THE SOUTH AFRICAN

HAEMOVIGILANCE REPORT

2023

IHC | INDEPENDENT HAEMOVIGILANCE COMMITTEE

Haemovigilance Report 2023

The 24th 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 that 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

AHTR	acute haemolytic transfusion reaction
API	alternate products issued
BTS	blood transfusion services
COVID	coronavirus disease 2019 (COVID-19)
DAE	donor adverse event
DAT	direct antiglobulin test
DHTR	delayed haemolytic transfusion reaction
FFP	fresh frozen plasma
FiO_2	fraction of inspired oxygen
FNHTR	febrile non-haemolytic transfusion reaction
GMP	good manufacturing practice
Hb	haemoglobin
HBV	hepatitis B virus
HCV	hepatitis C virus
HIV	human immunodeficiency virus
HLA	human leukocyte antigens
HNA	human neutrophil lipocalin
IBCT	incorrect blood component transfusion
ICU	intensive care unit
ID-NAT	individual donation nucleic acid testing
IHC	Independent Haemovigilance Committee
ISBT	International Society of Blood Transfusion
PM	post mortem
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 Foreword

Over the past two and a half years the Independent Haemovigilance Committee (IHC) has learnt much about the systems within the blood services of South Africa. These lessons have been applied to ensure improved, rigorous data collection and tracking, so that those at risk of transfusion-related complications can be identified and offered appropriate help where necessary.

The UK's *2022 Annual SHOT (Serious Hazards of Transfusion) Report*[1] points out that "A system in which both complications of transfusion and near misses are openly reported and shared is crucial to advancing blood safety". During 2023 the IHC encouraged the blood services to revisit "near miss" definitions as well as how the data is captured and the process of review. Awareness of the importance of "near miss reporting" has increased amongst the blood bank staff and this awareness is now filtering through to healthcare workers. We look forward to recording the positive impact of this in future reports.

The monthly IHC meetings with blood bank staff and donor staff have led to a "sharing culture" rather than a "reporting culture", which has been helpful at an organisational level as the two blood transfusion services seek to align their policies, procedures and processes. The aim is that, with time, the sharing culture extends beyond the blood services to healthcare workers in both the private and public sector.

> "In a country with limited resources, education is essential to prevent incorrect blood product transfusion ..."

A current area of concern is the reluctance of some healthcare workers to report an error or near miss, particularly if – by sheer luck – compatible blood was transfused and no harm done. It is hoped that healthcare workers will come to realise that there are a number of advantages to sharing the adverse events which occur due to errors by hospital and/or blood bank staff. Doing so enables us to investigate the error, analyse the system, look for trends and use what we learn as training material to increase awareness amongst all healthcare workers, thus reducing the chance of a similar adverse event occurring in the future.

In a country with limited resources, education is essential to prevent incorrect blood product transfusion, an issue of great concern in South Africa as it accounted for 29.5% of all serious adverse events in 2023.

The IHC's goal is to foster trust and transparency so that healthcare workers regard the *Haemovigilance Report* as a source of information on safety and sufficiency of the 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.

3 Executive Summary

The 24th 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 2023 calendar year.

The report paints a picture of a blood transfusion service under considerable stress, with extended periods of cutbacks due to supply constraints. The cutbacks were spread over a seven-month period of the year and, importantly, continued for another two months into the following year.

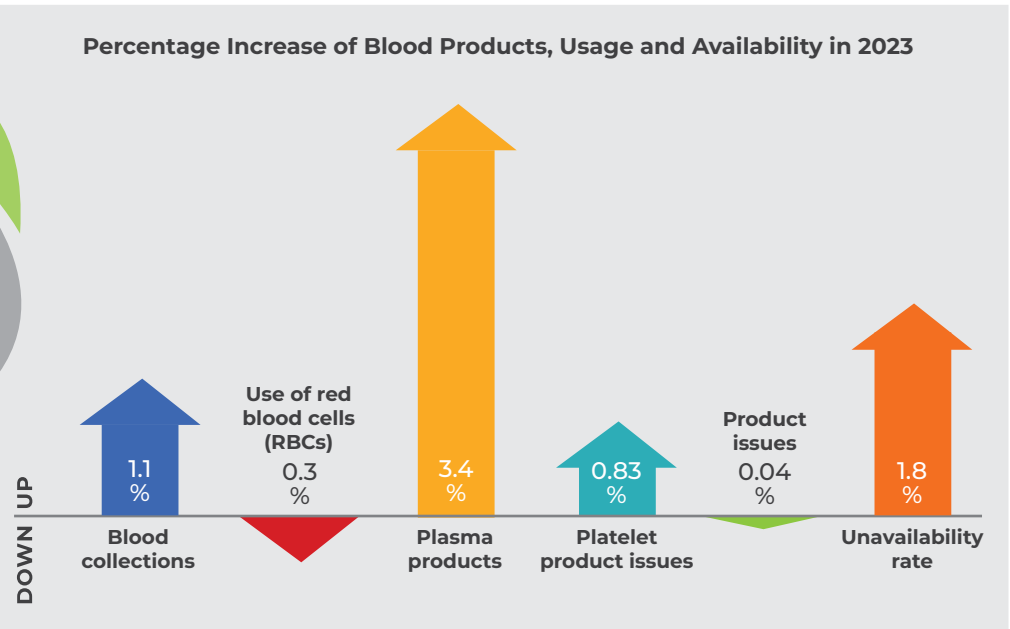
> "The national transfusion rate was determined to be 16.89/1000 population, marginally down on the 17.3/1000 population reported in 2022."

Although whole blood collections increased by 1.1% in 2023, this was still associated with a slight decrease of 0.3% in the usage of red blood cells (RBCs) year on year. There was a 3.4% increase in the use of plasma products and a modest 0.83% increase in platelet product issues. Overall, product issues were 0.04% down on the previous year, largely due to the approximately 3 000 fewer RBC units being issued.

The national transfusion rate was determined to be 16.89/1000 population, marginally down on the 17.3/1000 population reported in 2022. Of concern is that the data show a decrease in transfusion rate for six of the nine provinces, which is perhaps a reflection of the constrained national supply.

In another indication of a constrained system, the rate at which alternate products were issued (API) was notably higher in 2023 compared to 2022. The API figures increased for all product lines in 2023, with the unavailability of filtered RBCs worsening year on year (0.7% in 2022 vs 1.17% in 2023). An even greater decline in availability of apheresis platelets was observed with a product unavailability rate amounting to 1.8%.

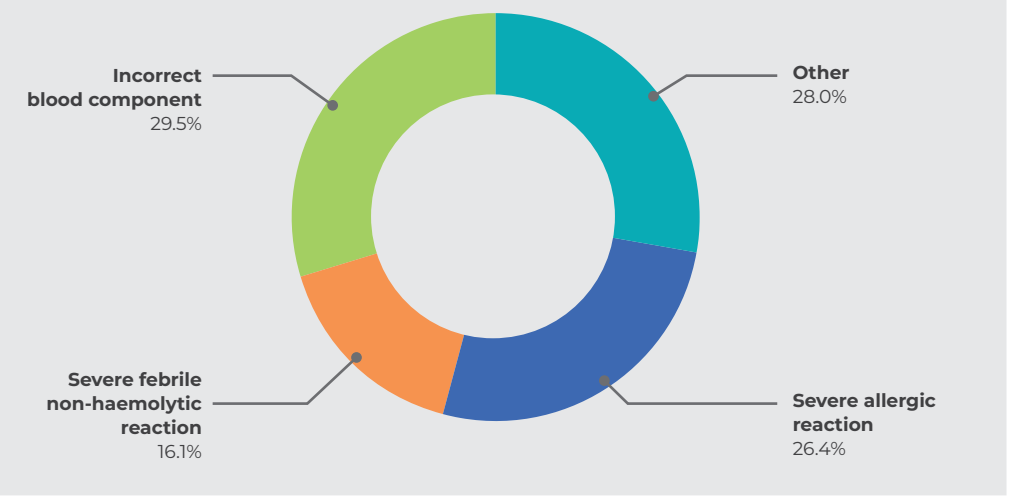
Transfusion rate
16.89/
1000



These are concerning statistics, especially in view of the anticipated increases in demand due to population growth and further normalisation of clinical activity post COVID.

There was an appreciable increase in the serious adverse events associated with a blood or blood product transfusion. Transfusion-related adverse events occurred at a rate of 24.8/100 000 transfusions in the year, compared to a rate of 15.2/100 000 transfusions in the previous year. This must, however, be interpreted with some caution as this report includes data on a category of adverse events (severe FNHTR) not previously reported. The top three adverse events reported were: incorrect blood component transfusion (29.5%), severe allergic (26.4%) and severe febrile non-haemolytic transfusion reaction (16.1%).

Transfusion-related adverse events
24.8/ 100 000
(includes data on a category previously not included)



> Of particular concern in this report are observed lapses in adherence to protocols pertaining to the blood transfusion process, in particular the aspects of sampling, crossmatching, issuing and transfusing the product[6].

Of particular concern in this report are observed lapses in adherence to protocols pertaining to the blood transfusion process, in particular the aspects of sampling, crossmatching, issuing and transfusing the product[6]. These lapses resulted in wrongful or inappropriate transfusion of patients, accounting for almost a third (29.5%) of all serious adverse events reported. Some events were the result of a single error at one or other phase of the transfusion pathway, while others were due to any combination of errors involving multiple participants (including ward staff, laboratory staff and messengers). These errors caused severe reactions in more than 50% of patients who had received incompatible transfusions and could have resulted in severe consequences had the recipients not been successfully resuscitated.

In this regard, the Independent Haemovigilance Committee notes that there were a few instances where Rh-incompatible transfusions were knowingly or unknowingly transfused in an emergency, but without applying the standard protocols applicable to females of childbearing age. This could have devastating consequences for the patient and must clearly be a focus area for future hospital staff education.

> An encouraging development in 2023 is the increased reporting of near misses, as these are helpful in the identification of areas of vulnerability in the blood transfusion value chain.

An encouraging development in 2023 is the increased reporting of near misses, as these are helpful in the identification of areas of vulnerability in the blood transfusion value chain.

It is also pleasing to see that there were no reports of viral or bacterial transfusion-transmitted infections (TTIs). Strict donor screening and testing, coupled with bacterial surveillance, has now ensured no bacterial TTIs in the five years up to and including 2023. There were no viral TTIs in 2023 either, despite a slight increase in the human immunodeficiency virus (HIV) donor prevalence rate from 0.17 to 0.21. Donor prevalence rates for hepatitis B and C viruses (HBV and HCV) were fairly stable compared to the previous year, apart from a slight uptick in the HCV donor prevalence. One case of transfusion-transmitted malaria was reported.

Donor adverse events (DAEs) increased in 2023 compared to the previous year, with a calculated DAE rate of 41.7/100 000 donations (cf. 38.7/100 000 donations in 2022). Unsurprisingly, the most common adverse events were faints (vasovagal reactions) at 76.4% of the total reported. Overall, the majority of donor adverse events were minor in nature.

The *2023 Haemovigilance Report* represents a much more nuanced account of the blood transfusion services in South Africa than previous years' reports have done. This is thanks in no small part to the improvements in data quality. The extent to which the system was stretched as a result of insufficient blood supplies is an obvious cause for concern, and calls for a concerted effort to recruit more donors to grow the pool. Of course doing so will have the unintended consequence of an increased risk of TTIs but, on available evidence, the blood services have appropriate safeguards in place to manage that risk.

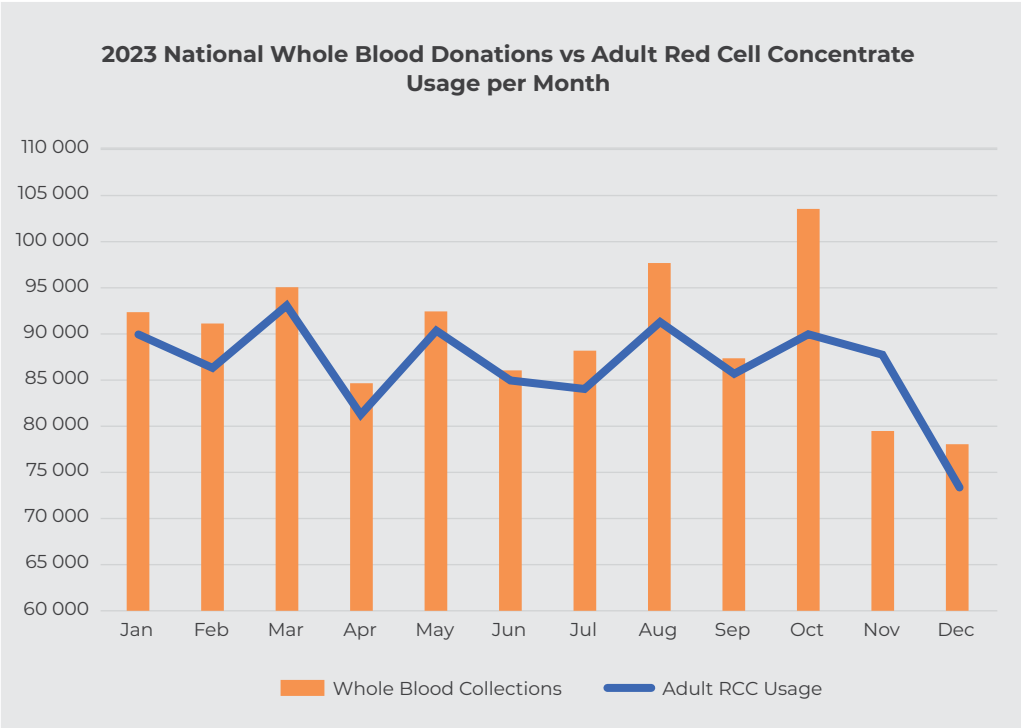
4 Blood Collections, Sufficiency & Blood Products Issued

The year 2023 presents an unexpected picture in the supply-demand relationship. Firstly, the national whole blood collections increased 1.1% on the previous year, yet blood usage was 0.3% below that for 2022. Secondly, with an estimated population growth of 0.87% per year, the total population would have grown by at least half a million in the period under review, implying an expectation of an increase rather than a decrease in the use of blood.

In total, the whole blood collections in 2023 increased by 12 295 units compared to the previous year, but this was associated with a 0.3% reduction in the number of red blood cell (RBC) units issued (approximately 3 000 units less).

A month-on-month analysis reveals critical shortages during the months of June (collections 939 units) and November, with a shortfall of 8 115 units. This is despite October being a standout month for collections, with an impressive collections level of nearly 14 000 units.

The shortages in June and November triggered the imposition of supply cutbacks, with physicians being engaged by the blood services on the use of alternative products and on measures to safeguard patients while awaiting blood.



Compared to 2022 the use of RBCs decreased by 0.3% in 2023, however there were increases of 3.5% and 0.8% respectively in the use of plasma products and platelets.

The ratio of apheresis platelets to pooled platelets issued (50.3%:49.7%) has remained relatively stable, when compared to that in 2022 (49.7%:51.3%). Overall, slightly more platelet products were used in 2023 compared to 2022 (737 units more).

There is a slight shift in usage patterns of plasma products, with a marginal 1.1% decline in the use of fresh frozen plasma (FFP) associated with a 6.6% increase in the use of cryoprecipitate.

Total blood product issues were 479 less than the previous year.

The table below shows a consolidated view of blood product issues during the past five years. Following a steady increase from the year 2020, product availability declined marginally in 2023 (0.03%) and it remains to be seen if this will be continued into the next year.

Blood Product Issues 2019–2023: South Africa

Product	Category	2019	2020	2021	2022	2023
Plasma Products	Fresh frozen plasma	151 325	139 442	142 392	153 957	152 244
	Cryoprecipitate/ cryo wet	40 775	39 239	46 776	54 804	58 456
	Cryo-poor plasma					5 373
	Total	**192 100**	**178 681**	**189 168**	**208 761**	**216 073**
Platelet Products	Pooled platelets	38 514	37 755	41 943	43 909	43 689
	Apheresis platelets	39 567	39 440	41 113	43 289	44 243
	Total	**78 081**	**77 195**	**83 056**	**87 198**	**87 932**
Red Cell Products	**Total**	**1 148 235**	**953 760**	**993 498**	**1 050 909**	**1 047 757**
Total Products		**1 418 416**	**1 209 636**	**1 265 722**	**1 346 868**	**1 346 389**

Red Cell Transfusion

According to Census 2022[2], published in 2023, the total population of South Africa in 2023 was 62 027 503. With total red cell usage at 1 047 757 units, the national transfusion rate is therefore determined as 16.9/1 000 population.

This is slightly lower than the 17.3/1 000 population reported in 2022 but, with the adjustments for population size as per Census 2022, the corrected transfusion rate for 2022 becomes 16.95/1 000 population. This makes the transfusion rates in 2020 and 2022 very similar.

Provincially the pattern is as before, with Gauteng leading the pack. Gauteng also shows a marginal (1.2%) increase in transfusion rate from the previous year.

Six provinces recorded **decreases** in transfusion rate, ranging from 0.1%–1.0%. Of particular concern is the Eastern Cape, which not only shows a 0.9% decrease from 2022's transfusion rate but also a steady decline over the preceding three years.

North West recorded an impressive 1.3% increase in the transfusion rate, followed by Gauteng at 1.2% and Western Cape at 0.2%.

Provincial Red Cell Transfusion Rates 2018–2023

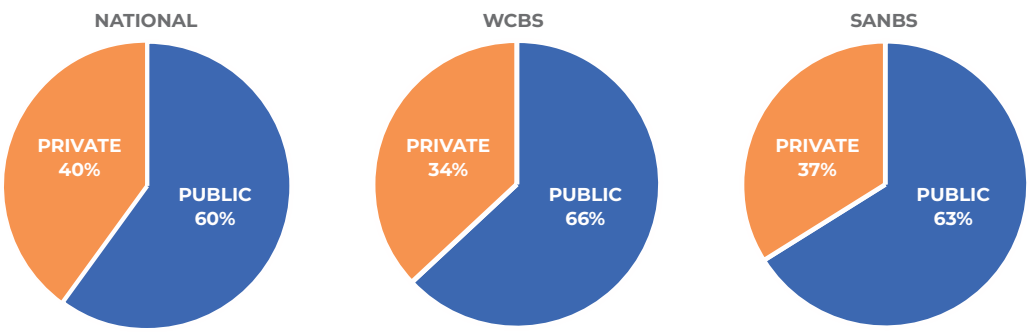
Transfusion Rate per 1 000 Population	2018	2019	2020	2021	2022	2023
Gauteng	23.3	28.4	22.8	23.4	24.2	25.4
KwaZulu-Natal	13.7	18.2	15.0	15.6	16.5	15.1
Western Cape	20.0	20.7	17.6	17.8	18.1	18.3
Eastern Cape	10.9	12.8	9.9	11.1	11.2	10.3
Limpopo	12.1	15.2	12.6	12.2	13.4	12.7
Mpumalanga	12.7	15.5	13.7	14.1	15.0	14
North West	11.4	14.0	11.8	11.7	12.6	13.9
Free State	13.9	16.6	13.3	14.1	14.4	13.7
Northern Cape	11.4	13.7	10.2	10.6	11.9	11.8

Red Blood Cell Use in the Public & Private Sectors

There was a 0.3% increase in the private sector share of RBCs but, notably, the percentage split between public and private remains about 60:40 in favour of the public sector. This has been the trend over the past three years and is unlikely to change much without additional investment in the public sector to stimulate an increase in clinical activity, especially at the secondary and tertiary levels of care.

When viewed according to blood service, the split is 63% public in SANBS and 66% public in WCBS.

RBC Unit Use in the Public and Private Sectors



Sufficiency of Blood

The predictability of supply of blood and blood products is dependent on how product stocks are managed.

In this regard, the blood services undertake continuous educational campaigns on patient blood management, a process which should ensure that the right product reaches the right patient at the right time and for the right reason.

The principles underlying patient blood management[3] include the timely treatment of anaemia, controlling blood loss, optimising the patient's physiology to withstand the consequences of anaemia and avoiding inappropriate transfusions.

Sometimes the blood services experience stock shortages and respond to this by restricting supplies or issuing alternate products. This is done in consultation with the requesting physician.

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Product cutbacks for 2023

Cutbacks, otherwise known as restrictive issues, are a mechanism used to manage limited supplies of blood. They are mainly applied to group O patients and not to paediatric or emergency patients.

The cutback process is triggered when the blood bank receives a request for two or more units for a patient that is group O. The blood bank staff contact the doctor and request that the order be reduced. If approved, only one unit is issued. If the doctor disapproves, the full order is processed. Importantly, the process is not enforced if the doctor cannot be contacted. Under those circumstances, the full order is processed.

SANBS

Cutbacks were enforced for a total of 135 days, spread over seven months of 2023. Of a total of 883 848 issues of group O RBC units, 10 241 units were held back (1.14% of all requests).

WCBS

This service did not keep data in terms of the number of units held back, but reports that cutbacks were enforced on four occasions, for about two weeks at a time, in April, June, August and October.

Percent of all blood requests held back
1.14%

Alternate product issued

When the product requested is not available in the blood bank, an alternate product is issued after consultation with the clinician. Typically, alternate products are issued in the following instances:

- Standard RBCs instead of filtered RBCs
- Pooled platelets instead of apheresis platelets
- Adult product instead of paediatric product

Red blood cell products

In the year under review, a total of 1 675 filtered RBCs were not available at the time of request, prompting the clinician to opt for standard RBCs. In total, 171 100 units of filtered RBC were issued during the year, compared to 169 056 units in the previous year. This is a 1.2% improvement in the availability of filtered RBCs, despite a 0.3% decrease in total RBC issues.

Platelet products

A total 31 398 units of apheresis platelets were issued, as against 577 pooled platelet units issued as alternate product, amounting to an unavailability rate of 1.80% for apheresis platelets (range 0.75%–3.46%). Compared to the 0.03%–0.06% unavailability range reported in 2022, this represents a massive drop in product availability in the year under review.

The platelet shortages have no correlation to those reported for RBC, with August, November and July experiencing the highest alternate products issued (API). Notably, these months were associated with the highest product issues.

Plasma products

Plasma products are seldom a logistical or stock control challenge, due to a long shelf life. On occasions cryoprecipitate or cryo-poor plasma may take longer to reach outlying areas.

Plans to address product unavailability

Filtered red blood cells

The traditional approach to the production of filtered RBCs entailed predicting demand based on the previous year's use. A fairly conservative view was taken, primarily due to the associated high cost of filters and the risk of losses due to expiry should the filtered RBC units not be required.

A more pragmatic approach was subsequently adopted by the blood service, which entailed predicting demand on a real-time basis through close collaboration between the specialised processing and inventory departments. The rate of API was used as an indicator of the success of this model.

To improve filtered RBC production, in recent years a whole-of-business approach has been adopted instead. This considers a myriad variables to be used in predictive analytics, including data sets on collections and usage trends over time, environmental risks, donor deferrals, viral markers and population growth. This information not only helps with predicting demand a year in advance, but also allows for redistribution of products from one blood bank to another based on prediction of need on a short-term basis.

> With the predictive models now in place for a few years, the blood services are satisfied with their ability to correctly predict demand for the coming year.

Apheresis platelets

Whereas the availability of apheresis platelets has not been a concern for the WCBS over the years, it remains an ongoing challenge for the SANBS, and this is even more apparent in the year under review. To address this, a number of interventions have been made.

A task team was established to focus on the technical aspects of production, such as the improvement of the apheresis split rate and the review of plasma vs platelet additive solution. Filtered pooled platelets have been introduced as an additional alternate product, although this is yet to be rolled out nationally. From a change management perspective, the blood services are continually encouraging a switch in clinical practice to greater use of pooled platelets. However, for this to gain sufficient traction, the blood services will have to provide assurances about how infection risk will be mitigated, especially in the oncology and transplant practice environments.

All products

Predictive analytics are used to help ensure security of supply, in the same way as they are used to predict the availability of RBC. With the predictive models now in place for a few years, the blood services are satisfied with their ability to correctly predict demand for the coming year. What now seems to be a challenge is how to grow the pool of donors to meet the demand so ably predicted.

All these measures notwithstanding, a fundamental commitment by clinicians to use the right product for the right indication will be a critical success factor.

Indications for blood product use can be found in the *Clinical Guidelines for the Use of Blood and Blood Products in South Africa*[6].

5 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. TRAEs may be described in three entities/groups:

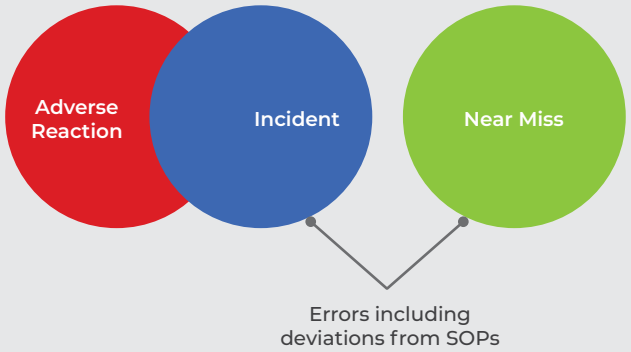
a) An **adverse reaction** is an undesirable response or effect in a patient, temporally associated with the administration of blood or blood component. It may, but need not, be the result of an incident.

b) 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 (SOPs) or hospital policies, leading to an incorrect blood component transfusion (IBCT). An incident may or may not lead to an adverse reaction.

c) 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.

These definitions and the diagram below, provided by the International Society of Blood Transfusion (ISBT) Working Party on Haemovigilance[4], show the relationship between the various entities, which may overlap or occur in isolation.

Adverse Event: Inter-Relationship Between Entities



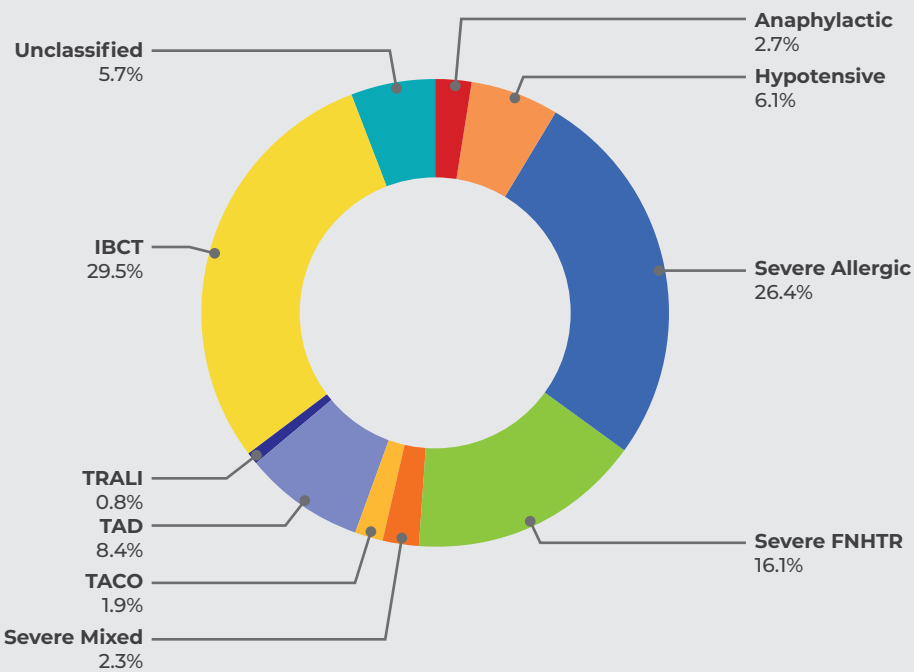
An **acute transfusion reaction** is defined as a reaction that occurs at any time during or up to 24 hours following transfusion of blood or components. The most frequent signs are fever, chills, pruritus or urticaria, which typically resolve promptly without specific treatment or complications.

In 2023 a total of 1 005 adverse reactions (graded as mild, moderate and severe) were reported to the blood bank staff in hospitals throughout the country. This translates to a transfusion reaction rate of 95.9 per 100 000 transfusions. In keeping with international practice, such as described in the UK's *Annual SHOT (Serious Hazards of Transfusion) Report*[1], the South African Independent Haemovigilance Committee (IHC) only reports on serious adverse events of transfusion of which there were 261 during this 12-month period. They make up 25.9% of total adverse events associated with transfusion of recipients.

In 2023, a total of 1 047 757 blood products were transfused and 261 serious adverse events (SAEs) reported which translates to a 2023 SAE rate of 24.8/100 000 transfusions. This is higher than the rate of 15.2/100 000 in 2022, which is to be expected due to the new inclusion of severe febrile non-haemolytic transfusion reactions (FNHTRs) in the IHC Severe Reaction Report and the improved tracking and tracing of IBCTs.

1 047 757
blood products transfused in 2023
+
261
serious adverse events (SAEs) reported
=
SAE rate of
24.8/ 100 000
transfusions

Serious Adverse Events Reported in 2023 (*n*=261)



FNHTR, febrile non-haemolytic transfusion reaction; IBCT, incorrect blood component transfusion; TACO, transfusion-associated cardiac overload; TAD, transfusion-associated dyspnoea; TRALI, transfusion-related acute lung injury; severe mixed, severe mixed allergic/FNHTR

Adverse Reactions in Patients

Febrile, allergic, mixed allergic/febrile non-haemolytic transfusion reactions, anaphylactic & hypotensive reactions (*n*=140)

> Febrile, allergic, mixed allergic/FNHTR, hypotensive and anaphylactic reactions are unpredictable and mostly unpreventable. This highlights the importance of transfusing blood and blood products only when truly required.

Febrile, allergic, mixed allergic/FNHTR, hypotensive and anaphylactic reactions are unpredictable and mostly unpreventable. This highlights the importance of transfusing blood and blood products only when truly required.

As we align with international reporting practice, we no longer report the mild or moderate FNHTRs, mild mixed allergic/FNHTR and mild allergic reactions in the *South African Haemovigilance Report*. These are, however, reported via the blood bank staff to the Haemovigilance Officers.

Severe febrile non-haemolytic transfusion reactions (*n*=42)

An FNHTR occurs during a transfusion or within four hours following transfusion, and without evidence of haemolysis or bacterial contamination. It may be accompanied by headache and nausea. The criteria for an FNHTR to be classified as severe are fever ≥39 °C AND a change of ≥2 °C from pre-transfusion value. The increase in temperature may or may not be associated with chills/rigors.

2023 is the first time severe FNHTRs have been reported in the *South African Haemovigilance Report*.

Severe and moderate allergic reactions (*n*=69)

An allergic reaction is the result of an interaction between an allergen and 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.

A mild allergic reaction occurs during transfusion or within four hours. It may present only with muco-cutaneous signs and symptoms: morbilliform rash with pruritus, urticaria (hives), localised angioedema, oedema of lips, tongue and uvula, periorbital pruritus, erythema and oedema, conjunctival oedema.

In this form the reaction usually presents no immediate risk to the life of the patient and responds quickly to symptomatic treatment like antihistamine or steroid medications. This type of allergic reaction is called ‘minor or mild allergic reaction’ in many hemovigilance systems and is not reported. All other allergic cases, whether moderate or severe, are reported by the IHC.

Severe allergic reactions with risk to life occur within 24 hours of transfusion and can involve respiratory and/or cardiovascular systems. The respiratory signs and symptoms may be laryngeal (tightness in the throat, dysphagia, dysphonia, hoarseness, stridor) or pulmonary (dyspnoea, cough, wheezing/bronchospasm, hypoxemia). Such a reaction usually occurs during or very shortly after transfusion.

Severe mixed allergic/febrile reaction (*n*=6) by definition[1] has features of both allergic and FNHTR, at least one of which is in the severe category.

Anaphylactic reaction (*n*=7) usually presents 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.

Hypotensive reaction (*n*=16) manifests 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). It may be accompanied by facial flushing and gastrointestinal symptoms.

Febrile, Allergic, Mixed, Anaphylactic & Hypotensive Reactions 2021–2023

Category of Reaction	No. of Reactions Reported in 2021 (% of SAE)	No. of Reactions Reported in 2022 (% of SAE)	No. of Reactions Reported in 2023 (% of SAE)
Severe FNHTRs	Not reported to IHC	Not reported to IHC	42 (16.1%)
Moderate & severe allergic reactions	32 (7.4%)	76 (37.1%)	69 (26.4%)
Moderate & severe mixed allergic/ febrile reactions	Not reported	Included in 'severe allergic'	6 (2.3%)
Anaphylactic reactions	40 (9.3%)	8 (3.9%)	7 (2.7%)
Hypotensive reactions	33 (7.6%)	15 (7.3%)	16 (6.1%)

The noticeable change in numbers and percentages in the table above reflects the stepwise alignment with international reporting categories and applying definitions more firmly.

The majority of the allergic-type reactions (i.e. excluding severe FNHTR) listed above were due to red cell transfusions, with only 10 (10.2%) due to platelet transfusions and 18 (18.3%) due to fresh frozen plasma (FFP) transfusions. Severe FNHTR were due to red cell transfusion, with the exception of one FFP and one platelet transfusion.

The use of a revised Adverse Event Report form in the Western Cape has resulted in an improvement in the collection of clinical data, in the administering of medication given when managing the adverse event and in the patient outcome.

Pulmonary adverse reactions (*n*=29)

Transfusion-Associated Circulatory Overload (*n*=5)

Transfusion-associated circulatory overload (TACO) is defined by 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:

a) Acute or worsening respiratory compromise
b) Evidence of acute or worsening pulmonary oedema
c) Evidence for cardiovascular changes not explained by the patient's underlying medical condition
d) Evidence of fluid overload
e) Supportive result of relevant biomarkers

Transfusion-Related Acute Lung Injury (*n*=2)

Transfusion-related acute lung Injury (TRALI) is defined as 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:

a) Acute onset
b) Hypoxaemia
c) Bilateral infiltrates on chest X-ray
d) No evidence of circulatory overload
e) 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.

Transfusion-Associated Dyspnoea (*n*=22)

TAD is defined as respiratory distress within 24 hours of transfusion that does not meet the criteria of TRALI, TACO or severe allergic reaction that is not explained by the patient's underlying condition. Respiratory distress is the most prominent feature.

Pulmonary complications form a significant proportion (12.1%) 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 TACO cases, with the result that most end up in the broader category of TAD.

There were two cases of TRALI for the 12 months under review. Both patients were 60+ years, diagnosed with cancer and received red cell concentrate (RCC) transfusions. Unfortunately one patient demised. There were five cases of TACO, all of which involved RCC transfusions. The youngest patient was 51 years and the eldest 81 years. Four out of the five patients had significantly impaired renal function and only one patient had a history of acute blood loss. Unexpectedly 60% were male.

The *2022 SHOT Report*[1] noted a trend for TACO to occur more in the elderly with comorbidities, in females and in non-bleeding patients. Apart from gender, our 2023 TACO data was similar.

Pulmonary Adverse Reactions 2021–2023

Category	No. of Cases 2021 (% of total)	No. of Cases 2022 (% of total)	No. of Cases 2023 (% of total)
TRALI	1 (0.1%)	0	2 (0.8%)
TACO	4 (0.3%)	4 (2%)	5 (1.9%)
TAD	84 (8.5%)	26 (12.6%)	22 (8.4%)

The difference in number of TAD cases in 2022 vs 2021 may be ascribed to applying the definition of TAD more strictly (especially excluding cases with symptoms suggestive of an allergic response) and improved clinical data on the revised Adverse Event Report form.

Unclassified adverse events (*n*=15)

An **unclassified adverse event** is defined as the occurrence of an adverse reaction temporally related to transfusion, which cannot be classified according to an already defined ATE, with no risk factor other than transfusion and no other explaining cause. This number has remained relatively stable over the past two years: 13 in 2022 and 15 in 2023.

Delayed haemolytic adverse events (*n*=0)

A **delayed haemolytic transfusion reaction (DHTR)** manifests 24 to 48 hours after transfusion, with features similar to acute haemolytic transfusion reaction (AHTR), although usually less severe. DHTR may present as inadequate rise in haemoglobin (Hb) or an unexplained fall in Hb after transfusion.

There were no DHTRs reported in 2023. These reactions are not common, but more likely to occur in chronically transfused patients. The insidious nature of the anaemia and jaundice may present a diagnostic challenge unless linked to the transfusion. The low reporting rate may be due to patients missing the signs and clinicians not linking symptoms to the transfusion during post-transfusion follow-up.

Incorrect Blood Component Transfusion (*n*=77 units)

IBCT is defined as 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.

It 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.

There were 55 patients transfused with 77 incorrect RCC units, accounting for 29.5% of all SAEs reported to the IHC in 2023. Three patients did not require a blood transfusion at all, but fortunately two received ABO-compatible RCC and the other had a moderate reaction.

> “There were 55 patients transfused with 77 incorrect units, and three patients did not require a transfusion at all ...”

Acute haemolytic transfusion reactions

An **acute haemolytic transfusion reaction (AHTR)** occurs when there is rapid destruction of RBCs 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 is confirmed by a fall in haemoglobin, a rise in lactate dehydrogenase, a positive direct antiglobulin test (DAT) and incompatible crossmatch.

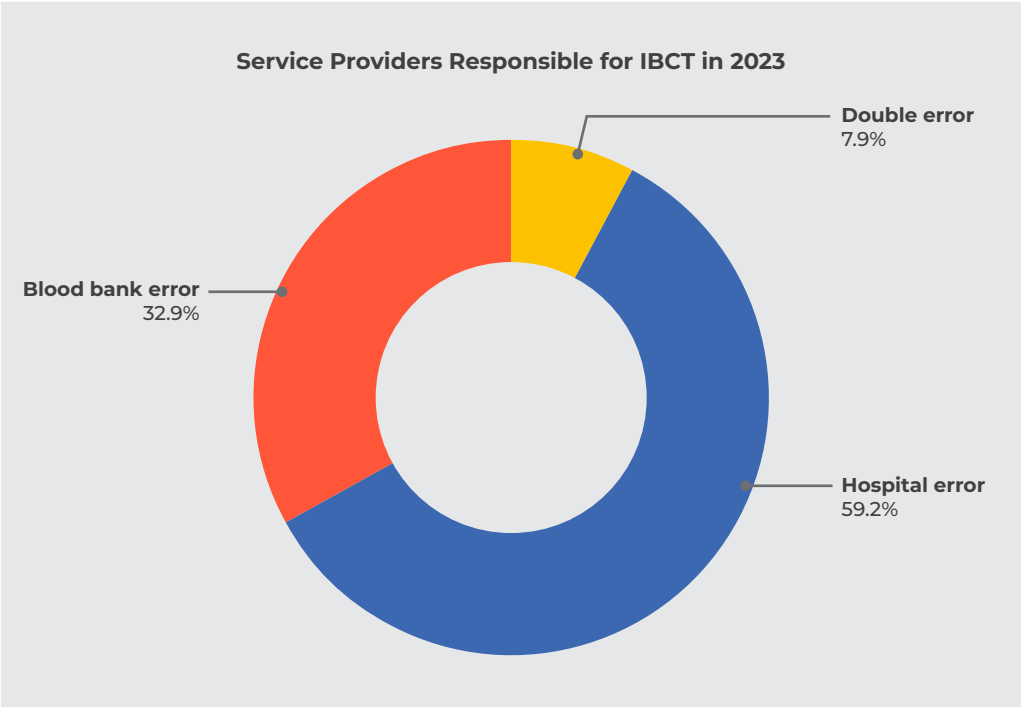
In four of the six IBCT cases where evidence of haemolysis was noted, two or more incompatible units had been transfused per patient.

To ensure the safety of blood transfusion recipients, staff are trained and certified on SOPs, which are designed to provide stepwise instructions and checks and balances to ensure safety. Failure to follow the SOP is more likely to result in an error which may be life threatening. In 2023 59.1% of IBCTs were the result of a single error by hospital staff and 32.9% of IBCT were due to a single error by blood bank staff. Double errors occurred in the remaining 8% (i.e. error by blood bank *and* hospital staff or error by hospital both when collecting crossmatched blood from hospital fridges *and* when administering the transfusion).

> In 2023 59.1% of IBCTs were the result of a single error by hospital staff and 32.9% of IBCT were due to a single error by blood bank staff. Double errors occurred in the remaining 8%.

Hospital errors are largely due to poor patient identification (or lack of patient identification) resulting in "wrong blood in the tube" (WBIT) when taking the crossmatch sample, or due to administering the blood to the incorrect patient or due to failing to verify the patient details when collecting the blood.

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.



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

a) ABO-compatible transfusion
b) ABO-incompatible transfusion
c) Rh-incompatible transfusion
d) Serologically incompatible transfusion

ABO-compatible IBCT (*n*=22 RCC units)

Understandably, none of the patients who received ABO-compatible RBCs had a life threatening reaction, but it needs to be noted that two patients had unpredictable allergic reactions and two did not require blood products at all.

Error Type	Type of Error
Hospital error	WBIT (2); Administering blood (10)
Blood bank error	Crossmatch sample mix-up due to transcription error (6)
Double error	Incorrect name on sample + Blood Request form correct (2); Wrong unit collected from ward fridge and administered (2)

ABO-Incompatible IBCT (*n*=43 RCC units)

ABO-incompatible transfusions can result in the most severe reactions and be life threatening. The reaction may vary in severity depending on the volume of RCC transfused, the blood group mismatch, the immune reaction of the patient and the time taken to detect.

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/or symptoms or signs of AHTR.

Of the 43 incompatible RCC units, 27% had no reaction, 17.2% had a mild reaction, 51.7% had a severe reaction and 3.4% of outcomes were unknown.

Hospital error	WBIT (14); Administering blood (10)
Blood bank error	Crossmatch sample mix-up due to transcription error (9); Crossmatch error (7)
Double error	Blood bank transcription error + hospital administering incorrect unit (2); Blood bank issuing error + hospital administration (1)

ABO-incompatible blood groups which resulted in severe reactions (*n*=17)

> 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.

Rh-Incompatible IBCT (*n*=8 RCC units)

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 = 5 units; Gynaecology = 1 unit; Surgery = 1 unit, Casualty = 1 unit).

Hospital error	Known group O-negative, given emergency group O-positive (1); One unit group O-negative transfused then, out of necessity, two O-positive transfused resulting in haemolysis (2); Four patients with unknown blood group, each received one unit of group O-positive blood, taken from the hospital emergency fridge (4)
Blood bank error	Three units of group O-positive RCC issued to a group B-negative, with two units recalled when error was detected (1)

To improve the outcome of patients who receive Rh-incompatible blood, hospital staff should use the Rh kit provided in the emergency fridge. If a woman of childbearing age is identified as being Rh-negative, to prevent complications in any future pregnancy Rh-negative blood must only be transfused in dire emergency as a life-saving measure and anti-D immunoglobulin should be administered intramuscularly at the same time.

Only one of the cases shown above had a note indicating that the Rh kit had been used after the first group O-positive unit had been transfused and that group O-negative units were subsequently transfused. As expected, there was no immediate reaction, but it is of concern that the only patient who received advice or anti-D immunoglobulin was in the case that occurred due to blood bank error. There was no note in any of the other cases about anti-D immunoglobulin management or advice to the patient on the need for follow-up of future pregnancies.

Serologically Incompatible IBCT (*n*=4 RCC units)

There were four cases:

Case 1: A patient had JKa antibodies, which was recorded in the patient's records on the blood bank information technology system but missed

Case 2: One staff member identified the antibody but another staff member issued two units of FYa + RCC. The patient received about 100 ml before the blood bank notified the ward of the error. The other unit was returned to the blood bank unused

Case 3: One patient was DAT-positive, which was undetected

Case 4: One donor was DAT-positive, but this was not detected and the unit not removed during processing

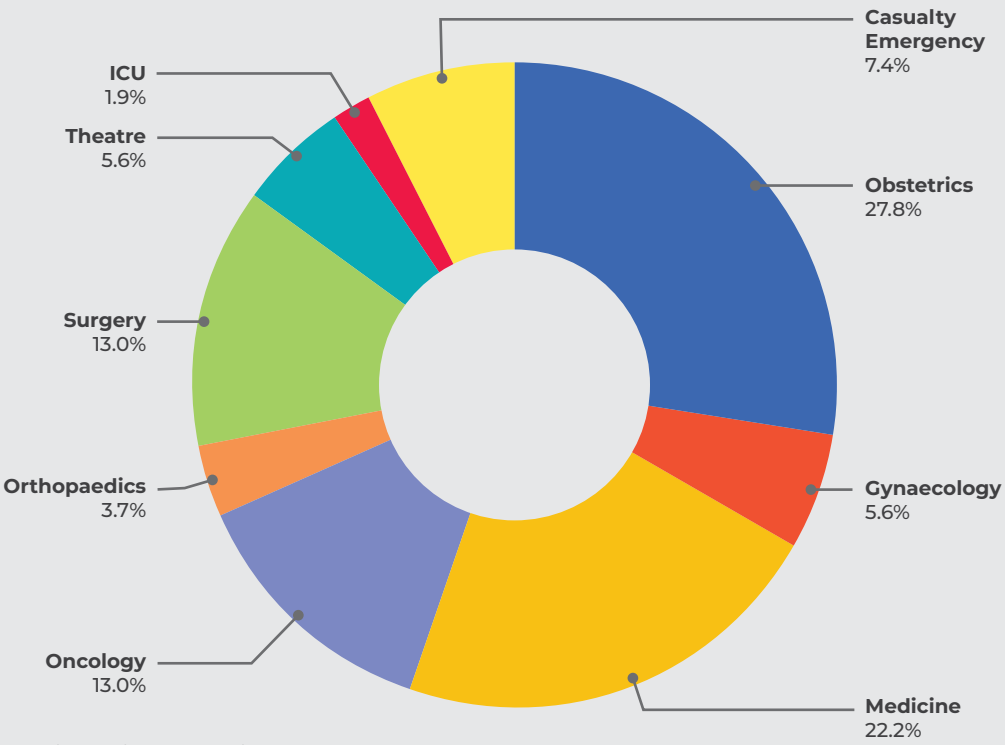
Of the four serologically incompatible transfusions, three had no reaction and one had a moderate reaction.

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.

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, e.g. Obstetrics and medical departments. Similarly, the low error rates reported for Intensive Care Units (ICUs) may be a reflection of the experience and seniority of staff requesting and administering blood, as well as the relatively more controlled clinical activity there.

Clinical Areas in which IBCTs were Reported



ICU, intensive care unit

Comparison of origin of error 2021–2023

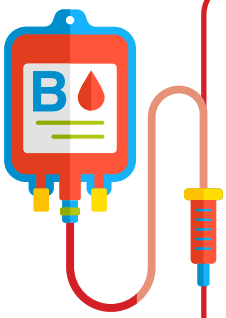
Due to the change in reporting method over the past three years to align more with international practice, it is difficult to make a meaningful comparison of error origin between 2021 and 2023.

In 2021 IBCTs 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%). Between 2021 and 2022 the actual case numbers have more than doubled, emphasising the need to document these errors.

In 2023 the IHC has gone a step further and documented the number of individual units incorrectly transfused, as several patients receive more than one IBCT. The increase in numbers is therefore due to improved staff awareness of the need to track and trace every incorrect unit associated with each IBCT event instead of only investigating events where the patient was negatively affected.

Origin of Errors 2021–2023

Year	Total No. Error Events	Hospital Origin	Blood Bank or Laboratory Origin
2021	27	22 cases	5 cases
2022	63	41 cases	22 cases
2023	55	33 cases (46 units)	22 cases (32 units)



Example of a double error by hospital & blood bank staff

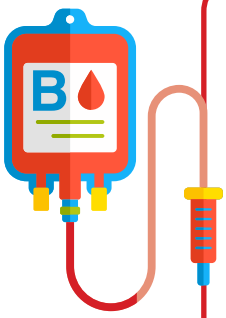
A 31-year-old male in the surgical ward, admitted for repair of a gunshot wound, experienced an adverse event within one to two hours of starting the transfusion. After <100 ml RCC the patient became restless, dyspnoeic, dropped SATS, developed a tachycardia, rigors and sweating. The blood bank staff checked the pre and post sample, which were both group O.

The unit transfused was labelled group O but on testing was found to be group B. The blood bank technician had trusted the unit label and not read the instrument blood group result.

On further investigation of the mislabelled unit, it was found that the donor collection staff had swapped and mislabelled two donor specimens: one donor was a short bleed so the insufficient unit was discarded and only a sample was registered. This group O sample was then unfortunately linked to the group B unit.

This is an example of a donor collection staff error and a blood bank crossmatch error because the SOP was not strictly adhered to.

Note: SOP must be followed at all times to avoid errors.



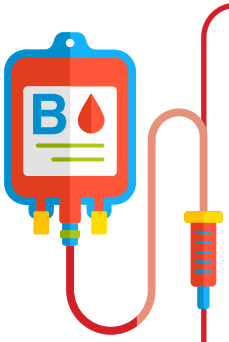
Example of a hospital sample error (WBIT)

A 36-year-old female was treated in the Casualty department of a regional hospital for retained products of conception. She became critical and was transferred to a tertiary hospital for further management of the bleeding. Due to mis-identification of the patient, the first crossmatch sample (taken in Casualty at the regional hospital) was found to be group AB-positive but the patient was actually group O-positive, i.e. WBIT.

Five AB-positive units of RCC were issued and transfused on the crossmatch result of the first specimen, resulting in AHTR. The patient was transferred to ICU, where the diagnosis changed from acute blood loss to renal disease. Regrettably, the transfer from the regional hospital to the tertiary hospital delayed receipt of the confirmatory Group O blood specimen.

Misidentification of the patient resulted in WBIT and multiple ABO-incompatible units transfused, causing haemolysis and acute renal impairment.

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



Example of incorrect blood product transfusion "out of necessity" but the long-term outcome should have been considered

A 31-year-old female was treated at a tertiary hospital for a postpartum haemorrhage, suffering acute blood loss which resulted in an Hb drop to 5.6 g/dL. An Rh-positive ward stock unit was transfused to the patient, who is a known Rh-negative female patient on the blood transfusion services' (BTS) IT system. There was no communication with the blood bank.

The blood bank supervisor picked up this error when capturing the ward stock transfusions. The supervisor indicated that the ward had an Rh kit but no Rh rapid test was done prior to the transfusion, and that there were O-negative units available in the ward stock fridge at the time of this incident.

When the error was detected, blood bank staff inquired as to the condition of the patient who had already been discharged, with no anti-D given and without any counselling regarding the long-term impact of an Rh-incompatible blood transfusion in women of childbearing age. The ward staff confirmed that no reaction occurred and the patient was well post transfusion, so no Adverse Event Report form was completed.

Note: Communication between blood bank and clinicians is key. There may be instances where providing Rh-incompatible RCC is life saving and should not be withheld, but this must be done only after careful consideration of the long-term impact on women of childbearing age.

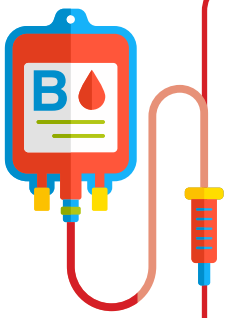
Near Misses

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.

There were 13 near misses, involving 18 units, reported in 2023. In the *2022 Haemovigilance Report* there were no near misses reported and the IHC made a recommendation that this was an area that requires increased awareness, clarification of definitions for data collection and training for the BTS staff. It is encouraging to see the beginnings of near-miss reporting.

Near Misses Reported in 2023 (*n*=18)

Type of near miss	Details
WBIT	Picked up by blood bank staff as a blood group discrepancy (6)
Errors in crossmatching	Picked up by the blood bank supervisor when checking, who communicated with ward staff and recalled the units that had not yet been transfused (2)
Mislabelling of dispatching bags	Two patients were each issued with three units of correct blood but they were placed in incorrectly labelled dispatch bags. Ward staff noted three IBCTs in the first patient and phoned the blood bank, who then phoned Casualty where the other patient was already being transfused. Five IBCTs were averted through rapid communication
Blood bank crossmatch error	The first two incompatible units were transfused, but when the third and fourth units were issued the doctor notified the blood bank that there was a blood-group discrepancy



Example of a near miss where rapid communication prevented five IBCTs

At a busy blood bank two orders for RCC on emergency were received and they were issued four minutes apart. Patient SM, in Ward 2, was issued with three RCC units correctly crossmatched as group A. Patient TM, in Casualty, was issued with three units of RCC correctly crossmatched as group B. The blood bank technician labelled all units correctly, but placed the two orders into incorrectly labelled dispatch paper bags.

Within an hour of issuing the blood, the nurse from Ward 2 called to inform the blood bank that while doing the patient identification, she had discovered the patient details were that of a patient in Casualty. The blood bank staff quickly phoned Casualty, however the transfusion of one group A unit was already nearing completion into the group B patient. Luckily, the other two units in Casualty were returned, as were the three units from Ward 2.

The nurse carrying out the correct patient identification SOP averted five IBCTs as a result of her immediate action. Fortunately, the one unit that was transfused did not cause a reaction.

This is an example of a double error (blood bank staff and Casualty staff), involving six units: crossmatched and labelled correctly but dispatched in incorrectly labelled delivery bags. The outcome was the transfusion of one ABO incompatible unit and five near misses. The nurse's quick thinking and timeous communication prevented the patient in Casualty receiving all three units.

Note: Patient identification and patient detail verification are vital at each step in the transfusion process

Transfusion-Associated Mortalities

There were 26 transfusion-associated patient mortalities reported to the South African Haemovigilance Programme in 2023. 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.

> "Imputability assigns the likelihood that an adverse reaction in a recipient can be attributed to the blood or blood component transfused."

The process of assessing imputablity

Imputability assigns the likelihood that an adverse reaction in a recipient can be attributed to the blood or blood component transfused.

The lack of clinical detail and lack of resources to carry out post-mortems (PMs), only two were documented, makes assigning imputability a challenge. 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[4], the Adverse Event Report form, the report from the treating clinician, the PM report (if available) and any significant laboratory reports (if available).

In 2023, the IHC assigned imputability to the 26 reported cases of transfusion-associated mortality as follows: Definite (certain) = 0; Probable (likely) = 7; Possible = 7; Unlikely (doubtful) = 9; Not assessable = 3.

Recommendations

- Continue to introduce the revised Adverse Event Report form across the country as quickly as possible, to improve the data collected on adverse events.
- Promote the reporting of near miss events to identify and control risks before actual harm occurs, providing opportunities to improve transfusion safety and focus more on the system than on the human error.
- Continue training of both hospital staff and blood transfusion staff on the importance of processes and procedures, e.g. patient identification, and on the importance of following them to avert errors which have serious implications.
- Create a culture of caring for patient safety by readily sharing reports and data.

6 Transfusion-Transmitted Infections & the Lookback Programme

Transfusion-transmitted infection (TTI) is defined as when 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. In this chapter the spectrum of TTIs will be covered, namely bacterial, viral or parasitic transmissions.

To mitigate the risk of TTIs, 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 blood into the pouch. The latter significantly decreases contamination with skin flora. It is from this diverted blood that samples are drawn for screening for human immunodeficiency virus (HIV), hepatitis B virus (HBV) and hepatitis C virus (HCV).

Transfusion-Transmitted Bacterial Infection

Transfusion-transmitted bacterial infection is the 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.

There have been no reported cases of transfusion-related bacterial infections or confirmed related fatalities in the last five years in South Africa. This is achieved by donor screening and testing and bacterial surveillance screening of at least 1% of platelet products.

> "Typical of a low-income country, South Africa has minimal screening and a passive haemovigilance reporting system, which leads to under-reporting ..."

Product screening to detect bacterial contamination

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 underreporting of transfusion-related bacterial infection 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 this rate is significantly more than the quality-standard requirement of 1% of platelet products. The BTS obtain 4 ml–10 ml from samples of only 10%–20% of

platelets collected countrywide, and incubate these for 24 hours post collection. If a positive culture occurs within seven days of collection there is a notification process to alert the doctor who prescribed the unit in question. No pathogen reduction technology is currently used in South Africa.

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].

A compliance score of 98%–99% has been maintained year on year for the past five years, but this has been exceeded in 2023–2024 with a compliance score of 99.67% for apheresis platelets and 99.7% for pooled platelets. For the period under review, only 22 platelet products had positive cultures:

- 14 (64%) Gram-positive bacteria – mostly skin flora
- 1 (4%) Gram-negative bacteria – *Sphingomonas paucimobilis*
- 7 (32%) No growth

Environmental screening

The South African National Blood Service (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 practises environmental screening across the value chain, which involves taking environmental samples from apheresis donor clinics, processing labs and blood banks. According to strict standard practice, environmental samples are only required in production (GMP) related areas, but this screening of additional areas does provide assurance of cleanliness.

The Western Cape Blood Service (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.

Transfusion-Transmitted Viral Infection

The definition of a **transfusion-transmitted viral infection** is as per the definition for a TTI, but specifically related to a virus. The most common viruses associated with transfusion-transmitted viral infections are HIV, HBV and HCV.

The risk of viral infection transmission depends on certain factors, such as the burden of disease in the country which impacts/reflects in the viral prevalence in the donor population, the level of donor screening and the technology used to detect the specific viruses.

Viral prevalence in the donor population

In South Africa, all blood donations are screened through a combination of serological and molecular tests for HIV, HBV, HCV 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, 3 418 of the 1 146 063 donations collected tested positive for HIV, HBV and/or HCV. During this 12-month period, there was an increase in the prevalence of HIV, HBV and HCV in the South African donor population and some donors tested positive for more than one viral marker.

Viral-Positive Blood Donors in 2023

Virus	No. Positive Donors	Prevalence
HIV	2 406	0.21
HBV	783	0.07
HCV	229	0.02
Total donations	1 146 063	

The increase in viral markers in the donor population is most probably related to concerted efforts by SANBS and WCBS to recruit new blood donors. The percentage of donors who test positive for one of the viral markers is higher in first-time donors than in repeat donors.

In the table below, the overall trend reflects a "return to business as usual" in recruiting new donors post COVID. New donors must continually be recruited to maintain a voluntary non-remunerated blood donor base which can provide sufficient blood for patients in South Africa.

National Viral Prevalence in Blood Donors 2019–2023

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

> "There have been no confirmed cases of viral TTIs in South Africa, in the last eight years."

There is a trend of decreasing HBV due to the post-1994 HBV vaccination programme which is showing benefits in the general population.

The HIV prevalence increase in the donor population from 2022 to 2023 is to be noted. Now at the same level as in 2019, it reflects the return to "business as usual" for the BTS post-COVID.

The HCV prevalence increase in 2023 is also to be noted with concern and may reflect the impact of increased recreational drug use in South Africa.

A noteworthy finding was that no viral TTI event was reported in South Africa in 2023, although there was one malaria TTI.

There have been no confirmed cases of viral TTIs in South Africa in the last eight years.

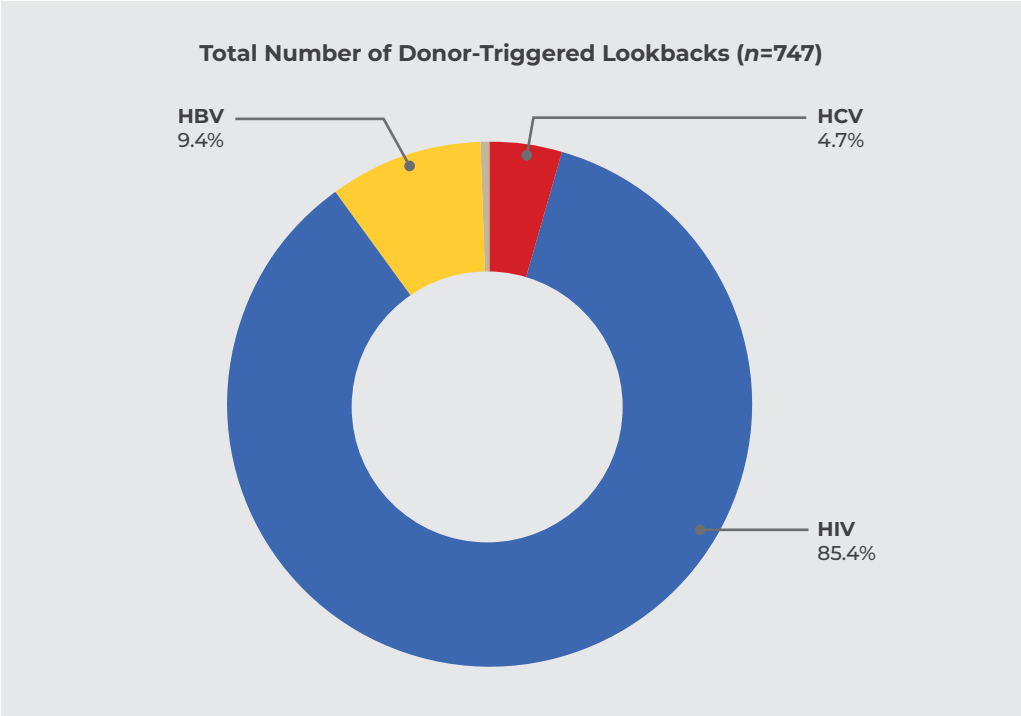
The Lookback Programme

The TTI 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 associated with donor-triggered lookbacks presents an additional challenge when phylogenic testing is requested.

Of the 747 donor-triggered cases, 84.9% were for HIV, 9.4% for HBV and 4.6% for HCV. There were three HIV/HCV co-infection cases and one HIV/HBV co-infection case.

The table overleaf highlights the challenge of tracing patients to provide a confident final outcome: in 75.2% of investigations, either the BTS were still awaiting feedback from the patients' clinician or the patient was untraceable, declined testing or had died. 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.

The prolonged time period frequently associated with donor-triggered lookbacks presents an additional challenge when phylogenic testing is requested. This is because 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.

Donor-Triggered Investigation Outcomes 2023

Outcome	No. of Patients
Recipient retested negative	108
Recipient positive before transfusion	76
Phylogenetic analysis for potential HIV TTI	0
Recipient died between transfusion & initiation of look back	141
Unresolved (awaiting feedback from clinician)	179
Untraceable patient	152
Other*	87
Recipient declined testing	3
HBV immune**	1
Total	**747**

*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

**An HBV lookback where the recipient was found to be HBV immune

Recipient-Triggered Lookback Investigations

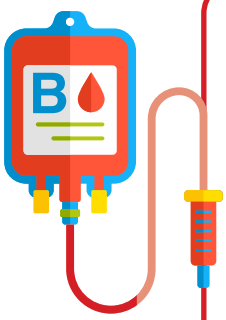
A recipient-triggered lookback investigation is initiated when the BTS are informed that a blood recipient has tested positive for a TTI and that the infection may have been transfusion-transmitted. The implicated donors are identified and their donation history reviewed. Where the timeframe of subsequent donations does not prove that the donor was not in a window period for the infection, the implicated donors are recalled for further testing.

The blood service is satisfied there is no TTI when an investigation concludes that 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.

Outcome of Recipient-Triggered Lookbacks 2023

Infection	Resolved	Unresolved
HIV	2	0
HBV	0	0
HCV	0	0
Malaria	2	0
Total	**4**	**0**

As indicated in this table, there are far fewer recipient-triggered lookbacks compared with donor-triggered lookbacks. All four cases were resolved, with the outcome of one case documented as a malaria transfusion transmission.



Example of a malaria TTI case

In South Africa, blood donors are required to answer malaria-related questions but blood donations are not routinely screened for malaria. There were two cases in the reporting year where transfusion-transmitted malaria was queried by the treating physicians. The patient in Case 1 received blood products from three donors and all three donors were recalled, tested for malaria and found to be negative, thus proving the infection not to be transfusion related. In Case 2, a patient in Intensive Care received six blood products: four prior to testing positive for malaria and two after the malaria test. Out of the four donors recalled, three tested negative but one tested positive for malaria. In this malaria TTI case, the patient was successfully treated for malaria but demised from his medical condition, while the donor was deferred from donating blood in the future.

A lookback requires considerable logistics and resources to track and trace the donor, counsel on the need for additional testing, take and test the blood sample and communicate the outcome to both the donor and the patient's doctor.

“A lookback requires considerable logistics and resources to track and trace the donor, counsel on the need for additional testing, take and test the blood sample and communicate the outcome to both the donor and the patient's doctor.”

Recommendations

- 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.

7 Donor Haemovigilance

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.

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 monitoring and managing 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 Adverse Events

A **DAE** is an unintended or unfavourable outcome during the process of blood donation.

Donor Adverse Events 2023

Event Type		Total	% of Total DAEs	DAE Rate per 100 000 Donations
Local Reactions	Haematoma	704	14.7	61.4
	Arterial puncture	8	0.2	0.7
	Delayed bleeding	49	1.0	4.3
	Nerve irritation	4	0.1	0.3
	Tendon injury	0	0.0	0.0
	Nerve injury	1	0.0	0.1
	Painful arm	187	3.9	16.3
	Total no. local reactions	**953**	**19.9**	**83**
Vasovagal Reactions	Faint immediate type	2 122	44.6	185.2
	Faint immediate, accident	133	2.9	11.6
	Faint delayed type	1 376	28.7	116.6
	Faint delayed, accident	80	2.1	7.0
	Total no. vasovagal reactions	**3 671**	**76.7**	**320**
Other Reactions	Citrate reaction	143	3	12.5
	Haemolysis	3	0.1	0.3
	Generalised allergic reaction	17	0.4	1.5
	Acute cardiac symptoms	1	0.0	0.1
	Total no. other reactions	**164**	**3.4**	**14**
Total		**4 788**	**100**	**41.7**

A total of **1 146 063** blood donations were made by voluntary non-remunerated donors in South Africa during the 2023 calendar year. A total of 4 788 DAEs were reported for the year, which translates to a rate of 41.7/100 000 donations.

In line with international DAE trends and previous years, the vasovagal reactions (commonly known as faints) account for 76.4% of all DAEs in South Africa. The immediate faint occurs most frequently (44.3%), followed by delayed faints (28.7%) and both these categories may be associated with accidents.

The most common local DAE is the formation of a haematoma, either during the donation process or post donation. Haematomas account for 14.7% of all DAEs.

Donor Adverse Events per 100 000 Donations 2019–2023

Donations & Donor Adverse Events	2019	2020	2021	2022	2023
Total number of whole blood donations	913 530	837 790	881 366	1 146 063	1 146 063
DAEs per 100 000 donations	45.8	43.8	37.2	38.7	41.7

The actual number of DAEs has increased in comparison to previous years, but this must be viewed in the light of the variation in the number of donations through the years. This is why it is important to assess the rate of DAEs per 100 000 donations. This rate has increased compared to 2021 and 2022, but is not yet at the pre-COVID rate. A trend in this direction may be expected as the BTS return to "business as usual" post COVID.

Donor Adverse Events 2019–2023

Event Type		2019	2020	2021	2022	2023
Local Reactions	Haematoma	703	626	536	630	704
	Arterial puncture	2	2	3	6	8
	Delayed bleeding	28	31	34	31	49
	Nerve irritation	3	6	2	45	4
	Tendon injury	0	1	1	0	0
	Nerve injury	2	5	0	0	1
	Painful arm	158	154	157	125	187
Vasovagal Reactions	Faint immediate type	2 749	2 484	2 064	2 016	2 122
	Faint immediate, accident	126	107	124	131	133
	Faint delayed type	1 057	977	1 021	1 313	1 336
	Faint delayed, accident	104	72	75	95	80
Other Reactions	Citrate reaction	106	57	57	114	143
	Haemolysis	18	0	2	1	3
	Generalised allergic reaction	2	8	8	13	17
Total		**5 058**	**4 530**	**4 084**	**4 520**	**4 788**

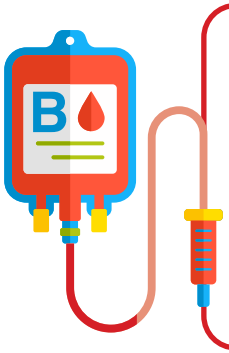
The increase in “Other Reactions”, namely citrate and generalised allergic reactions, is due to the increase of apheresis procedures to collect apheresis platelets and source plasma.

The majority of DAEs will be minor (e.g. faints and haematoma) and result in transient or temporary discomfort, but a few donors may have a serious adverse 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 or incapacitating, or which results in hospitalisation.

During 2023 the BTS made a concerted effort to collect data on SAEDs. In order to collect such data the BTS further defined SAEDs as any donor who required referral to Casualty/Emergency or additional medical oversight for further observations and/or management.



Example of an SAED Case (Delayed faint)

A 42-year-old female donated whole blood and, within 30 minutes of her leaving the donor clinic, staff were called to attend to her in the shopping mall. The donor was pale and sweating, she had low blood pressure and she had a laceration on her head. She was started on intravenous fluids and referred to Casualty, where a skull X-ray and blood tests were done. The blood tests and skull X-ray were normal but she was kept overnight for neurological observation. Within a week the donor had fully recovered.

Delayed faints most often occur outside the BTS area of control and donors are therefore far more at risk of injury. It is also more challenging to manage both the adverse event itself and the potentially negative attention of bystanders in these settings. To prevent such events, donors are advised to drink the fluids provided and wait at least 15 minutes post donation before leaving the donor clinic.

Overall, the DAE rate has improved compared to the pre-COVID rate in 2019, with a decrease in the more common DAEs (e.g. faints). However, the increase in arterial puncture events 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 donors with more education on post-donation care to prevent complications.
- The BTS to provide ongoing education to medical collection staff on localised complications and to implement measures to improve early detection and follow-up on donors suspected of a local DAE, e.g. an arterial bleed.

8 Conclusion

The *2023 South African Haemovigilance Report* presents a more granular account of the blood transfusion services than previous reports have done. This is a result of improvements in the collection of the clinical information required to assess the performance of the haemovigilance system.

Notable in this regard must be the achievement of yet another year without any report of bacterial/viral transfusion-transmitted infections (although a single case of infection with malaria was reported). Encouraging too is the initiation of near miss reporting, a necessary enhancement of the haemovigilance system. This must be supported as a focus area.

This report also exposes some areas of concern that will require focused attention in the year ahead. Strategies for improvement include:

- Concerted donor drive by the blood services to stabilise blood stocks. An increase in the transfusion rate would be a useful success indicator.
- Targeted strategy to address the poor adherence to blood transfusion protocols, with a view to driving down the rate of transfusion errors. Anecdotal evidence suggests these errors are the result of pressurised, under-resourced clinical environments, suggesting the need for a wider and more collaborative approach in addressing them.
- Intensify efforts to educate blood users about the use of blood held in emergency ward fridges especially when required for female patients of childbearing age.
- Improved reporting of incorrect blood component transfusion even when no adverse reaction is observed.

In summary, this report suggests a South African blood transfusion system that has suffered a minor setback, with a number of quality indicators going the wrong way.

10 References

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