THE SOUTH AFRICAN HAEMOVIGILANCE REPORT

2022

IHC | INDEPENDENT HAEMOVIGILANCE COMMITTEE

Haemovigilance Report 2022

The 23rd 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.

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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 appropriate measures can be taken to improve transfusion safety.

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UK English has been used in this report.

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

Contents

1 Abbreviations

BTS	blood transfusion services
COVID	coronavirus disease of 2019 (COVID-19)
DAE	donor adverse event
DAT	direct antiglobulin test
FiO_2	fraction of inspired oxygen
FNHTR	febrile non-haemolytic transfusion reaction
GP	general practitioner
Hb	haemoglobin
HBV	hepatitis B virus
HCV	hepatitis C virus
HIV	human immunodeficiency virus
HLA	human leucocyte antigen
HNA	human neutrophil antigen
IBCT	incorrect blood component transfusion
ICU	intensive care unit
ID-NAT	Individual donation nucleic acid testing
IHC	Independent Haemovigilance Committee
NICU	neonatal intensive care unit
QC	quality-control
RBC	red blood cell
RCC	red cell concentrate
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
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 Transfusion Reaction Classifications & Definitions

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.

The haemovigilance definitions aim to standardise and report all these 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 (2011)* as amended (available at www.isbt.org).

This year a *Mixed febrile/allergic reaction* category has been added to the definitions, as per the UK's *Annual SHOT (Serious Hazards of Transfusion) Report*[1].

Category of Adverse Events	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.

Category of Adverse Events	Definition
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 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.
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 of 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 hypoxaemia with a PaO_2/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 or anti-HNA 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 Events	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 FNHTR: i. Fever ≥39 °C AND a change of ≥2 °C from pre-transfusion value, AND ii. 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 DAT 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.
Transfusion-transmitted infection	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 (HIV), hepatitis B and hepatitis C.

Category of Adverse Events	Definition
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 or 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.

**Mixed febrile/allergic reaction*, as described by the *Annual SHOT Report 2022*[1], has been incorporated into the South African set of definitions to accommodate the serious adverse event which has both a febrile and an allergic component. For the year 2022, these mixed reactions were incorporated into the *Severe allergic reactions* count.

3

Foreword

The Independent Haemovigilance Committee (IHC) has crafted the 2022 Haemovigilance Report after reviewing and discussing serious adverse events on a case-by-case basis. The annual statistics on blood collections, usage and adverse events have also been analysed, using the population figures from Statistics SA, mid-year population estimates 2022.

> “Blood transfusion is a cornerstone of modern healthcare and, while it can be lifesaving, it may also carry risks which are life threatening.”

Although still in its infancy, the IHC – through discussions with the two South African blood transfusion services (SANBS and WCBS) – has streamlined the process of reporting by identifying discrepancies in the services’ reporting systems and their interpretation of guidelines, with the aim of working towards a standardised national system. This streamlining has significantly changed the way this report is formulated.

Like many countries, South Africa looks to the UK’s *Annual SHOT (Serious Hazards of Transfusion) Report*[1] as the gold standard for haemovigilance reporting, so the IHC endeavours to improve blood safety by applying the lessons learnt both from the *2022 SHOT Report*[1] and from our unique South African setting. For the year 2022, the IHC followed international best practice and only reported serious adverse events of blood transfusion. By no longer reporting mild allergic reactions and febrile non-haemolytic transfusion reactions, the total number of transfusion adverse events has decreased compared to previous years, thus making comparison to previous years’ adverse events/100 000 transfusions of little value.

Blood transfusion is a cornerstone of modern healthcare and, while it can be lifesaving, it may also carry risks which are life threatening. The fear of a transfusion-transmitted infection (TTI) has been the focus of the general public, the medical fraternity and blood services throughout the world since the early 1980s. With improved testing for TTIs and the ability to modify blood products (e.g. leuco-reduction and pathogen inactivation), the focus for blood services has now shifted somewhat. It is increasingly important to instead identify where the system may have failed: emerging pathogens, patient blood management and transfusion-related adverse events, especially incorrect blood component transfusion (IBCT).

IBCT is a major focus in this 2022 Haemovigilance Report and its IBCT data is significantly different compared with previous years. This is a result of improved reporting, which now includes cases that were previously not reported.

South Africa is steadily recovering from the COVID years, however the difference between blood collections and blood usage has not yet grown sufficiently to allow for much buffer stock. This is why the IHC has introduced the concept of monitoring lack of product and lack of correct product as part of the Haemovigilance Report.

Adverse events are generally thought to be underreported in South Africa. Because this particular report includes several changes in reporting methods and applies definitions more strictly, it may be difficult for the reader to conclude whether the results indicate an increased awareness and improved reporting or whether they actually show a deterioration in the system that is leading to more errors. Time will tell as we see the trends develop over the next few years.

4 Executive Summary

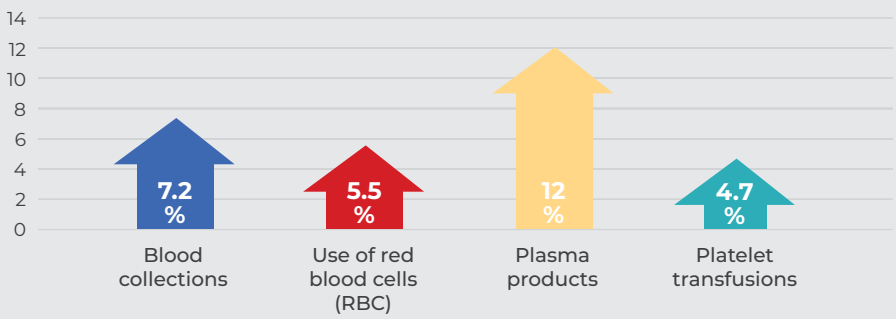
The 23rd edition of the South African Haemovigilance Report provides an overview of blood product usage and serious adverse events related to transfusion and blood donation in the country during the 2022 calendar year.

Throughout 2022 the blood transfusion services experienced a stepwise recovery in blood usage as healthcare facilities returned to the "new normal" post the COVID pandemic. It is encouraging to see the recovery of blood collections and, although the total number (and percentage) of new donors was less in 2022 compared to 2019, that a large part of the new-donor recovery since COVID was driven by young donors of the 16–19 age group.

There was a notable increase in the usage of red cells (5.5%) and plasma products (12%) compared with 2021, made possible by an associated 7.2% increase in blood collections. The uptick in blood product usage no doubt reflects a health system in recovery following COVID, resulting in increased activity on the service platforms.

Platelet transfusions recorded a 4.7% increase on the previous year, with pooled platelets comprising 50.35% of the total administered. This remains a concern for the blood transfusion services' platelet strategy, which seeks to encourage greater use of pooled rather than single donor platelets.

Percentage increase of blood products, usage and availability in 2022



> "The uptick in blood product usage no doubt reflects a health system in recovery following COVID, resulting in increased activity on the service platforms."

The total number of transfusions in the year under review was 1 346 868. Of these, 205 serious adverse events were reported, translating into an incidence rate of 15.2/100 000 units transfused. This is lower than reported in the previous year because the 2022 South African Haemovigilance Report only reports *serious* adverse events.

Incorrect blood component transfusions account for 30.7% of serious adverse events. This is a worrying observation, indicating a need to intensify efforts to address system failures both at the patient's bedside (wrong blood in the patient sample tube and misidentification when administering the transfusion) and at the blood bank (cross-matching and issuing of blood products).

> More focused training on the complications of blood donation and the management thereof should be done with donor staff.

Significantly, no transfusion-transmitted infections were reported. This very positive finding highlights the effectiveness of the donor-recruitment and donor-screening process, which is supported by state-of-the-art testing technology in place across the South African blood service platform. However, the challenges of the Lookback Programme – which resulted in no outcome for 62% of donor-triggered lookbacks – must be kept in mind.

Unclassified reports accounted for 6.3% of the serious adverse events due to incomplete or insufficient information. The reasons for these are multiple and systemic, and include the level of cooperation from treating clinicians, access to and quality of patient records, downstream clinical information from third parties in the case of patient mortality, and incomplete laboratory analysis due to late reporting of adverse events. Once again, a collaborative effort is necessary to address the weaknesses in the system.

There is a slight increase in the donor adverse event (DAE) rate, with a total of 4 519 DAEs reported. This translates to a rate of 38.73/100 000 donations (c.f. 37.2/100 000 donations in 2021). There was a notable decrease in faints, a common DAE which accounted for 78.9% of the total, but the increase in local DAEs such as nerve irritation and arterial puncture is of concern. More focused training on the complications of blood donation and the management thereof should be done with donor staff.

The 2022 South African Haemovigilance Report presents a picture of a blood service which has recovered from the COVID pandemic, although the blood supply requires further improvement to keep abreast with the demand for blood products. The error rate and lack of attention to detail when verifying the identity of a patient suggests that healthcare workers remain under stress post pandemic.

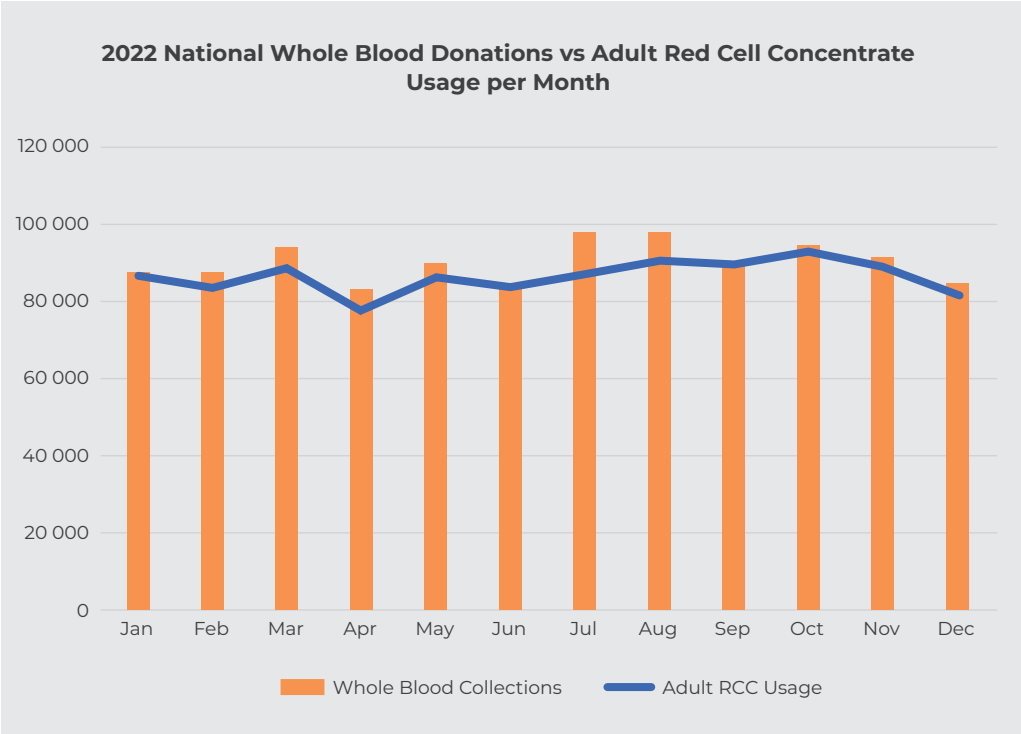
Overall, the report paints an encouraging post-COVID picture of blood transfusion services in South Africa being committed to improving the sufficiency and safety of blood products as well as donor and patient safety.

5 Blood Collections & Blood Product Issues

Blood Product Issues

As in previous years, the balance between collections and demand fluctuated from month to month during 2022, with relative oversupply in some months and critical stock levels in others. Critically low stock levels were reached in June and September, partly due to school-going donors being away on term breaks and to religious adherence precluding some donors from donating during the fast. Usage tapers down from around October to December, in line with the slowdown in clinical practice across both public and private platforms.

There was a notable increase in the usage of red cells and plasma products compared to the previous year and this was made possible by an associated 7.2% increase in blood collections. The uptick in blood product usage no doubt reflects a health system in recovery following COVID, resulting in increased activity on the service platforms.



Compared to 2021, the use of red blood cells (RBC) increased by 5.5%, with plasma products showing a 12% increase.

Platelet transfusions recorded a 4.7% increase on the previous year, with pooled platelets comprising 50.35% of the total administered. This is a fraction lower than the previous year and remains a concern for the blood services' platelet strategy, which seeks to encourage greater use of pooled rather than single donor platelets.

The table below shows a consolidated view of blood product issues before and after COVID and up to the reporting year. From experiencing a peak across all product lines in 2019, there is an appreciable drop in 2020 because of the COVID lockdown particularly impacting collections and elective surgeries. Product availability improved in 2021 (5.5%) and that recovery is continued into 2022 across all product lines (7% increase).

Blood Product Issues 2018–2022: South Africa

Product	Category	2018	2019	2020	2021	2022
Plasma Products	Fresh frozen plasma	145 732	151 325	139 442	142 392	153 957
	Cryoprecipitate/ cryo wet	35 407	40 775	39 239	46 776	54 804
	Total	**181 139**	**192 100**	**178 681**	**189 168**	**208 761**
Platelet Products	Pooled platelets	38 945	38 514	37 755	41 943	43 909
	Apheresis platelets	35 851	39 567	39 440	41 113	43 289
	Total	**74 796**	**78 081**	**77 195**	**83 056**	**87 198**
Red Cell Products	**Total**	**929 122**	**1 148 235**	**953 760**	**993 498**	**1 050 909**
Total Products		**1 185 057**	**1 418 416**	**1 209 636**	**1 265 722**	**1 346 868**

Red cell transfusion

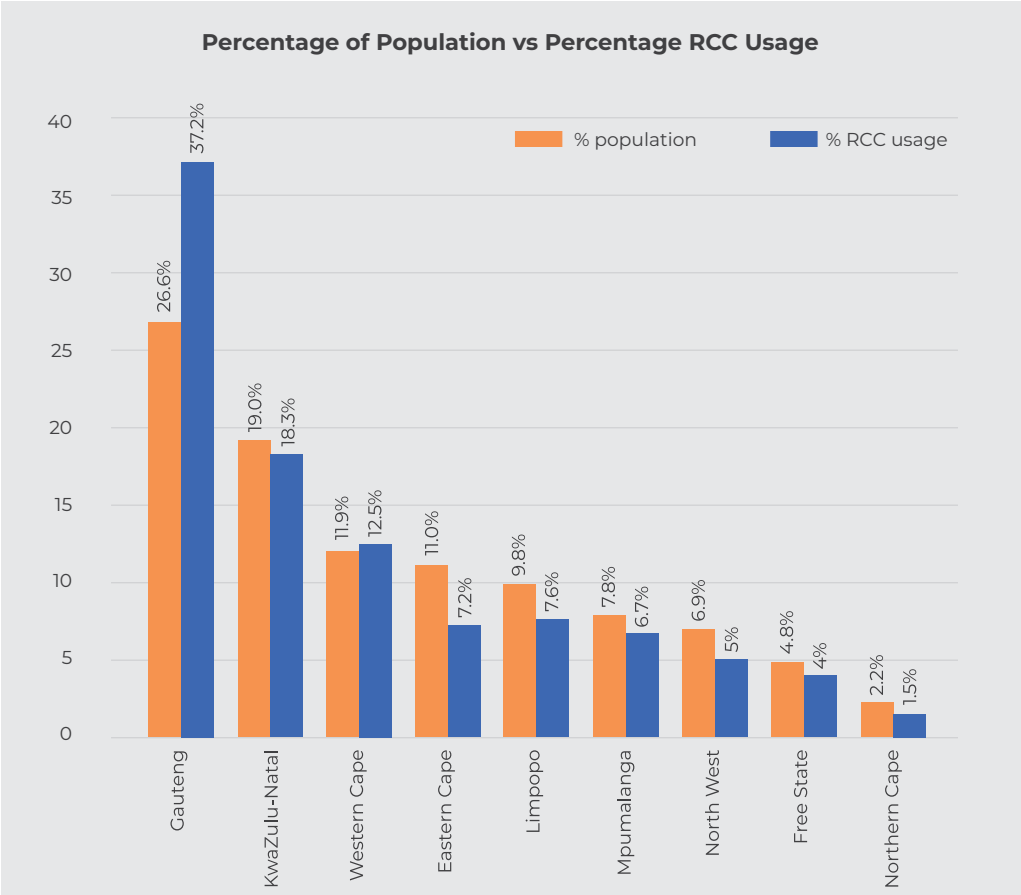
Continuing the trend from previous years, RBC continue to drive the demand for blood products, accounting for 78% of all product issues (78.4% in 2021). With the total population estimate for 2022 at 60.6 million[2] and red cell concentrate (RCC) calculated as a ratio of the number of products issued per 1 000 population, the overall transfusion rate for the country is 17.3/1 000 population.

This is an improvement on the previous year's transfusion rate of 16.5/1 000 population and is likely an indication of increased clinical activity and improving access to care.

However, the overall transfusion rate requires further interrogation at provincial level because of the diversity of resources and populations by geographical area.

Provincial Red Cell Transfusion Rates per 1 000 Population 2022

Province	Population	% of Country Population	RCC Usage (Incl. Whole Blood; Excl. Designated & SANBS International Donations)	% RCC	Transfusion Rate per 1 000 Population
Gauteng	16 098 571	26.6	389 550	37.2	24.2
KwaZulu-Natal	11 538 325	19.0	190 939	18.3	16.5
Western Cape	7 212 142	11.9	130 408	12.5	18.1
Eastern Cape	6 676 691	11.0	74 909	7.2	11.2
Limpopo	5 941 439	9.8	79 516	7.6	13.4
Mpumalanga	4 720 497	7.8	70 592	6.7	15.0
North West	4 186 984	6.9	52 587	5.0	12.6
Free State	2 921 611	4.8	42 093	4.0	14.4
Northern Cape	1 308 734	2.2	15 560	1.5	11.9
Total	**60 604 994**	**100**	**1 046 154**	**100**	



While there is no consistent relationship between provincial population size and transfusion rate, Gauteng has maintained a steady increase through the years. As the most populous province in South Africa, with a 26.6% share of the population, Gauteng accounted for more than one third of all blood issues, resulting in an RCC transfusion rate of 24.2/1 000 population. This is slightly higher than the previous year.

The second highest transfusion rate of 18.1/1 000 population was recorded for the Western Cape, a province with a population less than half the size of Gauteng's.

The usage pattern in Gauteng and the Western Cape is to be expected, given their level of urbanisation and that they have appreciably more private and tertiary hospitals providing levels of care that often require blood products.

The transfusion rate for KwaZulu-Natal is 16.5/1 000 population, even though it is the next most populous province after Gauteng and has four million more citizens than the Western Cape.

> "Transfusion rates in the Eastern Cape have remained subdued over the period, which is in line with the poor levels of development of this rural province."

An encouraging sign is the increased transfusion rates in the rural and poorly resourced provinces of Limpopo, Mpumalanga and the Northern Cape, all of which have shown a gradual increase over time. The Northern Cape shows the highest rate of increase, at 1.3% compared to last year, and is followed by Limpopo, with a 1.2% increase from 2021.

The Eastern Cape, fourth largest province by population size, has made very little progress in the past three years and remains below 12/1 000 population.

Overall, all provinces show an upward trend in blood usage patterns.

Below is a comparison of provincial transfusion rates over the five-year period to 2022. Gauteng, consistently the most populous province, leads the pack by averaging a little under 25% per annum over the period. This statistic reflects not only the size of the population but also the relatively larger number of hospitals, both public and private, based in the province. The Western Cape may have a smaller population size than KwaZulu-Natal, but it boasts two academic complexes (Gauteng has three) and has a large private-sector component.

Transfusion rates in the Eastern Cape have remained subdued over the period, which is in line with the poor levels of development of this rural province.

Provincial Red Cell Transfusion Rates 2018–2022

Transfusion Rate per 1 000 Population	2018	2019	2020	2021	2022
Gauteng	23.3	28.4	22.8	23.4	24.2
KwaZulu-Natal	13.7	18.2	15.0	15.6	16.5
Western Cape	20.0	20.7	17.6	17.8	18.1
Eastern Cape	10.9	12.8	9.9	11.1	11.2
Limpopo	12.1	15.2	12.6	12.2	13.4
Mpumalanga	12.7	15.5	13.7	14.1	15.0
North West	11.4	14.0	11.8	11.7	12.6
Free State	13.9	16.6	13.3	14.1	14.4
Northern Cape	11.4	13.7	10.2	10.6	11.9

Red blood cell use in the public & private sectors

The percentage split in RBC use between public and private sectors has not changed much over the past four years, but 2022 showed a slight shift towards the public sector. This is to be welcomed as the public sector caters for the needs of 80% of the South African population and proportionately more resources should therefore be made available to this sector.

Red Cell Concentrate Percentage Usage in South African Public & Private Sectors 2019–2022

RCC Percentage Usage	2019	2020	2021	2022
Public	62.2	61.3	59.7	60.4
Private	37.8	38.7	40.3	39.6

Sufficiency of blood

A comprehensive view of haemovigilance requires that consideration also be given to whether the blood services were able to meet the demand for blood and blood products during the period under review.

In this regard, the Independent Haemovigilance Committee has reviewed monthly data from SANBS, which issues 87.5% of RBC in the country, pertaining to levels of buffer stock, frequency of stock not being available or alternative product being issued.

When product buffer stock levels are low, e.g. less than two days of group O RCC, the blood banks implement a cutback system. This process is meant to conserve critical supplies and, in practice, entails issuing fewer products than are requested, subject to consultation with and consent by the treating doctor. The doctor is encouraged to consider other options to safeguard the patient, but is able to request additional supplies should the indication for blood transfusion be sustained. Importantly, the cutback programme does not apply to actively bleeding patients.

Sometimes, due to stock non-availability, an alternative product is issued instead of the one requested. The blood banks discuss this with the treating doctor and obtain their consent when alternative products are to be issued. This data is captured and contributes to the overall picture of sufficiency of blood and blood products.

> “Overall, the data suggests acceptable sufficiency levels of blood and products for the year in all nine provinces.”

In the year under review, cutbacks in the issuance of RBC ranged from 0%–2.5% with an annual average of 0.61%. Significantly, no cutbacks were reported for the months of June and September when buffer stock levels were critically low.

Less than 1% (range 0.14%–0.70%) of orders were fulfilled with an alternative product due to stock being unavailable. Filtered RBC accounted for the high end of the range.

Non-availability of blood stocks is rare because, if necessary, standard red cells may be substituted for filtered red cells and an adult red cell unit may be issued in place of a paediatric unit. Shortages of standard RBC were reported 0.03% of the time, filtered RBC was not available for 0.05% of all requests and paediatric RBC was unavailable at a rate of 0.03%. Platelet non-availability ranged from 0.03%–0.06%, the higher number representing pooled platelets. This is because pooled platelets are issued as an alternative product when apheresis platelets are not available.

Overall, the data suggests acceptable sufficiency levels of blood and products for the year in all nine provinces.

These data compare favourably with those reported in the UK’s *2022 SHOT (Serious Hazards of Transfusion) Report*[1] (https://doi.org/10.57911/wz85-3885). In that report, lack of component accounts for 2% of all blood product requests, however there is a system in place to ensure that the patient returns at another time to receive the component required. This is possible because the UK system is information rich and has effective feedback mechanisms between prescriber and issuer of blood and blood products.

The South African blood services need to improve this capability to ensure complete and accurate capturing of information and the dispersal thereof to all participants in the blood product value chain.

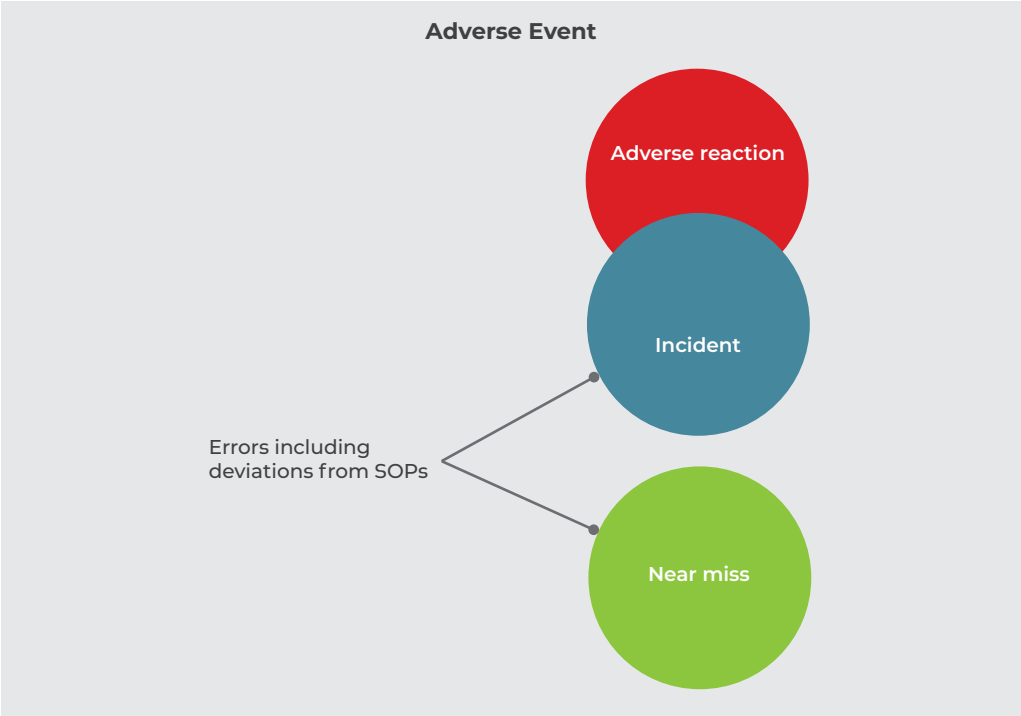
Subject to the quality of information received from the various facilities and doctors, the next Haemovigilance Report will attempt to give more granularity to the analysis of blood sufficiency, especially as it pertains to whether cutbacks have compromised patient care.

6 Transfusion-Related Adverse Events

This chapter is about transfusion-related adverse events (TRAEs), highlighting the three categories of adverse reaction, incident and near miss. The definitions and diagram (below) provided by the ISBT Working Party on Haemovigilance[3], show the relationship between the various entities, which may overlap or occur in isolation.

A 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 may or may not result in a reaction in the recipient.

The diagram below is useful to assist in understanding the adverse event terminology.

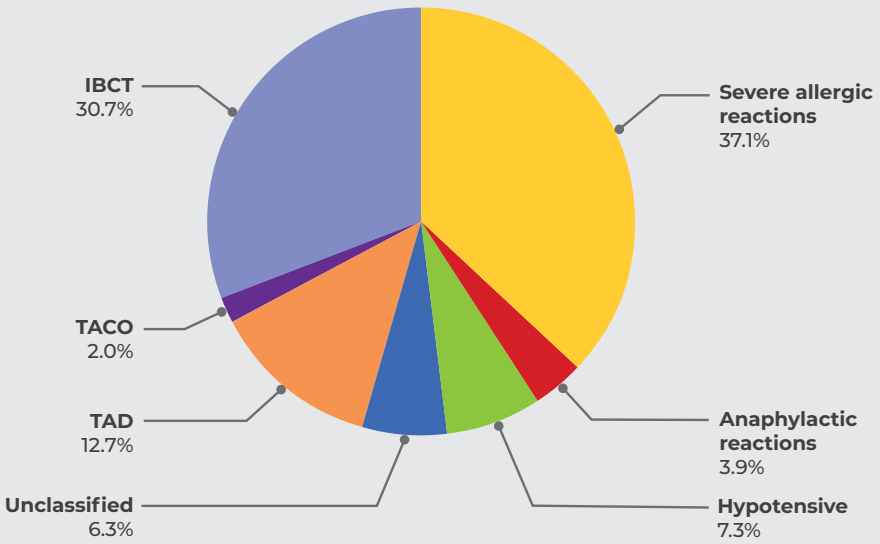


Source: ISBT Working Party on Haemovigilance

An **incident** is a case where the patient is transfused with blood or 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 (SOPs) or hospital policies, leading to an incorrect blood component transfusion (IBCT). An incident may or may not lead to an adverse reaction.

A **near miss** is an error or deviation from SOPs or policies that could have led to a wrongful transfusion or to a reaction in a recipient, but was discovered before the start of the transfusion.

Total Number of Serious Adverse Events of Transfusion 2022 (n=205)



IBCT – incorrect blood transfusion
TACO – transfusion-associated cardiac overload
TAC – transfusion-associated dyspnoea

1 346 868
blood products transfused in 2022
+
205
serious adverse events (SAEs) reported
=
SAE rate of
15.2 per 100 000
transfusions

A total of 1 346 868 blood products were transfused in 2022 and 205 serious adverse events (SAEs) were reported. This translates to an SAE rate of 15.2/100 000 transfusions in 2022.

Adverse Reactions in Patients

Febrile, allergic, anaphylactic & hypotensive reactions (n=99)

Febrile, allergic, hypotensive and anaphylactic reactions are unpredictable and mostly unpreventable, highlighting the importance of transfusing blood and blood products only when truly required.

As previously discussed, in this year's report we align with international reporting practice and do not report the simple febrile non-haemolytic transfusion reactions (FNHTRs) or mild allergic reactions. Although severe FNHTRs were not separated out for the 12-month period under review, these will reflect in future South African Haemovigilance Reports. Another reporting change to note is that the Independent Haemovigilance Committee (IHC) has adopted the UK's *Annual SHOT (Serious Hazards of Transfusion) Report*[1] definition for a mixed febrile/allergic reaction and these have been included in the severe allergic reaction count for 2022.

Febrile, Allergic, Anaphylactic & Hypotensive Reactions 2022 vs 2021

Category of Reaction	No. of Reactions Reported 2022	Percentage of Serious Adverse Events 2022	No. of Reactions Reported 2021
Severe FNHTR	Not reported to IHC for 2022		Not reported to IHC for 2021
Moderate & severe allergic reaction (including mixed febrile/allergic reaction)	76	37.1%	32
Anaphylactic reaction	8	3.9%	40
Hypotensive reaction	15	7.3%	33

The majority of the allergic-type reactions listed above were due to red cell transfusions, with only eight (8.1%) due to platelet transfusions and 10 (10.1%) due to fresh frozen plasma transfusions. Fortunately, most of these reactions were without any serious consequences, as no morbidities or mortalities were reported in this group.

The unusual shift in number of cases per category between 2021 and 2022 may be partially due to the inclusion of mixed allergic reactions in the severe allergic category and to the decrease in hypotensive reactions as a result of strictly applying the criteria for drop in blood pressure.

Very few Adverse Event Report forms received included any indication of medication given during management of the adverse event.

Pulmonary complications (n=30)

Pulmonary complications form a significant proportion (14.7%) of the adverse reactions reported in South Africa. Unfortunately, the paucity of information, lack of investigation and often multiple comorbidities in these patients makes it challenging to accurately classify transfusion-associated cardiac overload (TACO) cases. Most therefore end up in the broader category of transfusion-associated dyspnoea (TAD).

There were no confirmed or suspected cases of transfusion-related acute lung injury (TRALI) for the 12 months under review. However, there were four cases of TACO, all of which involved red cell concentrate (RCC) transfusions in patients in the extremes of ages. Three were older than 80 years of age and one was seven months old.

Like the UK's *SHOT Report*[1] findings, the trend in South Africa is for TACO to occur more in the elderly with comorbidities, in females and in non-bleeding patients.

Pulmonary Complications 2022

Complication Type	No. of Cases 2022 (% of Total)	No. of Cases 2021 (% of Total)
TRALI	0	1 (0.1%)
TACO	4 (2%)	4 (0.3%)
TAD	26 (12.6%)	84 (8.5%)

The difference in number of TAD cases in 2022 vs 2021 may be a result of applying the definition of TAD more strictly, especially excluding cases with symptoms suggestive of an allergic response.

Unclassified adverse events (n=13)

In 13 cases, the IHC failed to categorise the reaction due to lack of clinical data and/or a lack of documentation of vital signs. These cases represent 6.3% of all SAEs reported to the IHC in 2022. This category has decreased from 209 cases (21%) in 2021.

One of the reasons for the decrease is that the 2021 data included minor reactions, whereas 2022 data is limited to SAEs.

Delayed adverse reactions

There were no delayed adverse reactions reported in 2022.

Incorrect Blood Component Transfusion (n=63)

IBCT has the potential to cause serious morbidity and death. The 63 error events recorded account for 30.7% of all SAEs reported to the IHC in 2022.

Hospital errors were due either to a sampling error resulting in wrong blood in the tube (WBIT) or to a misdirected transfusion to the incorrect patient. Both circumstances are due to not correctly identifying the patient.

The blood bank errors were due to incorrectly interpreting the crossmatch result, incorrect labelling of the specimen or not following procedure regarding issuing in an emergency.

Origin of Incorrect Blood Component Transfusion 2022

Hospital Errors (41)	ABO incompatible (20)	WBIT (8) & misdirected (12)
	ABO compatible (12)	1 double error* & misdirected (11)
	Rh incompatible (8)	Units taken from emergency ward stock (8)
	Serologically incompatible (1)	Patient with known antibodies given emergency ward stock (1)
Blood Bank Errors (22)	ABO incompatible (10)	Errors during crossmatch procedure (10)
	ABO compatible (0)	0
	Rh incompatible (3)	2 Rh-incompatible (2) & 1 high-titer O given to a low-titer patient (1)
	Serologically incompatible (9)	Antibody missed on routine crossmatch (9)
	DAT +ve donor cells (1)	Component laboratory error (1)

*Double error = Labelling by hospital staff and blood bank staff did not pick up discrepancies in documentation

How did the patients react?

Fortunately, there were no reported mortalities and overall only 13 patients developed severe reactions, including three cases who had evidence of haemolysis. Mild reactions were defined as patients who became restless, had rigors or experienced nausea and vomiting. Severe reactions were defined as patients who had cardiorespiratory signs and symptoms, signs of haemolysis, etc.

Understandably, none of the 12 patients who received ABO-compatible red cells had a reaction. However, it needs to be noted that three of the patients who received a transfusion had not had blood ordered and did not require blood products.

Of the 29 patients who received an ABO-incompatible red cell transfusion, eight had no reaction, nine had a mild reaction, 12 had a severe reaction and one outcome was unknown as the patient had been discharged by the time the error was detected. Transfusion of group A red cells to group O patients is associated with the greatest risk of severe reaction[2], but a severe reaction with haemolysis did occur in one group O patient who received group AB red cells.

Of the 10 serologically incompatible transfusions, three had no reaction, five had a mild reaction, one had a severe reaction and one patient's outcome was not documented.

For the 11 cases of Rh-incompatible transfusions, there was no immediate reaction. This was to be expected, however of concern is that only the three cases that occurred due to blood bank error were noted to have received advice on giving anti-D immunoglobulin. For none of the cases was there a note on management and follow-up of future pregnancies.

In at least 50% of the Rh-incompatible cases, the clinician knowingly transfused the Rh-incompatible red cell unit in an emergency setting as a lifesaving action.

Clinical areas where incorrect blood component transfusions were reported

The IHC noted the department or clinical area where the IBCT occurred, in an attempt to identify any high-pressure areas. The area was identified from the Blood Request forms and, while we acknowledge that the forms may not always reflect the final destination of the patient, it was noted that Casualty had an unexpectedly low number of IBCTs.

Obstetrics and Gynaecology was an area of concern, both in terms of the number of errors (Obstetrics 11, Gynaecology 10) and in terms of knowing how to manage Rh-negative patients who require a lifesaving blood transfusion. Other high-blood-use areas with high error rate were Medicine (nine) and Surgery (16).

In contrast, in high-pressure areas where errors would be expected, the 2022 case numbers were low: Casualty (one), Theatre (one) and Intensive Care Unit (three).

Other clinical areas with documented cases were Ear, Nose and Throat (one), Oncology (three), Orthopaedics (five) and Unknown (three).

These numbers should be reviewed with a background knowledge of blood usage within clinical disciplines – the higher error rate does align fairly well to clinical areas where there is high usage of blood.

Origin of errors 2022

Errors by Area/Ward 2022

Origin of Error	Clinical Area/Ward					Total Cases
	Surgical	Medical	Obstetrics & Gynaecology	Orthopaedics	Other	
Blood bank errors (n=22)	4	4	6 Obstetrics 3 Gynaecology	1	1 ENT 1 Oncology 2 Unknown	22
Hospital errors (n=41)	12 1 Theatre	5	5 Obstetrics 7 Gynaecology	4	1 NICU 2 ICU 2 Oncology 1 Casualty 1 Unknown	41
Total (n=63)	**17**	**9**	**21**	**5**	**11**	**63**

Comparison of origin of error 2021–2022

Due to the change in reporting method previously discussed, it is difficult to make a comparison of error origin between 2021 and 2022.

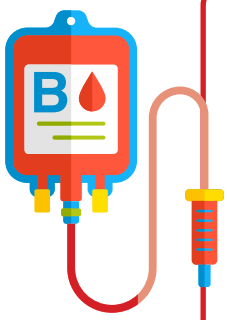
In 2021 IBCT accounted for 27 cases (2.7% of *all* adverse events), whereas in 2022 the IHC reported only on SAEs (of which IBCT accounts for 30.7%). The actual case numbers have more than doubled from the previous year, however, emphasising the need to document these errors.

Origin of Errors 2021–2022

Year	Total Error Events	Hospital Origin	Blood Bank or Laboratory Origin
2021	27	22	5
2022	63	41	22

Whether the error was made by staff in the hospital (66%) or by staff in the blood bank or laboratory (34%), the reasons appear very similar, as staff respond to stressful situations by taking short cuts and not following SOPs or safety checks.

The question that needs to be asked is whether additional training of these healthcare workers will adequately cover the impact and potential harm caused by willingly disregarding SOPs and safety checks.



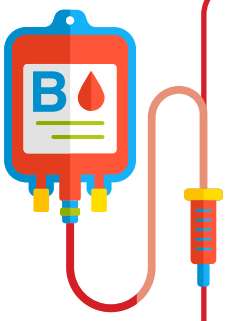
Example of a double error by hospital & blood bank staff

A doctor in the surgical ward ordered one unit of RCC for an 86-year-old male patient with carcinoma of the oesophagus. The blood sample for crossmatch was drawn from the correct patient, but the incorrect name was placed on the label. The blood bank technician failed to notice the name discrepancy between the sample and the Blood Request form.

The blood was crossmatched, issued to the ward and transfused. The patient received compatible blood (group O to group O) even though there had been a double error.

This is an example of misidentification because the SOP was not strictly adhered to.

SOP must be followed at all times to avoid errors.



Example of a hospital sample error

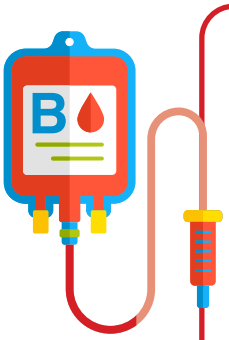
One unit of RCC for a patient in chronic renal failure was requested by a doctor in the medical ward. The crossmatch sample was taken from the wrong patient (group B), but the details of the correct patient were written on the sample and Blood Request form.

The blood was crossmatched and a group B RCC unit was issued. Within 90 minutes of the start of the transfusion, after approximately 100 ml RCC, the patient became restless, spiked a temperature and developed nausea and vomiting.

An Adverse Event Report form was completed and a post-transfusion sample taken. The post-transfusion sample was grouped as group O so a second sample was requested, which confirmed the patient was a group O.

This sampling error due to misidentification resulted in a group O patient receiving an ABO-incompatible unit, which resulted in an adverse reaction which was totally avoidable.

Positive verification of patient identity must be carried out prior to blood samples being taken for crossmatch of blood or blood products.



Example of a hospital-misdirected unit

An order for three units of RCC was initiated in Casualty for patient MA. The crossmatch was performed and the patient was found to be a group O, Rh positive. This patient was moved to Orthopaedics and the three units of group O RCC were issued to the ward on 7th June 2022, at 21:52.

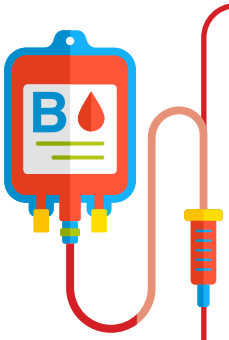
In the same Orthopaedic ward, another patient (MK) required two units of RCC. The request for patient MK was made the same day, at 21:17. The sample was crossmatched and found to be group A, Rh positive. The two units for patient MK were issued to the ward on 8th June 2022, at 02:43.

At 10:41 on 8th June, the doctor phoned to inform the blood bank that one unit meant for patient MK had unfortunately been transfused to patient MA. Within less than an hour of transfusion start, after <50 ml RCC, patient MA had a severe reaction to the misdirected group A, Rh-positive unit. Patient MA experienced back pain, chest pains, joint/muscle pain, flushing/sweating, restlessness/anxiety, shivering and rigors, presenting less than an hour into the transfusion.

Red cell serology confirmed the misdirected transfusion: blood intended for patient MK (group A) was transfused to patient MA (group O). The unit transfused to patient MA was incompatible within the ABO blood group system and this incompatibility can cause a severe haemolytic transfusion reaction.

In this case, the patient had a severe acute reaction but showed no signs of haemolysis and stabilised within 24 hours.

Positive verification of patient identity must be carried out prior to the transfusion of blood or blood products.



Example of incorrect blood product transfusion "out of necessity"

An 18-year-old female had a post-partum haemorrhage, suffering acute blood loss and causing her Hb to drop to 6 g/dL. The doctor ordered two units of RCC and the patient was crossmatched as group O, Rh negative. The blood bank only had one unit of group O, Rh negative in stock at the time, so this was issued while a second unit was ordered from another blood bank.

Ten days later, the blood bank supervisor was checking the emergency ward stock fridge and noted a unit of group O, Rh-positive RCC had been transfused to this patient.

No adverse event protocol could be followed as the patient had been discharged. There was no note that anti-D immunoglobulin had been given or that any counselling had been undertaken regarding the long-term impact of Rh-incompatible blood in a patient of childbearing age. On follow-up by the Haemovigilance Officer, the doctor in charge could not recall the case.

Communication between blood bank and clinicians is key. There may be instances where providing Rh-incompatible RCC is lifesaving and should not be withheld. However, this must be done after careful consideration of the long-term impact on women of childbearing age. If the Rh-negative mother has been sensitized to Rh-positive blood, her immune system will make antibodies to attack her baby, if it is Rh positive, resulting in haemolytic disease of the newborn.

Errors by hospital and blood bank staff are definitely areas that need to be focused on.

South Africa is not alone in this IBCT challenge:

> **Beware of the dirty dozen, reduce these and reduce errors: lack of communication, pressure, lack of assertiveness, complacency, stress, lack of resources, fatigue, lack of knowledge, lack of awareness, distractions, teamwork & norms.**
>
> *– UK's 2022 SHOT Report*[1]

Near Misses

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.

Unlike in the UK, no near misses were reported in South Africa in 2022. We acknowledge that this is an area that requires further input from the blood transfusion services and the IHC as to how to encourage reporting of near misses, and how to document and capture the data.

In 2021, the IHC recommended increasing staff awareness of the impact of misdirected units, encouraging the tracing of both index unit(s) involved in a misdirected adverse event as well as other units involved in the mix-up, and recording the final outcome. This has increased the number of reported IBCTs and should also increase awareness and reporting of near misses.

> **Errors (including near miss) continue to account for majority of the reports. In 2022, 2908/3499 (83.1%) of all reports were due to errors. Near miss events continue to account for a large proportion, 1366/3499 (39.0%) of the incidents reported to SHOT.**
>
> *– UK's 2022 SHOT Report*[1]

Mortality

There were 26 patient mortalities reported to the South African Haemovigilance Programme in 2022. 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.

The lack of clinical detail and lack of resources to carry out post-mortems on these patients (only three were documented) makes assigning imputability challenging. It can, however, be stated that none of the 26 deaths were conclusively attributed to a transfusion reaction.

Conclusion

There has been an improvement in collection of data and follow-up, however many of the Adverse Event Report forms contain little or no information regarding the management of the reaction or medication given. In addition, few of the forms record any detail on the patient outcome.

A revised Adverse Event Report form, which guides clinicians as to what data is required, has been introduced in some geographic areas in South Africa and this has improved the granularity of the data, allowing us to classify adverse events with more insight.

Recommendations

- Continue to introduce the revised Adverse Event Report form across the country, to improve the data collected on adverse events.
- Promote the reporting of near misses to assist to identify and control risks before actual harm results, providing opportunities to improve transfusion safety and focus more on the system than on the human error.
- Continuous training of both hospital staff and blood transfusion staff on the importance of processes and procedures and on the importance of following these to avert errors with serious implications.
- Create a culture of caring for patient safety.

7

Transfusion-Transmitted Infections & the Lookback Programme

This chapter will deal with bacterial contamination surveillance and viral transmission as well as the function of the Lookback Programme.

Bacterial Contamination

Product screening

In South Africa there is no routine bacterial surveillance on red cell products, as platelet products are a more sensitive indicator of potential bacterial contamination. Typical of a low-income country, South Africa has minimal screening and a passive haemovigilance reporting system, which leads to under-reporting of transfusion-related septic reaction cases.

Approximately 10%–20% of platelet products – apheresis platelets and pooled platelets – are tested for bacterial contamination as part of the countrywide quality-control (QC) programme. The variation is due to geographic location and logistics, however the rate is significantly more than the quality-standard requirement of 1% of platelet products.

> “In South Africa there is no routine bacterial surveillance on red cell products, as platelet products are a more sensitive indicator of potential bacterial contamination.”

Currently <10/1 000 QC samples from platelet products test positive for bacteria, compared to 1/1 000 to 1/5 000 in Europe and North America[4]. This high rate may still represent under-reporting, given the much lower rate of testing: 10%–20% of products here vs 100% of products in most high-income countries, according to literature published by blood services in high-income countries.

There have been no reported cases of transfusion-related septic reactions or confirmed related fatalities in the last five years in South Africa. In comparison, in high-income countries where 100% of platelets are tested for bacterial contamination or pathogen reduction technology is performed, the reported rate of transfusion-related septic reactions is 1/100 000.

To mitigate the risk of bacterial contamination, the blood transfusion services (BTS) follow recommended best practice by questioning the donor for symptoms of possible infection, disinfecting the donor arm prior to donation, using validated disinfectants, and diverting the first 30 ml of blood into the pouch which significantly decreases contamination with skin flora.

Best practice for bacterial surveillance requires the collection of a sample (8 ml–16 ml) of platelet product 24–36 hours post-donation, directly from the product bag, for all platelet products. This sample will be tested for bacterial growth using standard microbiological methods. In South Africa, we obtain 4 ml–10 ml of product – via a

sampling pouch – from only 10%–20% of platelet products collected. This pouch is incubated for 24 hours post-collection and then tested for bacterial growth using standard microbiological methods over a seven-day incubation period. No pathogen reduction technology is currently used in South Africa.

SANBS Product Contaminant Data Following Implementation of Strict Infection Prevention Control Procedures 2018–2022

Contaminant	2018–2019	2019–2020	2020–2021	2021–2022	Total
Gram-positive cocci	29	16	20	7	72 (65%)
Gram-positive bacilli	7	14	7	2	30 (27%)
Gram-negative bacilli	2	3	0	4	9 (8%)
Total	**38**	**33**	**27**	**13**	**111**

In the above table, the decreasing number of contaminants was enhanced by strict COVID-related infection prevention control. Most isolates (>90%) were Gram-positive bacteria, with only 5% being true pathogens (three *Staph aureus*, one *Klebsiella spp*. and one *Pseudomonas spp.*).

Environmental screening

SANBS introduced strict infection prevention control procedures prior to the COVID pandemic, to mitigate against much higher bacterial contamination rates in platelets at the time. The impact of this policy has been further enhanced by COVID-related hygiene measures introduced in 2020 and 2021.

SANBS practices environmental screening across the value chain, which involves taking environmental samples from apheresis donor clinics, processing labs and blood banks. Strictly, environmental samples are only required in production good-manufacturing-practice-related areas, but this screening does provide assurance of cleanliness.

WCBS does not perform routine environmental screening to the same extent, but places agar plates in blood bank and reagent laboratory laminar flow hoods on a monthly basis to identify contaminants.

Viral Prevalence in the Donor Population

In South Africa, all blood donations are screened through a combination of serological and molecular tests for hepatitis B virus (HBV), hepatitis C virus (HCV), human immunodeficiency virus (HIV) and syphilis. Individual donation nucleic acid testing (ID-NAT) for viral infections was implemented in the South African BTS in 2005.

The current ID-NAT Ultrio Elite assay has reduced the window period for detection to 4.5 days for HIV, 16.3 days for HBV and 2.2 days for HCV[5].

In the year under review, 2 828 of the 1 166 703 donations collected tested positive for HIV, HBV and/or HCV. During this 12-month period, there was no change in the prevalence of HBV or HCV in the donor population, while the HIV prevalence increased slightly from 0.15% in 2021 to 0.17% in 2022 but has not returned to pre-COVID prevalence.

In 2022,
2 828
of the
1 166 703
donations tested positive for
HIV, HBV
and/or
HCV

Viral-Positive Blood Donors 2022

Virus	No. Positive	Prevalence
HIV	2 016	0.17%
HBV	695	0.06%
HCV	117	0.01%

The increase in HIV prevalence in the donor population from 2021 to 2022 reflects the return to recruiting new donors post-COVID. Although the total number (and percentage) of new donors was less in 2022 compared to 2019, the number and percentage of young donors (16–19 years) were considerably higher in 2022. A large part of the new-donor recovery since COVID was driven by these young donors. New donors must continually be recruited to maintain a voluntary non-remunerated blood donor base which can provide sufficient blood for patients.

National Viral Prevalence in Blood Donors 2019–2022

Virus	2019	2020	2021	2022
HIV	0.21	0.19	0.15	0.17
HBV	0.09	0.08	0.06	0.06
HCV	0.01	0.01	0.01	0.01

A noteworthy finding was that no transfusion-transmitted infection (TTI) event was reported in South Africa in 2022, although many donor-triggered lookbacks were investigated. The blood service is satisfied there is no TTI when an investigation concludes the infection in the recipient was not caused by transfusion, either because no infected donors were identified (after all donors were traced) or because the implicated donor(s) was excluded by phylogenetic testing.

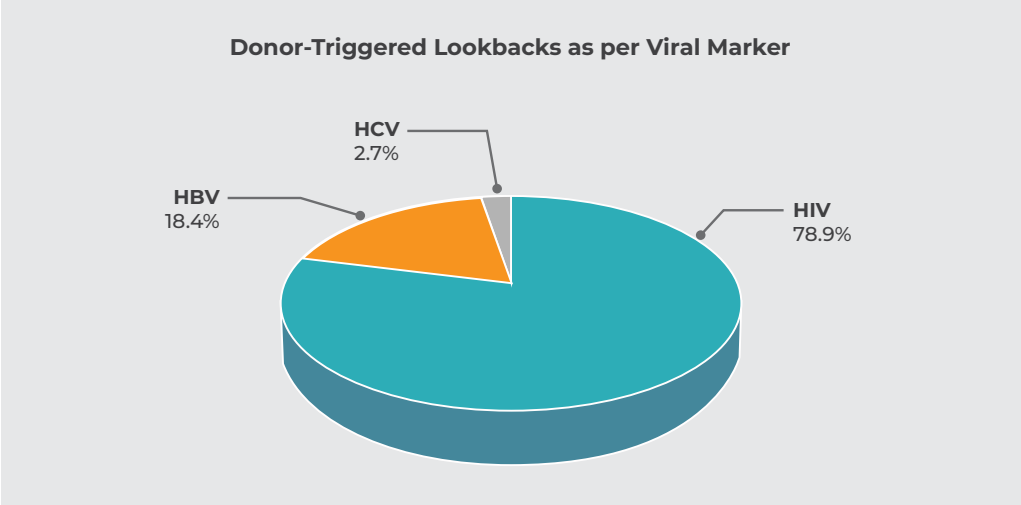
The Lookback Programme

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

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.

Donor-triggered lookback investigations

In a donor-triggered lookback investigation, the recipient/s of the previous negative units are identified and their treating doctors are notified. As far as possible, the patient is recalled, counselled and tested for the relevant viral marker and the result is reported to the BTS.



> The prolonged time period frequently experienced in donor-triggered lookbacks presents an additional challenge when phylogenic testing is requested.

Of the 792 donor-triggered cases, 78.9% were for HIV, 18.4% for HBV and 2.7% for HCV. There were no co-infection cases or non-routinely tested infections such as malaria.

In the table below, the challenge of tracing patients to provide a final/confident outcome is highlighted by the fact that in 62.2% of investigations, the patient was still awaiting clinician's feedback, was not traceable, declined testing or had died. These challenges are understandable as there may be a considerable time period between the transfusion to the recipient and the donor testing positive for a viral marker when they return for further donations.

The prolonged time period frequently experienced in donor-triggered lookbacks presents an additional challenge when phylogenic testing is requested. This is because either the patient or the donor or both may have started antiretroviral therapy, reducing the viral load and making phylogenic testing inconclusive due to lack of material.

nor-Triggered Investigation Outcomes 2022

Outcome	No. of Patients
Recipient retested negative	124
Recipient positive before transfusion	64
Phylogenetic analysis for potential HIV TTI	1
Recipient died between transfusion & initiation of lookback	161
Unresolved (awaiting feedback from clinician)	179
Untraceable patient	149
Other*	109
Recipient declined testing	4
HBV immune	0
Phylogenetic analysis for potential HBV TTI	1
Total	**792**

*Other: Doctors not traceable or refuse to participate in the Lookback Programme, foreign patients not traceable, patients who do not honour the appointment for blood samples

The table below reflects a relatively constant number of viral-positive donors who have triggered a lookback over the past 10 years.

Donor-Triggered Lookback Investigations 2012–2022

2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022
629	849	1 129	978	979	948	866	884	916	930	792

Recipient-triggered lookback investigations

A recipient-triggered lookback investigation is initiated when the BTS is informed that a blood recipient has tested positive for a TTI and that the infection may have been transfusion-transmitted. 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.

Outcome of Recipient-Triggered Lookbacks 2022

Virus Type	Resolved	Unresolved
HIV	4	1
HBV	1	0
HCV	0	0
Malaria	1	0
Total	**6**	**1**

As indicated in the table above, there are far fewer recipient-triggered lookbacks compared with donor-triggered lookbacks. Two thirds of the cases were resolved as no TTI having occurred.

One 2022 case remains unresolved due to outstanding information. This case was reported by the patient herself, however she did not provide the requested doctor details to initiate the lookback and there has not been any further communication from the patient or doctor. In this case, one of her donors was found to have two subsequent donations negative for TTIs. As no official documentation was received to initiate the investigation, the second donor was not recalled.

Recommendations

- The BTS to provide guidelines for the investigation of potential transfusion-related septic reactions.
- The BTS to review and standardise the trigger for initiating a recipient-triggered lookback.
- The BTS must continue to inform and educate clinicians about the Lookback Programme process and the importance of participating in the programme to ensure the safety of the blood supply.
- The donor collection staff and telerecruiting staff should be made aware of the importance of the donor cell phone number as a critical point of contact and the need to update and confirm contact details at each donation.

8 Donor Haemovigilance

Donors willingly give their gift of life and their time with no expectation of reward. The blood transfusion services (BTS) of South Africa recognise the important role of the donor and undertake to minimise the risks of blood donation by maintaining quality donor care and managing and monitoring donor adverse events (DAEs). All donors should be fully informed about the blood donation process and be made aware of DAEs prior to signing their consent forms.

Donor haemovigilance is the systematic monitoring of adverse reactions and incidents in the whole chain of blood donor care, with a view to improving the quality of that care and safety for blood donors. **DAEs** are an unintended or unfavourable outcome during the process of blood donation.

Donor Adverse Events

Donor Adverse Events 2022

Event Type		Total	% of Total DAEs	DAE Rate per 100 000 Donations
Local Reactions	Haematoma	630	13.9	54.00
	Arterial puncture	5	0.1	0.43
	Delayed bleeding	31	0.7	2.66
	Nerve irritation	4	0.1	0.34
	Tendon injury	0	0.0	0.00
	Nerve injury	1	0.0	0.00
	Painful arm	165	3.7	14.14
	Total no. local reactions	**836**		**71.65**
Vasovagal Reactions	Faint immediate type	2 016	44.6	172.79
	Faint immediate, accident	131	2.9	11.23
	Faint delayed type	1 313	29.1	112.54
	Faint delayed, accident	95	2.1	8.14
	Total no. vasovagal reactions	**3 555**		**304.70**
Other Reactions	Citrate reaction	114	2.5	9.77
	Haemolysis	1	0.0	0.09
	Generalised allergic reaction	13	0.3	1.11
	Total no. other reactions	**128**		**10.97**
Total		**4 519**	**100**	

A total of **1166 703** blood donations were made by 608 279 voluntary non-remunerated donors in South Africa during the 2022 calendar year. A total of 4 519 DAEs were reported for the year, which translates to a rate of 38.73/100 000 donations.

Donor Adverse Events per 100 000 Donations 2019–2022

Donations & Donor Adverse Events	2019	2020	2021	2022
Total number of whole blood donations	91 360	837 790	881 366	934 777
DAEs per 100 000 donations	45.8	43.8	37.2	38.7

It is well documented, both internationally and in South Africa, that younger donors are more likely to experience a vasovagal event during donation[6,7]. This is why an explanation for the 2021 decrease in DAEs was that there had been a decrease in young donors due to school closure during COVID. Although the total number (and percentage) of new donors was lower in 2022 compared to 2019, a large part of the new-donor recovery since COVID has been driven by young donors in the 16–19 age group.

Donor Adverse Events 2019–2022

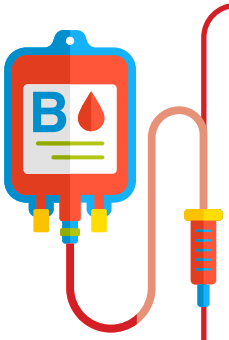
Event Type		2019	2020	2021	2022
Local Reactions	Haematoma	703	626	536	630
	Arterial puncture	2	2	3	6
	Delayed bleeding	28	31	34	31
	Nerve irritation	3	6	2	45
	Tendon injury	0	1	1	0
	Nerve injury	2	5	0	0
	Painful arm	158	154	157	125
Vasovagal Reactions	Faint immediate type	2 749	2 484	2 064	2 016
	Faint immediate, accident	126	107	124	131
	Faint delayed type	1 057	977	1 021	1 313
	Faint delayed, accident	104	72	75	95
Other Reactions	Citrate reaction	106	57	57	114
	Haemolysis	18	0	2	1
	Generalised allergic reaction	2	8	8	13
Total		**5 058**	**4 530**	**4 084**	**4 520**

The majority of DAEs will be minor (e.g. faints and haematoma) and result in transient or temporary discomfort, however a few may have a severe adverse donor reaction.

Serious Adverse Events of Donation

A serious adverse event of donation (SAED) is an unintended response in a donor, associated with the collection of blood or blood components that is fatal, life threatening, disabling, incapacitating or results in hospitalisation or morbidity.

There was a concerning increase in the rare SAED of arterial puncture (0.014% for blood donation) in 2022: although numbers are small, the case numbers doubled. Arterial puncture may lead to severe haematoma in one third of cases and/or aneurysm, pseudoaneurysm or formation of a brachial fistula.



Example of a serious adverse event of donation – arterial puncture

A 66-year-old male first-time donor donated whole blood. The donation began well and the phlebotomist adjusted the needle to reduce the blood flow. At the time there was no visible bruising, but hours later a haematoma developed.

The swelling and bruising of his arm increased and, over the next four weeks, he visited his general practitioner (GP) three times. On the third visit he was referred to a vascular surgeon, who on ultrasound confirmed a subcutaneous haematoma. On a fourth visit to the GP, a pulsatile mass was felt, with pain radiating to his shoulder. He was referred back to the vascular surgeon, who detected the formation of a pseudoaneurysm.

The surrounding haematoma and arterial wall were repaired, with a good outcome of a palpable distal radial pulse and decreased swelling of the arm. This donor lost four months of work and was duly compensated.

Reminder of arterial puncture alert signs: rapid filling of the bag (three to four minutes), bright red blood, pain in the arm, visible bruising or swelling and pulsatile needle.

Overall, the DAE rate remained relatively stable, with some decrease in the more common DAEs (e.g. faints). However, the increase in the local SAEDs of nerve irritation and arterial puncture needs to be noted and more focused donor staff training should be done on complications of blood donation and the management thereof.

Recommendations

- The BTS to provide additional education on localised complications to medical collection staff and to implement measures to improve early detection and follow-up on donors suspected of a local SAED (e.g. arterial bleed).
- Continued education of staff and donors that, although SAEDs are rare, both staff and donors need to be aware of the early warning signs to prevent progression of an adverse event.

9 Conclusion

The 2022 South African Haemovigilance Report has helped identify weaknesses in the blood services value chain which, if not addressed, have the potential to compromise patient care.

Accordingly, the following key interventions must be given priority in the year ahead:

- Effective and timely communication of findings by the Independent Haemovigilance Committee to everyone involved in the care pathway of patients who are prescribed blood and blood products. This will enhance patient safety and prevent future harm. Communication must be underpinned by a feedback mechanism to confirm receipt of findings and to report on measures undertaken to mitigate against a recurrence.
- About one third of all serious adverse events were due to transfusion errors, with a two thirds to one third split between hospital and blood bank respectively. Consideration should be given to monthly reporting on the effectiveness of the measures instituted to address the identified gaps.
- Intensify educational campaigns to address knowledge gaps as a means to achieving quality improvement. One of the focus areas should be the use of emergency blood ward stocks in the treatment of postpartum haemorrhage. This is meant to address growing uncertainty amongst healthcare workers about the use of Rh-incompatible blood in actively bleeding women of childbearing age.
- Severe allergic reactions are unpredictable and in most cases unpreventable. They constitute 37% of the serious adverse events reported, emphasising the need for there to always be a clear indication for the transfusion of blood or blood component.
- Improve the quality and adequacy of information provided after a transfusion-related incident. Data presented in this report show that 6.3% of serious adverse events could not be classified due to insufficient information. If not effectively addressed, poor data has the potential to compromise the integrity of the haemovigilance system, with the resultant misdirection of efforts to improve patient care.

We would like to thank all those who have taken the time and made the effort to participate in and contribute to the South African haemovigilance system during 2022.

10

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