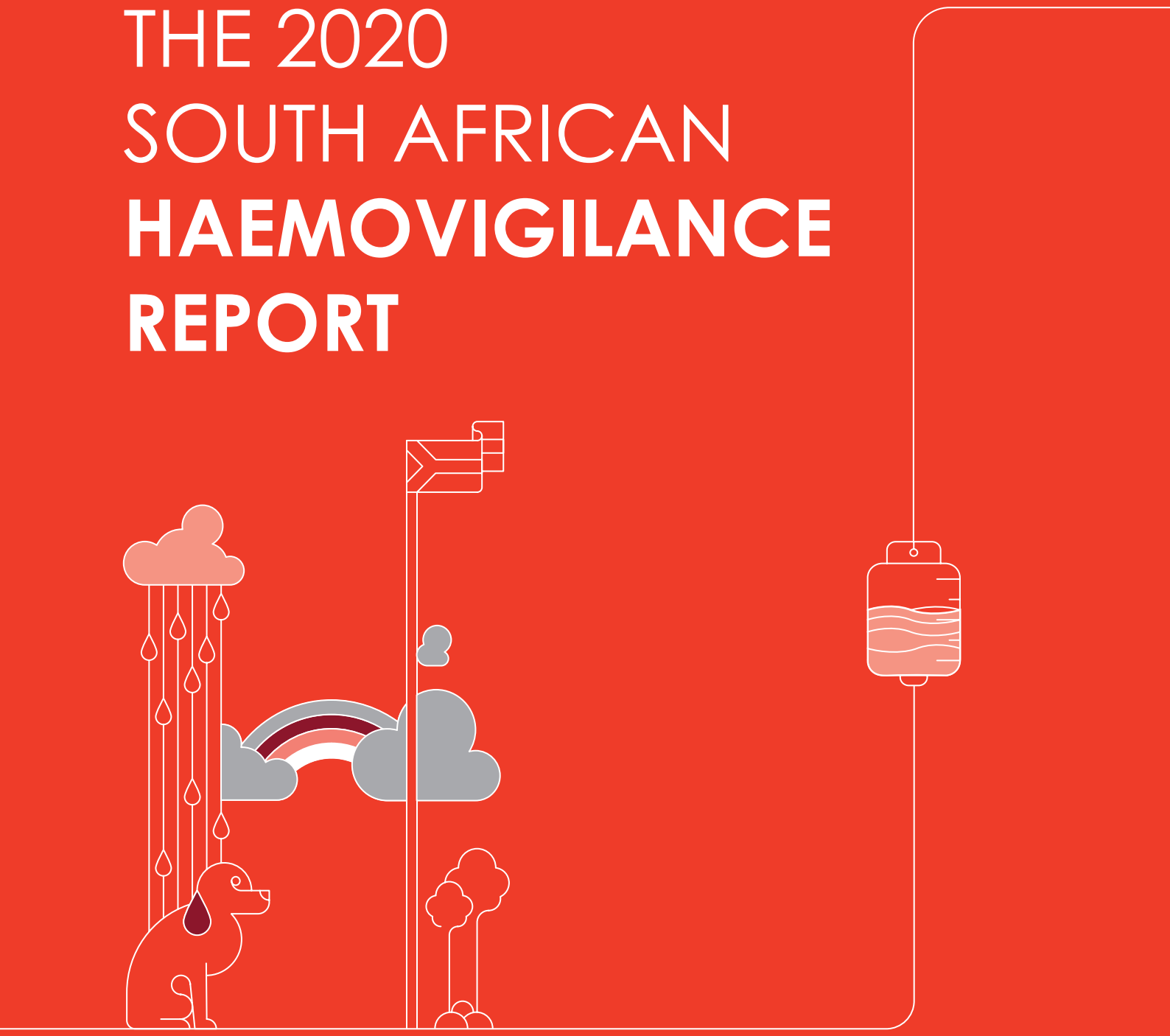
THE 2020 SOUTH AFRICAN **HAEMOVIGILANCE REPORT**



Western Cape Blood Service
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SANBS
South African National Blood Service

Haemovigilance Report 2020

The 21st 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.

List of Authors and Contributors

Compiled by:

- **Dr Caroline Hilton**
  (Head, Medical Division, WCBS)
- **Dr Solomuzi Ngcobo**
  (Lead Consultant, Medical Affairs, SANBS)
- **Sr Francis Ledwaba**
  (National Haemovigilance Officer, SANBS)

Contributors:

- **Dr Karin van den Berg**
  (Medical Director, SANBS)
- **Dr Gregory Bellairs**
  (CEO/Medical Director, WCBS)
- **Dr Ute Jentsch**
  (Lead Consultant, Pathology: Specialised Services and Quality Control, SANBS)
- **Lookback Officers**
  (SANBS)
- **Specialised Donation and Donor Clinic Departments**
  (WCBS)
- **Ms Ronel Swanevelder**
  (Analytics Specialist, SANBS)
- **Mr Kevin de Smidt**
  (Manager, Information Technology Services, WCBS)
- **Immunohaematology: Red Cell Serology staff**
  (SANBS)

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Contact Details

National Haemovigilance Office:

South African National Blood Service

Private Bag X14
Weltevreden Park
1715

Tel: +27 (0)11 761 9371

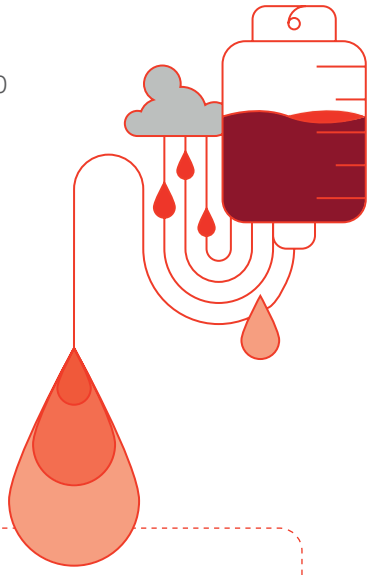
www.sanbs.org.za

Western Cape Blood Service

PO Box 79
Howard Place
7450

Tel: +27 (0)21 507 6000

www.wcbs.org.za



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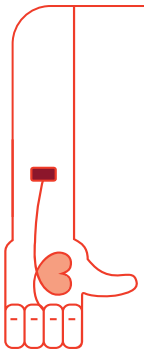
Abbreviations



Category	Definition
AHTR	Acute haemolytic transfusion reaction
ATR	Acute transfusion reaction
DAE	Donor adverse event
DAT	Direct antiglobulin test
DHTR	Delayed haemolytic transfusion reaction
DSTR	Delayed serological transfusion reaction
FFP	Fresh frozen plasma
FNHTR	Febrile non-haemolytic transfusion reaction
GMP	Good manufacturing process
HBV	Hepatitis B virus
HCV	Hepatitis C virus
HIV	Human immunodeficiency virus
ID-NAT	Individual donation nucleic acid testing
IHN	International Haemovigilance Network
IPC	Infection prevention control
ISBT	International Society for Blood Transfusion
PBM	Patient blood management
PPE	Personal protective equipment
QC	Quality control
RCC	Red cell concentrate
RDP	Random donor platelet
SANBS	South African National Blood Service
SDP	Single donor platelet
TAD	Transfusion-associated dyspnoea
TA-GvHD	Transfusion-associated graft-versus-host disease
TTI	Transfusion-transmissible infection
TRALI	Transfusion-related acute lung injury
TACO	Transfusion-associated circulatory overload
WCBS	Western Cape Blood Service
WHO	World Health Organization

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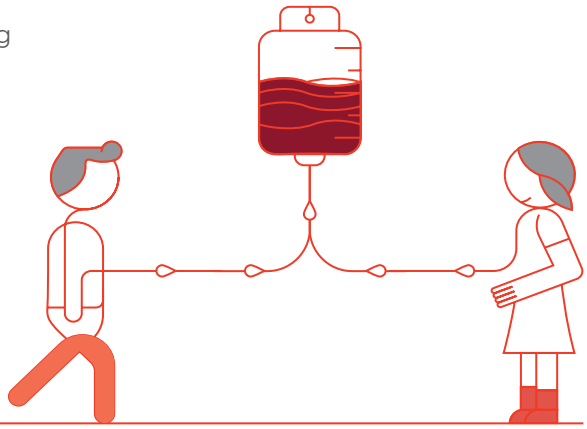

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Foreword:

A Message from the Haemovigilance Team

The haemovigilance teams at WCBS and SANBS would like to thank all healthcare workers and blood collection and blood banking staff for their assistance in providing the necessary information for this report. Haemovigilance is an essential part of monitoring blood donation and transfusion safety in our country, and is reliant on the cooperation and assistance of everyone involved in this life-saving service. The blood services endeavour to provide the safest blood products for our patients and welcome suggestions or comments from our blood product users.

We would also like to extend our sincere gratitude to the many healthcare workers who selflessly battled the COVID-19 pandemic in 2020.

Please direct any queries to the respective haemovigilance co-ordinators at the two blood services:

- **Dr Caroline Hilton** (Head, Medical Division, WCBS)
  caroline@wcbs.org.za
- **Dr Solomuzi Ngcobo** (Lead Consultant, Medical Affairs, SANBS)
  solomuzi.ngcobo@wcbs.org.za
- **Sr Francis Ledwaba** (National Haemovigilance Officer, SANBS)
  francis.ledwaba@sanbs.org.za

Executive Summary

This is the 21st edition of the South African Haemovigilance Report, which provides an overview of blood product usage and adverse events related to transfusion and blood donation in the country during the 2020 calendar year.

The COVID-19 pandemic had a significant impact on every sector in South Africa, including the blood services. The healthcare sector responded to the need to prioritise hospital space for COVID-19-affected patients by postponing elective surgeries and non-essential medical care. This, along with other socio-economic factors such as the alcohol sales ban during certain lockdown periods causing a reduction in the trauma patient load[1], resulted in a 14.72% decline in overall blood product usage compared to the previous calendar year. This was most notably seen in red cell concentrate (RCC) usage that dropped by 16.94% compared to platelet and plasma product usage that declined by 6.99% and 1.13% respectively.

The more urbanised and populated provinces continue to have the highest RCC transfusion rates in the country, with Gauteng (22.75 units per 1000 population) and the Western Cape (17.59 units per

1000 population) in the lead. The public healthcare sector used 61.34% of all RCC products in 2020, which is disproportionate to the number of people who access public healthcare in South Africa.

Adverse transfusion reactions occurred at a rate of 86.16 per 100 000 products transfused in 2020. This is the highest rate seen in the past three years, although surmised under-reporting of transfusion reactions and the passive nature of the haemovigilance monitoring system in South Africa make accurate data collection and comparison over time, challenging. Febrile non-haemolytic and allergic transfusion reactions accounted for the majority of reactions, as has been consistently seen in the past. The rate of misdirected transfusions increased in 2020, which is of concern as these events are potentially life-threatening and usually attributable to human error. There were no confirmed cases of either transfusion-transmitted disease or blood product-related mortality reported in 2020.

A total of 1 035 902 donations were made at the South African blood services in 2020, of which 4537 were associated with donor adverse events (DAEs). This resulted in a steady DAE rate of 0.438 per 100 donations compared to previous years. Vasovagal reactions were the most commonly reported DAEs (80.23%), followed by haematomas at the venepuncture site (13.8%).

Key findings from the 2020 South African Haemovigilance Report

- A total of 1 209 636 blood products were issued from the South African blood services between 1 January 2020 and 31 December 2020.
- Overall blood product usage declined by 14.72% compared to 2019, which translates to a decline from 24.13 to 20.29 blood products per 1000 population.
- RCC usage dropped by 16.94%.
- The overall RCC transfusion rate in 2020 was 16.0 per 1000 population.
- While 61.34% of RCC products were used in the public healthcare sector, RCC usage is disproportionately lower in government-run facilities compared to the private sector.
- A total of 1042 adverse transfusion reactions were reported to and classified by the South African blood services in 2020, resulting in an increase in the adverse event rate to 86.16 incidents per 100 000 products transfused compared to 77.98 per 100 000 products in 2019.
- Febrile non-haemolytic transfusion reactions (31.86%) and allergic reactions (30.13%) accounted for the majority of adverse reactions. There was an increase in misdirected transfusion events from 1.4 to 2.48 incidents per 100 000 products transfused.
- There were no confirmed cases of transfusion-transmitted infection or transfusion-related patient death reported to the blood services in 2020.
- The DAE rate was 0.438 per 100 donations which is similar to the rate in 2019.

Recommendations from the South African Haemovigilance Programme

- Ongoing support of restrictive and responsible blood product usage in keeping with Patient Blood Management (PBM) principles[2] to avoid unnecessary risk to patients.
- Encouragement of the use of haemovigilance information by clinicians and hospital management to initiate and guide PBM strategies.
- Promotion of the recognition and timeous reporting of transfusion-related adverse events for accurate haemovigilance surveillance.
- Encouragement of thorough investigation of incidents to identify system-related and human factors that need to be addressed.
- Specific focus on the prevention of misdirected transfusions by educating hospital staff to be vigilant at each step of the transfusion process, particularly during patient verification prior to transfusion.
- Education of hospital staff on the importance and availability of the lookback programme in order to encourage their cooperation with the blood services.
- Ongoing encouragement of the South African population to donate blood to increase the blood donor pool to exceed 1% of the population.

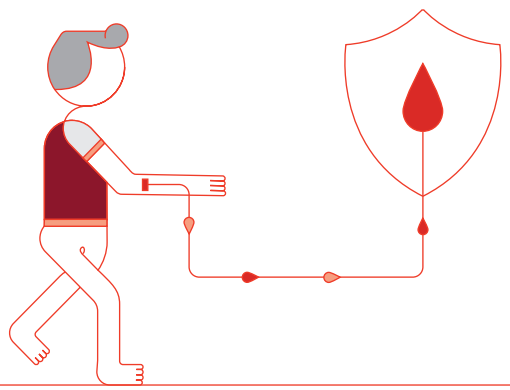
Chapter 1:

Introduction

1.1 What is haemovigilance?

Haemovigilance involves the recording, reporting, analysis and evaluation of all adverse events associated with blood donation and transfusion practices. This process provides the blood services with valuable information to identify and mitigate risks to donors and patients, and to improve the safety of blood products. The acknowledgement of the risks associated with blood product usage by clinicians should also promote the appropriate use of these resources. Successful haemovigilance reporting relies on communication and interdisciplinary cooperation between all professionals involved in the handling of blood products. The implementation and maintenance of a high-quality haemovigilance system is a major challenge in resource-poor settings.

National haemovigilance programmes can be managed by competent regulatory authorities (e.g. in France, Germany and Switzerland), by the blood services themselves (e.g. in Japan, Singapore and South Africa), by professional organisations (e.g. in the Netherlands and the UK), by public health authorities (e.g. in Canada), or by private/public partnerships (e.g. in the USA). The ideal type of haemovigilance system would be governed by a body that is independent from the country's blood services and has adequate resources to actively monitor all donation- and transfusion-related adverse events.



1.2 Haemovigilance in South Africa

The South African Haemovigilance Programme was established in 2000. The respective haemovigilance office divisions of the South African National Blood Service (SANBS) and the Western Cape Blood Service (WCBS) collate their data on an annual basis to produce a report, as required by the Department of Health. National data is also submitted to the International Haemovigilance Network (IHN) and the World Health Organization (WHO) on an annual basis. The definitions within this report are based on those agreed upon by the International Society of Blood Transfusion Working Party on Haemovigilance in collaboration with the IHN.

DAEs are reported by the collection staff of the blood services and by donors themselves (in the event of delayed reactions taking place after the donor has left the donation clinic), while transfusion-related adverse events require voluntary reporting by hospital staff. The blood services in South Africa do not currently employ dedicated staff to monitor the outcome of each transfusion event, as is done in some first-world facilities. It is therefore acknowledged that reporting of transfusion-related adverse events may not be comprehensive as this practice is not mandatory.

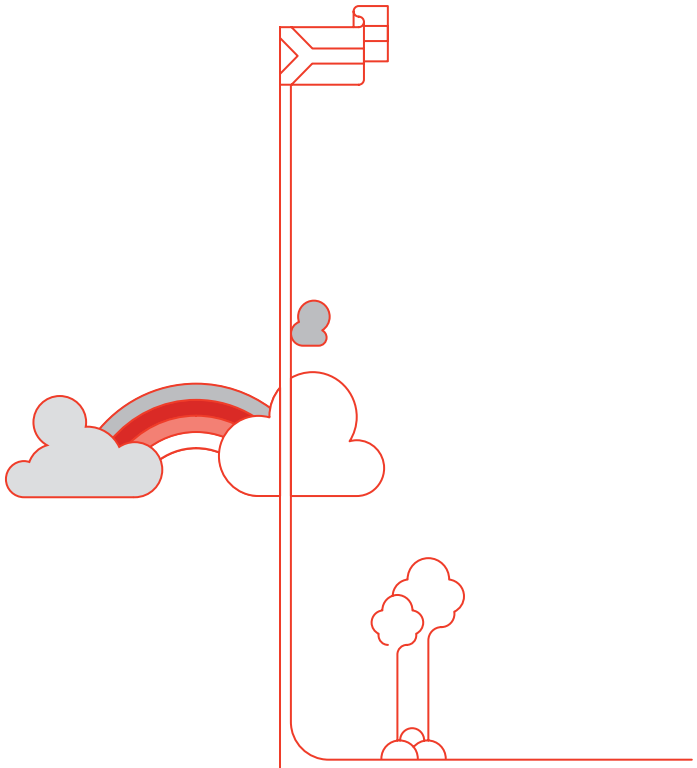
When suspected transfusion-related adverse events are reported to the hospital blood bank, the blood services conduct serological investigations and request a written report from the attending clinician. Additional microbiological or serological investigations may be performed, depending on the symptoms reported. This information is reviewed by the haemovigilance offices of the blood services and the event is classified according to IHN definitions (see Appendix 1). There are occasions when a written report is not supplied (or is incomplete) and the reporting clinician cannot be reached for discussion of the incident. These cases are treated on an individual basis depending on the amount of information supplied in the telephonic report to the Blood Bank, or regarded as 'unclassifiable' if there is insufficient information.

1.3 Objectives of the South African Haemovigilance Programme

- Monitor adverse transfusion reactions and DAEs.
- Create awareness among healthcare professionals of the risks associated with blood donation and transfusion.
- Generate evidence-based recommendations aimed at improving donor and patient safety.
- Communicate findings to all key stakeholders.
- Create national and international cooperation to promote accurate, non-biased and standardised haemovigilance reporting.

1.4 The future of haemovigilance in South Africa

The need for an external body to monitor haemovigilance in South Africa has been recognised by the blood services and they are working towards establishing an independent Haemovigilance Committee. SANBS reported at the National Blood Safety Meeting in October 2020 that a phased implementation was being planned over a four-year period, with the objective of having a functional independent Haemovigilance Committee by Year 5 (2025). The blood services acknowledge the importance of this body being recognised by the South African Department of Health, as well as by local and international regulatory and authoritative bodies within the healthcare and transfusion medicine sectors.



Chapter 2:

Blood Product Issues in South Africa

2.1 Annual number of blood products issued 2018–2020

A total of 1 209 636 blood products were issued from the South African blood services between 1 January 2020 and 31 December 2020. This shows an overall decline of 14.7% compared to blood products issued in 2019 and translates to a decline from 24.1 to 20.3 blood products issued per 1000 population. When comparing the different categories of blood products, RCCs saw the biggest decline in usage (16.94%), while plasma and platelet product usage decreased by 7.0% and 1.1% respectively. The postponement of elective surgeries and reduction in trauma patient case load as a result of the alcohol ban during the COVID-19 lockdown periods may explain the decrease in product usage[1]. The implementation of PBM strategies resulting in the restrictive use of blood products may also have contributed to this change.

Platelet product usage remained unchanged at 1.3 per 1000 population. There was an ongoing shift in favour of single donor platelet (SDP) product usage (51.1%) compared to random donor platelet (RDP) (48.9%) in 2020, a trend that continued from 2019. This shift is more evident in the hospitals served by SANBS than WCBS, where the ratio of usage of SDP and RDP products is approximately 40:60. Plasma products saw a 7.0% decline from 2019 to 2020, and decreased from 3.3 per 1000 population in 2019 to 3.0 in 2020.

Table 1: Comparison of blood products issued 2018–2020

	2018	2019	2020
Red cell (adult, infant and emergency) concentrates	929 122	1 148 235	953 760
Plasma products	181 139	192 100	178 681
Fresh frozen plasma (FFP)	145 732	151 325	139 442
Cryoprecipitate	35 407	40 775	39 239
Platelet products	74 796	78 081	77 195
Random donor platelet (RDP) products	38 945	38 514	37 755
Single donor platelet (SDP) products	35 851	39 567	39 440

Table 2: Annual rate of transfusion in South Africa 2018–2020 per 1 000 population

	2018	2019	2020
Population estimate	57 725 600	58 775 022	59 622 350
Red cell concentrate (RCC)	16.09	19.54	16.00
Platelets	1.29	1.33	1.29
Plasma	3.14	3.26	3.0
All components	20.53	24.13	20.29

2.2 RCC transfusion rates by province 2020

RCC is the predominant product type issued from blood banks. Table 3 lists the nine provinces in South Africa in order of their population size, according to the 2020 mid-year population estimates published by Stats South Africa[3]. RCC usage is calculated as a ratio of the number of products issued per 1000 people within the province's population.

The overall RCC transfusion rate for the country declined from 24.1 per 1000 population in 2019 to 20.3 in 2020. The majority of RCC products were issued in the three most populated provinces in South Africa, namely Gauteng, KwaZulu-Natal and the Western Cape. Gauteng had the highest RCC transfusion rate per 1000 population at 22.8, which is lower than the transfusion rate seen in 2019. The Western Cape had the second highest transfusion rate at 17.6, while the Eastern Cape, the fourth most populated province in South Africa, had the lowest RCC transfusion rate in the country (9.9). All provinces showed a decline in transfusion rates compared to 2019. The increase in transfusion rates between 2018 and 2019 is explained in the 2019 South African Haemovigilance Report and is attributed to increased blood collection strategies by SANBS resulting in improved availability of blood products to healthcare facilities.

Analysis of transfusion rates requires an understanding of the distribution of healthcare resources in South Africa. The three most populated provinces have access to relatively advanced healthcare services and tertiary hospital facilities, while the less populated provinces are more rural and have limited healthcare resources.

Table 3: Red cell concentrate transfusion rates by South African province

Province	Population	% Country Population	RCC Usage	% RCC	Transfusion Rate per 1000 Population
Gauteng	15 488 137	25.98	352 371	36.95	22.75
KwaZulu-Natal	11 531 628	19.34	172 924	18.13	15.00
Western Cape	7 005 741	11.75	123 241	12.92	17.59
Eastern Cape	6 734 001	11.29	66 591	6.98	9.89
Limpopo	5 852 533	9.82	74 000	7.76	12.64
Mpumalanga	4 679 786	7.85	63 993	6.71	13.67
North West	4 108 816	6.89	48 552	5.09	11.82
Free State	2 928 903	4.91	38 930	4.08	13.29
Northern Cape	1 292 786	2.17	13 158	1.38	10.18
Total	**59 622 331**	**100.00**	**953 760**	**100.00**	**20.29**

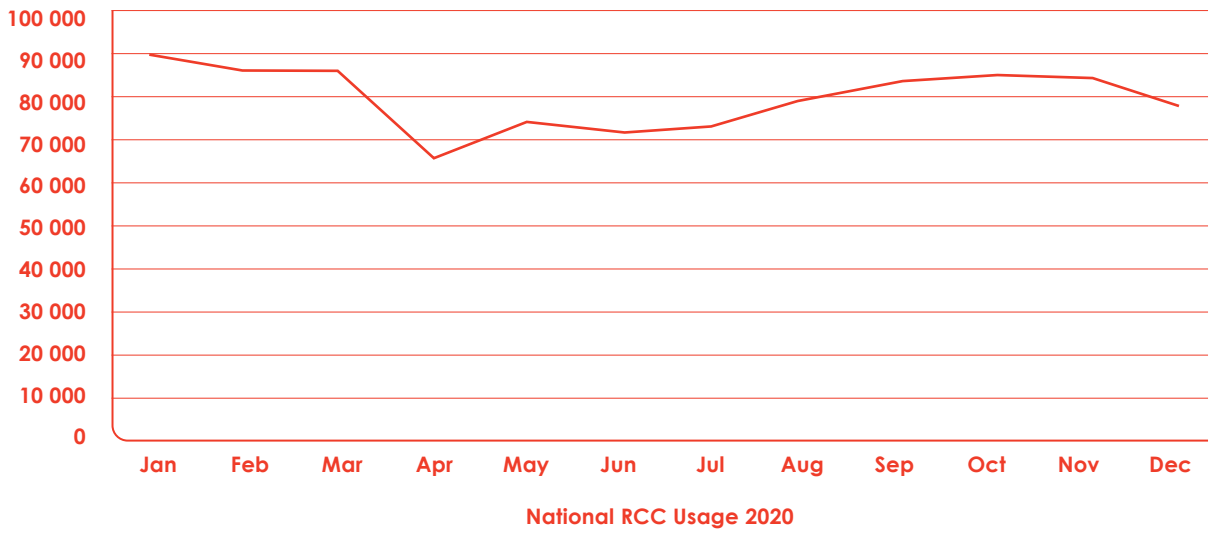
Table 4: Comparison of red cell concentrate transfusion rates per 1 000 population, 2018–2020

	2018	2019	2020
Gauteng	23.26	28.42	22.75
KwaZulu-Natal	13.67	18.21	15.00
Western Cape	19.98	20.72	17.59
Eastern Cape	10.85	12.79	9.89
Limpopo	12.09	15.2	12.64
Mpumalanga	12.68	15.49	13.67
North West	11.35	14	11.82
Free State	13.9	16.56	13.29
Northern Cape	11.43	13.67	10.18

2.3 National monthly RCC usage 2020

It is useful to review national RCC usage in 2020 on a monthly basis to assess the effect of the COVID-19 lockdown periods and the 'waves' of reported infection. Level 5 lockdown was implemented between 26 March and 30 April 2020 and resulted in both the social restriction of the population and the limitation of non-emergency medical procedures and consultations. The effect of these strategies resulted in the decline in national RCC usage by 22.6% between 26 March and 30 April. RCC usage increased slightly in May, then plateaued for the following two months while the 'first wave' of COVID-19 infection hit the country. Usage increased slightly from July to October when lockdown restrictions were eased, and dropped again at the start of the 'second wave' in December.

Graph 1: Monthly red cell concentrate usage in South Africa

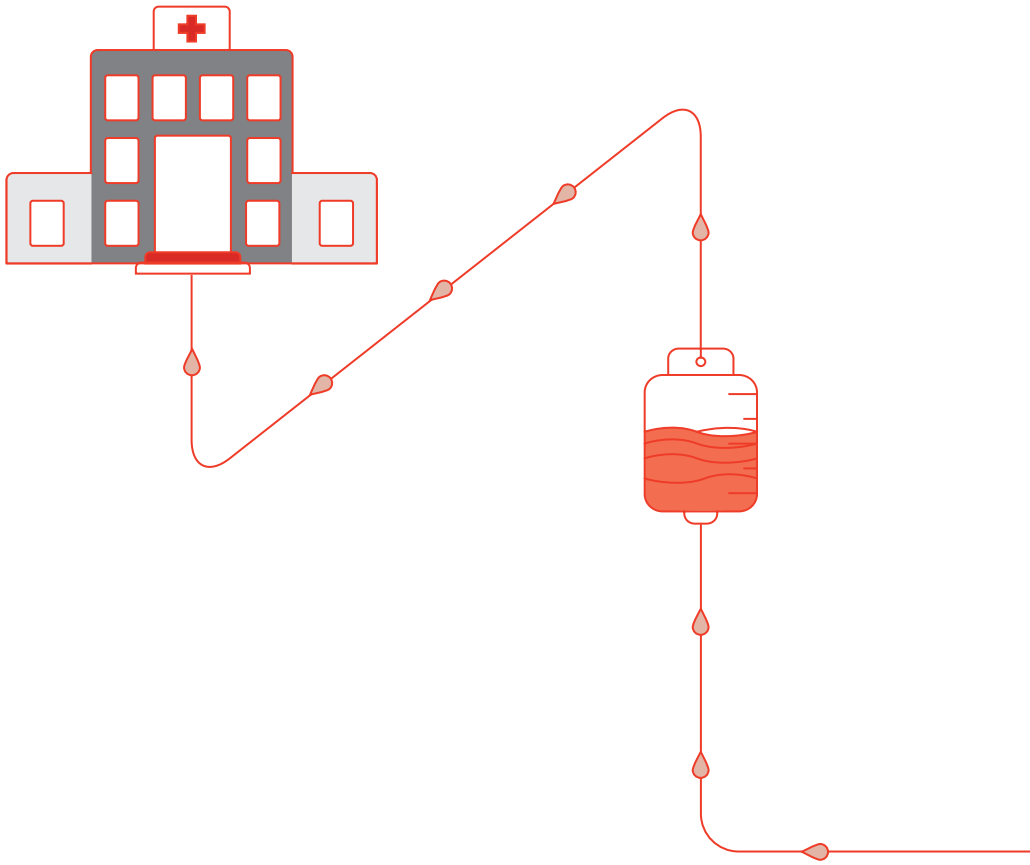


2.4 Private vs public RCC usage

Data for the 2020 calendar year shows that 61.3% of all RCC products were issued to the public sector, which is similar to the figure for 2019 (62.2%). However, the last General Household Survey conducted in South Africa in 2018, found that 83.6% of the population access the public sector for their medical care[3]. This would suggest a disproportionately high blood usage in the private sector compared to the public sector. The practising of restrictive blood product usage and access to blood products also influence blood usage in these sectors.

Table 5: RCC percentage usage in South African private and public sectors.

RCC Percentage Usage	2019	2020
Private	37.78	38.66
Public	62.22	61.34



Chapter 3:

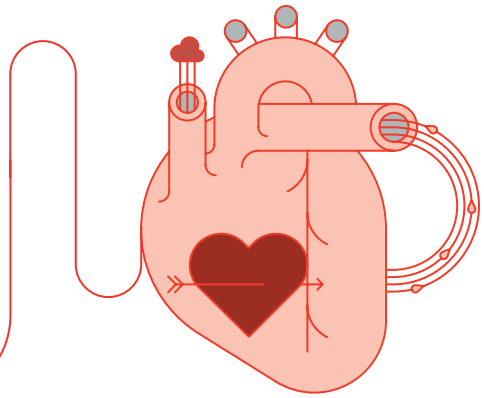
Transfusion-Related Adverse Events

The transfusion of blood and blood products is a core part of healthcare service delivery, but it poses potential life-threatening risks to the patient that should be carefully explained during the informed consent procedure.

3.1 Transfusion-related adverse events

A total of 1 042 transfusion-related adverse events were reported to and classified by the South African blood services in 2020, resulting in an adverse event rate of 86.2 per 100 000 patients transfused. This is higher than the overall rates reported in 2018 (81.4) and 2019 (78.0). The accuracy of these data is dependent on the voluntary reporting of transfusion-related adverse events to the blood services, which is surmised to be imprecise and likely an underestimation.

Febrile non-haemolytic transfusion reactions (FNHTR) were most commonly reported (31.9%), followed by allergic reactions (comprising mild allergic, severe allergic and anaphylactic subgroups) at 30.1%. 'Unclassifiable' reactions were the third most common group (21.6%) and are defined as reactions that are attributable to the transfusion of a blood product, but where classification is not possible due to incomplete provision of information. It can be challenging for the haemovigilance team to contact the treating clinician to discuss a reaction in more detail and additional investigations (such as chest x-rays for dyspnoea-related adverse reactions) may not have been done. There were no reports of acute or delayed haemolytic reactions from incompatible blood transfusions despite 30 events of misdirected transfusions. Three incidents of transfusion-related acute lung injury (TRALI) and five incidents of transfusion-associated circulatory overload (TACO) were reported in 2020, which was an increase compared to the previous two years.



3.2 Incorrect blood products transfused

Misdirected transfusions increased to 2.5 per 100 000 transfusions compared to 2018 (2.1/1 000) and 2019 (1.4/1 000). Misdirected transfusions are preventable errors where blood cross-matched for a patient is erroneously transfused to another patient. This can have life-threatening consequences in the event of an acute haemolytic transfusion reaction (AHTR) and is an area that the blood services dedicate significant training resources to. For the purposes of corrective-action implementation, each incident is carefully investigated to establish whether the error was attributable to hospital or blood bank staff. All such incidents are also reported to the hospital's Quality Assurance department.

Table 6: Transfusion-related adverse events

	Number	Percentage	Adverse Event per 100 000 Units Issued
Acute haemolytic transfusion reactions (AHTRs)	0	0	0
Allergic reactions	223	21.40	18.44
Severe allergic reactions	47	4.51	3.89
Anaphylactic reactions	44	4.22	3.64
Febrile non-haemolytic reactions (FNHTRs)	332	31.86	27.45
Transfusion-associated circulatory overloads (TACOs)	5	0.48	0.41
Transfusion-related acute lung injuries (TRALIs)	3	0.29	0.25
Transfusion-associated dyspnoea (TAD)	86	8.25	7.11
Hypotensive reactions	45	4.32	3.72
Unclassifiable due to incomplete or insufficient information	225	21.59	18.60
Total acute transfusion reactions	**1010**	**96.92**	
Delayed haemolytic transfusion reactions (DHTRs)	0	0	0
Delayed serological transfusion reactions (DSTRs)	0	0	0
Total delayed transfusion reactions	**0**	**0**	**0**
Misdirected transfusions (with and without ABO incompatibility)	30	2.88	2.48
Near misses	2	0.20	0.17
Transfusion-associated graft-versus-host disease (TA-GvHD)	0	0	0
Transfusion-transmitted infections	0	0	0
Grand total	**1042**	**100**	**86.16**

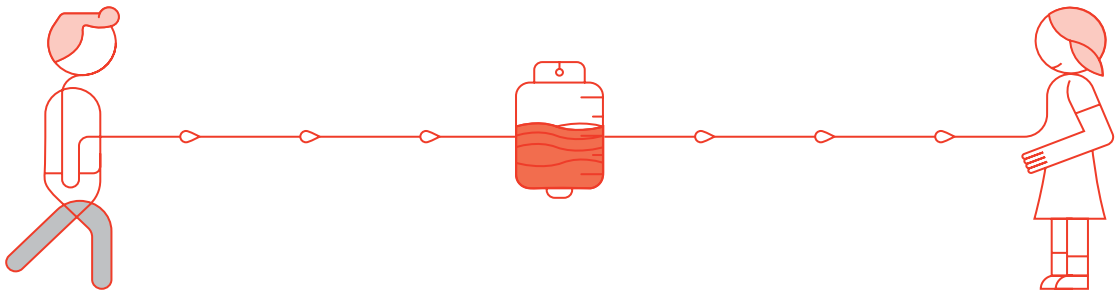


Table 7: Transfusion-related adverse events per 100 000 units blood products issued 2018–2020

	2018	2019	2020
Acute haemolytic transfusion reactions (AHTR)	0	0	0
Allergic reactions	21.6	18.27	18.44
Severe allergic reactions	1.4	4.13	3.89
Anaphylactic reactions	4	3.43	3.64
Febrile non-haemolytic reactions (FNHTRs)	25.1	23.10	27.45
Transfusion-associated circulatory overloads (TACOs)	0	0.21	0.41
Transfusion-related acute lung injuries (TRALIs)	0	0	0.25
Transfusion-associated dyspnoea (TAD)	5.6	5.25	7.11
Hypotensive reactions	2.7	5.25	3.72
Unclassifiable due to incomplete or insufficient information	16	17.64	18.60
Delayed haemolytic transfusion reactions (DHTRs)	0	0	0
Delayed serological transfusion reactions (DSTRs)	0	0	0
Misdirected transfusions (with and without ABO incompatibility)	2.1	1.4	2.48
Near miss	1.35	1.12	0.17
Total adverse reactions per 100 000 products transfused	**81.44**	**77.98**	**86.16**

3.3 Patient mortalities

There were 27 cases of potential transfusion-related patient deaths reported to the South African blood services in 2020. It was not possible to investigate whether these mortalities were causally related to the transfusion of a blood product as no autopsies were performed. The inability to fully investigate these cases again highlights the barriers to accurate haemovigilance surveillance in resource-poor settings with passive reporting systems.

Chapter 4:

Transfusion-Transmitted Infections and Lookback Investigations

In South Africa, all blood donations are screened for hepatitis B virus (HBV), hepatitis C virus (HCV), human immunodeficiency virus (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 blood services 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 2020, 2 959 of the1 035 902 donations collected, tested positive for HIV, HBV and/or HCV. Of these viral-positive donation, 2010 (0.19%), 842 (0.08%) and 107 (0.01%) donors tested positive for HIV, HBV and HCV respectively. All viral-positive donors are traced by the blood services and, if reached, offered counselling or referred for counselling at other healthcare facilities. Contacting donors is a major challenge to this process and is hampered by movement of people to undisclosed addresses or refusal to engage with the blood service staff. There were no confirmed incidents of transfusion-transmissible infection (TTI) in 2020.

4.1 Lookback investigations

All cases of potential TTI are investigated by the SANBS Lookback Office or WCBS Specialised Donation Department. The number of lookback investigations has steadily increased over the past decade, and has ranged between 866 and 949 cases on an annual basis in the past five years (Table 8).

Lookback cases are classified as either donor- or recipient-triggered. In a donor-triggered lookback investigation, a repeat blood donor tests positive for one of the screened viral infections and the recipients of the blood products from the previous donation are traced for testing to exclude a possible window period donation. Testing of patients involved in donor-triggered lookback cases should be managed by the treating clinicians. A recipient-triggered lookback investigation is initiated when the blood service is informed that a blood product recipient has tested positive for a TTI and 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 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.

The lookback services in South Africa face multiple challenges that result in the incomplete investigation of these cases. These include poor cooperation from healthcare facilities or doctors in contacting their patients for re-testing due to resource constraints, increasing workload and lack of awareness of the role of haemovigilance monitoring. The incomplete capturing of patient information by hospitals and the relocation of people also pose challenges. SANBS and WCBS will 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.

Table 8: Total number of donor-triggered lookback investigations 2010–2020

	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020
Total	546	642	629	849	1129	978	979	948	866	884	916

4.2 Donor-triggered lookback investigations

Tables 9 and 10 detail the 916 donor-triggered lookback cases investigated in 2020. Of these, two-thirds (66.4%) were investigations for potential window-period transmission of HIV, 28.2% for hepatitis B and 4.6% for hepatitis C. There were two lookback investigations for infections not routinely tested for by the blood services, namely rickettsia and influenza. These were reported by people who had donated blood and subsequently tested positive for these infections. They informed SANBS, but their blood products had already been transfused to a patient.

Table 10 summarises the outcomes of the investigations and shows that 52.3% of cases were resolved, which is an improvement from 2019 when 63.4% of cases remained unresolved. Of the cases where investigations were completed, 21.8% of patients under investigation had died, 19.5% tested negative for the infection under investigation, and 10.6% were already known to be positive with the infection prior to transfusion. Phylogenetic testing was performed in three cases and found to be negative in all. A total of 152 patients could not be traced for further investigation, which highlights one of the shortfalls of this programme.

Of the 258 recipients investigated for potential HBV transmission, seven people demonstrated evidence of immunity to hepatitis B (surface-antibody positive, core-antibody negative) which was suggestive of past infection or immunisation.

Table 9: Donor-triggered lookback investigations: transfusion-transmissible infections 2020

	2020
HIV	608
HBV	258
HCV	42
HIV/HBV co-infection	3
HIV/HCV co-infection	1
HBV/HCV co-infection	2
Other (Rickettsia and influenza)	2
Total	**916**

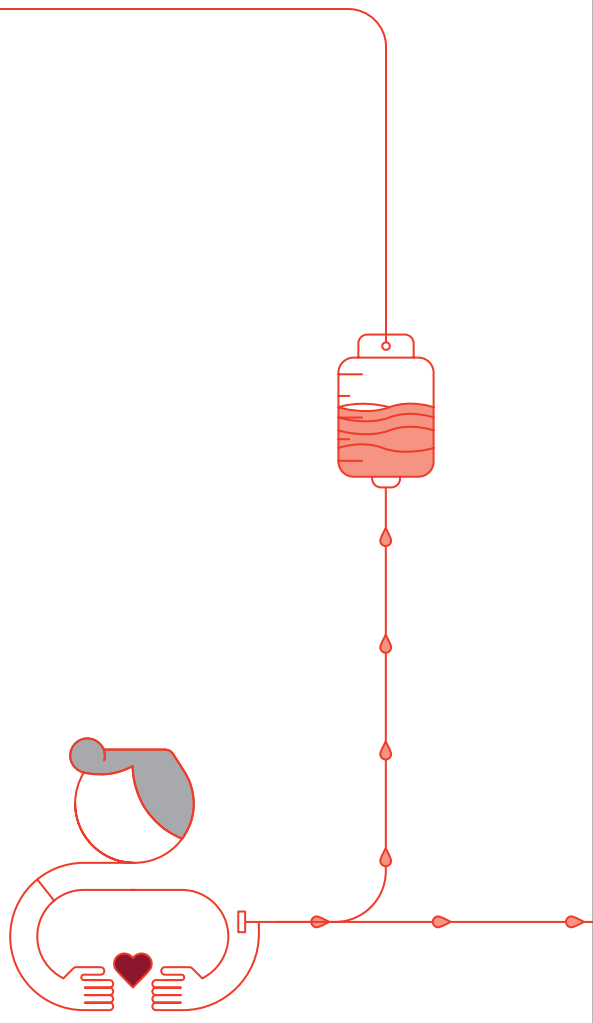


Table 10: Donor-triggered lookback investigations: outcomes

Investigation Outcomes	Total
Recipient died between transfusion and initiation of lookback investigation	200
Recipient tested negative for infection under investigation	179
Recipient tested positive for infection prior to transfusion	97
Phylogenetic analysis performed and confirmed negative (HIV)	1
Phylogenetic analysis performed and confirmed negative (HBV)	2
Unresolved cases (e.g. patient's clinician has been contacted but no feed-back provided)	240
Recipient could not be traced	152
Recipient declined testing	3
Other*	35
Total	**916**

**Refers to situations not described above (e.g. clinician could not be traced or had died, recipient was contacted but did not attend appointment for testing, hospital unable to provide recipient contact information).*

4.3 Recipient-triggered lookback investigations

A total of six recipient-triggered lookback cases were reported in 2020, all for the investigation of suspected HIV transmission (Table 11). Phylogenetic testing was performed in one case, while two are still awaiting collection of samples from donors.

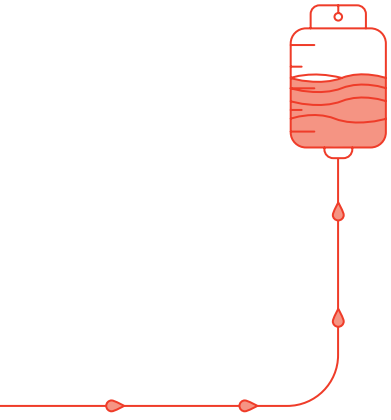


Table 11: Recipient-triggered lookback cases 2020

	Resolved	Unresolved
HIV	4	2
HBV	0	0
HCV	0	0
Other	0	0
Total	**4**	**2**

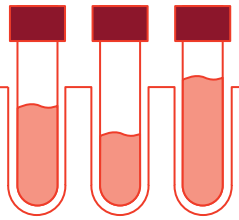
Chapter 5:

Bacterial Surveillance (SANBS) 2020

Compiled by Dr Ute Jentsch

Note: *the information in this chapter reflects testing at SANBS only and is aligned with the financial-year period (April 2020 to March 2021). WCBS does not have a dedicated microbiology surveillance laboratory but performs testing on a defined percentage of products as per quality control (QC) specifications.*

5.1 Bacterial surveillance and COVID-19



SANBS performs bacterial surveillance of the following:

- SDP and RDP products
- Red blood cell, plasma and QC samples
- Special products such as serum eye drops and stem cells
- Environmental sampling from apheresis clinics and SANBS laboratories
- Specialised areas such as clean rooms and the cellular therapy laboratory

The COVID-19 pandemic has affected the overall infection prevention control (IPC) scores of both products and the environment in a positive manner.

Table 12: Infection prevention control overview

IPC 2020/2021 (Year To Date)	Donor Clinics	Processing Labs	Labs/Blood Banks	Cellular Therapy Lab/ Clean Areas	Products
Overall IPC bacterial surveillance score	99%				
IPC audits	Including regular COVID-19 compliance audits				
Personal protective equipment (PPE) and disinfectants		Scrubs required for good manu-facturing process (GMP)	Material-based lab coats to be piloted		
IPC training	308 SANBS staff trained to date		N/A		
Basic housekeeping	Additional cleaning of surfaces and common touch items ongoing due to COVID-19				
National Hamper Hygiene Plan	National hamper cleaning in the process of being implemented		N/A		

5.2 Summary of product sterility and environmental cleanliness compliance 2020/2021

The microbiology laboratory in the QC Department performs bacterial screening to monitor the bacterial contamination rate of blood products and the environmental level of cleanliness.

Table 13: Summary of bacterial surveillance

% Compliance	SDP	RDP	Eye Serum	Stem Cells	Apheresis Environ-ment	Product Environ-ment	Lab Envi-ronment	Blood Bank Environ-ment	Cellular Therapy Lab Envi-ronment
Targets	95	95	100	100	<2+ growth	<2+ growth	<2+ growth	<2+ growth	0 growth
Q1	99.7	98.8	100.0	100	99.5	100	100	100	100
Q2	99.7	99	95.2	100	100	97.7	100	100	100
Q3	99.1	98.3	91.5	99	99.8	98.9	100	Not done	100
Q4	99.7	99.6	100	100	100	100	100	100	100
Average	99.6	98.9	96.7	99.7	99.8	99.1	100	100	100

Comments

- Overall product and environmental sterility scores have been consistently within target.
- Q2: Fungal growth was detected in one eye serum batch, which was discarded.
- Q2: One processing laboratory had evidence of bacterial contamination above the target, which was addressed.
- Q3: Media was not available due to lack of supplier availability.

5.3 Bacterial surveillance of blood products

Both SDP and RDP products are stored at room temperature and are a sensitive marker of the level of bacterial contamination. A QC model is followed whereby a proportion of SDP collections are tested for 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.

Contaminated products in the inventory are quarantined and discarded. No reports of bacterially contaminated products resulting in sepsis or patient mortality have been received by the SANBS Haemovigilance Programme. As this is a passive reporting system, these adverse events are likely under-reported.

The sterility scores for both SDP and RDP have been maintained at over 99%. In 2020/2021 SANBS performed QC testing on 65% of all SDP collections and on 3.8% of all RDP collections. Sterility testing is performed for all stem cell products and these results are excellent at 99.7%, with 100% scores achieved in three of four quarters.

Summary of microorganisms isolated per quarter from SDP products

Of the 30 bacteria that were isolated, 28 (93.33%) were Gram-positive bacteria, indicating skin and environmental commensals that remain the most common isolates in platelet products.

Two typical pathogens were isolated from stem cell products: Klebsiella pneumoniae and Staphylococcus aureus respectively. Bacterial sterility testing is routinely performed on all stem cell products, and the products are not released prior to availability of sterility results. In both instances the treating doctor was notified and the product was not released. In one instance, the same organism was cultured in the donor, suggesting the product was received already contaminated.

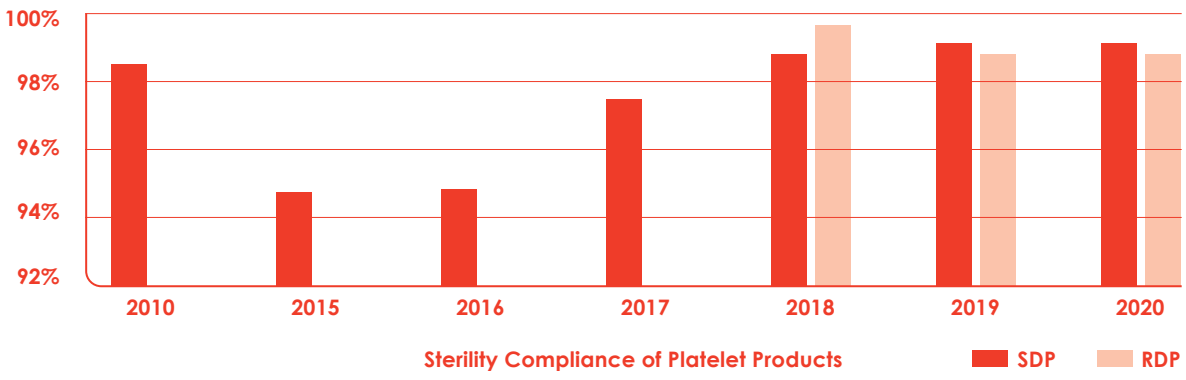
Table 14: Microorganisms isolated per quarter

	Cocci n = 16				Bacilli n = 14			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Gram-positive bacteria	7	2	4	3	1	9	3	1
Gram-negative bacteria	0	0	0	0	0	3	0	0
Fungi n = 0	0	0	0	0	0	0	0	0

Table 15: Organism species

	Q1	Q2	Q3	Q4
Organisms	Micrococcus luteus (x 3)	Staphylococcus epidermidis	Staphylococcus epidermidis	Staphylococcus epidermidis Staphylococcus warneri
	Staphylococci spp. (x 3)	Bacillus spp.	Bacillus cereus	Bacillus cereus
	Streptococcus mitis	Kocuria rosea	N/A	N/A
True pathogens	None	Staphylococcus aureus Klebsiella pneumoniae	None	None

Graph 2 Annual trends of platelet sterility



5.4 Environmental surveillance

Environmental samples from apheresis clinics are collected monthly and include samples from benches, air, hands and utensils/equipment. Environmental screening is now well entrenched in blood banks and processing sites. Overall, the level of hygiene is of a high standard. Increasing the cleaning frequency at all sites, using detergent and alcohol wipes, due to COVID-19 precautions has optimised environmental hygiene.

It is evident and encouraging that the rate of bacterial contamination of SDP and RDP products is being maintained at very low levels using conventional bacterial screening.

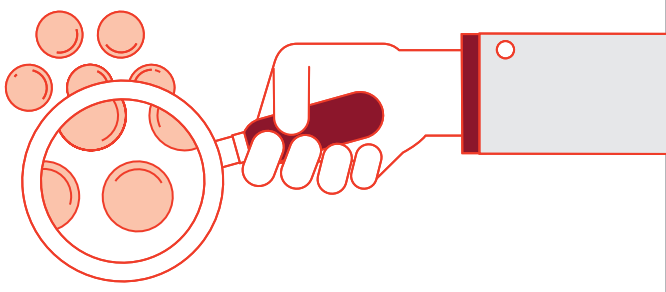
5.5 IPC training (learning and development)

Table 16: Summary infection prevention control training

	Eastern Cape	Free State/ Northern Cape	KwaZulu-Natal	Mpuma-langa	Vaal	Egoli	Northern Zone	Total
Q1	22	22	42	0	0	8	0	94
Q2	29	5	33	1	4	2	22	96
Q3	5	7	21	5	1	5	11	55
Q4	Online IPC training with certification				63			
Total	51	27	75	1	4	10	22	308

Comments

- 308 staff have been trained in IPC during the 2020/2021 financial year, using virtual platforms.
- The IPC induction booklet for cleaners has been developed.



5.6 IPC/GMP-compliant work clothing

In line with enhanced IPC awareness and practice at SANBS, more suitable staff work clothing is being looked at. It should be IPC/GMP-compliant, reflect the SANBS brand and support the Going Green initiative. The first objective for processing laboratories that are working towards GMP certification is the replacement of disposable laboratory coats with cotton coats, followed by the replacement of scrubs.

Chapter 6:

Donor Vigilance

While blood donation is generally a safe process, recognised complications can occur that negatively impact donor retention. It is important to monitor these complications and evaluate the effect of changes in pre-donation care and donation procedures in order to reduce these events. DAEs occur either at the clinic, where they are reported by the blood service staff, or after the donor has left the clinic, when reporting is dependent on the donor contacting the blood services.

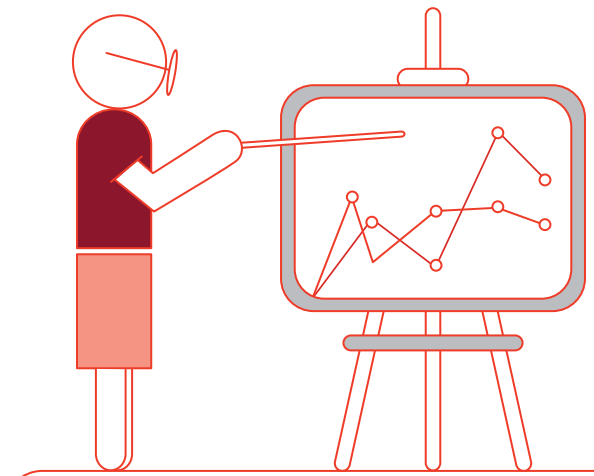
A total of 1 035 902 blood donations took place at the South African blood services in the 2020 calendar year. There were 4 537 DAEs reported for the year, which translates to a DAE rate of 4.38 per 1 000 donations. This is similar to the 4.58 per 1 000 donations recorded in 2019.

The most frequently reported DAE was vasovagal reactions (80.2%), of which the majority occurred at the donation clinic (71.2%) Of the 3640 vasovagal reactions reported, 179 (4.9%) were associated with some degree of injury to the donor. Haematoma at the venepuncture site is the second most commonly reported DAE (13.8%), followed by painful arm after donation (3.4%). Citrate reactions can occur with apheresis collection procedures, most commonly SDP collections, due to the introduction of this anticoagulant into the donor's circulation and a resultant temporary drop in plasma calcium levels. Citrate reactions saw a slight decline from 0.1 in 2019 to 0.06 per 1 000 donations in 2020.

Table 17: Donor adverse events 2020

		2019	DAE Rate 2019	2020	DAE Rate 2020
Local reactions	Haematoma	703	0.064	626	0.060
	Arterial puncture	2	0	2	0
	Delayed bleeding	28	0.003	31	0.003
	Nerve irritation	3	0	6	0.001
	Tendon injury	0	0	1	0
	Nerve injury	2	0	5	0
	Painful arm	158	0	154	0.015
Vasovagal reactions	Faint immediate type	2749	0	2484	0.240
	Faint immediate, accident	126	0.011	107	0.010
	Faint delayed type	1057	0.096	977	0.094
	Faint delayed, accident	104	0	72	0.007
Other reactions	Citrate reaction	106	0.010	57	0.006
	Haemolysis	18	0.002	0	0
	Generalised allergic reaction	2	0	8	0.001
Total		**5058**	**0.458**	**4537**	**0.438**

DAE definitions as per the International Society for Blood Transfusion (ISBT) IHN Working Group (2014): Standard for Surveillance of Complications Related to Blood Transfusion (www.isbt.org)

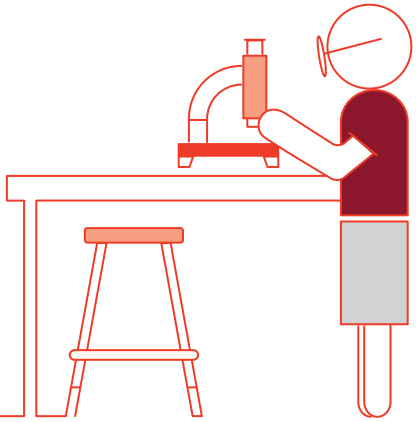


Chapter 7:
Conclusion

Conclusion

The COVID-19 pandemic hit South Africa in 2020 and resulted in changes to blood product usage and collection practices that the blood services have had to manage. Despite these challenges, SANBS and WCBS remain committed to ensuring delivery of the safest blood supply reasonably possible, and to reporting haemovigilance-related matters in a non-biased manner. This function will ultimately be performed by an external committee but will be supported completely by both blood services, who endeavour to continuously educate healthcare providers about the risks of blood product transfusions, the importance of obtaining informed consent from patients, and the necessity to monitor, investigate and report transfusion-related adverse events.

The success of any haemovigilance programme relies on accurate reporting of adverse events by clinicians and donors, and we thank those who have cooperated in these processes.



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Appendix 1

Transfusion Reaction Classifications and Definitions (IHN)

Definitions 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 reactions	Transfusion-related reactions that occur 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 reactions	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 bronchospasm causing hypoxia or angioedema causing respiratory distress.
Transfusion-associated Dyspnoea	Respiratory distress within 24 hours of transfusion that does not meet the criteria of transfusion-related acute lung injury, transfusion-related circulatory overload or severe allergic reaction that is not explained by the patient's underlying condition.
Hypotensive transfusion reaction	A drop in systolic and/or diastolic pressure of >30mm Hg occurring within one hour of completing the transfusion, provided all other adverse reactions with underlying conditions that could explain hypotension have been excluded.
Transfusion-associated circulatory overload	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 300mm Hg 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.

Category	Definition
Anaphylactic transfusion reactions	Hypotension, with one or more of urticaria, rash, dyspnoea, angioedema, stridor, wheezing and pruritus, within 24 hours of transfusion.
Febrile non-haemolytic transfusion reactions	Isolated fever of >39°C or equivalent, or a change of between 1-2°C from pre-transfusion 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.
Delayed transfusion reactions	Transfusion-related reactions that occur after 24 hours following transfusion of blood or components.
Delayed haemolytic transfusion reactions	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 reactions	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 to 12 days following transfusion of cellular blood components, associated with the presence in the patient of alloantibodies directed against the human platelet antigen system.
Transfusion-associated graft-versus-host disease	The introduction of immunocompetent lymphocytes into a susceptible host. The allogeneic lymphocytes engraft, proliferate and destroy host cells. Symptoms develop within 30 days of transfusion, presenting with fever, rash, liver function abnormalities, diarrhoea, pancytopenia and bone marrow hypoplasia.
Transfusion-transmitted infections	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 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 infections	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.

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SANBS Head Office
1 Constantia Boulevard,
Constantia Kloof, Extension 22,
Weltevreden Park 1715
www.sanbs.org.za

WCBS Head Office
Old Mill Road, Pinelands
Postal Address PO Box 79,
Howard Place, 7450
www.wcbs.org.za