donors' samples were swapped, resulting in incorrect blood group labels on the unit. This was not picked up in the blood bank because the incoming supply's blood group was not double-checked.
2	An issuing error by the blood bank was not picked up by ward staff when collecting and administering blood because the patient's identification was not checked.
3	Failing to timeously follow the SOP for a reported adverse event resulted in a second incompatible unit being issued by the blood bank, using the initial crossmatch sample which was wrong blood in the tube (WBIT).
4	In one IBCT case, the correct procedure was followed in an emergency issue of RCC, however – in the final stages of the crossmatch procedure – the units were found to be serologically incompatible. The prescribing doctor was immediately notified and the RCC units returned, but one unit had already been partially transfused.
5	A unit which had expired more than two weeks previously was collected from an emergency fridge and administered to a patient. This blood should have been removed from the emergency fridge and the hospital staff collecting and administering the blood transfusion should have checked the expiry date.

Hospital errors are largely due to poor patient identification (or lack of patient identification) resulting in WBIT when taking the crossmatch sample. They may also be due to administering the blood to the incorrect patient or failing to verify the patient details when collecting the blood, either from the blood bank or from the ward/emergency fridge.

When a patient receives a blood component intended for another patient, this is referred to as a misdirected transfusion. There were 22 misdirected transfusions and 10 WBITs identified in the 2024 hospital errors.

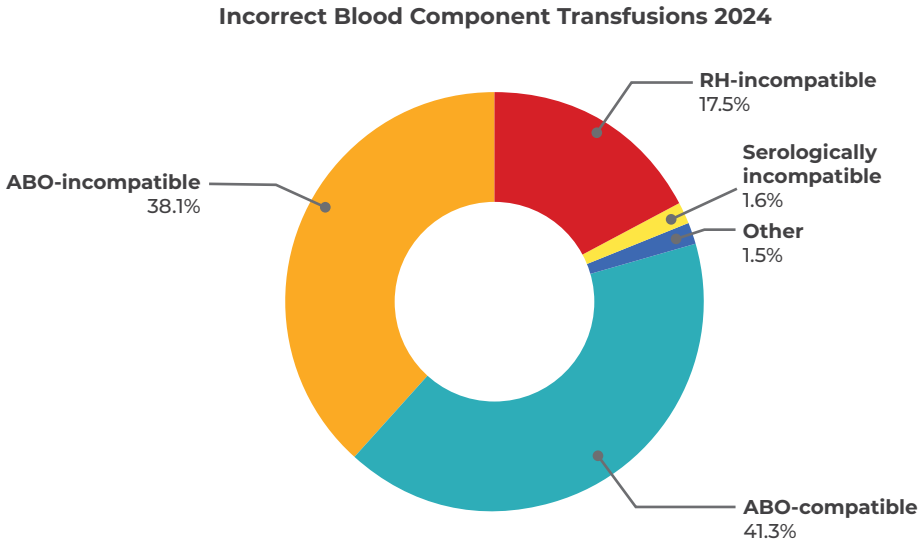
Collection of an incorrect unit is often the origin of a misdirected transfusion, especially when blood is collected from the blood bank and not immediately administered but kept in the ward/emergency fridge until required. Although not always documented in an Adverse Event Report, errors in collection of RCC units were noted seven times in the year under review. This once again highlights the importance of patient identification.

Blood bank errors are due to incorrect interpretation of crossmatch results, incorrect labelling of the tube (resulting in sample mix-ups and transcription errors of test outcomes) or incorrect issuing due to mislabelling.

Of concern are the six errors recorded when labelling tubes pre-transfusion. The second most common area of error was at the blood product's point of issue.

IBCT due to hospital error, blood bank error or both may result in the following:

- ABO-compatible transfusion
- ABO-incompatible transfusion
- Rh-incompatible transfusion
- Serologically incompatible transfusion
- Other – Expired blood



ABO-compatible IBCT (*n*=26 RCC units)

Understandably, none of the patients who received ABO-compatible RBCs had a life-threatening reaction, but it needs to be noted that one patient had a mild serological reaction due to warm antibodies, six patients received more than one misdirected unit and three did not require blood products at all.

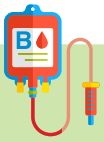
ABO-incompatible IBCT (*n*=24 RCC units)

An ABO-incompatible transfusion has the potential to cause serious morbidity and death. The most severe reactions occur due to transfusion of incompatible blood groups, which has the potential to cause an acute haemolytic reaction. One Group A patient who received more than one unit of group B RCC had a severe reaction with a temperature >39 °C, rigors, chest and flank pain and an increase in systolic blood pressure of >50 mmHg.

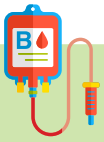
Fortunately, there were no known fatalities and, on follow-up with medical officers, none of the five patients with haemolysis nor the one patient with impaired renal function post-transfusion reaction required dialysis or any other treatment besides during the acute phase of the reaction.

ABO-Incompatible Blood Groups Units & Outcome 2024 (*n*=24 units)

ABO Incompatibility	Outcome	ABO Incompatibility	Outcome
Group A unit to group O patient (7)	Haemolysis (2); Impaired renal function (1); Severe reaction (1); Moderate reaction (1); No reaction (2)	**Group A unit to group B patient (2)**	Haemolysis (1); No reaction (1)
Group B unit to group O patient (9)	Haemolysis (1); Severe reaction (2); Moderate reaction (1); No reaction (5)	**Group B unit to group A patient (5)**	Haemolysis (1); Severe reaction (3); No reaction (1)
Group AB unit to group O patient (1)	Moderate reaction (1)		



KEY LEARNING Positive patient identification is essential = not only name and initials but also date of birth, gender and hospital number. Patient identification MUST be done before taking the crossmatch sample, when collecting blood from the blood bank or from a ward fridge AND during the pre-transfusion administration procedure.



KEY LEARNING Pre-transfusion safety checks provide the final opportunity to prevent an IBCT. Check the patient identity, the expiry on the unit AND the blood group.

Serologically incompatible transfusion (*n*=1)

Four units of FFP and four units of RCC were ordered on emergency crossmatch for a patient with a cancerous mass and low haemoglobin who required emergency surgery. The group O-positive units were immediately issued and the crossmatch continued as per SOP. In the final stages of crossmatching, the IAT (Indirect Antiglobulin Test for antibody screening) and direct antiglobulin test (DAT) came up positive. The doctor was immediately notified to stop the transfusion and the units were recalled. One unit had already been transfused, but the patient remained stable with no reaction noted.

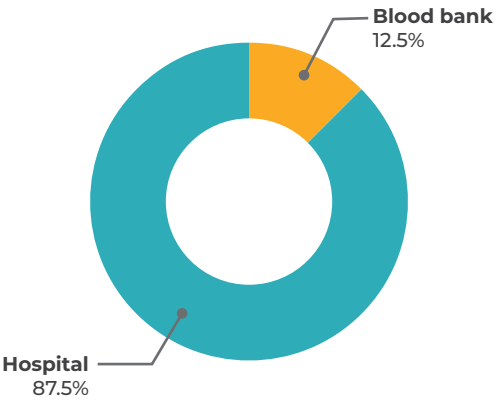
Rh-incompatible IBCT (*n*=11 RCC units)

In 2023, a total of eight Rh-incompatible units were transfused and, in all but one case, this was due to hospital staff error. By comparison, in 2024, there has been an increase in the number of Rh-incompatible units transfused and – more concerning – four (36%) cases originated in the blood bank.

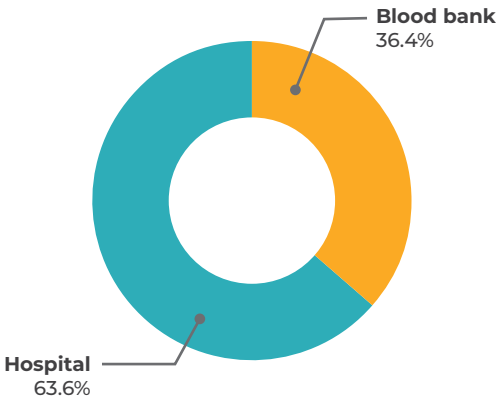
All Rh-incompatible units issued by hospital staff are regarded as an IBCT and reported as an 'error', but it is understood that these units were transfused in an emergency situation where the patient was experiencing acute blood loss (Obstetrics = 2 units; Gynaecology = 2 units; Surgery = 2 units, Medicine = 1 unit).

Although targeted education has been done, there remains a concern that hospital staff do not do the rapid Rh test prior to using emergency fridge blood. To improve the outcome of patients who receive Rh-incompatible blood, hospital staff should use the Rh kit provided in the emergency fridge.

Source of Rh Error 2023



Source of Rh Error 2024



KEY LEARNING Before selecting a unit from the emergency fridge, hospital staff should check the Rh group using the rapid Rh kit. Emergency blood should be used as a critical resource and not be wasted.

KEY LEARNING To prevent long-term complications in any future pregnancy, if a woman of childbearing age is identified as being Rh-negative, Rh-positive blood must only be transfused in dire emergency as a life-saving measure.

KEY LEARNING When Rh-positive blood is given to an Rh-negative woman of childbearing age, she should be counselled on the need for antenatal monitoring of future pregnancies and the use of anti-D immunoglobulin intramuscularly should be considered.

Clinical areas where incorrect blood component transfusions were reported

The department or clinical area where the IBCT occurred was identified from the Blood Request form, in an attempt to identify any high-pressure areas where errors may occur. These numbers include both hospital and blood bank errors as both at times work under extreme pressure.

These numbers should be reviewed with a background knowledge of blood usage within clinical disciplines. As in 2023, the higher error reporting in 2024 aligns fairly well with the clinical areas where there is high blood usage, e.g. Obstetrics and Medical departments. There were more (five) IBCT cases reported in intensive care units (ICUs) in comparison to only one case in 2023, only one surgical case reported in theatre and no errors originating from Casualty (which reported four last year). High pressure errors therefore show no definite trend at this point.

Clinical Areas in Which Incorrect Blood Component Transfusions Were Reported 2024 (*n* = 63 units)

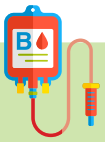
Clinical Area/Ward	No. of IBCT Units	Clinical Area/Ward	No. of IBCT Units
Surgery	15	ICU	5
Medicine	12	Paediatrics	1
Obstetrics	10	Cardiac surgery	1
Gynaecology	9	Theatre (surgical case)	1
Oncology	7	Orthopaedics	1

Near-Miss Event Reporting

In the *2022 Haemovigilance Report*, no near miss events were reported and the IHC made a recommendation that this was an area that required increased awareness, clarification of definitions for data collection and training for the blood transfusion services staff. It is encouraging to see the beginnings of near-miss reporting improve year on year. In 2023, 13 near miss events were recorded (involving 18 units) and, in 2024, this has increased to 50 near miss events.

Near Misses Reported 2024

Service Provider Responsible for Near Misses 2024	Type of Error	No.
Hospital error	Wrong blood in the tube (right patient, wrong label)	15
	Wrong blood in the tube (wrong patient, right label)	19
	Misdirected unit detected at the time of administering product	1
Blood bank	Transcription/labelling error	8
	Incorrect interpretation of results	2
	Dispatch error	5

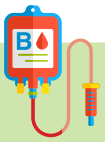


KEY LEARNING WBIT occurs when:

- the patient is not identified correctly at the time of phlebotomy;
- the sample is not labelled when still next to the patient;
- the sample is not labelled by the person taking the sample; and
- pre-printed sample labels are used.

To decrease the number of IBCTs due to WBIT, the Western Cape Blood Service (WCBS) adopted the 'second sample' policy as recommended by *SHOT*[3]. The initial rollout of the second sample policy for an onsite hospital began in the fourth quarter of 2023 at Khayelitsha Hospital. By the fourth quarter of 2024, WCBS had started expanding the policy to off-site hospitals. The uptake has been significantly higher in private hospitals compared to state hospitals.

In 2024, WCBS reported no IBCT due to WBIT: 31 WBITs were detected prior to transfusion and incorrect transfusions prevented.



KEY LEARNING: A proactive organisation will encourage transparent near-miss reporting as learning from near misses is as useful as learning from incidents without harm to the patient. Focus on identifying the system error rather than on the individual.

Transfusion-Associated Mortalities

There were 34 transfusion-associated patient mortalities reported to the South African Haemovigilance Programme in 2024. It is important to note that these cases were reported due to a temporal association between the patient's death and a blood product transfusion, which was not necessarily causative.

Only six post mortems (PMs) were requested and two verbal PM reports obtained. This reflects challenges such as:

- Family refusing permission for PM
- A lack of pathologists to do PMs
- Confidentiality and privacy laws preventing blood transfusion services having access to PM reports
- A lack of timeous notification of death and lack of documents

Once the post-transfusion investigation has been completed, the IHC assesses how closely the transfusion relates to the mortality by referring to the ISBT Working Party definitions[1], the Adverse Event Report form, the report from the treating clinician, the PM report (if available) and any significant laboratory reports (if available).

In 2024, the IHC assigned imputability to the 34 reported cases of transfusion-associated mortality as follows: Definite (certain) = 0; Probable (likely) = 3; Possible = 11; Unlikely (doubtful) = 11; Not assessable = 7; Excluded = 2.

7 Transfusion-Transmitted Infections & the Lookback Programme

> "... all healthcare professionals prescribing, consenting and administering blood and blood products to patients have up-to-date knowledge of blood donation testing, and of the small but potential risk of a window-period transmission ..."

Transfusion-transmitted infections (TTIs) may be bacterial, viral or parasitic. They will be documented as such when the recipient of a blood product has evidence of infection following a transfusion, with no clinical or laboratory evidence of infection prior to transfusion.

The blood transfusion services (BTS) follow a stepwise approach to mitigate the risk of TTIs by:

a) following recommended best practice by questioning the donor for symptoms of possible infection;
b) disinfecting the donor arm prior to donation using validated disinfectants;
c) diverting the first 30 ml of blood into the pouch. This significantly decreases contamination with skin flora;
d) using the 30 ml in the diversion pouch to take samples for screening for human immunodeficiency virus (HIV), hepatitis B virus (HBV) and hepatitis C virus (HCV);
e) monitoring the rates of infection in donors to sustain a safe supply of blood components;
f) testing for bacterial contamination in at least 1% of platelet products produced; and
g) performing environmental bacterial screening in areas of high risk for contamination.

It is important that all healthcare professionals prescribing, consenting and administering blood and blood products to patients have up-to-date knowledge of blood donation testing, and of the small but potential risk of a window-period transmission (when recent infection in the donor is not detected by routine testing).

Transfusion-Transmitted Bacterial Infection

There have been no reported cases of transfusion-related bacterial infections or confirmed related fatalities in the last five years in South Africa.

Product screening to detect bacterial contamination

In South Africa, there is no routine bacterial surveillance of red cell products. This is because platelet products are stored at room temperature and are therefore a more sensitive indicator of potential bacterial contamination.

There is a variation in the country's surveillance and notification procedure due to geographical locations and logistics. The South African National Blood Service (SANBS) has multiple apheresis and processing centres whereas the Western Cape Blood Service (WCBS) only has one apheresis centre and one processing centre.

SANBS has a greater number of samples to test so it makes economic sense for them to use their own microbiology laboratory to run sampling within 24 hours of collection. The prescribing doctor of any issued platelet product is notified if, at any time during the seven-day incubation period, the culture becomes positive. Because WCBS has only one apheresis and one processing site and far fewer surveillance samples, they outsource this function but alert the prescribing doctor as soon as they are notified by the laboratory of a positive culture.

Bacterial Surveillance of Platelet Products 2024

	WCBS		SANBS*	
	Pooled PLT	**Apheresis PLT**	**Pooled PLT**	**Apheresis PLT**
No. products tested	1 255	64	1 572	5 529
% of product tested	21.3%	1.7%	3.6%	24%
Positive cultures	3 Gram positive	0	5 Gram positive 1 Gram negative	7 Gram positive
Compliance score	99.8%	100%	99.75%	99.85%

*SANBS bacterial surveillance reported for 2024 financial year, not calendar year.

SANBS bacterial surveillance extends to other products which are produced in small quantities, such as eye serum and stem cell collection, where compliance scores are 98.5% and 98.9% respectively.

The majority of organisms cultured from platelet products were Gram-positive cocci – 13/14 (92%) for SANBS and 3/3 (100%) for WCBS – indicative of skin commensals and likely contaminants.

An impressive 98%–99% compliance score has been maintained year on year for the past five years and was exceeded in 2024. This is an indication of good manufacturing practice (GMP).

Transfusion-Transmitted Viral Infections

The risk of viral infection transmission depends on factors such as the burden of disease in the country (which reflects in the viral prevalence in the donor population), the level of donor screening and the technology used to detect specific viruses. In South Africa, the most common viruses associated with transfusion-transmitted viral infections are HIV, HBV and HCV.

Viral prevalence in the donor population

All South African blood donations are screened through a combination of serological and molecular tests for HIV, HBV, HCV and syphilis. The individual donation nucleic acid amplification test (ID-NAT) for viral infections was implemented in the South African BTS in 2005.

> "There was an increase in HIV, a marginal increase in HBV and no change in HCV prevalence."

During the 12-month period under review, 4 701 of the 1 264 226 donations collected and tested for HIV, HBV and HCV yielded a reactive result for one or more TTI viruses. There was an increase in HIV, a marginal increase in HBV and no change in HCV prevalence. There was only one co-infection of HIV/HCV and no HIV/HBV co-infections.

Viral-Positive Blood Donors 2024

Virus	No. Positive Donors	Prevalence
HIV	3 307	0.27
HBV	1 110	0.09
HCV	284	0.02
Total donations	**1 264 226**	

The table below shows the trend within the donor population of an increase in the prevalence of HIV to beyond the pre-COVID 2019 prevalence rate of 0.21, while HBV has steadily reverted back to the 2019 level of 0.90. HCV has remained unchanged in the past two years and has marginally increased since 2019. These changes in prevalence rates reflect the BTS's success in actively recruiting more donors to provide an adequate blood supply for a population which is undergoing an annual growth of approximately 1.2%[2].

> "... there have been no confirmed cases of viral TTIs in South Africa in the past nine years."

National Viral Prevalence in Blood Donors 2019–2024

Virus	2019	2020	2021	2022	2023	2024
HIV	0.21	0.19	0.15	0.17	0.21	0.27
HBV	0.09	0.08	0.06	0.06	0.07	0.09
HCV	0.01	0.01	0.01	0.01	0.02	0.02

A noteworthy finding was that there was no known viral TTI event reported in 2024, which means that there have been no confirmed cases of viral TTIs in South Africa in the past nine years.

The Lookback Programme

The TTI Lookback Programme was established in 1986. It has been incorporated into the Haemovigilance Programme since 2005.

Donor-triggered lookback investigations

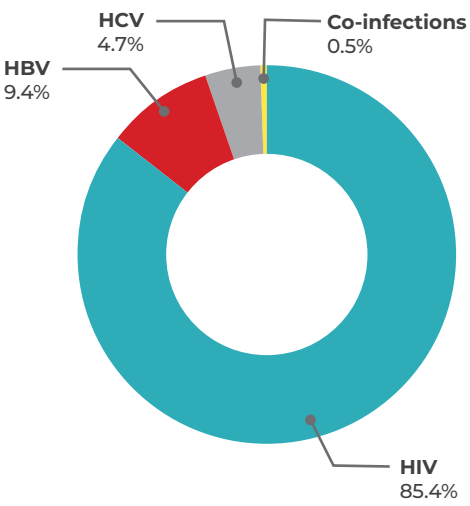
The Lookback Programme aims to trace all patients who are identified as recipients of blood from donors who test positive for a TTI on a subsequent donation, where the previous negative unit may possibly have been donated in a window period.

In November 2023, SANBS implemented eProgesa, a Blood Electronic Computer System (BECS), and the new system introduced 12-digit unit numbers instead of the eight-digit unit numbers previously used on the Meditech system. This unfortunately disrupted the Lookback application previously used by SANBS to perform a unit enquiry because the 12-digit numbers incorrectly defaulted to 'No lookback' status on the lookback application. As a result, none of the implicated unit numbers generated since the implementation of the eProgesa system were reported.

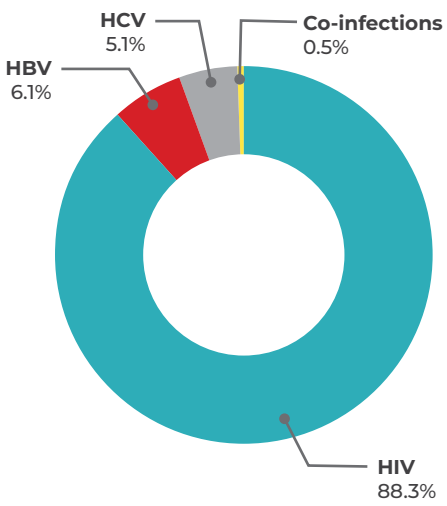
The 401 cases reported for the year 2024 are therefore considered an underestimate. The SANBS IT division is working on this challenge in order to restore the work flow and, in the meantime, all outstanding affected 2024 donor-triggered lookback cases are being retrieved and reported.

Due to this under-reporting issue, we cannot comment on the actual figures, but in the graphs below we can see that the trend remains the same as in 2023, with HIV dominating the focus of the Lookback Programme, followed by HBV and HCV. An update of the 2024 lookback investigations will be included in the *2025 Haemovigilance Report*.

Total Number of Donor-Triggered Lookbacks 2023 (*n*=747)



Total Number of Donor-Triggered Lookbacks 2024 (*n*=429)



The table below highlights the challenge of tracing patients to provide a final, confident outcome. These challenges are understandable as there may be a considerable time period between the transfusion to the recipient and when the donor tests positive for a viral marker when they return for further blood donations.

Donor-Triggered Investigation Outcomes 2024

Outcome	No. of Patients
Recipient retested negative	77
Recipient positive before transfusion	35
Phylogenetic analysis for potential HIV TTI	1
Recipient died between transfusion & initiation of look back	83
Unresolved (awaiting feedback from clinician)	90
Untraceable patient	95
Other*	43
Recipient declined testing	5
HBV immune**	0
Total	**429**

*Other: Doctors who are not traceable or refuse to participate in the Lookback Programme; foreign patients who are not traceable; patients who do not honour the appointment for blood samples.
**An HBV lookback where the recipient was found to be HBV immune.

Recipient-triggered lookback investigations

There are far fewer recipient-triggered lookbacks compared with donor-triggered lookbacks. The lack of TTIs for the past nine years and the low numbers of recipient-triggered lookback investigations provide reassurance of the safety of the South African blood supply as a result of the effective policies and procedures in place to reduce TTI.

Outcome of Recipient-Triggered Lookbacks 2024

Infection	Resolved	Unresolved
HIV	5	1
HBV	5	0
HCV	0	0
Other (CMV*)	1	0
Total	**11**	**1**

*Cytomegalovirus

The one unresolved case is due to the inability to contact one donor for repeat testing. Further follow-up will be required. All the other implicated donors have been found to be negative.

Although the BTS does not routinely test for cytomegalovirus (CMV), the risk of a CMV infection is mitigated by providing leucodepleted red cell concentrate (RCC) to all paediatric cases under one year of age and to immunocompromised patients on request. In the CMV lookback investigation, four donors were implicated and were successfully traced for CMV testing: three donors tested immune but not infective (i.e. CMV PCR-negative, CMV IgM-negative and CMV IgG-positive), and one donor was negative for all tests.

The residual risk of HIV, HBV and HCV

> “Using ID-NAT Ultrio Elite[5], the window period for detection is 4.6 days for HIV, 13.1 days for HBV and 2.8 days for HCV.”

The calculations for residual risk and the window period of HIV and HBV are presented annually at the National Blood Safety meeting. The residual risk of HCV is not routinely calculated as it is so low, however it has now been agreed to do the calculations for HCV in 2025.

The window period is the time very early in the course of infection when the tests in use cannot yet detect the virus but there may still be a sufficient amount for transmission. Using ID-NAT Ultrio Elite[5], the window period for detection is 4.6 days for HIV, 13.1 days for HBV and 2.8 days for HCV.

The chance or residual risk of a potentially infectious HIV or HBV window-period donation not being detected on testing in South Africa is estimated by modelling. The Busch method[4] is used, using the NAT yields as incident infections. The residual risk in 2024 for HIV was 1:137 961 and for HBV was 1:34 448.

The main purpose of calculating residual risk is to show the trend. In practice, however, we see far fewer TTIs because modelling tends to overestimate the risk and present a worst-case scenario.

8

Donor Haemovigilance

> Although donation is generally safe, an unintended response in a donor may occur during or after the collection process of blood or blood components.

Blood donors are an essential first link at the beginning of the value chain that is required to support safe transfusion of patients. Although donation is generally safe, an unintended response in a donor may occur during or after the collection process of blood or blood components.

Appropriate donor care includes giving donors information about the risks of blood donation and encouraging them to speak up if they are not feeling well during the donation. Staff need to be trained to recognise warning signs of an impending donor adverse event (DAE), implement measures to minimise risk and provide appropriate first-line management thereof.

In the 2024 calendar year, a total of 1 204 226 blood donations (including apheresis and therapeutic donations) were made, of which 1 119 726 were whole blood donations made by voluntary non-remunerated donors, at mobile and fixed centre blood donation sites around South Africa.

Historically, the serious adverse event of donation (SAED) rate has been calculated on whole blood donations and not on all donations. As all donors may experience adverse events, it has now been agreed to change this approach and to include other donations as well as whole blood. This will be done for the *2025 Haemovigilance Report*.

> … vasovagal reactions (commonly known as faints) account for the majority of all DAEs and haematoma was the most common local DAE.

During 2024, DAEs were unfortunately under-reported within the South African National Blood Service (SANBS) due to the introduction of a new Blood Electronic Computer System (BECS). The reasons for under-reporting are multifactorial: staff not inputting data, staff inputting data incorrectly or data not pulling through to reports. This lost data is not retrievable and thus the 2024 DAE/100 000 donations gives an incorrect impression.

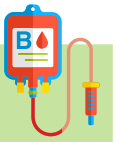
In line with international DAE trends and previous years, however, vasovagal reactions (commonly known as faints) account for the majority of all DAEs and haematoma was the most common local DAE.

Donor Adverse Events per 100 000 Donations 2019–2024

Donations & Donor Adverse Events	2020	2021	2022	2023	2024
Total number of whole blood donations	837 790	881 366	934 777	1 146 063	1 119 726
DAEs per 100 000 donations	43.8	37.2	38.7	41.7	28.4*

*Under-reported in 2024 due to technical issues associated with a new computer system.

KEY LEARNING: Having a good IT system in place still requires staff to have knowledge, skills and training.



Serious Adverse Events of Donation

A SAED is an unintended response in a donor, associated with the collection of blood or blood components, that is fatal, life threatening, disabling or incapacitating, or which results in hospitalisation.

In order to collect such data, the blood transfusion services (BTS) have further defined SAEDs as any event as a result of which the donor required referral to Casualty/Emergency or additional medical oversight for further observations and/or management. The data collection has improved considerably over recent years, with a total of 21 SAEDs being recorded during 2024.

The table below summarises these SAEDs by category. The categories have been adapted from those used in the UK's *Annual SHOT (Serious Hazards of Transfusion)* Report[3] to reflect the emergency procedures followed by the BTS in South Africa. In comparison with the UK, we note more donors are referred to Casualty or a general practitioner (GP). This is because mobile clinics and donor fixed sites are often a long way from the blood transfusion doctor on call and paramedical emergency services may be limited.

Serious Adverse Events of Donation 2024

Category	Detail of Cases	No. of Cases
Problems relating to insertion of needle requiring hospital/ intervention: Tendon or nerve injury	Neuropraxia for 5 months & treatment ongoing	1
Problems relating to insertion of needle requiring hospital/ intervention: Vascular	Post-donation immediate, swelling & painful figures, observed in Casualty with arm raised. No haematoma detected	1
	Swollen arm, GP queried compartmental syndrome, vascular surgeon investigated. No brachial arterial damage. Specialist report queried as to whether there was damage to a small branch of brachial artery during venesection	1
	Extreme pain, sudden swelling, immediately taken to Casualty. Referred to a vascular surgeon who reconstructed the pseudoaneurysm of brachial artery	1
	Swollen, painful inflamed arm. Phlebitis treated with antibiotics. An incision & drainage were later done in Casualty	1
Injury resulting in a fracture	Delayed faint & ankle fracture	1
	Delayed faint & zygomatic arch fracture, with impacted nerve causing diplopia. 2 surgical procedures required	1
Vasovagal (within donor centre/mobile collection clinics)	Required intravenous infusion (IVI) fluids & observations in Casualty/Emergency	3
	Required IVI fluids & admitted for seizure/concussion observation >24 hours	2
Delayed vasovagal (beyond donor area)	Required IVI fluids & observation in Casualty/Emergency	2
	Low haemoglobin (Hb) 9.5 g/dL & referred for further management	1
	Required IVI fluids, laceration suture & observation in Casualty	2
	Required IVI fluids, sutures & observation in Intensive Care Unit (ICU) for 3 days for confusion	1
Cardiovascular accident/ transient ischemic attack (TIA)	Immediate loss of speech post donation	1
	Delayed vasovagal with aphasia & decreased arm & leg function	1
Blood splash	Blood splash onto cheek & possible eye splash. Sent to GP for transfusion-transmitted infection (TTI) test and antiretroviral drugs (ARVs) till source blood results known	1

- 61% (13/21) of SAEDs occurred at mobile collection clinics
- 33% (7/21) of SAEDs were triggered by a delayed faint occurring >30 minutes after donation
- 19% (4/21) of SAEDs required only intravenous fluids and observation

KEY LEARNING Donors must be encouraged to speak up if they experience pain or paraesthesia at the time of venepuncture. Donation should be stopped and the needle carefully withdrawn if the donor has immediate symptoms suggestive of nerve or tendon injury.

DONORS SHOULD be encouraged to report painful swollen arms early, rather than only days post donation.

9 Changes in Strategy & Procedure to Improve Safety

The following is a summary of the interventions by the blood services in response to issues of concern raised, either in previous editions of this report or in direct feedback from the Independent Haemovigilance Committee.

Process Issues

Incorrect blood component transfusion

This arises from any combination of errors from the three components of the blood supply pathway.

First, hospital errors may arise from non-adherence to collections protocols at donor centres or poor sampling techniques in the ward involving specimen taking or labelling. Oftentimes this happens when an individual collects multiple specimens at a time without labelling each one as they are drawn. Sometimes, due to lack of attention to detail, an incorrect patient file is referenced for completion of the requisition for blood.

Second, in the blood bank, a common cause of error is the manual transcription of crossmatch results when, for some reason, the process cannot be completed automatically using the electronic crossmatch system. An incorrect blood group may be assigned or the operator may overlook the patient's previous history on the system.

Third, hospital staff failing to follow established protocols regarding identification of patients before starting blood transfusions frequently results in incorrect blood being transfused to patients or patients receiving blood or blood product transfusions when none were indicated.

It is also not uncommon that, in cases of severe acute haemorrhage, the treating doctors prescribe emergency blood transfusions with blood kept in the emergency ward fridge, without any regard for immunological consequences in women of childbearing age.

All these observations have featured before, either in previous haemovigilance reports or in the monthly summaries shared with the blood services.

Some interventions to address product safety risks

SANBS

- Transcription errors: A process facilitating the printing of results has been implemented to minimise transcription
- A batch-grouping interface has been approved and is pending implementation. This will remove the need for transcription
- Blood banks have been capacitated with additional staff/reassigned personnel to provide another layer of assurance in pre-analytic patient identification
- The blood bank process flow is being reviewed to ensure improvement
- There is an ongoing programme by the Learning and Development division to educate staff on the importance of compliance with applicable processes and protocols
- Monthly morbidity and mortality meetings are being held, with reported incidents being used as learning opportunities
- A dedicated task team has been established to review the errors and recommend improvements

WCBS

A second-sample crossmatch policy for first-time blood recipients has been implemented. This limits the risk of a wrong sample (wrong blood in the tube) being processed for a patient for whom a blood request has been received by the blood bank and is applicable to patients who do not have a history with the blood service, i.e. there is no record of a blood group for the patient. If there is no record, the ward will be requested to submit a second specimen to confirm a match with the first sample. The normal compatibility testing process will then be followed and an appropriate unit(s) issued.

Security of Supply

This applies to plasma and platelet products.

Measures to reduce the frequency of alternate product issues

SANBS

The platelet strategy involves three elements:

1. Devolving access to platelets to all blood banks
2. Increasing the split rate gradually to a target of 1.66
3. Producing and promoting the use of filtered pooled platelets so these can increasingly be used more than apheresis platelets

WCBS

This blood service has not experienced any real challenges with product availability.

10 Conclusion

The South African blood services are currently meeting the demand for products by adapting to trends and adjusting their approach where possible.

Allied to these technological advancements, education on blood and blood products is of paramount importance and every opportunity should be used to empower health professionals.

11 References

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