THE 2019 SOUTH AFRICAN HAEMOVIGILANCE REPORT

Western Cape Blood Service
Do something remarkable

SANBS
South African National Blood Service

Haemovigilance Report 2019

The 20th South African Haemovigilance Report

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This report does not identify or attempt to identify individual patients, clinicians or healthcare institutions. On the contrary, every reasonable effort has been made to prevent their identification.

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 only on adverse transfusion-related events in South African hospitals. This report is a snapshot of currently available data, which have been obtained from limited resources.

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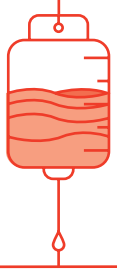
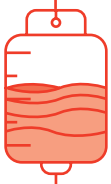


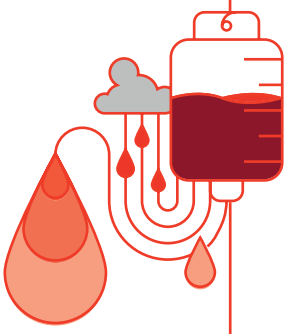
Abbreviations

CATEGORY	DEFINITION
AHTR	Acute haemolytic transfusion reaction
ATR	Acute transfusion reaction
DAT	Direct antiglobulin test
DHTR	Delayed haemolytic transfusion reaction
DSTR	Delayed serological transfusion reaction
FFP	Fresh frozen plasma
FNHTR	Febrile non-haemolytic transfusion reaction
HBV	Hepatitis B virus
HCV	Hepatitis C virus
HIV	Human immunodeficiency virus
HLA	Human leucocyte antigen
IBCT	Incorrect blood component transfused
IHN	International Haemovigilance Network
RCC	Red cell concentrate
SANBS	South African National Blood Service
SDP	Single donor platelet
TA-GvHD	Transfusion-associated graft-versus-host disease
TTI	Transfusion-transmissible infections
TRALI	Transfusion-related acute lung injury
TACO	Transfusion-associated circulatory overload
WCBS	Western Cape Blood Service

Transfusion reaction classifications and definitions

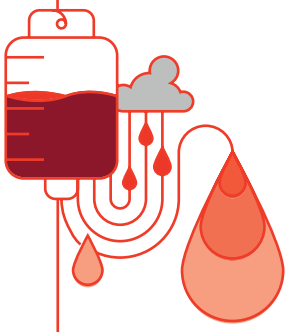


CATEGORY	DEFINITION
Acute transfusion reactions	Transfusion-related reactions that occur at any time during or up to 24 hours following transfusion of blood or components. The most frequent reactions are fever, chills, pruritus or urticaria, which typically resolve promptly without specific treatment 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.

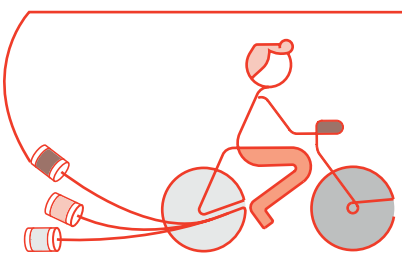


CATEGORY	DEFINITION
Transfusion-associated Dyspnoea	Respiratory distress within 24 hours of transfusion that does not meet the criteria of transfusion-related acute lung injury, transfusion-related circulatory overload or severe allergic reaction that is not explained by the patient's underlying condition.
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	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.
Anaphylactic transfusion reactions	Hypotension, with one or more of urticaria, rash, dyspnoea, angioedema, stridor, wheezing and pruritus, within 24 hours of transfusion.

Transfusion reaction classifications and definitions



CATEGORY	DEFINITION
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	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.



CATEGORY	DEFINITION
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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Foreword: A message from the Medical Directors

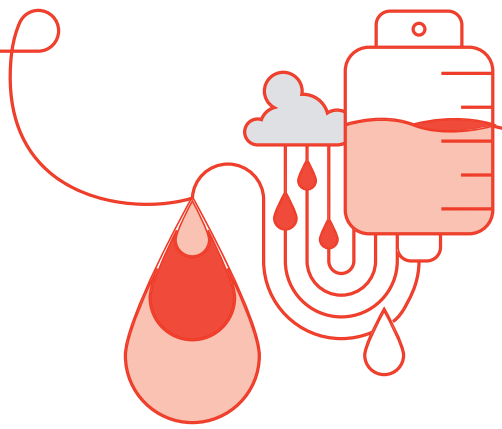
Haemovigilance is a relatively new area of transfusion medicine, and is indispensable to the safety and quality of blood transfusions. Triggered by the tragic events of contaminated blood in the 80s–90s, the pioneering work on haemovigilance was carried out in France in 1992. Thereafter, other countries, such as Germany in 1994, Greece in 1995, Luxembourg and the UK in 1996 developed haemovigilance programmes, which were driven by and focused on improving transfusion safety from the vein of the blood donor to the vein of the patient.

After two decades, haemovigilance has grown into a worldwide network which observes, records, collects, reports, monitors, evaluates and analyses the blood transfusion information in a controlled way, and uses its results to identify preventable errors, assess the hazards, and recommend or implement measures of corrective action. By operating this haemovigilance programme, the untoward effects of blood transfusion can be better understood and the quality and safety of the transfusion chain improved. Therefore, the WHO recommended the development of haemovigilance systems to monitor and improve the safety of transfusion processes, in December 2007.

The South African haemovigilance programme currently operates as a passive and voluntary system compared to that of other developed countries, where mandatory reporting of all adverse events associated with transfusions is legislated by law. The haemovigilance divisions of South African National Blood Service (SANBS) and Western Cape Blood Service (WCBS) receive adverse transfusion reaction reports from clinicians throughout all hospitals in South Africa. These blood services' haemovigilance teams review these reaction reports and additional information is sought from the reporting clinician, when required, to accurately classify the type and severity of the adverse event. The data is collated nationally for submission to the International Haemovigilance Network (IHN) and for publication in the annual National Haemovigilance Report, as required by the Department of Health. The haemovigilance definitions and reporting structure are based upon those agreed by the International Society of Blood Transfusion Working Party on Haemovigilance in collaboration with the IHN (ISBT/IHN).

During the next year, our haemovigilance team will be implementing projects to further improve the haemovigilance system, including the following:

- Implementing an electronic system for capturing monitoring trend analysis and reporting.
- Identifying important measurements for monitoring.
- Improving collaboration between internal teams.
- Improving reporting and corrective action through hospital liaison and medical liaison teams.
- Improving educational content designed in accordance with trends in errors.



We believe that in this way we can continue to further improve blood donor, and patient outcomes.

Executive Summary

This 2019 South African Haemovigilance Report is the 20th edition. It provides an overview of blood transfusion and donation-related adverse events, and information on blood products issued to health care facilities in South Africa during the 2019 calendar year.

A total of 1 418 416 units of blood and blood products were issued by the South African blood services from 01 January 2019 to 31 December 2019. Of these, 1 148 235 (80.95%) were red cell concentrates (RCCs), 78 081 (5.50%) were platelet products and 192 100 (13.54%) were plasma products. Blood and blood product issues were compared over the three-year period from 2017 to 2019, and showed an increase of 33.40% in the use of RCC units, a 10.70% increase in the use of platelet products and a 6.86% increase in plasma products' usage. The likely reason for the increase in blood product usage relates to improved availability of blood products due to enhanced blood collection strategies by the South African Blood Service (SANBS). The use of single donor platelet (SDP) products has shown a gradual increase from 2017 with a shift towards 50:50 usage compared to random donor platelet (RDP) products. RDP usage has dropped from 58.42% of total platelet products in 2017 to 50.67% in 2019. The reasons for this deserve further exploration, as while SDP products reduce the risks of alloimmunisation and exposure to infection from multiple donors, these products are significantly more costly to the blood user, and more challenging for the blood collection services to produce.

In 2019, 1 114 adverse transfusion events were reported to the haemovigilance programmes of the South African blood services. Of these, 369 (33.13%) were allergic reactions (including mild allergic reactions, severe allergic reactions and anaphylaxis), 330 (29.62%) were febrile non-haemolytic transfusion reactions (FNHTRs), and 252 (22.62%) were regarded as unclassifiable reactions due to limited information in the report or confounding comorbid issues. Noting the adverse events associated with transfusion, the transfusion services are actively involved in and lead Patient Blood Management (PBM) initiatives in South Africa in an attempt to further the appropriate use of blood and blood products, thus optimising outcomes.

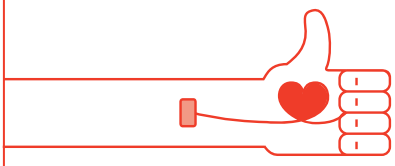
A total of 5 058 donor adverse events were reported in 2019 compared to 4 130 events recorded in 2017, showing a marked increase of 22.47%. This likely reflects improved capture and reporting of adverse event data, rather than deterioration in donor safety. The most frequently reported adverse incident associated with blood donation was vasovagal reactions, representing 79.79% of all donor adverse events.

In 2019, the national prevalence of HIV, HBV and HCV among the blood donor population was 0.21%, 0.10% and 0.01% respectively. There were no confirmed cases of transfusion-transmissible infections (TTIs), although investigations could not be concluded for several cases due to the lack of submission of patient blood samples. Phylogenetic analysis was required for the investigation of three cases of suspected TTIs.

The 2019 Haemovigilance Report notes thirteen key findings and eight recommendations:

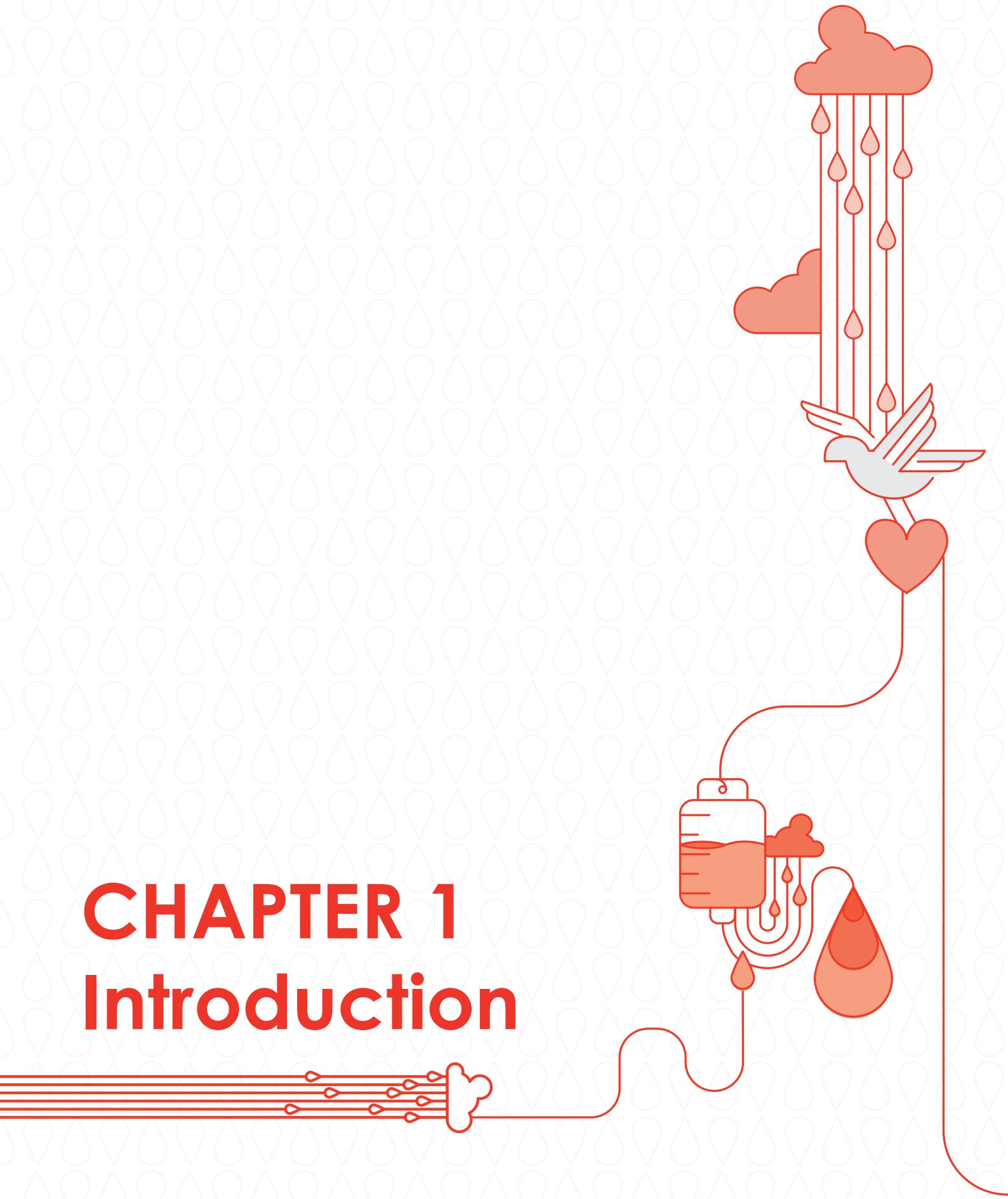
Key findings

1. There was a 27.61% increase in blood and blood products issued compared to 2017.
2. There was an increase in the transfusion rate per 100 000 of the South African population from 19.60 in 2017 to 24.13 in 2019 (23.11% increase).
3. In 2019, the majority (53.81%) of RCCs were issued in Gauteng and KwaZulu-Natal (KZN), the two provinces where 45.03% of the South African population reside.
4. The RCC transfusion rate was highest in Gauteng at 28.42 per 1 000 population, followed by Western Cape and KwaZulu-Natal at 20.72 and 18.21 per 1 000 of the population, respectively.
5. RCCs issued to public sector and private sector hospitals amounted to 62.22% and 37.78% respectively.
6. There were 348 022 patients who received blood and blood products in South Africa with the majority (72.73%) being in the public healthcare sector and 27.27% in the private healthcare sector.
7. In 2019 there was a 9.64% increase in the reporting of transfusion-related adverse events reported to the national haemovigilance programme compared to 2017.
8. Adverse transfusion events were reported in 77.98 per 100 000 blood and blood products units issued in 2019 compared to 91.41 per 100 000 units issued in 2017, demonstrating a 14.69% decrease.
9. There were no confirmed transfusion-related deaths reported in South Africa in 2019.
10. There were no confirmed transfusion-transmitted infections reported in the country in 2019.
11. The most frequently reported adverse transfusion events were allergic reactions and febrile non-haemolytic transfusion reactions (FNHTR, representing 33.13% and 29.62% of all adverse events respectively.
12. Human errors continue to contribute to transfusion-related adverse events – incorrect blood component transfused (IBCT) events comprised 1.9% of all adverse transfusion events. This is important to highlight as these incidents can be life threatening and should be easily avoidable by adhering to safe transfusion practices.
13. There were 5 058 donation-related adverse events reported in 2019 representing a 23.12% increase from 2017.



Recommendations

1. Promote the recognition and management of transfusion-related adverse events.
2. Maintain and improve existing capacities for haemovigilance data reporting.
3. Implement programmes at a national level to improve accurate haemovigilance reporting, including look-back investigations for suspected transfusion-transmitted infections.
4. Encourage thorough investigation of incidents to identify system-related and human factors that need to be addressed.
5. Continue to educate clinicians on basic PBM principles and the correct administration of blood and blood products.
6. Provide specific educational focus for the prevention of misdirected transfusions by encouraging hospital staff to be vigilant at each step of the transfusion process, particularly patient verification prior to transfusion.
7. Educate and train clinicians on the importance and availability of the lookback programme.
8. Encourage the use of information in the national haemovigilance report by clinicians and hospital management to initiate and guide patient blood management strategies.



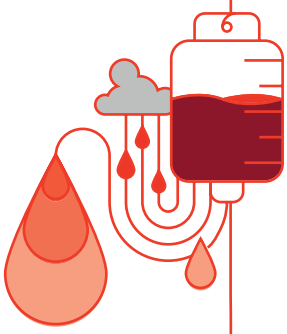
CHAPTER 1
Introduction

1.1 What is Haemovigilance?

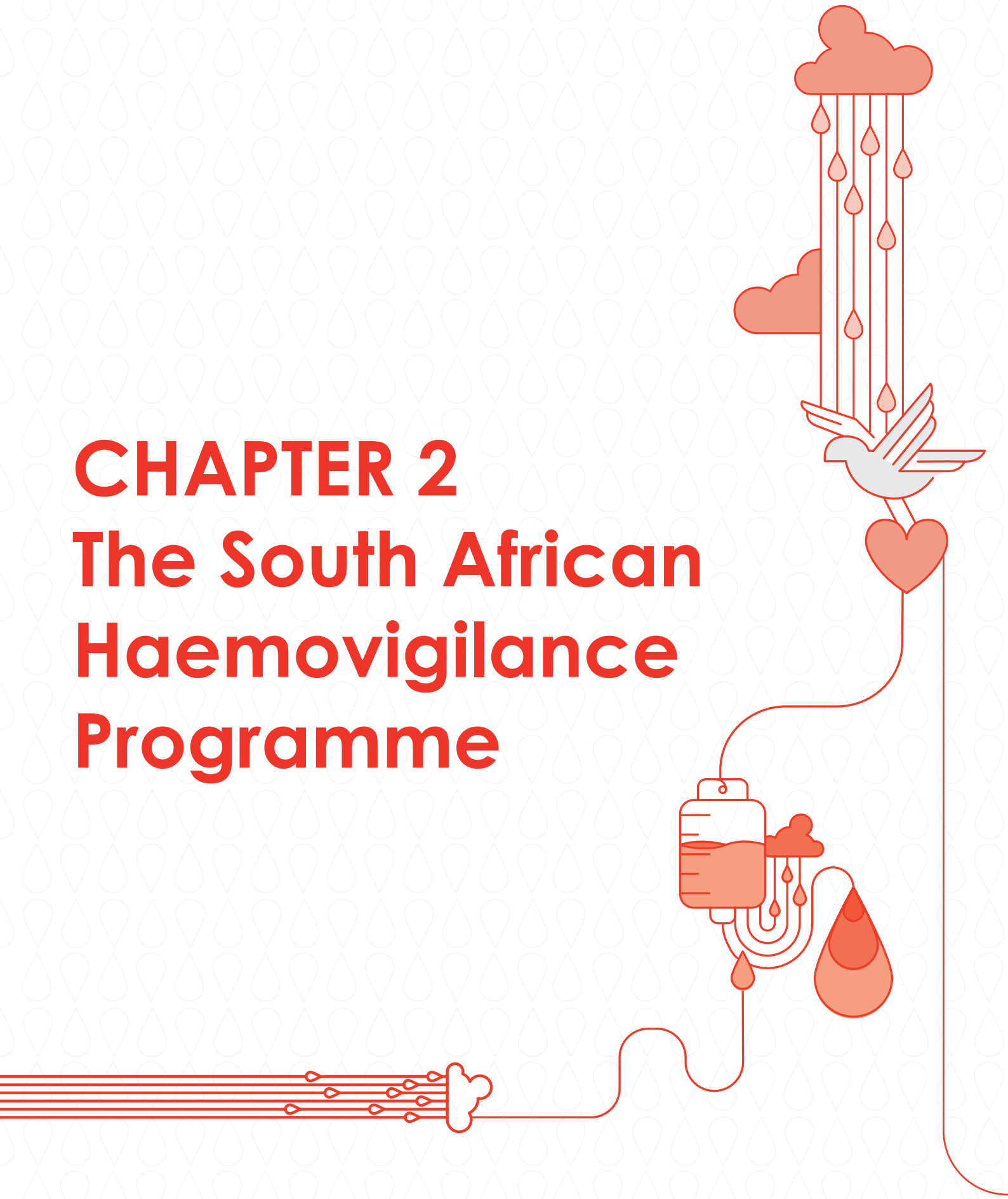
Haemovigilance involves the recording, reporting, analysis and evaluation of suspected adverse donation and transfusion events. Corresponding measures are then derived to improve the quality and safety of transfusions, thereby promoting patient safety. The system is based on the reporting of all incidents and reactions occurring during the transfusion process, from donor selection to the administration of blood products to the patient. The evaluation of haemovigilance provides a picture of the current transfusion-related risks, can pinpoint the cause of preventable transfusion incidents, and reveal areas where corrective measures are necessary and possible.

Accurate and valuable haemovigilance monitoring is dependent on reliable reporting. This responsibility lies in the hands of the donor, in the blood transfusion services as producers of labile blood products, and in the prescribing clinicians. The treating doctor is responsible for identifying and then reporting a transfusion reaction that occurs in his/her institution to a reporting body. It is important to note that different national haemovigilance programmes are managed by either competent regulatory authorities (e.g. France, Germany, and Switzerland), by blood transfusion services (e.g. Japan, Singapore, and South Africa), by professional organisations (e.g. Netherlands, and UK), by public health authorities (e.g. Canada), or by private/public partnerships (e.g. USA). The reports are compiled from the transfusion reaction data that is submitted by the treating clinicians. The analysis and evaluation of this data provide an up-to-date overall picture of transfusion safety, and the nature and magnitude of the risks expected during the transfusion of labile blood products.

In order to obtain a comprehensive overview of transfusion-associated incidents, the involvement of all institutions that administer blood components is essential. This requires direct communication between all involved stakeholders, as haemovigilance thrives on the interdisciplinary cooperation of all professionals involved in the handling of blood products. The implementation and maintenance of a high quality system poses a major challenge that should not be underestimated and one that requires great commitment from responsible stakeholders, as well as considerable resources and time.



CHAPTER 2
The South African Haemovigilance Programme



The South African Haemovigilance Programme was established in 2000. The haemovigilance divisions of the South African National Blood Service (SANBS) and the Western Cape Blood Service (WCBS) receive adverse transfusion reaction reports from clinicians in South African hospitals. The blood services' haemovigilance teams review the reports and if needed, additional information is sought from the reporting clinicians in order to accurately classify the type and severity of the adverse event.

The data is entered into a secure database in which clinicians and patients' names are not included. The data is collated nationally for submission to the International Haemovigilance Network (IHN) and for publication in the Annual National Haemovigilance Report, as required by the Department of Health. The haemovigilance definitions and reporting structure are based on those agreed upon by the International Society of Blood Transfusion Working Party on Haemovigilance in collaboration with the IHN.

2.1 Caveats

- Reporting of haemovigilance data to SANBS and WCBS is voluntary.
- Data is reconciled by both blood services.
- All the adverse events in this report are reported cases rather than confirmed cases.
- The definitions for the adverse events in this report align with those used by the International Haemovigilance Network (IHN) and International Society of Blood Transfusion (ISBT).

Figure 2.1

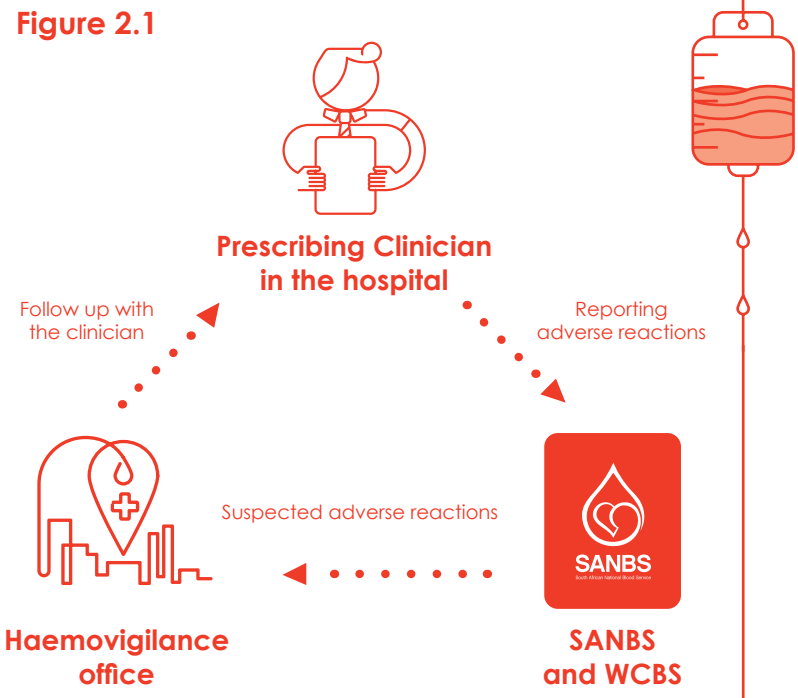


Figure 2.2

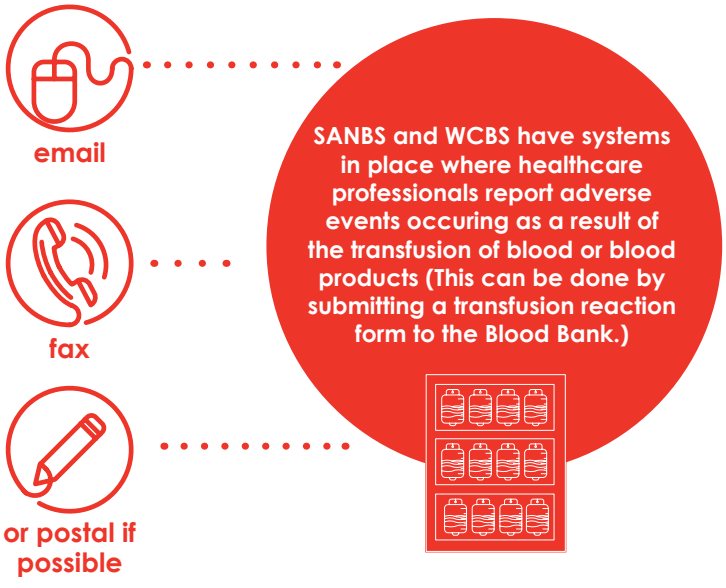
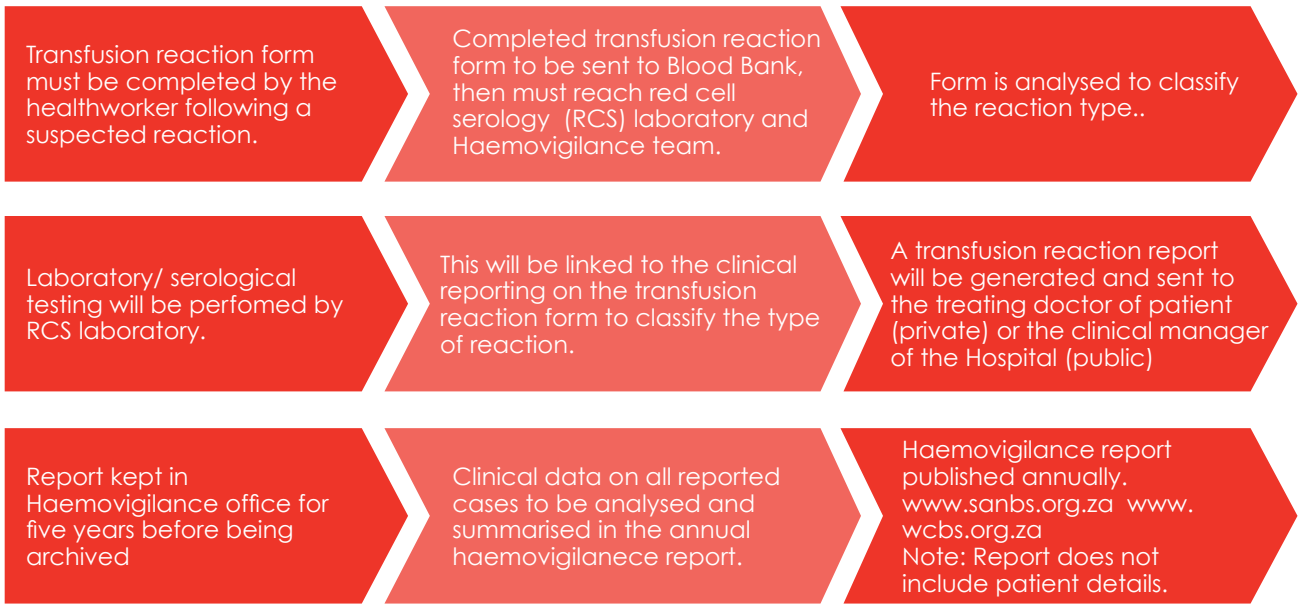


Figure 2.3

The detailed process of managing adverse events



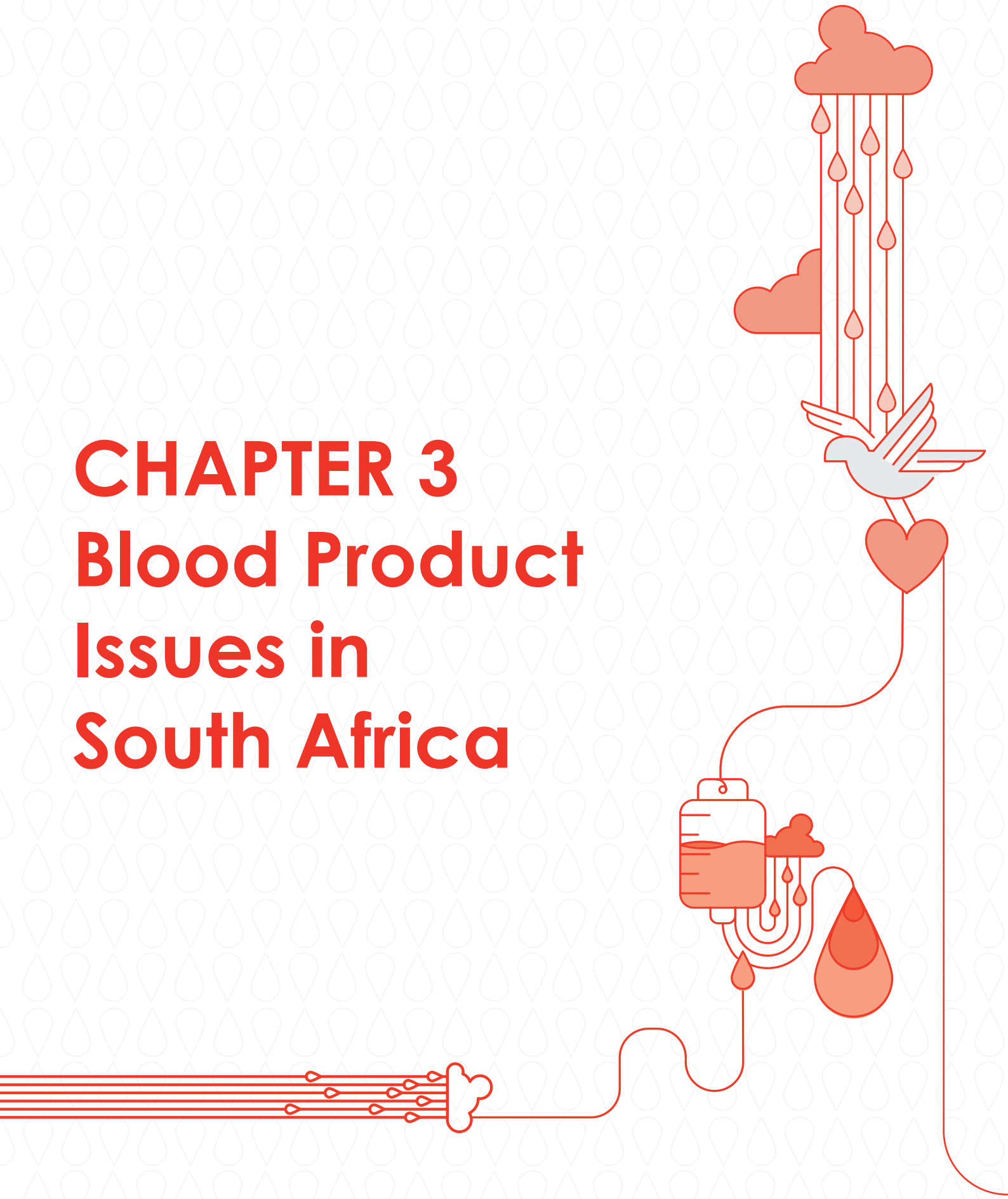
2.2 Why does South Africa have a National Haemovigilance Programme?

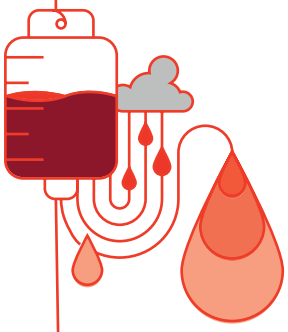
It is widely acknowledged that haemovigilance is an important tool to enhance the effective and appropriate use of blood and blood products. South Africa's haemovigilance programme intends to improve transfusion practice and product quality by identifying recurrent factors that compromise patient and donor safety. This is achieved by the continuous collection and analysis of data related to the donation and transfusion of blood products, but is heavily reliant on accurate and timeous reporting by clinicians, and cooperation among all stakeholders. Haemovigilance is an integral part of providing a safe blood supply to the people of South Africa.

The main objectives of the haemovigilance programme in South Africa are to:

- Monitor adverse transfusion reactions and donor adverse events.
- Create awareness among healthcare professionals of the risks associated with blood and blood product transfusions, and blood donation.
- Generate evidence-based recommendations through the promotion of research.
- Communicate findings to all key stakeholders.
- Create national and international cooperation to promote accurate, non-biased and standardised haemovigilance reporting.

CHAPTER 3
Blood Product Issues in South Africa





3.1 Annual number of blood Components Issued: 2017 to 2019

A total of 1 418 416 units of blood and blood products were issued in South Africa in 2019. Table 3.1 shows the annual number of blood components issued over the 2017-2019 three-year period. The number of red cell concentrate (RCC) and platelet units issued between 2017 and 2019 increased by 33.40% and 10.70% respectively. There has been a 34.94% increase in the issue of single donor platelet (SDP) products from 2017 to 2019, with a corresponding 6.55% decline in the use of random donor platelet (RDP) products over the same period. This demonstrates a gradual increase in the use of SDP (compared to RDP) products with a shift towards a 50:50 split. In 2017 the ratio was 58.43% random donor platelets to 41.58% single donor platelets, compared to the 2019 ratio of 49.33% and 50.67% respectively. The use of plasma products also increased by 6.86% over the same period.

Table 3.1 Comparison of RCC, platelet and plasma products issued (2017 – 2019)

Blood Component	2017	2018	2019	% Change Compared To 2017
Total red cell products	**861 178**	**929 122**	**1 148 235**	**33.40%**
Random donor platelet products (58.42%)	**41 212 (58.43% of total platelet products**	**38 945 (52.07% of total platelet products)**	**38 514 (49.33% of total platelet products)**	**-6.55%**
Single donor platelet products (41.58%)	29 322 (41.57% of total platelet products	35 851 (47.93% of total platelet products)	39 567 (50.67% of total platelet products)	34.94%
Total platelet products	**70 534**	**74 702**	**78 081**	**10.70%**
Fresh frozen plasma	150 781	145 732	151 325	0.36%
Cryoprecipitate	28 975	35 407	40 775	40.72%
Total plasma products	**179 756**	**181 139**	**192 100**	**6.86%**
Total components	**1 111 468**	**1 184 963**	**1 418 416**	**27.61%**

3.3 RCC Transfusion Rates by Province: 2019

In 2019, the majority (53.81%) of RCCs were issued in Gauteng and KwaZulu-Natal (KZN), the two provinces where 45.03% of the South African population reside as shown in Table 3.3. Table 3.3 also indicates that Gauteng has the highest RCC transfusion rate at 28.42 per 1 000 population, followed by the Western Cape at 20.72 and KZN at 18.21. The lowest transfusion rate is reported for the Eastern Cape (12.79 per 1 000 population). The different transfusion rates are probably a reflection of variable healthcare access in the nine provinces. The predominantly rural provinces, such as the Eastern Cape, Limpopo and Mpumalanga, have lower transfusion rates than urbanised provinces such as Gauteng and Western Cape. Tertiary hospitals that use relatively higher amounts of blood and blood products are mainly situated in Gauteng and the Western Cape.

Table 3.3 Transfusion rates by South African province

PROVINCE	Population	% of the country population	RCC	% RCC	Transfusion rate per 1 000 population
Gauteng	15 176 115	25.82%	431 289	36.36%	28.42
KwaZulu-Natal	11 289 086	19.21%	205 551	17.45%	18.21
Western Cape	6 844 272	11.64%	141 832	13.89%	20.72
Eastern Cape	6 712 276	11.42%	85 897	7.29%	12.79
Limpopo	5 982 584	10.18%	90 949	7.72%	15.20
Mpumalanga	4 592 187	7.81%	71 147	6.02%	15.49
North West	4 027 160	6.85%	56 381	5.11%	14.00
Free State	2 887 465	4.91%	47 889	4.37%	16.56
Northern Cape	1 263 875	2.15%	17 281	1.48%	13.67
Unallocated			19	0.002%	
Total	**58 775 022**	**100.00%**	**1 148 235**	**100%**	**19.54**

3.4 Patients who were Transfused

A total of 348 022 patients received at least one unit of blood and blood products in 2019 – i.e. 348 507 transfusion episodes took place. Of the total patients transfused, 253 116 and 94 906 were from public and private healthcare sectors respectively. This translates to 72.73% and 27.27% of patients that were transfused in public and private healthcare sectors respectively. This again shows that relatively more patients were transfused in the private healthcare sector than public healthcare sector in view of the fact that only 16.4% of the South African population access private healthcare sector.

Gauteng had the highest number of patients transfused at 122 592 followed by KZN with 64 234 patients, with the least being Northern Cape at 5 537 patients. This translates to 35.23%, 18.46% and 1.58% being transfused in Gauteng Province, KZN and Northern Cape respectively. A total of 186 826 patients were transfused in Gauteng Province and KZN translating to 53.69% of the total number of patients transfused.

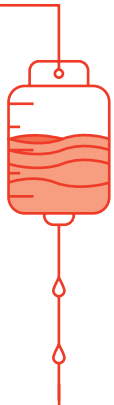


Table 3.4 Patients transfused in 2019

PROVINCE	Public sector patients	Private Sector patients	Total	% of all patients
Gauteng	81 974	40 618	122 592	35.23
KwaZulu-Natal	47 360	16 874	64 234	18.46
Western Cape	23 442	14 073	37 515	10.78
Limpopo	29 035	3 724	32 759	9.41
Eastern Cape	20 428	5 585	26 013	7.47
Mpumalanga	18 640	4 356	22 996	6.61
North West	16 708	3 894	20 602	5.92
Free State	11 123	4 651	15 774	4.53
Northern Cape	4 406	1 131	5 537	1.59
Total	**253 116 (72.73% of total)**	**94 906 (27.27% of total)**	**348 022**	**100,.00**

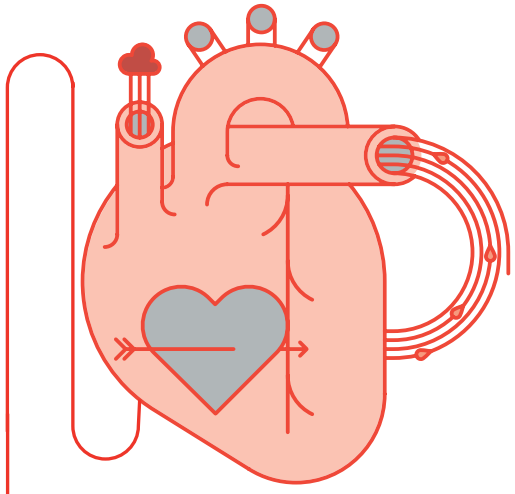
3.5 RCC Transfusion Rates in 2019: Public Versus Private Hospitals

It is estimated that 16.4% of the South African population have medical aid cover and presumably access the private health care sector, resulting in 83.6% of the population relying on the public healthcare sector. The figures in Table 3.4 show that there are relatively more transfusion episodes taking place in the private healthcare sector compared to public health care sector, which is likely a reflection of inequitable healthcare access in South Africa. It could also be questioned whether restrictive blood product usage in line with patient blood management principles occurs in the private healthcare sector.

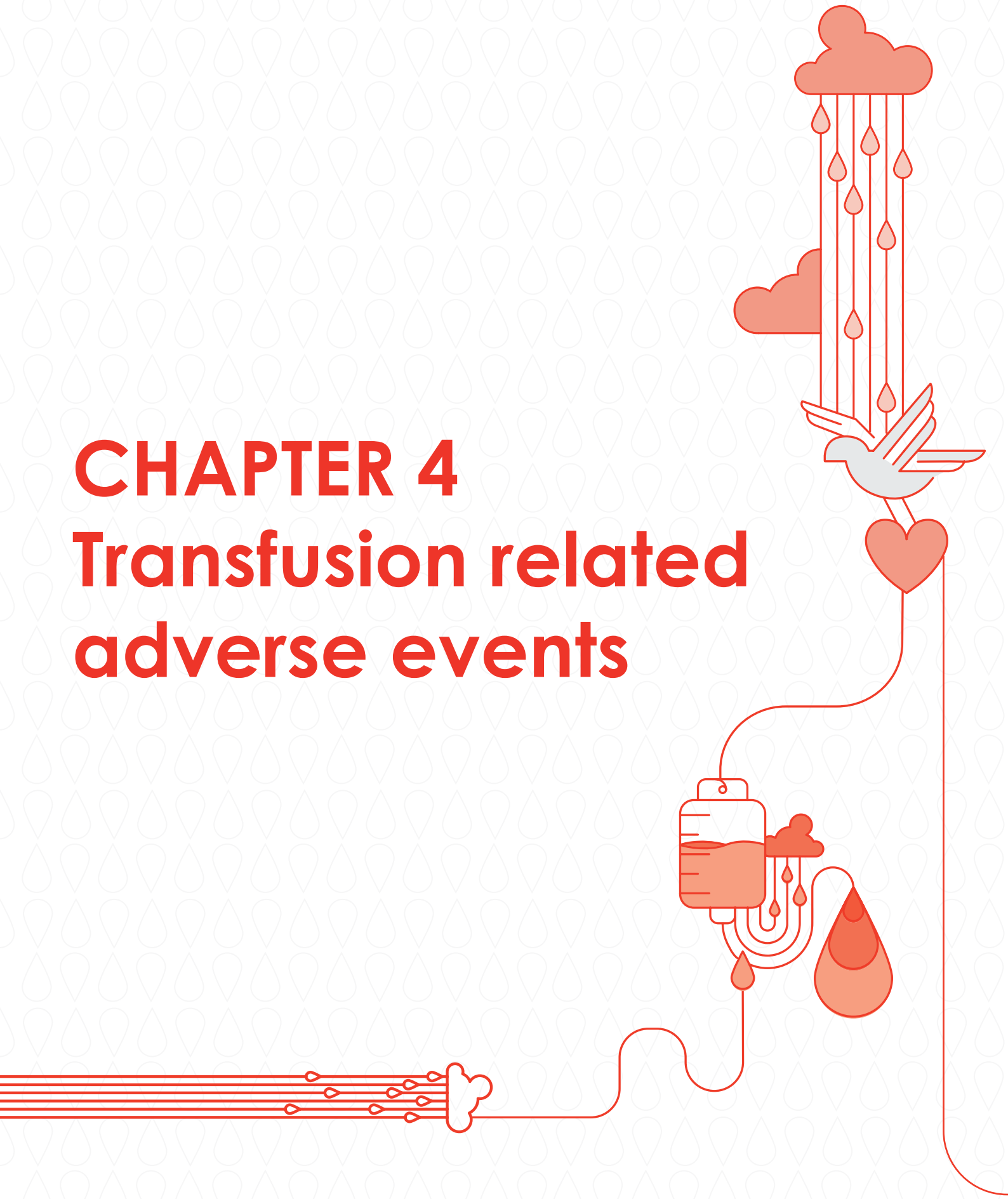
Table 3.5

Transfusion Rate In South African Public Vs Private Hospitals In 2019

SECTOR	RCC
Public	714 419 (62.22%)
Private	433 797 (37.78%)
Unknown	19 (0.002%)
Total	1 148 238 (100%)



CHAPTER 4
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, there are also risks associated with transfusions that can be life threatening. This chapter provides details on adverse transfusion events reported in South Africa in 2019.

Table 4.1 shows that 1 114 transfusion related adverse events reports were received and analysed by the South African haemovigilance offices in 2019. Of these, allergic reactions (including mild, severe and anaphylactic subtypes) were the most common, contributing to 33.13% of all reactions. Febrile non-haemolytic transfusion reactions (FNHTRs) were the second most frequently reported incidents, accounting for 29.62% of all reactions. A total 252 cases (22.62%) were regarded as unclassifiable due to incomplete information being supplied by the reporting clinicians, which is an ongoing challenge for the South African haemovigilance service. A total of 20 misdirected transfusion reactions were reported in 2019 – these refer to incidents where a patient is transfused with a blood product intended for another patient. These incidents can be life threatening in the event of blood group incompatibility and a subsequent acute haemolytic transfusion reaction (AHTR). This requires ongoing education of staff regarding the correct and safe administration of blood products. Most misdirected transfusions are as a result of failure of correct patient identification by hospital staff, which is preventable.

The overall reported adverse transfusion event rate for South Africa in 2019 was 77.98 per 100 000 units issued compared to 91.41 in 2017. Allergic transfusion reactions were reported in 25.83 of 100 000 products issued and FNHTRs in 23.10 per 100 000 products issued. It is reassuring to note that the rate of adverse events steadily decreased from 91.41 per 100 000 units in 2017 to 77.98 per 100 000 units in 2019, as indicated in Table 4.2. This decline could potentially be due to continuous education and training of healthcare workers on the prevention of adverse events provided by the blood services over the years.

Table 4.1 Transfusion Adverse Events In 2019

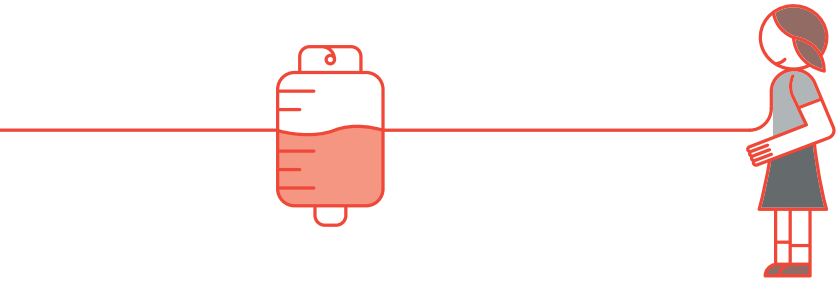
ADVERSE EVENTS		Num-ber	%	TR per 100 000 units issued
Acute transfusion reactions (ATRs)	Acute haemolytic transfusion reactions (AHTRs)	0	0%	0
	Mild allergic reactions	261	23.43%	18.27
	Severe allergic reactions	59	5.30%	4.13
	Anaphylactic reactions	49	4.40%	3.43
	Febrile non-haemolytic reactions (FNHTRs)	330	29.62%	23.10
	Transfusion-associated circulatory overload (TACO)	3	0.26%	0.21
	Transfusion-related acute lung injury (TRALI)	0	0%	0
Total components	Transfusion-associated dyspnoea (TAD)	75	6.73%	5.25
	Hypotensive reactions	45	4.03%	5.25
	Unclassifiable (incomplete information)	252	22.62%	17.64
	Total ATR	**1 078**	**96.77%**	**75.46**
Delayed transfusion reactions	Delayed serological transfusion reactions (DSTRs)	0	0%	0
	Total delayed reactions	**0**	**0%**	**0**
Incorrect blood component transfused (IBCT)	Rh incompatible transfusions	0	0%	0
	Misdirected transfusions (with and without ABO blood group incompatibility)	20	1.79%	1.4
	Total (IBCT)	20	1.79%	1.4
Other reactions	Near miss	16	1.6%	1.12
	Transfusion-associated graft-versus-host disease (TA-GvHD)	0	0%	0
	Transfusion-transmitted infections (TTIs)	0	0%	0
	Total (other)	16	1.44%	1.12
All types	Total adverse events	1 114	100%	77.98

Table 4.1
Transfusion Adverse Events In 2019

	2017	2018	2019
Units of blood products issued	1 111 468	1 184 963	1 418 416
Adverse reactions	1016	965	1 114
Rates per 100 000 total issues	91.41	81.44	77.98

4.2 Mortalities

There were 17 patient mortalities reported to the South African Haemovigilance Programme in 2019. 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 were not necessarily causative. Of the 17 cases reported and investigated, none of the patient deaths was conclusively attributed to a transfusion reaction. It is again important to declare that post-mortem investigations were not performed in 16 of the cases due to reasons such as family refusal. A post-mortem was done in only 1 reported case, but the treating doctors did not release the results to SANBS despite numerous requests.



4.3 Hospital Errors As A Cause Of Transfusion Reactions

Annual data from the Serious Hazards of Transfusion (SHOT) report consistently demonstrate human error to be one of the main causes of adverse transfusion incidents. It is unfortunate as these are preventable. In South Africa, 62 episodes of hospital errors were reported causes of transfusion reactions in 2019, equating to an error rate 5.49 per 100 000 units issued.

It is very important that the following questions are posed and answered when such preventable events happen:

Why did it happen?
What can be learned from this?
What corrective and preventative actions should be implemented to reduce the likelihood of recurrence?

When such an event occurs, urgent training is arranged for the relevant healthcare workers in that hospital. The blood transfusion services will continue with their efforts in ensuring that such incidences are minimised through the use of education campaigns and continuous training.

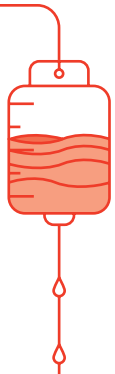
CHAPTER 5
Transfusion-transmitted infections and lookbacks

In South Africa, all blood donations are screened for syphilis, Hepatitis B virus (HBV), Hepatitis C virus (HCV) and Human Immunodeficiency Virus (HIV) through the following tests: HBV surface antigen (HBsAg), HBV DNA, HCV serology, HCV RNA, HIV-1/2 serology, HIV RNA and syphilis serology. In 2019, of the total of 949 151 donations collected, 2 959 donors tested positive for either HIV, HBV or HCV. Of these viral positive donors, 2 010 (0.21%), 842 (0.09%) and 107 (0.01%) donors tested positive for HIV, HBV and HCV respectively. All viral positive donors have to be traced by the blood services, offered counselling or referred for counselling at other healthcare facilities, and ultimately be directed to seek medical assistance. In 2019, no transfusion-transmitted infection (TTI) events were reported to the South African blood services.

5.1 Lookback Investigations

All cases of potential TTI are investigated by the Lookback office. Lookback cases can be either donor or recipient triggered. In a donor-triggered lookback investigation, a repeat blood donor would test positive for one of the screened viral infections and the recipients of the blood products associated with his or her previous donation would be traced for testing. The risk in this scenario would be potential transmission to the patient if the donation took place within the window period of these infections. Testing of patients involved in donor-triggered lookback cases should be managed by the treating clinicians. A recipient-triggered lookback investigation would be initiated when the blood service is informed that a blood product recipient has tested positive for a TTI and is requested to investigate whether this was acquired via transfusion. The implicated donors are traced and either tested for the infection, or their donation histories scrutinised for potential HIV, HBV or HCV TTI.

5.2 Donor-Triggered Lookbacks



Tables 5.1 and 5.2 detail the 884 donor-triggered lookback cases investigated in 2019. Of these, 631 cases (71.38%) were for HIV, 217 cases (24.55%) for HBV, 25 cases (2.83%) 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). Of these 884 cases, 95 recipients (10.74%) were retested and found to be negative for the infection under investigation, 65 recipients (7.35%) were infected with the same infection prior to the transfusion, phylogenetic analysis (comparing the viral DNA in the patient and donor) was done for 3 cases (0.34%), 130 (14.70%) patients had died, 72 recipients (8.14%) were untraceable, and 3 patients (0.34%) declined testing. A total of 511 cases (57.80%) remained unresolved. Of the phylogenetic analysis performed, one case confirmed no genetic linkage between the viruses isolated from the patient and donor blood, implying that the source of infection was not from a blood product transfusion.

The fact that 64.36% of lookback cases remain inconclusive reflects the challenges that the lookback officers encounter when trying to investigate these cases.

These challenges include:

- Doctors and hospital managers may not appreciate the importance of the Lookback Programme in haemovigilance monitoring.
- Patients in public hospitals provide incorrect contact information (or their contact information changes) and are therefore untraceable when attempts are made to contact them.
- Doctors occasionally refuse to take part in lookback investigations.

SANBS and WCBS will continue to sensitise and educate clinicians on the importance of the Lookback Programme in so far as blood safety is concerned.

Table 5.1 Donor-Triggered Lookbacks In 2019

Donor-Triggered Lookbacks	Numbers	% of Total
HIV	631	71.38%
HBV	217	24.55%
HCV	25	2.83%
HIV/HBV Co-infection	7	0.79%
HIV/HCV Co-infection	2	0.23%
Other	2	0.23%
Total	**884**	**100%**

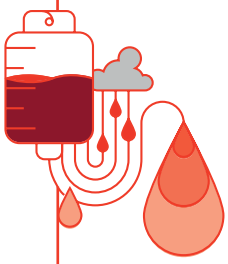


Table 5.2 Donor-Triggered Investigation Outcomes In 2019

Donor-Triggered Outcomes Of Investigations	Numbers
Recipient retested negative	95
Recipient positive before transfusion	65
HIV positive recipients – phylogenetic analysis	3
Recipient died between transfusion and initiation of lookback	130
Unresolved	511
Untraceable patient	72
Other	4
Refused/declined testing	3
HBV Immune	1
HBV positive recipient – phylogenetic analysis	0
Total	**884**

5.3 Recipient-Triggered Lookbacks

Table 5.3 illustrates that a total of 12 recipient-triggered lookback investigations were reported in 2019. Of the 6 HIV-related cases, 4 have been resolved as not being attributed to transfusion transmitted infection. The 3 HBV-related lookback cases are unresolved as the recipients had multiple transfusions and some of the implicated donors have been untraceable. All the donors who have been successfully recalled have tested negative for all markers. There was also one HCV-related lookback which was resolved as not being transfusion transmitted. The cytomegalovirus (CMV)-related case has 19 implicated donors, of which 2 have not been retested. The malaria-related case has 26 implicated donors, of which 19 have been successfully traced and tested.

Table 5.3 Recipient-Triggered Lookbacks In 2019

	Number of cases	
Types of Recipient-Triggered Lookbacks	**Resolved**	**Unresolved**
HIV	4	2
HBV	0	3
HCV	1	0
Other – malaria; CMV	0	2
Total	5	7

CHAPTER 6
Bacterial Surveillance (SANBS) 2019

Note: the reporting below is aligned with the SANBS business year (April 2019 to March 2020).
SANBS performs bacterial surveillance of the following:

- SDP and RDP platelet products;
- Red blood cells, plasma and quality control samples;
- Specialised products such as eye serums and stem cells;
- Environment: apheresis clinics and SANBS laboratories; and
- Specialised areas such as clean rooms cellular therapy (CT) laboratory.

Table 6.1 Infection Prevention Control (IPC) at a glance

Projects	Donor Clinics	Processing Labs	Blood Banks / other Labs	Special areas
Benchmarked antiseptics/ disinfectants	*2% CHX/ IPA swabs replaced with IPA swabs only			
Product QC	Apheresis Collections	Pooled platelets		Stem cells
Environmental bacterial surveillance	Apheresis clinics	**NEW:** Included in environmental surveillance in the last nine months of 2019/2020	**NEW:** Included in environmental surveillance in the last six months of 2019/2020	
IPC audits	New intervention			
IPC training	639 SANBS staff trained in IPC			
GMP certification accreditation	NA	Planned	NA	Planned: Reagents Lab
National Hamper Hygiene Plan	Wipes used as a temporary measure	Hamper cleaning tender initiated for a national programme		These areas have dedicated hampers

***CHX/ IPA – Chlorhexidine/ Isopropyl alcohol**

Table 6.2 Summary of Product % sterility and Environmental Compliance for 2019/2020

% Compliance	SDP	RDP	Eye Serum	Stem Cells	APH ENV	PROC ENV	Lab ENV	BBK ENV	Clean Room
Target	**>95%**	**>95%**	**100%**	**100%**	**<2+ growth**	**<2+ growth**	**<2+ growth**	**<2+ growth**	**0 growth**
Quarter 1	99%	99%	100%	external testing	99%	96%	**91%**	Not imple-mented yet	100%
Quarter 2	99%	99%	**90%**	91%	100%	98%	98%	**80% (pilot)**	**94%**
Quarter 3	99%	99%	100%	100%	100%	99%	**86%**	100%	100%
Quarter 4	99%	99%	94%	100%	100%	99%	100%	99%	100%
Total number compliant / total number tested	3208/3234	1629/1648	**105/110**	283/288	3186/3195	1196/1213	**1827/1941**	**143/160**	**267/272**
Average (rounded):	99%	99%	**96%**	**98%**	100%	98%	**94%**	**92%**	**98%**

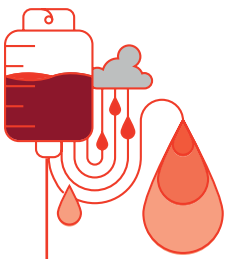
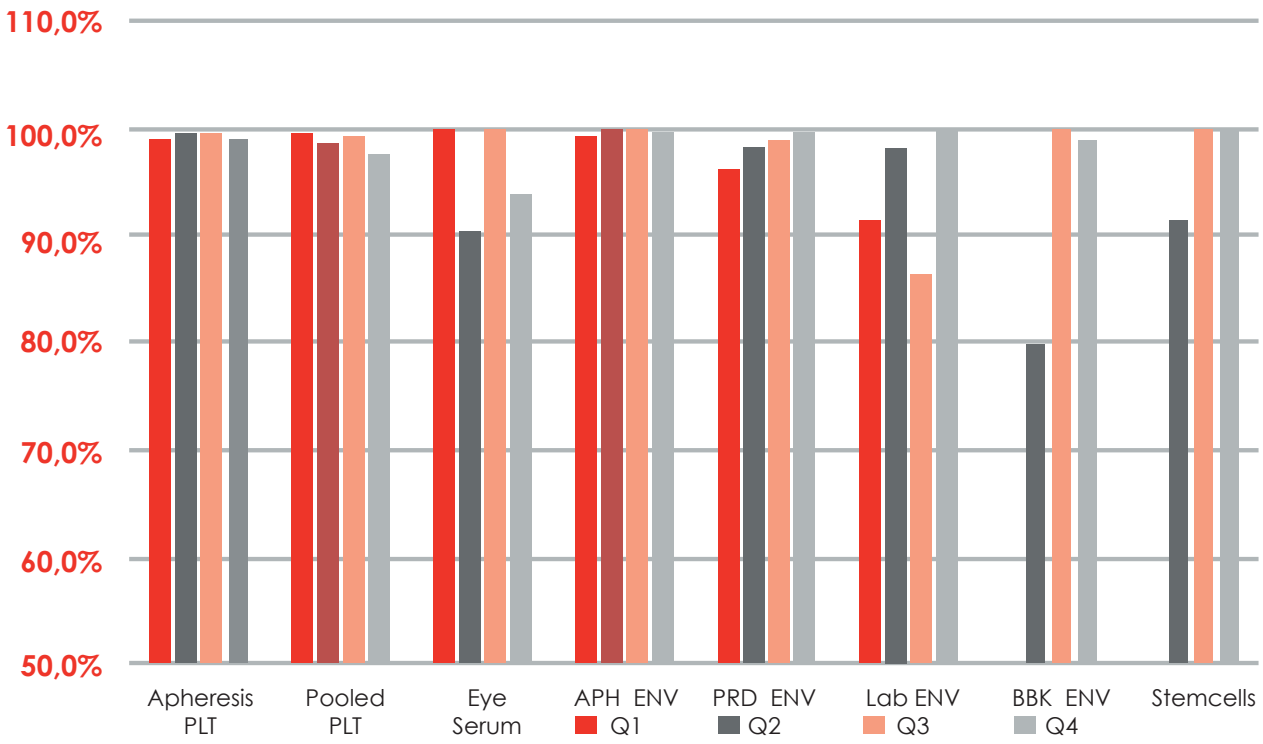
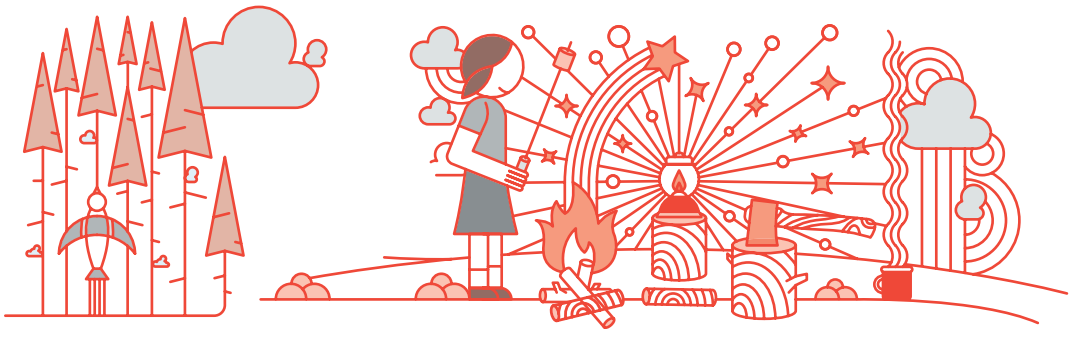
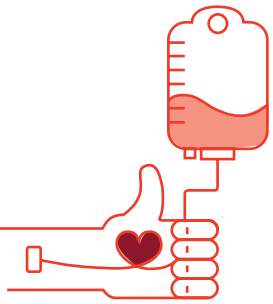


Figure 6.1 Bacterial Screening 2019





6.1 Bacterial Surveillance of Blood Products



Both SDP and RDP products stored at room temperature are a sensitive marker of the level of bacterial contamination. A quality control (QC) model is followed whereby a proportion of SDP collections are tested for bacterial contamination. This is linked to a notification system whereby the clinician in charge of the patient who has received a contaminated product is informed. Contaminated products in the inventory are quarantined and discarded. No reports of sepsis or mortality of patients receiving a contaminated product have been received by the SANBS haemovigilance programme to date.

As this is a passive reporting system, these adverse events are likely to be underreported.

- In 2019/2020 SANBS collected 10 554 SDP products. A total of 3 234 QC samples were tested, which constitutes 31% of total SDP collections.
- In 2019/2020 SANBS collected 37 505 RDP products. A total of 1 648 QC samples were tested, which constitutes 4% of total RDP collections.
- Both SDP and RDP products have maintained a bacterial contamination rate of 1%, similar to the previous two years.
- Stem cell sterilities have shown a trend of increasing towards 100% compliance following optimizing of workflow and IPC processes. Of note, unlike routine blood donations which come from healthy donors, autologous stem cell products are often collected from immunosuppressed patients and therefore positive sterilities resulting from a bacteraemia must be excluded.

Figure 6.2 Percentage Sterility Of Sdp Products Per Month (April 2019 – March 2020)

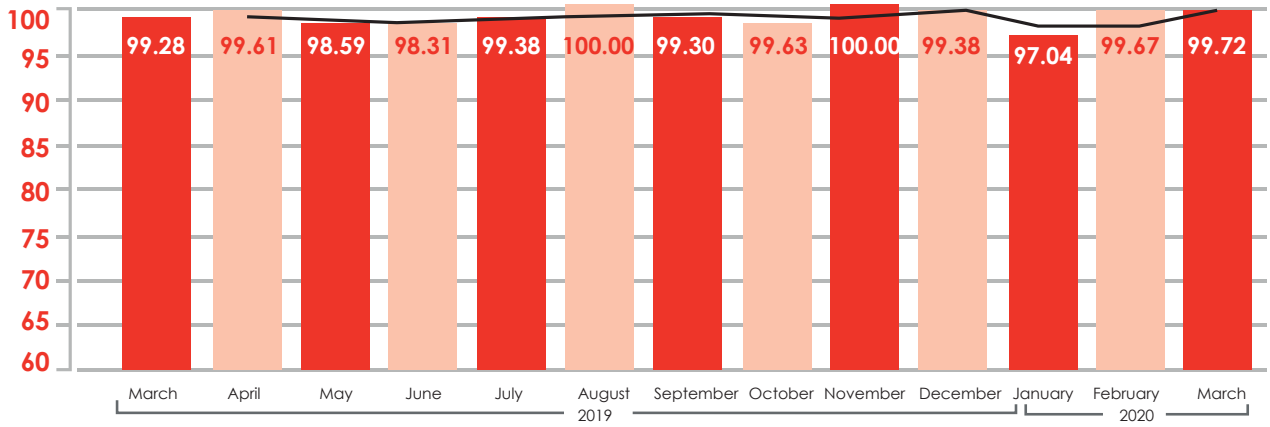
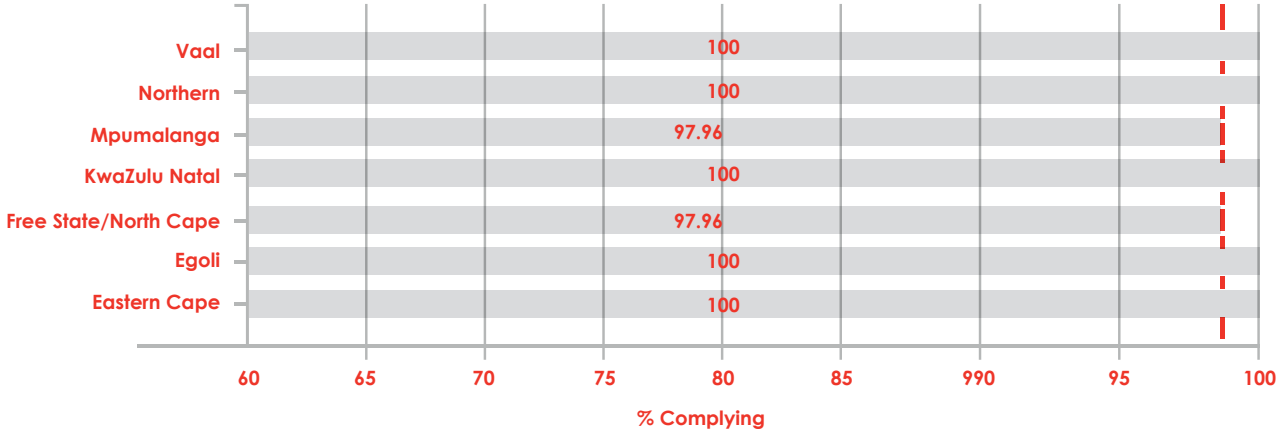


Figure 6.3 Percentage Sterility of RDP products per site (April 2019 – March 2020)



6.2 Summary of Microorganisms isolated per quarter from SDP products

Thirty bacteria were isolated of which 28 were Gram-positive – these indicate 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.* Bacterial sterility testing is routinely performed on all stem cell products and the products are not released prior to availability of these 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 had been received already contaminated.

Table 6.3 Isolated organisms

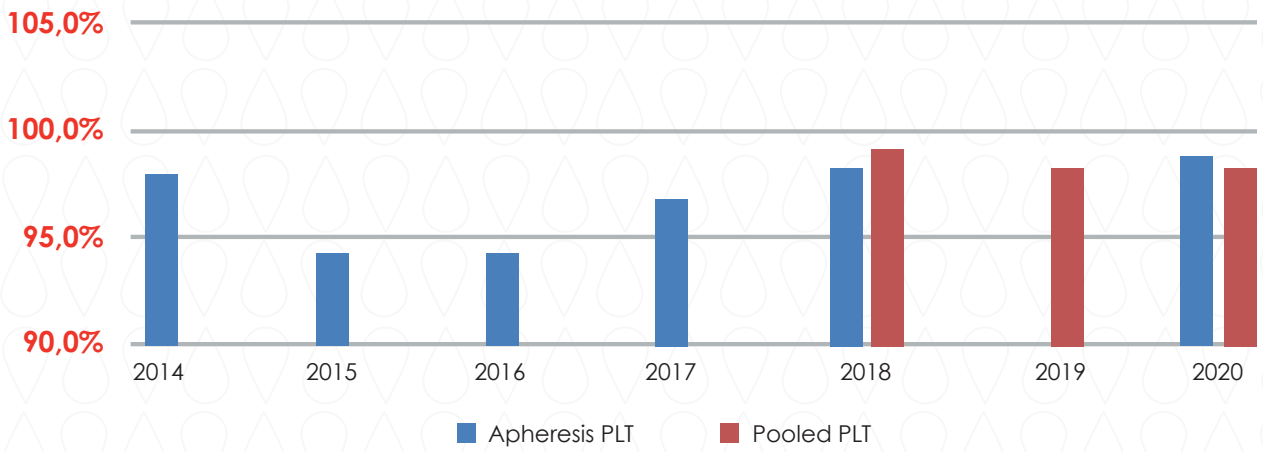
	Cocci n = 16				Bacilli n = 14			
	*Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Gram Positive Bacteria	7	2	4	3	1	9	3	1
Gram Negative Bacteria	0	0	0	0	0	3	0	0
Fungi n = 0	0	0	0	0	0	0	0	0

*Q= quarter

Figure 6.3 Percentage Sterility of RDP products per site (April 2019 – March 2020)

Top three organisms	*Q1	Q2	Q3	Q4
	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

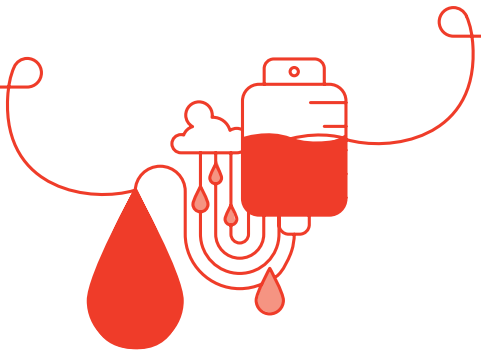
Figure 6.4 Annual trends of platelet sterility
Sterility Compliance Platelet Products

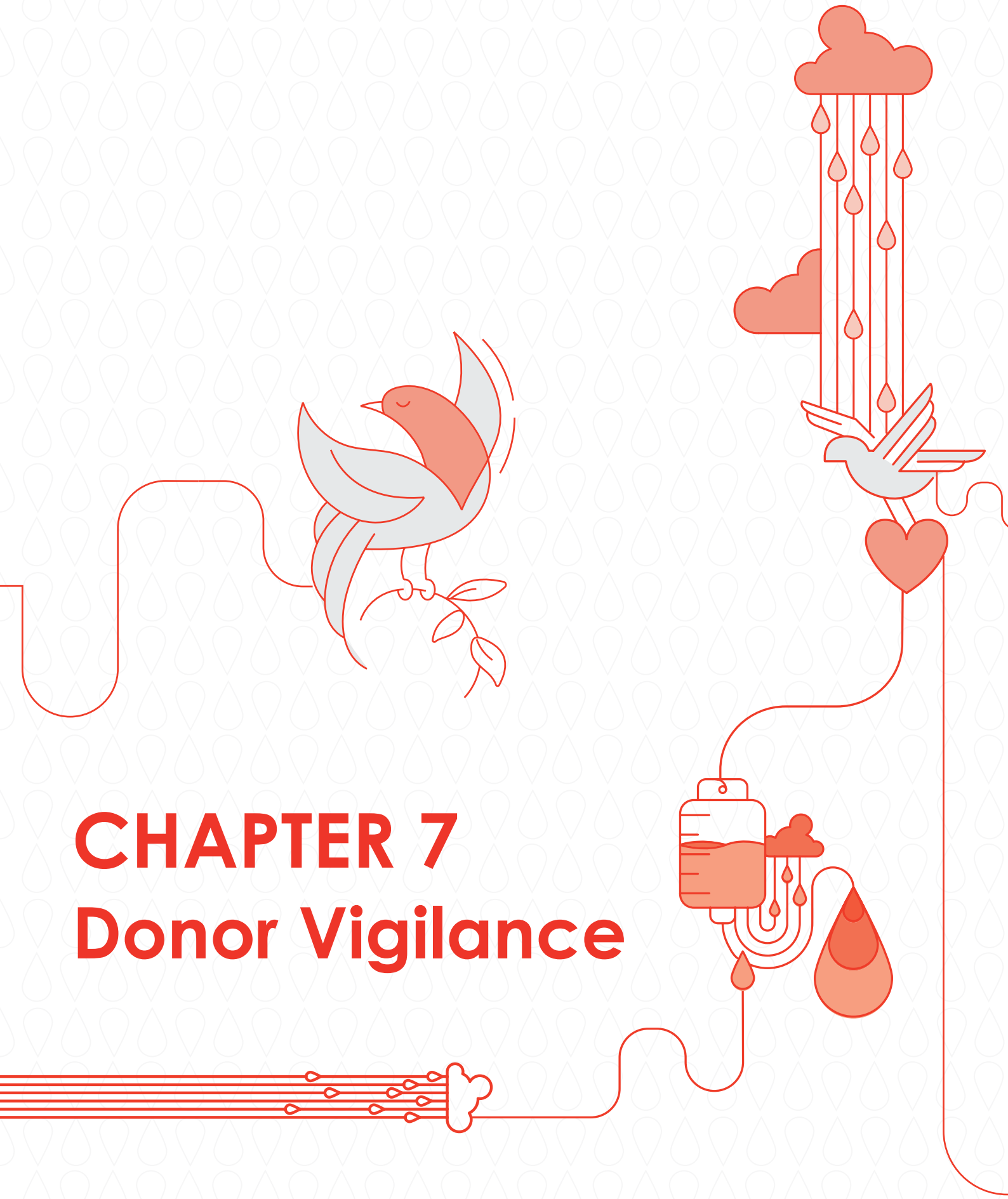


6.3 Environmental Surveillance

Environmental samples from apheresis clinics are collected monthly and include samples from benches, air, hands, utensils and equipment. Environmental screening was introduced into blood banks and processing sites. Overall, the level of hygiene is well controlled. Detergent and alcohol wipes have been introduced to optimize environmental hygiene with intermittent cleaning of surfaces and common touch items.

It is evident and encouraging that the rate of bacterial contamination of SDP and RDP products is being maintained at very low levels. To reduce the residual risk, SANBS has introduced the use of 2% Chlorhexidine/ 70% isopropyl alcohol swabs to clean donor skin, and the feasibility of introducing pathogen reduction technology for platelet products is being considered.





CHAPTER 7
Donor Vigilance

7.1 Donor Adverse Events

Approximately 107 million blood donations are collected globally every year. In high-income countries the rate is 39.2 donations per 1 000 population while middle-income and low-income countries show rates of 12.6 and 4.0 per 1 000 population respectively (3). Less than 1% of South African population donate blood and that is a concern with regards to blood sufficiency. In low-income countries, up to 65% of blood transfusions are given to children under five years of age, whereas in high-income countries, the most frequently transfused patient group is over 65 years of age, accounting for up to 76% of all transfusions (5).

Whilst blood donation is generally a safe process, recognised donor complications can occur. Donor vigilance is the systematic monitoring of adverse reactions and incidents in blood donor care to improve the quality and safety of this practice. It is important to evaluate the impact of changes in donation procedures to enhance this process.

There were 5 058 donor adverse events (AE) reported in South Africa, in 2019. The overall reported rate of donation-related adverse events fluctuated, rising from 4 130 events in 2017 to 5 659 in 2018, then decreasing to 5 058 events in 2019. The most frequently reported donation adverse events were vasovagal reactions (79.79%). In vasovagal reactions, the donor experiences dizziness, sweating and nausea, and in a small proportion of donors, loss of consciousness. Vasovagal reactions can occur during the donation or up to eight hours thereafter. Events that occur in the donor centre are classified as 'immediate', and those that occur after the donor has left the donor centre are considered 'delayed' events. It is cause for concern that there was an increase in reported vasovagal events from 3 557 in 2017 to 4 036 in 2019, although this may be attributable to improved reporting by donors and clinic staff. There was a marked decline in citrate reactions in apheresis donors from 764 in 2017, to 596 in 2018 and 106 in 2019.

The other major category of donor adverse events is caused by venepuncture, most frequently manifesting in haematomas and painful arms, with less frequent local complications including arterial puncture, nerve injuries and nerve irritations.

Table 7.1 Donor Adverse Events Reported (2017–2019)

Year	2017	2018	2019
Local symptoms	**1 119**	**1 111**	**896 (17.71% of total AEs)**
Arterial puncture	7	0	2
Delayed bleeding	46	32	28
Haematoma	788	822	703
Nerve injury	1	13	2
Nerve irritation	16	1	3
Painful arm	260	241	158
Tendon injury	1	2	0
Other	**768**	**721**	**126 (2.49% of total AEs)**
Citrate reaction	764	596	106
Generalised allergic reaction	3	124	18
Haemolysis	1	1	2
Vasovagal reactions	**3 557**	**3 827**	**4 036 (79.79% of total AEs)**
Faint delayed type	1 651	1 407	1057
Faint delayed, accident	101	188	104
Faint immediate type	1 654	1 856	2 749
Faint immediate, accident	151	376	126
Grand total	**4 130**	**5 659**	**5 058 (100% of total AEs)**

8 Conclusion

The South African Haemovigilance Programme endeavours to continuously highlight and to educate healthcare providers on the importance of monitoring, evaluating and reporting of transfusion adverse events. Human error rates remain a concern to be addressed by all parties involved, along with improved reporting and management of patients who experience adverse transfusion events.

The two blood transfusion services in South Africa remain committed to ensuring blood safety, supporting healthcare workers when reporting transfusion adverse events, investigating system failures, and isolating processes that will prevent recurrence. Ongoing surveillance and review of donor adverse events is vital and enables the blood services to minimise risks related to blood donation. The blood services aim for continuous improvement in an environment with various challenges.

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