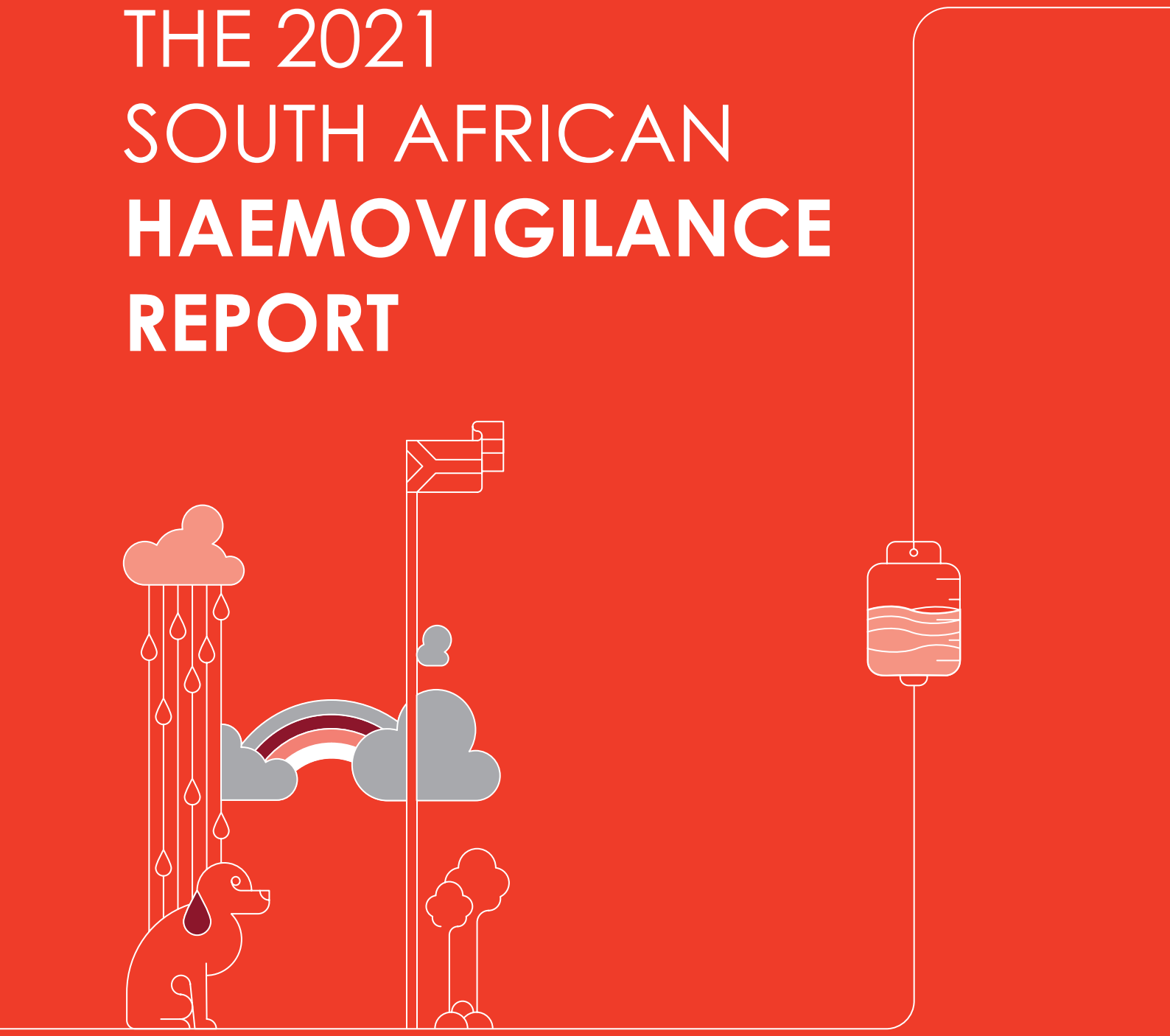
THE 2021 SOUTH AFRICAN **HAEMOVIGILANCE REPORT**



Western Cape Blood Service
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SANBS
South African National Blood Service

Haemovigilance Report 2021

The 22nd 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. Its data, analyses and conclusions are intended to provide healthcare professionals and the public with general information regarding haemovigilance surveillance in South Africa. This report is a snapshot of currently available data that has been obtained from limited sources.

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Acknowledgements

The South African National Blood Service (SANBS) and the Western Cape Blood Service (WCBS) acknowledge and are grateful for the contribution of individuals and departments to this report.
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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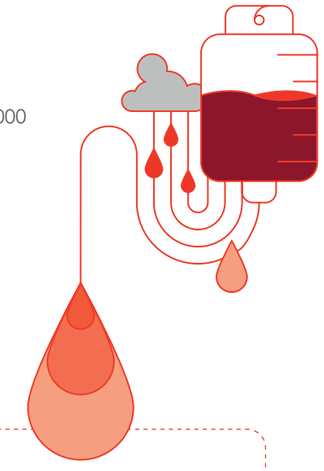


ISBN: 978-0-6397-3078-3

Title: The 2021 South African Haemovigilance Report

UK English has been used in this report.

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

Table of Contents

Abbreviations

AHTR	- Acute haemolytic transfusion reactions
BTS	- Blood transfusion services
CXR	- Chest x-ray
DAE	- Donor adverse event
DAT	- Direct antiglobulin test
DHTR	- Delayed haemolytic transfusion reactions
DSTR	- Delayed serological transfusion reactions
FFP	- Fresh frozen plasma
FiO2	- Fraction of inspired oxygen
FNHTR	- Febrile non-haemolytic transfusion reaction
IBCT	- Incorrect blood component transfusion
ID-NAT	- Individual donation nucleic acid testing
IHC	- Independent Haemovigilance Committee
IPC	– Infection Prevention Control
HBV	- Hepatitis B
HCV	- Hepatitis C
HIV	- Human immunodeficiency virus
HV	- Haemovigilance
NICD	- National Institute of Communicable Diseases
PBM	- Patient blood management
PCR	- Polymerase chain reaction
QC	- Quality control
RCC	- Red cell concentrate
RDP	- Random donor platelets
NICD	- National Institute of Communicable Diseases
SANBS	- South African National Blood Service
SDP	- Single donor platelets
SHOT	- Serious Hazards of Transfusion (UK Report)
TACO	- Transfusion-associated circulatory overload
TAD	- Transfusion-associated dyspnoea
TRALI	- Transfusion-related acute lung injury
TTI	- Transfusion-transmitted infections
WB	- Whole blood
WCBS	- Western Cape Blood Service

Transfusion Reaction Classifications & Definitions

Haemovigilance (HV) 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 to prevent their occurrence. This includes local venepuncture accidents, graft-versus-host disease and mild to severe transfusion reactions. The HV 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) (www.isbt.org).

Category	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	A reaction where there are clinical and 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 and laboratory signs of haemolysis are present. No single criterion exists to definitively diagnose this rare disorder. It is associated with fever 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 broncho-spasm causing hypoxia or angioedema causing respiratory distress.
Transfusion-associated dyspnoea	Respiratory distress within 24 hours of transfusion that does not meet the criteria of transfusion-related acute lung injury, transfusion-related circulatory overload or severe allergic reaction that is not explained by the patient's underlying condition.
Hypotensive transfusion reaction	A drop in systolic and/or diastolic pressure of >30 mmHg occurring within one hour of completing the transfusion, provided all other adverse reactions with underlying conditions that could explain hypotension have been excluded.
Transfusion-associated circulatory overload	Volume infusion that cannot be effectively processed by the recipient, either due to high rates and volumes of infusion or underlying cardiac or pulmonary pathology, and that results in any four of the following occurring within six hours of transfusion: • Acute respiratory distress • Tachycardia • Increased blood pressure • Acute or worsening pulmonary oedema • Evidence of positive fluid balance
Transfusion-related acute lung injury	Acute hypoxemia with PaO2 fraction of inspired oxygen (FiO2) 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.
Anaphylactic transfusion reaction	Hypotension, with one or more of urticaria, rash, dyspnoea, angioedema, stridor, wheezing and pruritus, within 24 hours of transfusion.
Febrile non-haemolytic transfusion reaction	Isolated fever of >39 °C or equivalent, or a change of 1–2 °C from pretransfusion value with or without minor rigors and chills, but without haemolysis or features of an allergic reaction. The patient may have one or more of myalgia, nausea, changes in blood pressure or hypoxia. The most common cause is a reaction to passively transfused cytokines or to recipient antibodies and leukocytes in the donor's blood.

Transfusion Reaction Classifications & Definitions (Continued)

Category	Definition
Delayed transfusion reaction	Transfusion-related reactions that occur after 24 hours following transfusion of blood or components.
Delayed haemolytic transfusion reaction	The recipient develops antibodies to red blood cell antigens. This usually manifests between 24 hours and 28 days after 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 of a transfusion, despite an adequate haemoglobin response to transfusion that is maintained.
Post-transfusion purpura	Thrombocytopenia arising 5–12 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.
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 same parasite in the recipient's blood and parasite or specific antibodies in the donor blood.
Incorrect blood or component transfused	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.

Foreword

This year is the first time the haemovigilance data has been reviewed and the South African Haemovigilance Report written by members of the Independent Haemovigilance Committee (IHC). This change in strategy confirms the commitment of blood transfusion services (BTS) of South Africa to improving the safety of blood transfusion for patients in South Africa.

The IHC is in its infancy, starting with two independent members who provide vast experience and knowledge in the field of anaesthetics and transfusion medicine but are not directly involved with either SANBS or WCBS. It is envisaged that the IHC will mature and, with time, will increase its resources.

Like many countries, South Africa looks to the UK SHOT Report as the gold standard and the IHC will endeavour to apply lessons learnt from the 2021 Annual SHOT Report[1], as well as those from our unique South African setting, to improve blood safety.

The South African Haemovigilance Report has been published for over two decades and during this time there has been a persistent, although variable, problem with incorrect blood component transfusion (IBCT). This challenge has refused to go away even with enormous emphasis, effort and resources being put into training of hospital and blood banking staff. For this reason, a section in the report will be dedicated to errors in the blood transfusion value chain and the efforts being made to improve on this track record.

On a positive note and looking forward, BTS in South Africa have made a concerted effort to be more outward looking and to improve the clinical interface by becoming involved in patient blood management (PBM)[2], which includes the decision to transfuse or not and the choice of appropriate product. As opposed to focussing narrowly on improving the patient's laboratory test results, the clinicians' input and focus on whether blood is necessary and on the outcome of patients post transfusion should bode well for patient safety. Haemovigilance and PBM will have a positive impact on both the safety of blood products and the process of transfusion in South Africa.

Blood safety is more than the sufficiency and quality of blood components; it includes the safety of all "vein to vein" processes. Likewise, haemovigilance needs to be seen as more than a collation of data. Rather, it is a review of quality and safety, taking lessons learnt from adverse events and errors and improving safety through education. Haemovigilance has moved from being primarily a monitoring system for transfusion-transmitted infection (TTI) to being an expansive system that offers the opportunity to measure the adverse events of new innovative technologies such as pathogen inactivation.

Executive Summary

The 22nd edition of the South African Haemovigilance Report provides an overview of blood product usage and adverse events related to transfusion and blood donation in the country during the 2021 calendar year.

Throughout 2021 the COVID pandemic continued to impact the transfusion services, leaving no departments untouched, but having the greatest impact on blood collection and blood usage as well as staff wellbeing in general. The strong foundation of Infection Prevention & Control, which had been a quality requirement for the BTS, ensured that COVID regulations were successfully implemented for staff, donors and patients.

Red cell usage and plasma product usage remained lower than in the pre-pandemic year of 2019. This was most notably seen in red cell concentrate (RCC) usage that dropped by 13.5% compared to a plasma product usage decrease of 1.5%. The use of platelet products increased by 6.4% in 2021 compared to 2019, and this was due to the concerted effort to overcome a chronic shortage of pooled and single donor platelets.

The total number of transfusions in the year under review was 1265722. Of these, 989 adverse events were reported, translating into an incidence rate of 78.1/100 000 units transfused. This is lower than the 86.16/100 000 reported in the previous year.

Continuing the trend from the previous two reporting periods, febrile non-haemolytic transfusion reactions and allergic reactions comprised the bulk of the adverse reactions reported, at 35.8% and 20.7% respectively.

Misdirected transfusions accounted for 2.1% of all reported adverse events (2.7/100 000 transfusions) which is an increase from the previous year's 2.48/100 000 transfusions. This is a worrying observation, given that the rate for 2019 was a much lower 1.4/100 000 transfusions. There is thus a clear need to intensify efforts to address system failures in issuing, handling and administration of blood products, and a collaborative approach will be required.

Significantly, no TTIs were confirmed. This probably reflects the effectiveness of the infection prevention control (IPC) policies and

state-of-the-art testing technology in place across the South African blood service platform, in conjunction with an effective donor-recruitment and donor-screening process.

Notably though, one-fifth (21.1%) of the events were unclassifiable due to incomplete or insufficient information. The reasons for this 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, or incomplete laboratory analysis due to late reporting of adverse events. Once again, a collaborative effort is necessary to address the weaknesses in the system.

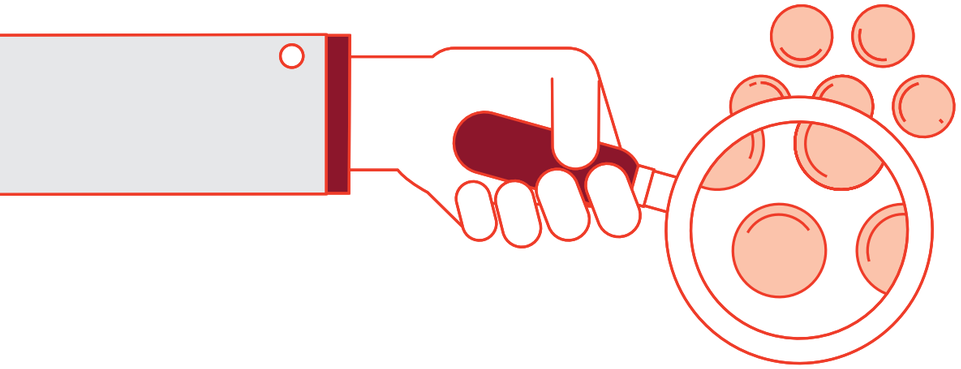
Donor adverse events showed a downward trend from the previous two reporting periods, with a calculated event rate of 37.2/100 000 transfusions (45.8 and 43.8 in 2020 and 2019 respectively).

This decrease is likely attributable to the significant decline in collections from scholar donors due to schools being closed during lockdown. The contribution of this donor group to total collections decreased by almost half from 2019.

Vaso-vagal events were the leading cause of donor adverse events (DAEs), constituting 80% thereof, with 75% due to fainting spells without associated injury. Puncture site haematoma was the next most common DAE at 13.1%. Injuries to vital structures such as arteries, nerves and tendons are rare during the venepuncture procedure, but this year there was cause for concern as three arterial punctures and one tendon injury were reported. Staff were provided additional training on recognition of arterial puncture and the management thereof.

This DAE data suggests that the technical aspects of donor care are being managed well by the BTS and the collections staff must be commended for this. No doubt some work still needs to be done, especially to address the immediate-type fainting spells in donors.

The 2021 South African Haemovigilance Report presents a mixed bag of successes and concerns, depending on the indicators considered. Overall though, the report paints an encouraging picture of BTS in South Africa.



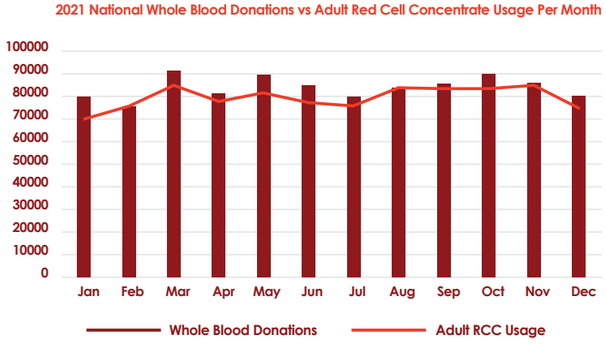
Chapter 1:

Blood Collection & Blood Product Issues in 2021

Blood Product Issues

Throughout 2021 the COVID pandemic continued to impact the BTS, leaving no departments untouched, but having the greatest impact on blood collection and blood usage as well as staff wellbeing in general. The BTS managed these challenges and provided safe blood products when required. Blood collection venues such as schools and businesses, plus "big events" where blood drives previously occurred, continued to be closed or have limited access.

Blood usage fluctuated, depending on the level of lockdown and ICU and hospital COVID admissions. This challenged the blood bank inventory logistics due to narrow margins between blood collection and blood issued.



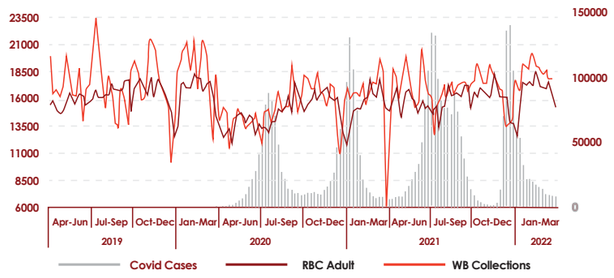
Infection Prevention and Control measures were successfully implemented, according to the COVID regulations, to ensure the safety of stakeholders, including staff, donors and patients.

During these challenging times there were opportunities for the BTS to become agile and innovative and to make a positive contribution to healthcare in South Africa:

a) Joined a global collaboration in a clinical trial for the use of convalescent plasma .

b) Performed sero-prevalence studies on donors to determine the proportion of donors who had been exposed to the SARS-CoV-2 virus, resulting in the development of antibodies, and extrapolating these findings to the general population. This public health data was used with other data by the COVID-19 Ministerial Advisory Committee and Modelling Consortium.

SANBS Weekly Whole Blood Collection, Red Cell Issues & Reported COVID -19 Cases 2020-2022



SANBS collected weekly data of blood collections and usage throughout the COVID pandemic.

The graph to the left shows the direct impact of the peaks and troughs of the COVID waves. Prior to April 2020 blood collections were planned to be higher than usage to allow for discards due to test positives, processing, products that did not meet quality standards and a small percentage of blood products expired.

During the pandemic, however, it was definitely not business as usual as the leeway between collections and usage was small. The staff and donors should be congratulated on providing sufficient blood when it was required, with very few episodes of short supply.

Blood Product Issues

Red cell usage and plasma product usage remained lower than in the pre-pandemic year of 2019. This was most notably seen in RCC usage that decreased by 13.5%, whereas plasma product usage only decreased by 1.5%.

The use of platelet products increased by 6.4% in 2021 compared to 2019. The BTS had put a new strategy in place to overcome the chronic shortage of platelets, however its full potential could only be realised once the demand for platelets rebounded as clinicians once again began to treat oncology cases, do elective surgery, etc.

The platelet strategy to encourage clinicians to use pooled platelets rather than single donor platelets (SDP) has not yet gained full buy-in from the blood users. In 2019, SDP made up 50.67% of platelet products used compared to 49.5% in 2021. Likewise, the desired increase in pooled platelets usage has not occurred, with only a slight shift from 49.33% in 2019 to 50.5% in 2021.

Comparison of Blood Product Issued between 2019 - 2021

Product	Category	Total 2019	Total 2020	Total 2021
Red cell products				
	Total red cell products (adults, paeds, emergency)	**1 148 235**	**953 760**	**993 498**
Plasma products	Fresh frozen plasma	151 325	139 442	142 392
	Cryoprecipitate/cryo wet	40 775	39 239	46 776
	Total plasma products	**192 100**	**178 681**	**189 168**
Platelet products	Pooled platelet units	38 514	37 755	41 943
	Apheresis platelet products (infant products counted individually)	39 567	39 440	41 113
	Total platelet products	**78 081**	**77 195**	**83 066**
Total blood products		**1 418 416**	**1 209 636**	**1 265 722**

Red Cell Transfusion

As in many countries, transfusion in South Africa is red cell driven as this is the most commonly required blood product. As a standard, RCC usage is calculated as a ratio of the number of products issued per 1 000 population. As per mid-2021 estimates by StatsSA[3], the South African population is estimated as being 60 142 979 people.

The overall transfusion rate for the country is relatively low at 16.5/1 000 population. This is mostly a reflection of lack of access to healthcare during the pandemic, although PBM may have had some impact. The focus in PBM is on patient outcomes, taking into account several management options to conserve a patient's own blood as well as ensuring that any blood and blood products that patients receive are safe and appropriate[2]. In Australia, where PBM has been successfully implemented, the aim is a transfusion rate of 17/1 000 population for a total Australian population of 25 766 605.

In a country as geographically diverse as South Africa, with differing assigned resources, the 16.5/1 000 overall transfusion rate needs further review at provincial level. Almost half (45.4%) of the South African population resides in the two most populated provinces of Gauteng and KwaZulu-Natal and accounted for 55.3% of RCC transfusions in 2021. Gauteng had the highest transfusion rate of 23.4/1 000, which was lower than the 2019 transfusion rate of 28.4/1 000. The Western Cape had the second highest transfusion rate at 17.8/1 000, which was lower than the 2019 rate of 20.7/1 000. The trend of a higher transfusion rate in Gauteng and the Western Cape is expected as these provinces have more tertiary and private hospitals that use relatively higher amounts of blood and blood products.

The more rural provinces, such as Eastern Cape, Northern Cape and North West, have transfusion rates below 12/1 000 population which reflects the challenge of access to healthcare.

Red Cell Transfusion Rates Per 1 000 Population in South African Provinces 2021

Province	Population	% of Country Population	RCC Usage (incl. whole blood; excl. designated & SANBS international donations)	%RCC	Transfusion rate per 1000 population
Gauteng	15 810 388	26.3	369 356	37.2	23.4
Kwazulu Natal	11 513 575	19.1	179 899	18.1	15.6
Western Cape	7 113 776	11.8	126 618	12.8	17.8
Eastern Cape	6 676 590	11.1	74 252	7.5	11.1
Limpopo	5 926 724	9.9	72 496	7.3	12.2
Mpumalanga	4 743 584	7.9	66 674	6.7	14.1
North West	4 122 854	6.9	48 406	4.9	11.7
Free State	2 932 441	4.9	41 385	4.2	14.1
Northern Cape	1 303 047	2.2	13 816	1.4	10.6
Total	**60 142 979**	**100.0**	**992 902**	**100.0**	**16.5**

The trend of a decrease in transfusion rate in all nine provinces may be due to PBM which is gaining momentum with clinicians, however the impact of COVID throughout 2021 cannot be totally discounted as a contributing factor.

Comparison of Red Cell Concentrate Transfusion Rates Per 1 000 Population 2019-2021

Transfusion Rate per 1000 population	2019	2020	2021
Gauteng	28.4	22.8	23.4
Kwazulu Natal	18.2	15.0	15.6
Western Cape	20.7	17.6	17.8
Eastern Cape	12.8	9.9	11.1
Limpopo	15.2	12.6	12.2
Mpumalanga	15.5	13.7	14.1
North West	14.0	11.8	11.7
Free State	16.6	13.3	14.1
Northern Cape	13.7	10.2	10.6

In the table above, the trend over the past 3 years of consistently higher usage in red cells per 1 000 population in Gauteng, the Western Cape and KwaZulu-Natal is to be expected as there are more tertiary hospitals and specialised services in these provinces – such as burns units, specialised surgical units and stem-cell transplant units – which use more blood products. The overall downward trend in utilisation in 2020 and 2021 is likely the result of the COVID-pandemic's impact on hospitalisation patterns which influenced blood utilisation.

It is estimated that 15% of the South African population had medical aid membership and cover providing access to the private healthcare sector in 2021. The remaining 85% of the population relied on the public healthcare sector. The private sector, representing approximately 15% of the population, had an RCC usage of 400 080 units (40.3%) compared to the public sector, representing 85% of the population, which used 592 814 units (59.7%). While we know the exact number of units transfused in South Africa, the medical aid membership is more difficult to define and measure. It remains a fact that there is a big disparity between private and public sector, with the private sector transfusion rate in the order of four times that of the public sector, which is likely a reflection of inequitable healthcare access in South Africa and the impact of the COVID pandemic.

Red Cell Concentrate Percentage Usage in South African Private & Public Sectors 2019-2021

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

Over the past three years there has been very little change in the percentage of RCC used in the private sector vs the public sector. Of concern is the slow creep of increase in consumption of this scarce resource by the private sector.

Recommendation

Collaborate with PBM groups to ensure appropriate transfusion decisions are made, taking into account the benefits, risks and alternative management options.

Chapter 2:

Transfusion-Related Adverse Events

Transfusion-Related Adverse Events

The transfusion of blood and blood products is a core part of healthcare service delivery. While the use of blood and blood products can be lifesaving, it is sometimes forgotten that this commonly used medical intervention is essentially a transfer of living human cells and as such carries risks which can be life threatening.

A total of 1 265 722 blood products were issued in 2021 and 989 adverse events were reported during this period. The standard measurement for adverse events is per 100 000 units transfused and this was 78.1/100 000 units transfused in 2021. This rate is similar to the 2019 rate of 78/100 000, but lower than the 2020 rate of 86.2/100 000.

2021 Transfusion Adverse Events

Transfusion Adverse Events	No. of cases	Percentage	Adverse event per 100 000 units transferred
Acute haemolytic transfusion reactions (AHTR)	0	0.0	0.0
Allergic reactions	205	20.7	16.2
Severe allergic Reactions	32	3.2	2.5
Anaphylactic Reactions	40	4.0	3.2
Febrile non-haemolytic reactions (FNHTR)	354	35.8	28.0
Transfusion-associated circulatory overload (TACO)	3	0.3	0.2
Transfusion-related acute lung injury (TRALI)	1	0.1	0.1
Transfusion-associated dyspnoea (TAD)	84	8.5	6.6
Hypotensive reactions	33	3.3	2.6
Unclassifiable due to incomplete or insufficient information	209	21.1	16.5
Total Acute Transfusion Reactions	961		
Delayed haemolytic transfusion reactions (DHTR)	0	0.0	0.0
Delayed serological transfusion reactions (DSTR)	0	0.0	0.0
Total Delayed Transfusion Reactions	0		
Misdirected transfusions (with and without ABO incompatibility)	27	2.7	2.1
Total IBCT Reactions	27		
Near miss	1	0.1	0.1
Transfusion-associated graft-versus-host disease (TA-GvHD)	0	0.0	0.0
Transfusion-transmitted infections (TTI)	0	0.0	0.0
Total Percentage		100	
Total Number of Cases Reported	**989**		
Total Adverse Reactions/100 000 Products Transfused			**78.1**

Overview of Transfusion-Related Adverse Events

The clinical impact of adverse events can be viewed with regards to interventions required and impact on patient morbidity or mortality. Mild reactions (which seldom cause morbidity and require management with antipyretics, antihistamines or no medication, plus careful monitoring), account for 59.8% of reported adverse events.

Febrile non-haemolytic transfusion reactions (FNHTR) were most reported at 35.8%, followed by mild allergic reactions at 20.7%. Hypotensive reactions only accounted for 3.3% of events. Febrile, allergic and hypotensive reactions are an unavoidable and largely unpredictable risk of transfusion.

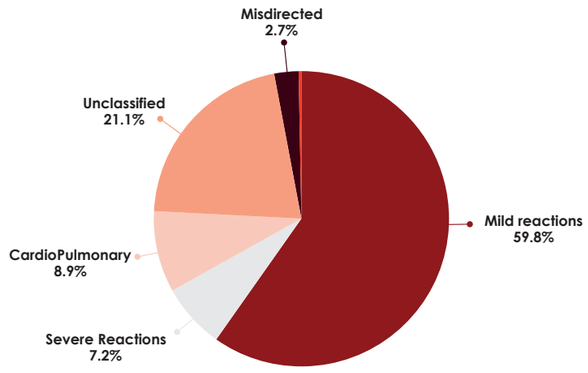
Severe allergic reactions and anaphylactic reactions made up a further 7.2%.

The cardiopulmonary adverse events should be viewed as a group together due to the challenge of a finite investigation for each individual group, but for the purpose of this report they are classified into the three groups: transfusion-related acute lung injury (TRALI), transfusion-associated circulatory overload (TACO) and transfusion-associated dyspnoea (TAD). Only one case of TRALI was reported (0.1%), while TACO cases accounted for 0.3% and TAD cases for 8.5%. The reason for the relatively large percentage of TAD is the lack of clinical data and additional investigations such as chest x-ray (CXR), which make it difficult to confirm TRALI or TACO. It is important, however, to recognise TACO as this is potentially an avoidable adverse event.

There were no reported cases of acute haemolytic transfusion reactions or delayed transfusion reaction. The low or no reporting of delayed reactions is most likely due to an immature haemovigilance system.

The unclassified reactions due to insufficient information remain high at 21.1%.

Overview of Adverse Events 2021



Incorrect Blood or Component Transfusion

Incorrect Blood or Component Transfusions are preventable errors where blood cross-matched for a patient is erroneously transfused to another patient. This can have far-reaching complications such as death, need for dialysis, etc.

IBCT due to misdirected units represent 2.7% of all adverse events in South Africa, however it is one of the areas where recognising the error and improving the system will improve patient safety. In 2021, misdirected transfusions decreased to 2.1/100 000 compared to 2.5/100 000 in 2020, but remained higher than in 2019 (1.4/100 000). In each case of IBCT, the system failure is investigated and assigned as either a hospital staff error or a blood bank error.

Origin & Clinical Area of Incorrect Blood or Component Transfusion

Adverse events reporting in South Africa is a voluntary system and under-reporting is a result of issues such as staff shortages, lack of understanding of the importance of reporting and lack of resources to investigate.

The ideal is to create a culture of safety, in which the SYSTEM that allowed a mistake to occur is changed instead of the INDIVIDUAL being scapegoated. All such incidents are also reported to the Haemovigilance Officers and to the individual hospital's Quality Assurance department. The table below highlights that many errors occur in non-emergency clinical settings, with the majority due to lack of identification of the patient when hanging the blood product unit and the balance due to sample error (one in the blood bank and one in the wards).

Transfusion of blood to the wrong patient is one of the most serious hazards of transfusion and can potentially result in patient death. In 16/27 cases of IBCT, the RCC unit was ABO compatible; however in 11/27 the RCC unit was ABO incompatible. In the ABO-incompatible cases there were no reported deaths or severe morbidity as, in many instances, the transfusion was stopped after small volumes had been transfused or the patients' immunogenicity did not result in an acute haemolytic reaction.

Origin & Clinical Area of Incorrect Blood or Component Transfusion

Origin of error	Clinical area/ward					Total cases
	Surgical	Medical	Obstetrics & gynaecology	Emergency	Pediatrics	
Blood bank errors	0	2	2	1	0	5
Hospital errors	7	5	5	4	1	22
Total	7	7	7	4	1	27

As can be seen in the table below, there has been a decrease in reported IBCT. This trend may be a result of the BTS dedicating significant training resources to educate hospital and blood bank staff on the prevention, investigation and management of adverse events. Whilst recognising the pressures clinical and laboratory staff endure, especially during the COVID pandemic, it is of concern that errors continue to be made and many are in non-emergency clinical settings. There is also a concern that there may be a low level of reporting as the South African IBCT (2.1%) is low in comparison to SHOT[1] (8.4% in 2021).

Incorrect Blood Component Transfusion Report 2007, 2014 & 2021

	2007	2014	2021
No. of cases	21/402	35/963	35/963
As a percentage of adverse events	5.2%	3.6%	2.7%

Over the past decade, the percentage of adverse events which are due to IBCT have decreased, however each human error does have the potential to cause harm to or the death of a patient.

Near Misses

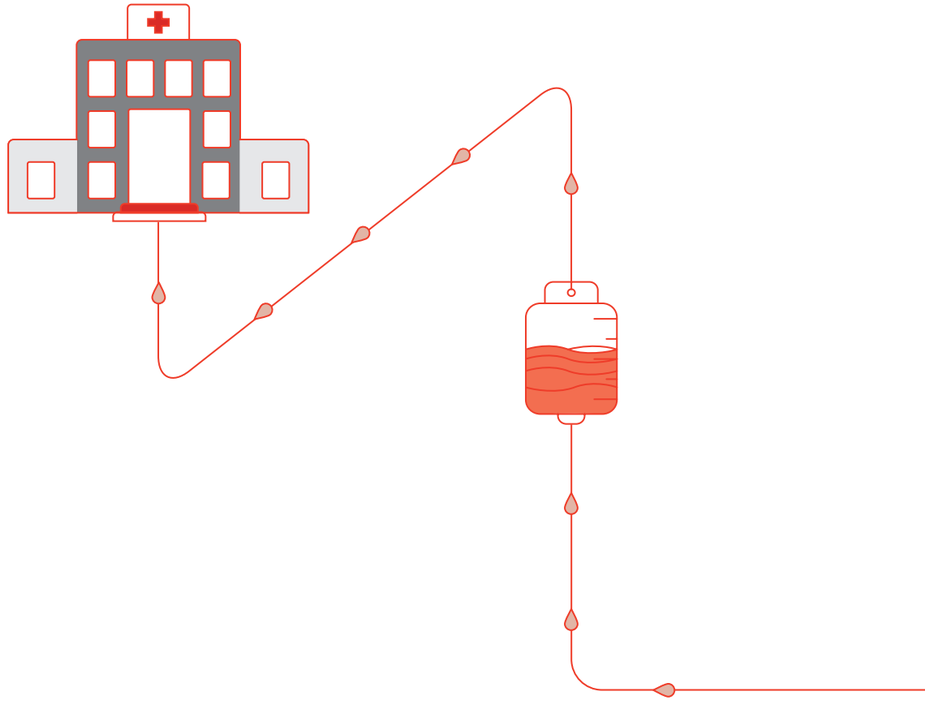
There was only one reported near miss. In comparison to SHOT 2021, this is low and most probably indicates under-reporting.

Mortalities Associated with Transfusion

There were 16 patient mortalities reported to the South African Haemovigilance Programme in 2021. 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 makes assigning imputability a challenge. It can, however, be stated that none of the 16 deaths were conclusively attributed to a transfusion reaction.

Recommendations

- Review the current Adverse Event Report form to ensure it is easy to use and requests relevant data.
- Improve communication and collaboration between the clinical staff and the blood service to improve report quality and conclusive output.
- Improve educational content designed in accordance with the trends highlighted in the report.
- Continue to train doctors and nurses on the importance of positive patient identification at the time of collecting and labelling pre-transfusion samples and when setting up the transfusion at the bedside.
- Investigate ways to record and analyse "near misses". These are lost opportunities to identify weaknesses in the system and celebrate the positives of a culture of safety reporting.



Chapter 3:

Transfusion Transmitted Infections & the Lookback Programme

Transfusion Transmitted Infections & the Lookback Programme

In South Africa TTIs are generally perceived to be HIV, however infections may also be due to bacterial or viral contamination of a blood product. As a country with endemic malaria areas, malaria may be an additional source of infection.

Bacterial Contamination

No reports of bacterially contaminated products resulting in sepsis or patient mortality have been received by the Haemovigilance Programme. As this is a passive reporting system, these adverse events are likely under-reported due to a low level of suspicion. To confound the problem, patients receiving platelets are often on antibiotics or have an underlying infection.

SANBS & WCBS run a quality control (QC) surveillance model whereby a proportion of SDP collections are tested for bacterial contamination. Contaminated products in the inventory are quarantined and discarded. Both SDP and Random Donor Platelets (RDP) are stored at room temperature and are a sensitive marker of the level of bacterial contamination. This QC model is linked to a notification system which includes informing the clinician in charge of the patient who has received a potentially contaminated product.

Viral Infections

In South Africa, all blood donations are screened for hepatitis B virus (HBV), hepatitis C virus (HCV), HIV and syphilis through a combination of serological and genetic tests. Individual donation nucleic acid testing (ID-NAT) for the 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[4].

In the year under review, 2 448 of the 1 098 923 donations collected tested positive for HIV, HBV and/or HCV. However, this 12-month period showed a further decline in the prevalence of HIV and HBV in the South African donor population, whilst the HCV prevalence has remained static at 0.01. The decrease in viral prevalence of HIV and HBV is due to the reliance on repeat donors during periods of COVID lockdown when access to new donors was a challenge.

A noteworthy finding was that no TTI event was confirmed in South Africa in 2021.

Viral Prevalence in the South African Donor Population 2019-2021

National Donor Prevalence	2019	2020	2021
HIV	0.21	0.19	0.15
HBV	0.09	0.08	0.06
HCV	0.01	0.01	0.01

All viral-positive donors have to be traced by the BTS, offered counselling or referred for counselling at other healthcare facilities and, ultimately, be directed to seek medical assistance.

The Lookback Programme

All potential TTIs are investigated by means of the Lookback Programme. The Lookback Programme consists of two arms: a) the donor-triggered arm, and b) the recipient-triggered arm.

The donor-triggered arm

When a repeat donor is found to be viral-positive for one of the screened viral infections, this initiates the tracing of the recipients of the blood products associated with the donor's previous donation. They are tested for TTIs to exclude a possible window-period donation.
Testing of patients involved in donor-triggered lookback cases should be managed by the treating clinicians. It is emphasised to the clinicians that they are investigating a potential window-period transmission. In the event that the same pathogen is detected in both the donor and the recipient, phylogenetic testing is performed to establish a causal link between the donor and recipient pathogens.

Donor-Triggered lookbacks 2021

Donor-Triggered lookbacks 2021	Total
HIV	697
HBV	202
HCV	23
HIV/HBV co-infection	5
HIV/HCV co-infection	1
HBV/HCV co-infection	2
Other	0
Total	**930**

Of these, 930 donor-triggered lookback cases (74.9%) were for HIV, 202 cases (24.55%) for HBV, 25 cases (21/7%) for HCV, 7 cases (0.79%) for HIV/HBV co-infection, 2 cases (0.23%) for HIV/HCV co-infection, and 2 cases (0.23%) for non-routinely tested infections (cytomegalovirus and malaria).

The outcome of investigations of the 930 donor-triggered lookbacks are noted in the table below. The outcomes reflect some of the challenges of the lookback programme. For 2021, 63% of the recipients were not available for testing (258 died; 140 were untraceable; for 182 we are awaiting clinician's response; and 6 declined testing). These challenges are understandable as there may be a considerable time period between the transfusion to the recipient and when the donor returns for further donations and tests positive for a viral marker.

Donor-Triggered Investigations & Outcomes 2021

Donor-Triggered Investigation Outcome	Total
Recipient retested negative	160
Recipient positive before transfusion	92
Phylogenetic analysis for potential HIV TTI	3
Recipient died between transfusion and initiation of lookback	258
Unresolved (awaiting feedback from clinician)	182
Untraceable patient	140
Other*	85
Recipient declined testing	6
HBV-immune	3
Phylogenetic analysis for potential HBV TTI	1
Total	**930**

Footnote: Other includes doctor not traceable; doctor not willing to participate in the lookback programme; foreign patient; patient did not honour the appointment for sample retest.*

2021 Donor Triggered Lookback Investigations 2009 - 2021

Year	'09	'10	'11	'12	'13	'14	'15	'16	'17	'18	'19	'20	'21
Total	447	546	642	629	849	1129	978	979	948	866	884	916	930

Donor-triggered lookbacks steadily increased until 2014 and then there was an improvement in 2018 and 2019 after review of donor education, donor screening and retraining of donor staff. Unfortunately, in the past two years there has once again been an increase in repeat donors who test positive for a viral marker.

The recipient-triggered arm

This is initiated when the blood service is informed that the recipient of a blood product has tested positive for a possible TTI and is requested to investigate whether this was acquired via transfusion. The implicated donor/s are traced and either tested for the infection or their donation histories are scrutinised for potential evidence of HIV, HBV or HCV infection. In the event that the same pathogen is detected in both the donor and the recipient, phylogenetic testing is performed to establish a causal link between the donor and recipient pathogens.

Recipient-Triggered Lookbacks 2021

Recipient-triggered lookbacks 2021	Total	Total
	Resolved	Unresolved
HIV	2	0
HBV	1	0
HCV	0	0
Other - malaria	1	0
Total	4	0

There were no confirmed viral TTIs during this 12-month reporting period and all recipient-triggered lookbacks reported in this time period were resolved.

The recipient-triggered malaria case was investigated and confirmed, by quantitative polymerase chain reaction (PCR), as falciparum-positive in both the donor and recipient.
The donor and recipient infections were then genotyped by the PCR amplification of the highly variable genes. The parasite clones present in the donor were distinct from the parasite populations present in the recipient.
On the basis of this genotyping, it seemed highly unlikely that the infected donor blood was the source of the malaria in the recipient. The recipient made a full recovery from the malaria infection and gave a history of travel to Malawi, which is an endemic malaria area. This case is a good example of the detailed testing that is done by the National Institute of Communicable Diseases (NICD) for lookback cases in South Africa.

Recommendations

- The BTS must continue to inform and educate clinicians about the importance of the Lookback Programme so as to ensure the safety of the blood supply in the country.
- The Donor Collection staff and telerecruiting staff should be made aware of the importance of the donor cellphone number as a point of contact and the need to use every contact as an opportunity to update that number.

Chapter 4:

Donor Adverse Events

Donor Adverse Events

The South African BTS rely entirely on the goodwill of voluntary non-remunerated blood donors to ensure an adequate supply of blood components for the patients of South Africa. It is thus important for the BTS to do everything possible to ensure the safety of the donors throughout the donation procedure and for 24 hours post donation.
Whilst blood donation is generally a safe process, recognised complications may occur that negatively impact donor retention and make the recruitment of new donors more of a challenge. All donors should be fully informed about the blood donation process and be aware of adverse events of donation prior to signing their consent forms.

Donor Adverse Events 2021

2021		Total	% of total DAE	DAE rate per 100 000 donations
Local Reactions	Haematoma	536	13.1	48.78
	Arterial puncture	3	0.1	0.27
	Delayed bleeding	34	0.8	3.09
	Nerve irritation	2	0.0	0.18
	Tendon injury	1	0.0	0.09
	Nerve injury	0	0.0	0.00
	Painful arm	157	3.8	14.29
	Total No. Local Reactions	**733**		
Vaso-vagal reactions	Faint Immediate type	2 064	50.5	187.82
	Faint Immediate, accident	124	3.0	11.28
	Faint Delayed type	1 021	25.0	92.91
	Faint delayed, accident	75	1.8	6.82
	Total No. Vasovagal Reactions	3 284		
Other reactions	Citrate reaction	57	1.4	5.19
	Haemolysis	2	0.0	0.18
	Generalized allergic reaction	8	0.2	0.73
	Total No. Other Reactions	67		
	GRAND TOTAL	4 084		
	TOTAL DONATIONS 2021	1 098 923		

A total of 1 098 923 blood donations took place at blood service collection venues throughout South Africa during the 2021 calendar year. A total of 4 084 donor adverse events (DAE) were reported for the year, which translates to a rate of 37.2 DAE/100 000 donations. This relatively low rate of DAE, in comparison to 43.8 in 2020 and 45.8 in 2019, may be due in part to a lower percentage of scholars donating blood during the COVID pandemic. It is well established, both in South Africa [6] and internationally[5], that young donors experience more vasovagal events than older donors.

Percentage of Young Donors Forming Part of the National Donor Base 2019-2021

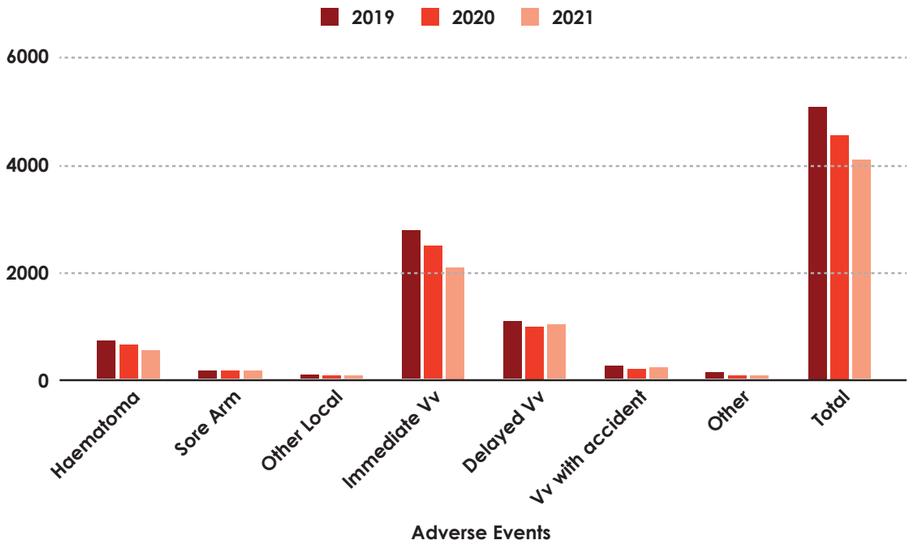
National Figures	Donors aged 16-19	Total donors	% of total donors
2019	104 286	540 690	19.3
2020	62 332	477 328	13.1
2021	65 067	480 147	13.6

This decrease in donations from young donors was due to schools either being closed or, once reopened, affected by COVID regulations and logistics which prevented the "normal" large blood-donor sessions occurring at schools. The BTS did encourage individual young donors to donate out of school, but this did not fully compensate for the loss of donations.

In 2021 the most frequently reported DAE was a vasovagal reaction, with the majority being immediate faints (50.5%). Delayed faints contributed a further 25% and 4.8% of faints were associated with some degree of injury to the donor. Haematoma at the venepuncture site was the second most reported DAE (13.1%).

Less frequent DAE, such as injury to vital structures in the arm, are collectively grouped under "Other" in the graph below. There was one tendon injury reported and – of more concern – three arterial punctures, two of which caused significant morbidity requiring surgery. As a result of the unexpected number of arterial punctures, donor staff received training on recognition and management of this rare DAE.

Donor Adverse Events 2019-2021



From the graph above, it can be seen that the DAE trend remained the same for the years 2019 to 2021, with vasovagal events (faints) being the most common (80%) and haematoma (13%) the second most common.

Recommendations

- BTS must ensure that donors are aware of the importance of reporting all adverse events of donation, especially those that occur after the donor has left the donation venue.
- Donor staff must be reminded to report all DAE and the donor outcome through the provided channels to the Haemovigilance Officers.

Chapter 5:
Conclusion

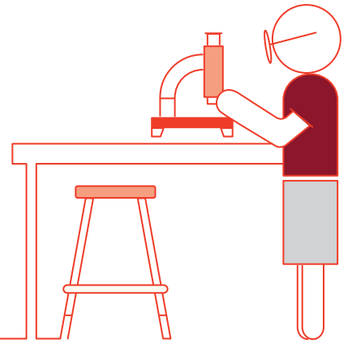
Conclusion

It is evident from the data that was reviewed for the compilation of the 2021 Haemovigilance Report for South Africa that the COVID pandemic continued to have an impact on blood supply and demand through 2021. Staff of the BTS and donors must be congratulated for providing an outstanding service to the patients of South Africa over a long period of time, with only a few periods where orders were cut back.

In the South African health system, which continues to remain under pressure, we need to encourage a good reporting culture. In order to achieve the goal of improved blood safety, reporters should provide as much detail as possible from both qualitative and quantitative standpoints, as this forms the basis of trend detection, identification of key learning points and recommendations for improvements to the process.

To quote from the 2021 SHOT Report: "Haemovigilance is not a recordkeeping function but focuses on proactively identifying safety issues ('signals') and taking actions to minimise or mitigate risk to patients and donors"1. In the year ahead we will endeavour to improve the reporting to help make Haemovigilance an important safety tool rather than a report to be filed annually.

We would like to thank all those who have taken the time and effort to participate in and contribute to the Haemovigilance System during 2021.



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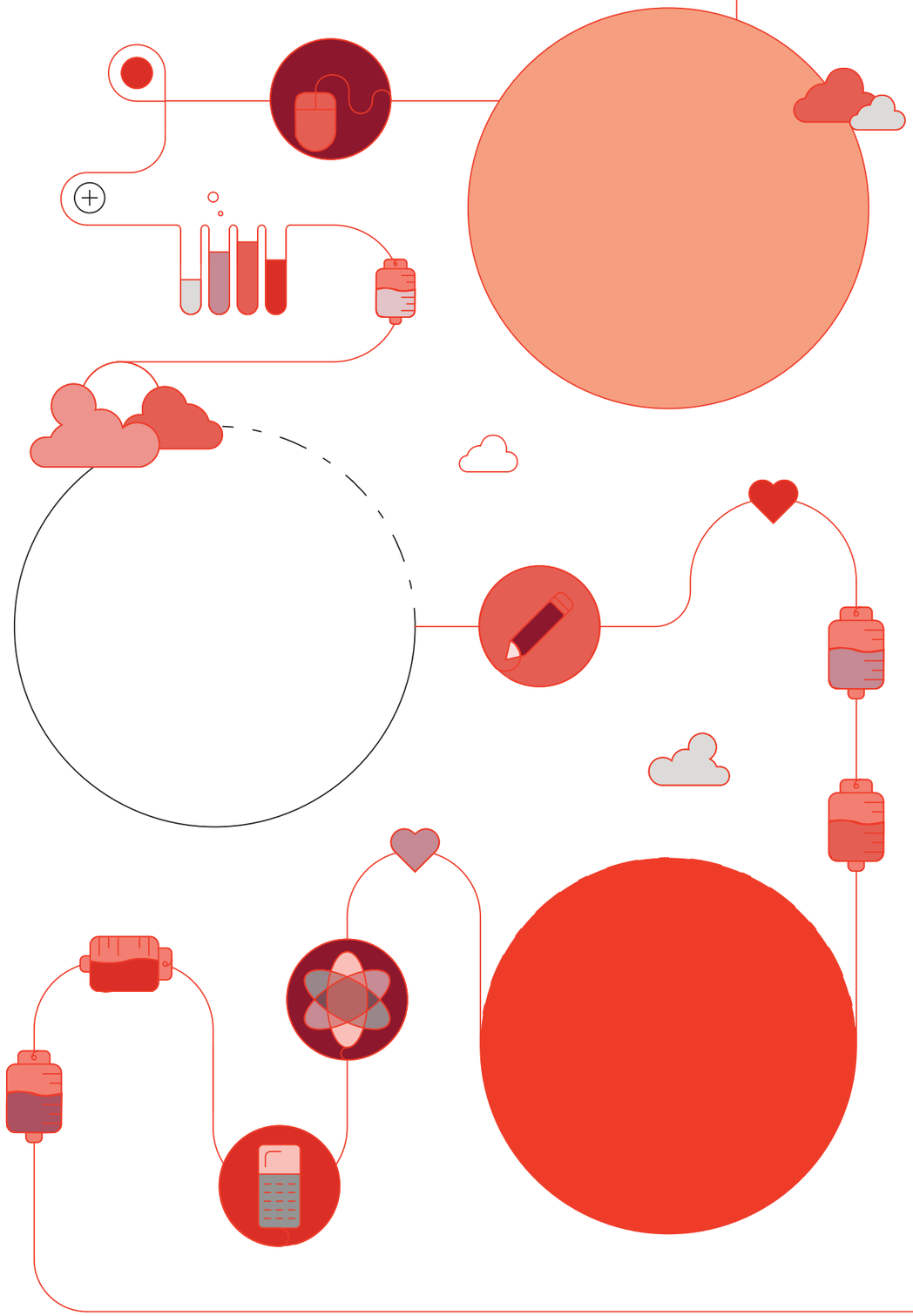

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