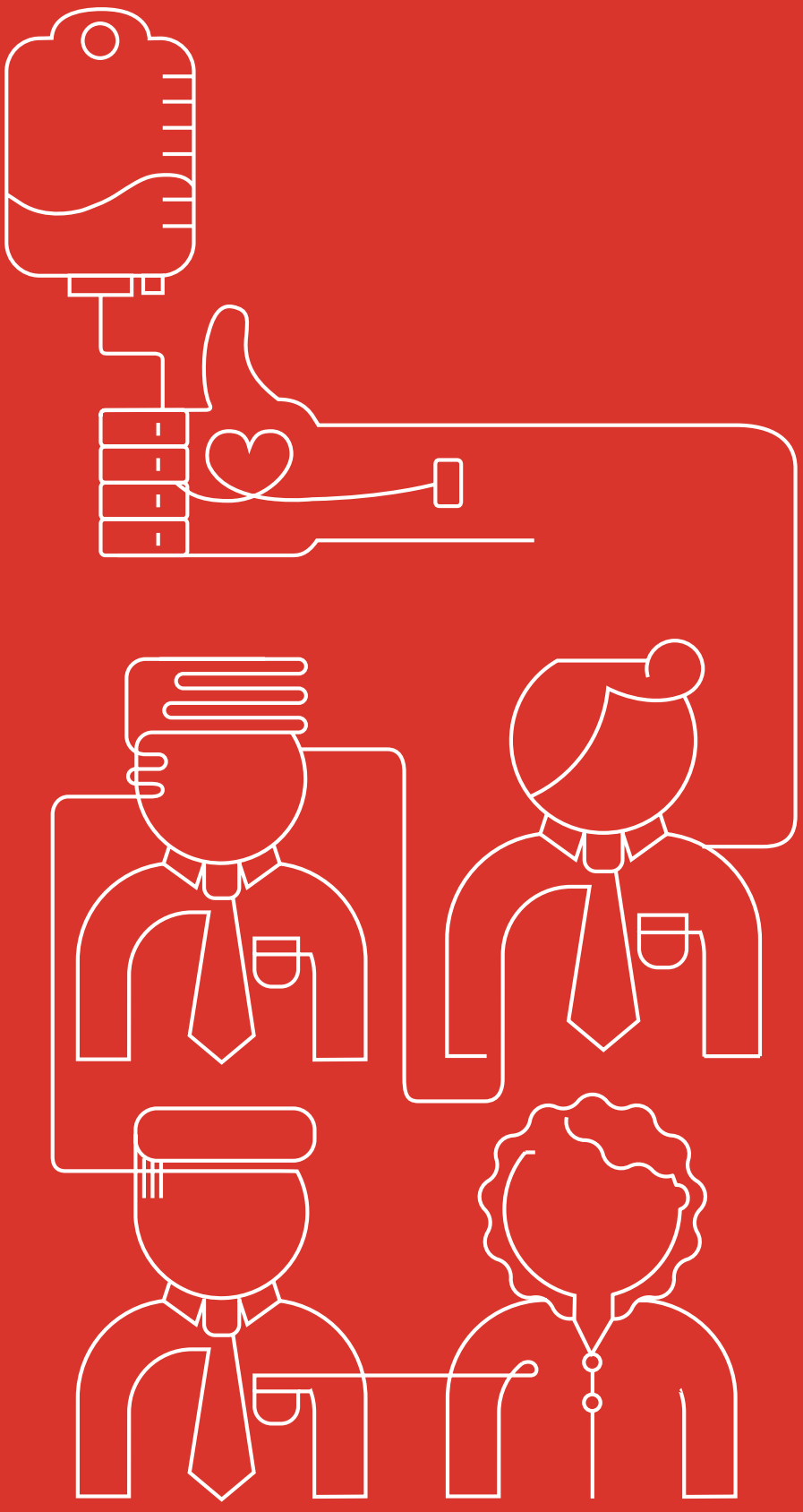
SOUTH AFRICAN HAEMOVIGILANCE REPORT 2018



THE 19TH SOUTH AFRICAN HAEMOVIGILANCE REPORT

Privacy Statement

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.

Acknowledgement

The South African National Blood Service (SANBS) and the Western Province Blood Transfusion Service (WPBTS) recognise and acknowledge the contribution of individuals and departments to this report. A number of stakeholders kindly provided transfusion safety and quality data to SANBS.

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

SANBS

WP Blood Transfusion Service
WP Bloedoortappingsdiens

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ABBREVIATIONS

CATEGORY	DEFINITION
AHTR	Acute Haemolytic Transfusion Reaction
ATR	Acute Transfusion Reactions
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 Antigens
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
WPBTS	Western Province Blood Transfusion Service

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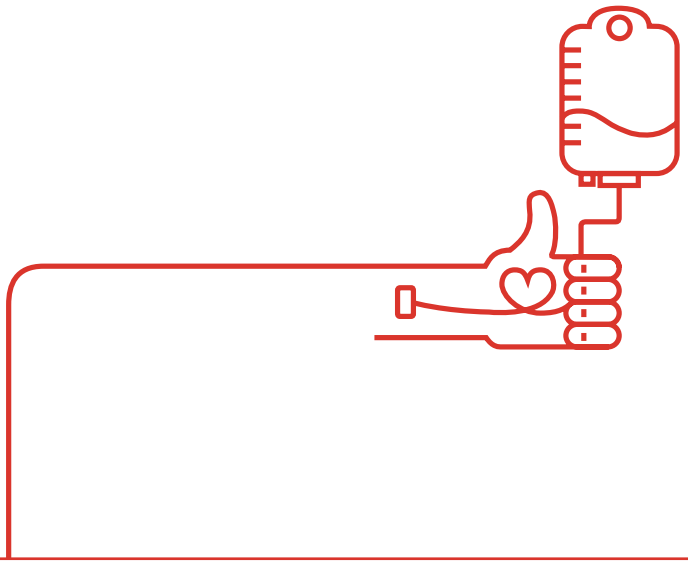


Transfusion Reaction Classifications And Definitions

CATEGORY	DEFINITION
Acute Transfusion Reactions	Transfusion-related reactions that occur at any time during or up to 24 hours following a 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, rise in lactate dehydrogenase, positive direct antiglobulin test (DAT) and positive 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 and 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 results in any 4 of the following occurring within 6 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 Reaction	Hypotension with one or more of: urticaria, rash, dyspnoea, angioedema, stridor, wheeze, pruritus, within 24 hrs of 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 >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 a 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 (development of antibody without positive DAT or evidence of haemolysis).
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. See Appendix D for common antibodies associated with delayed serologic transfusion reactions.
Post-transfusion Purpura	Thrombocytopenia arising five to 12 days following transfusion of cellular blood components associated with the presence in the patient of alloantibodies directed against the human platelet antigen system.
Transfusion-associated Graft-versus-host Disease	The introduction of immunocompetent lymphocytes into a susceptible host. The allogeneic lymphocytes engraft, proliferate and destroy host cells, and 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 and 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.

FOREWORD – MESSAGE FROM THE MEDICAL DIRECTORS

The World Health Organisation defines haemovigilance as 'the set of surveillance procedures covering the entire blood transfusion chain, from the donation and processing of blood and its components, through to their provision and transfusion to patients, and including their follow-up.

'It includes the monitoring, reporting, investigation and analysis of adverse events related to the donation, processing and transfusion of blood, and taking action to prevent their occurrence or recurrence. The reporting systems play a fundamental role in enhancing patient safety by learning from failures and then putting in place system changes to prevent them in future.'

In line with the above, patient blood management focuses on optimising patients' red cell mass, which reduces the need for blood product transfusions and results in better clinical outcomes.

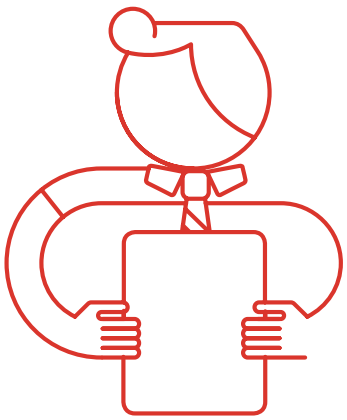
However, in many clinical situations, blood product transfusions cannot be avoided and are, in fact, lifesaving, and it is through the structured haemovigilance programme in South Africa that adverse events are reported to the blood services, investigated and published in an annual report such as this.

There have been numerous improvements in haemovigilance in South Africa in recent years, one of the most significant being the increasing focus on understanding adverse events affecting blood donors and minimising these wherever possible. The blood services also now have a robust understanding of the effects of repeated blood donation on certain groups of blood donors' iron status, and have put in place strategies to minimise donor iron depletion.

On the recipient side of the vein-to-vein equation, the Emerging Infectious Disease Working Group has been established by the blood services and the National Institute for Communicable Diseases. The group has developed a better understanding of transfusion-transmissible infections in the local context (for example HTLV, Hepatitis E and Cytomegalovirus) and has explored options to minimise their transmission.

In addition, the National Blood Safety Committee meets every year to analyse the trends of the transfusion-transmissible infections for which the services currently screen – HIV, hepatitis B and C, and syphilis. The introduction of nucleic acid testing in 2005 continues to contribute to the safety of blood products in South Africa, to such an extent that infection transmissions are rare, and the predominant complications of blood transfusion are allergic and febrile transfusion reactions.

This report is more concise than its predecessors, hence easier to understand. In addition, the data supplied by both blood services has been consolidated to provide a truly national picture, rather than a regional one. Special thanks are due to Dr Solomuzi Ngcobo, Dr Caroline Hilton and Sr Francis Ledwaba for their work in redeveloping this report.



EXECUTIVE SUMMARY

A total of **1 184 963** units of blood and blood products were issued by the South African blood services from 1 January 2018 to 31 December 2018. Of these, 929 122 (78.41%) were red cell concentrates (RCCs), 74 702 (6.30%) were platelet products and 181 139 (15.29%) were fresh frozen plasma (FFP) units. In as much as the appropriate use of blood and blood products saves lives, it may lead also to adverse transfusion reactions as indicated in the section below.

In 2018, **965** adverse transfusion events were reported to the haemovigilance programmes in the South African blood services. Of these, 320 (33.7%) were allergic reactions (including mild allergic reactions, severe allergic reactions and anaphylaxis), 298 (30.88%) were febrile non-haemolytic transfusion reactions, and 197 (20.41%) were regarded as unclassifiable reactions due to limited information in the report or confounding comorbid issues.

A total of **5 569** donor adverse events were reported in 2018.The most frequently reported adverse incident associated with blood donation were vasovagal reactions, which represent 59.03% of all donor adverse events.

In 2018, the national prevalence of HIV, HBV and HCV among the blood donor population was 0.21%, 0.10% and 0.01% respectively. During 2018, no cases of transfusion transmissible infection were reported.

THE KEY FINDINGS WERE

1. A total of 1 184 963 blood and blood were issued in the year 2018 with RCC being the product transfused the most (78.41%).
2. The majority (53.90%) of RCCs were issued in Gauteng and KwaZulu-Natal in 2018.
3. The RCC transfusion rate was highest in Gauteng at 23.26 per 1 000 population, followed by Western Cape and KwaZulu-Natal at 19.98 and 13.67 per 1 000 population respectively.
4. Adverse events were reported in 81.44 of 100 000 blood and blood products units issued.
5. The most frequently reported adverse transfusion events were allergic reactions (including mild and severe allergic reactions, and anaphylaxis) at 33.7%, giving an adverse event rate of 27.0 per 100 000 units issued.
6. Human errors continue to contribute to preventable transfusion-related adverse incidents, with incorrect blood component transfused (IBCT) events accounting for 2.6% of all reactions.
7. A total of 5 659 donation adverse events were reported in 2018.

THE MAIN RECOMMENDATIONS ARE:

1. Promote the recognition, management and reporting of transfusion-related adverse events through the implementation of specific national programmes.
2. Maintain and improve existing capacities for haemovigilance data reporting.
3. Encourage thorough investigation of incidents to identify system-related and human factors that need to be addressed.
4. Continue to educate clinicians on the correct administration of blood and blood products.
5. 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.
6. Encourage the use of information in the haemovigilance report by clinicians and hospital management to initiate and guide patient blood management strategies.

1. Haemovigilance In South Africa

Haemovigilance definitions

International Haemovigilance Network

'A set of surveillance procedures covering the whole transfusion chain (from the collection of blood and its components to the follow-up of recipients), intended to collect and assess information on unexpected or undesirable effects resulting from the therapeutic use of labile blood products, and to prevent their occurrence or recurrence.'

World Health Organisation

'Haemovigilance is required to identify and prevent occurrence or recurrence of transfusion-related unwanted events, to increase the safety, efficacy and efficiency of blood transfusion, covering all activities of the transfusion chain, from donor to recipient. The system should include monitoring, identification, reporting, investigation and analysis of adverse events near-misses and reactions related to transfusion and manufacturing.'

The South African Haemovigilance Programme

The South African Haemovigilance Programme was established in 2005. In 2016, the World Health Organisation reported that South Africa was one of 70 countries to have an established national haemovigilance system. It is also a member of the International Haemovigilance Network (IHN) with 38 other nations and one of only 12 countries in Africa to have a formalised system for transfusion-related adverse events.

The South African haemovigilance system involves all relevant stakeholders and is coordinated by the two blood collection services in the country, SANBS) and WPBTS. SANBS covers eight of the nine provinces in South Africa and supplies blood and blood products to 87% of the national population, while WPBTS meets the needs of the Western Cape province alone. In future, it is envisaged that the hospital transfusion committees, the national regulatory agency and National Department of Health would play a more active role in the South African Haemovigilance Programme.

The South African Haemovigilance Programme currently operates as a passive and voluntary system compared to other first-world countries where mandatory reporting of all adverse events associated with transfusions is legislated by law. The British haemovigilance reporting scheme, known as the Serious Hazards of Transfusion programme, started as a voluntary system and then progressed to compulsory and/or mandatory reporting systems required by the UK Blood Safety, Quality Regulations (2005), in which only limited errors and serious reactions are reported.

Why does South Africa have a national haemovigilance programme?

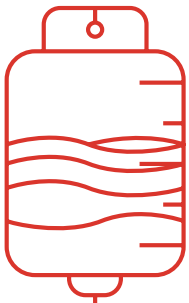
It is widely acknowledged that haemovigilance is an important tool to enhance the effective and appropriate use of blood and blood products. South Africa's haemovigilance programme intends to improve transfusion practice and product quality by identifying recurrent factors that compromise patient and 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.

National haemovigilance reporting process

The haemovigilance divisions of SANBS and WPBTS receive adverse transfusion reaction reports from clinicians from all hospitals in South Africa. The reports are reviewed by the blood services' haemovigilance teams 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 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 by the International Society of Blood Transfusion Working Party on Haemovigilance in collaboration with the IHN.

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.



Blood alone moves the wheels of HISTORY

– Martin Luther King

2. Red Cell Concentrates Transfused In South Africa 2018

RCC transfusion rates by province: 2018

A total of **929 122** units of red cell concentrates were issued by the South African blood services in the period 01 January 2018 to 31 December 2018. Table 2.1 indicates that Gauteng had the highest red cell concentrate transfusion rate, at 23.26 per 1 000 population, followed by Western Cape at 19.67 and Free State at 13.90. The lowest transfusion rate was in Eastern Cape (10.85 per 1 000 population). The different transfusion rates are probably a function of healthcare access in the nine provinces. The predominantly rural provinces, such as Eastern Cape, Limpopo and Mpumalanga, have lower transfusion rates than urbanised provinces such as Gauteng and Western Cape. Tertiary hospitals that use higher amounts of blood and products are mainly in Gauteng and Western Cape.

	Population	RCC	Transfusion rate per 1 000 population
Gauteng	14 717 000	345 201	23.26
KwaZulu-Natal	11 384 700	155 662	13.67
Western Cape	6 621 100	132 301	19.98
Eastern Cape	6 522 700	70 645	10.85
Limpopo	5 797 300	67 702	12.09
Mpumalanga	4 523 900	57 363	12.68
North West	3 979 000	45 170	11.35
Free State	2 954 300	41 071	13.90
Northern Cape	1 225 600	14 007	11.43
Total	**57 725 600**	**929 122**	**16.20**

(Table 2.1)

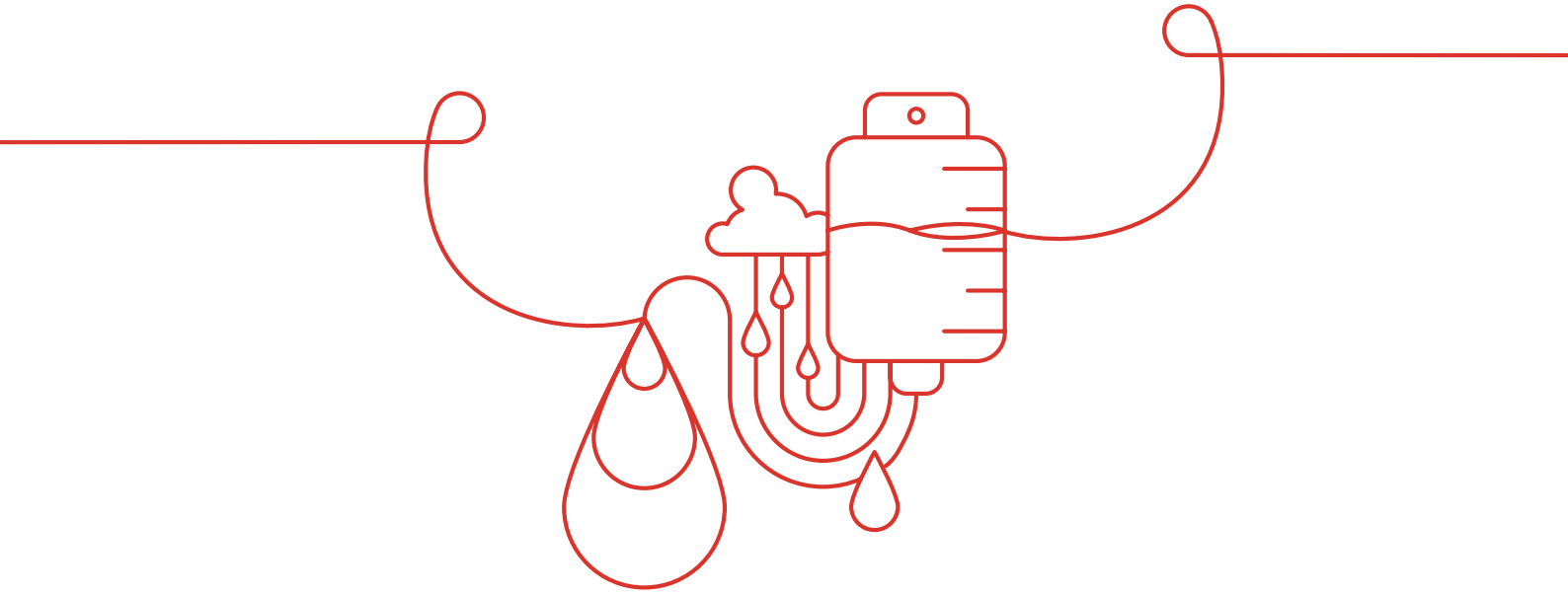
Recipients of blood components: 2018

Table 2.2 below provides information on the number of individual recipients (multiple transfusions to the same recipient are counted as one) of RCC, platelet and FFP components during 2018. This data applies only to SANBS.

		Red cell	Platelets	FFP
Gender	Female	193 739	14 012	20 422
	Male	95 191	12 453	13 909
	Unknown	3 397	96	71
Age (years)	Median	39	39	36
Units transfused	Median	2	1	2

(Table 2.2)

The median age of patients who received blood or blood product transfusions was 39 years - appropriate for the demographics of a developing country such as South Africa, which tends to have a younger population. In South Africa, the disease burden is distributed among non-communicable diseases (40.8%), HIV/Aids and other communicable diseases (25.5%), maternal and nutritional diseases (22.2%) and injuries (11.5%)[5] . The relatively low median age of patients requiring red cell concentrate transfusion could be attributable to the high burden of HIV/AIDS and maternal conditions such as obstetric haemorrhage as these tend to affect younger age groups more commonly. The median age of patients in developed countries is higher due to the majority of transfusion episodes being related diseases of the aged, such as cancers and chronic anaemia. This illustrates that the transfusion needs of developing and developed countries are different.



3. Transfusion Related Adverse Events In 2018

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 with transfusions that can be life-threatening. This chapter provides details on adverse transfusion events reported in South Africa in 2018.

	Adverse Events	Number	%	Adverse effects per 100 000 units issued
Acute Transfusion Reactions (ATRs)	Acute Haemolytic Transfusion Reactions (AHTRs)	0	0	0
	Mild Allergic Reactions	256	27	21.6
	Severe Allergic Reactions	17	1.8	1.4
	Anaphylactic Reactions	47	4.9	4.0
	Febrile Non-Haemolytic Reactions (FNHTRs)	298	31.4	25.1
	Transfusion-Associated Circulatory Overload (TACO)	0	0	0
	Transfusion-related Acute Lung Injury (TRALI)	0	0	0
	Transfusion-Associated Dyspnoea (TAD)	66	6.9	5.6
	Hypotensive Reactions	32	3.4	2.7
	Unclassifiable (incomplete information)	197	20.8	16
	Total (ATR)	**913**	**96.2**	**77.0**

(Table 3.1. continued…)

	Adverse Events	Number	%	Adverse effects per 100 000 units issued
Delayed Transfusion Reactions	Delayed Haemolytic Transfusion Reactions (DHTRs)	0	0	0
	Delayed Serological Transfusion Reactions (DSTRs)	0	0	0
	Total (Delayed Reactions)	**0**	**0**	**0**
Incorrect Blood Component Transfused (IBCT)	Rh Incompatible Transfusions	2	0.2	0.2
	Misdirected Transfusions (with and without ABO blood group incompatibility)	34	2.6	2.1
	Total (IBCT)	**36**	**3.8**	**3.04**
Other Reactions	Near miss	16	1.6	
	Transfusion Associated Graft-versus-host Disease (TA-GvHD)	0	0	0
	Transfusion Transmitted Infections	0	0	0
	Total (other)	**16**	**0**	**0**
	Total (Adverse Events)	**965**		**81.44**

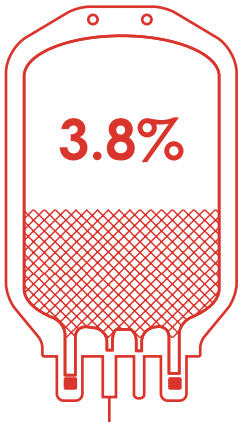
(Table 3.1)

Table 3.1 shows that **965** cases were received and analysed by the South African haemovigilance offices in 2018. Of these, allergic reactions (including mild, severe and anaphylactic subtypes) were the most common, contributing to 33.7% of all reactions.

FNHTRs were the second most frequently reported reaction, accounting for 34% of all reactions. A total of 197 cases (20.8%) were regarded as unclassifiable due to incomplete information being supplied by the reporting clinicians, which is an ongoing challenge for the haemovigilance services. The occurrence of misdirected transfusions is still worrying and requires ongoing education of staff on the correct and safe administration of blood products.

The overall reported adverse transfusion event rate for South Africa is 81.44 per 100 000 units issued. Allergic transfusion reactions are reported in 27.0 of 100 000 products issued respectively.

Incorrect Blood Component Transfused



4. Transfusion Transmitted Infections And Lookbacks

In South Africa, all blood donations are screened for Hepatitis B surface antigen (HBsAg), HBV DNA, anti-HCV, HCV RNA, anti-HIV-1/2, HIV RNA and syphilis antibody. In 2018, the prevalence of HIV, HBV and HCV among the blood donor population was 0.21%, 0.10% and 0.01% respectively. During 2018, no transfusion-transmitted infection (TTI) events were reported.

Lookbacks

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 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 clinician.

A recipient-triggered lookback case 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.

Tables 4.1 and 4.2 detail the 864 donor-triggered lookback cases investigated in 2018. Of these, 581 cases (67.24%) were for HIV, 239 cases (27.66%) for HBV, 30 cases (3.47%) for HCV, 10 cases (1.16%) for HIV/HBV or HIV/HCV co-infections, and four cases (0.46%) for non-routinely tested infections, including cytomegalovirus and malaria. Of these, 79 recipients (9.1%) were retested and found to be negative, 41 recipients (4.74%) were infected with the same infection prior to the transfusion, 123 (14.24%) had died and 59 recipients (6.83%) were untraceable. A total of 545 cases (63.08%) remained unresolved.

Donor-triggered Lookback Investigations	Total Number
HIV	581
HBV	239
HCV	30
HIV/HBV Co-infection	4
HIV/HCV co-infection	6
Other	4
Total	**864**

(Table 4.1)

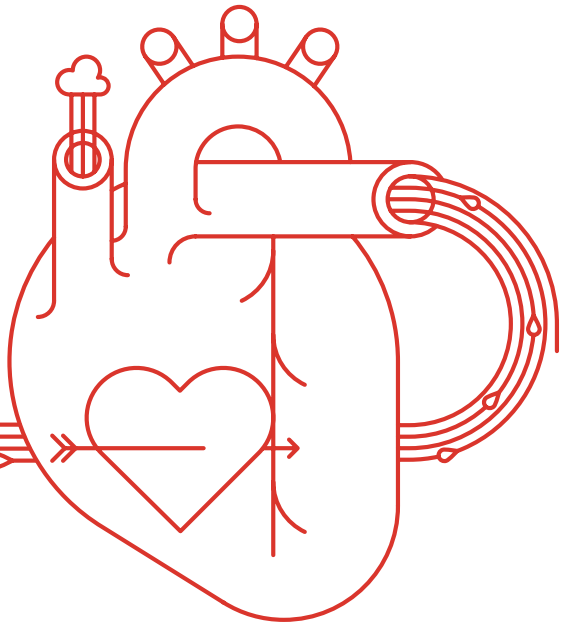
Donor-triggered Investigation Outcome	Total Numbers
Recipient Retested Negative	79
Recipient Positive Before Transfusion	41
HIV-positive recipients - phylogenetic analysis	1
Recipient died between transfusion and initiation of lookback	123
Unresolved	545
Untraceable patient	59
Other	13
Refused/declined testing	1
HBV Immune	1
HBV positive recipient - phylogenetic analysis	1
Total	**864**

(Table 4.2)

A heart that

GIVES

gathers...



– Tao Te Ching

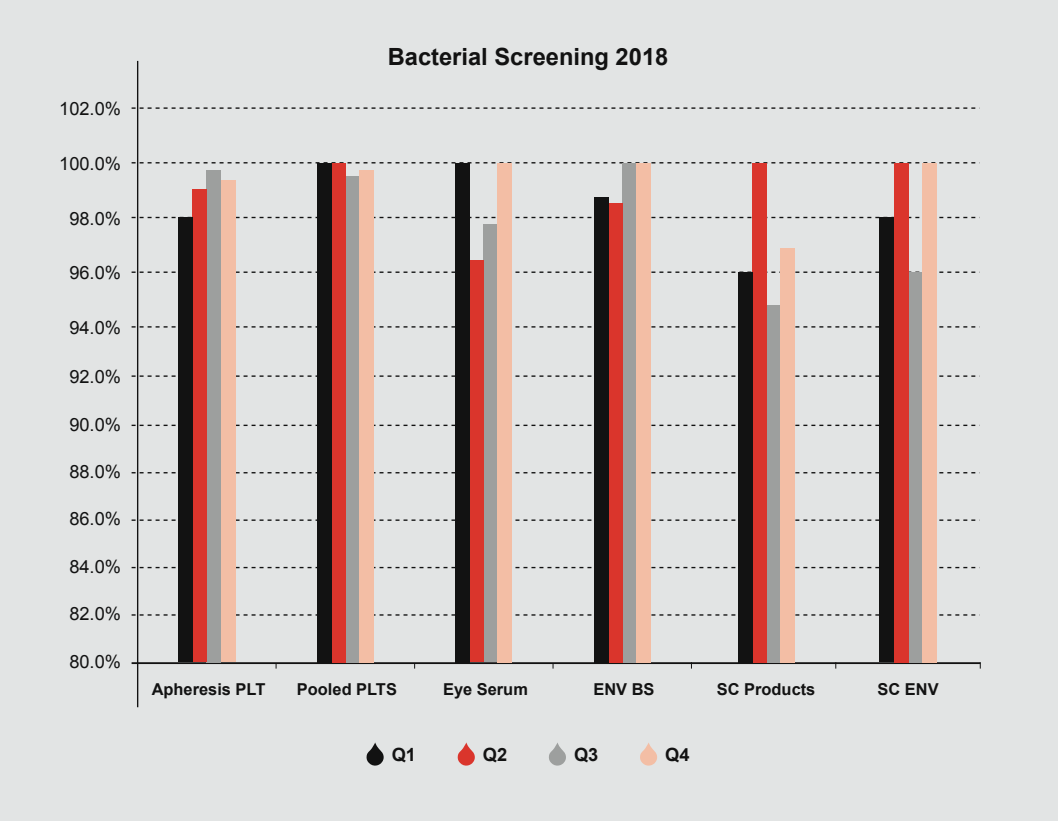
5. Bacterial Testing Of Platelets

Bacterial screening (SANBS): 2018

The reporting below is aligned with the SANBS business year (April 2018 to March 2019). SANBS performs bacterial surveillance of a range of blood products and environmental sites, as described in Table 5.1 below. The figures are for 2018/2019.

% Compliance	Apheresis Platelet	Pooled Platelet	Eye Serum	Environmental Blood Service	Stem Cells Product	Stem Cells SC Environmental
Quarter 1	98.0%	100%	100.0%	98.9%	96%	98%
Quarter 2	98.7%	100%	96.3%	100.0%	100%	100%
Quarter 3	99.5%	99.4%	97.7%	99.9%	95%	96%
Quarter 4	99.0%	100%	100%	100%	97%	100%
Quarter 1 to Quarter 4 average	**99%**	**99.7%**	**98.5%**	**99%**	**97%**	**98%**

(Table 5.1)



(Figure 5.1)

Bacterial surveillance of platelets products: 2018/2019

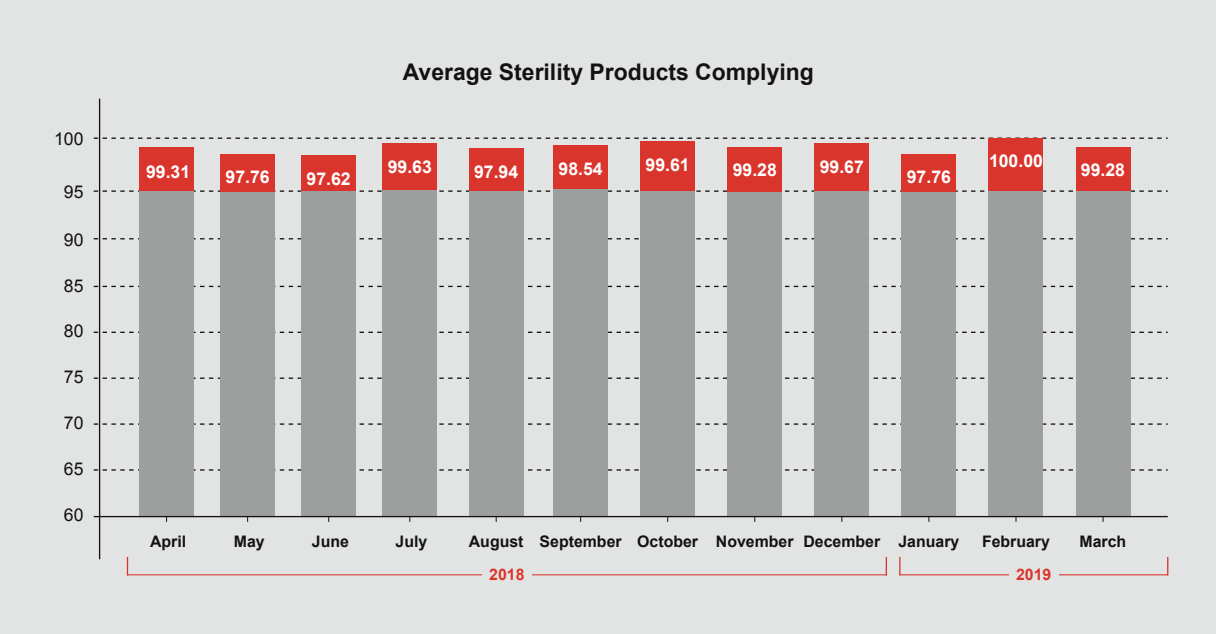
As platelet products are stored at room temperature, they are a good marker of the level of bacterial contamination. A quality control model is followed, whereby a proportion of single donor platelets (SDPs) collections is tested for bacterial contamination. This bacterial screening programme has been in place for the last 15 years to monitor bacterial contamination of SDP products, but has been optimised and aligned to international requirements in the last two years.

It is linked to a notification system which notifies the clinician in charge of a patient who has received a contaminated product. Contaminated products in the inventory are quarantined and discarded. No report of sepsis or mortality of patients receiving a contaminated product has been reported to the SANBS Haemovigilance Programme to date. As this is a passive reporting system, these adverse events are likely to be underreported. Bacterial surveillance is reported quarterly.

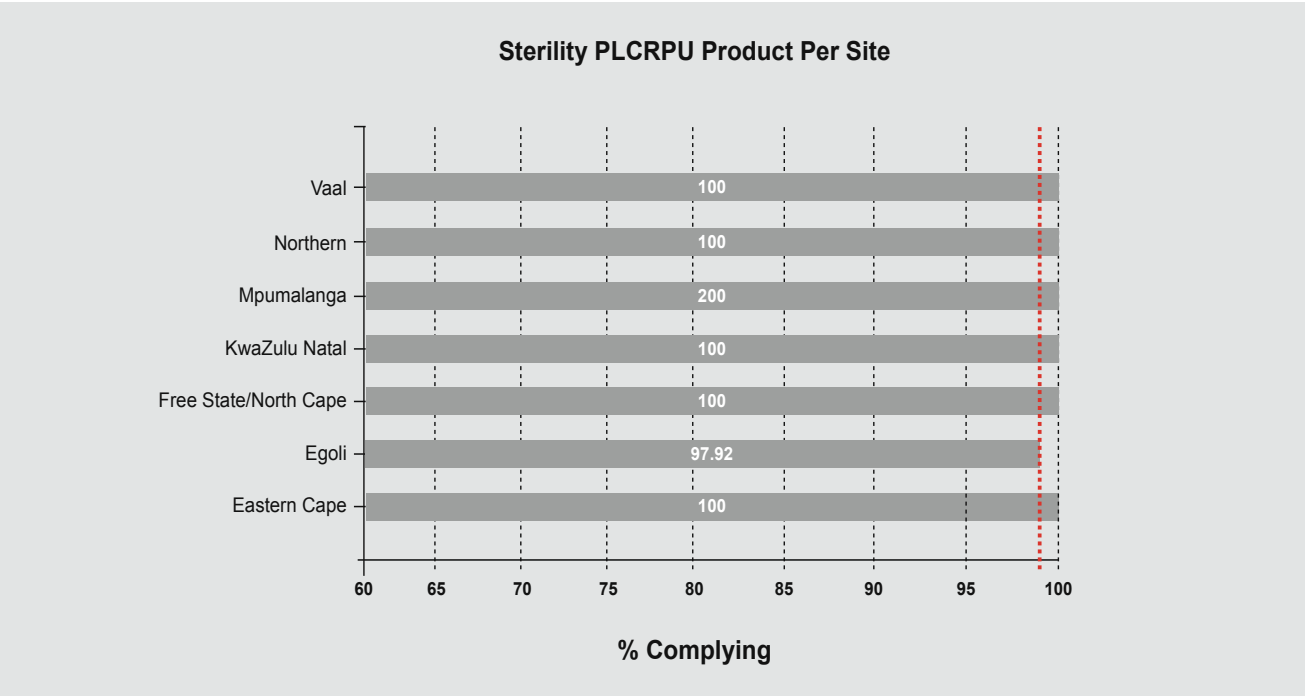
In 2018/2019, SANBS performed bacterial surveillance on 17 070 SDP products (21.2% of total collections) and 3 626 quality control samples.

% Compliance	Apheresis platelet tested (non-compliant/total tested) % positive	Pooled platelet (non-compliant/ total tested) % positive
Quarter 1	17/830 (2.1%)	0/7 (0%)
Quarter 2	11/824 (1.3%)	0/229 (0%)
Quarter 3	4/816 (0.5%)	2/332 (0.6%)
Quarter 4	8/792 (1%)	1/363 (0.3%)
Total	**40/3 262 (1.2%)**	**3/933 (0.3%)**

(Table 5.2)



(Figure 5.2)



(Figure 5.3)

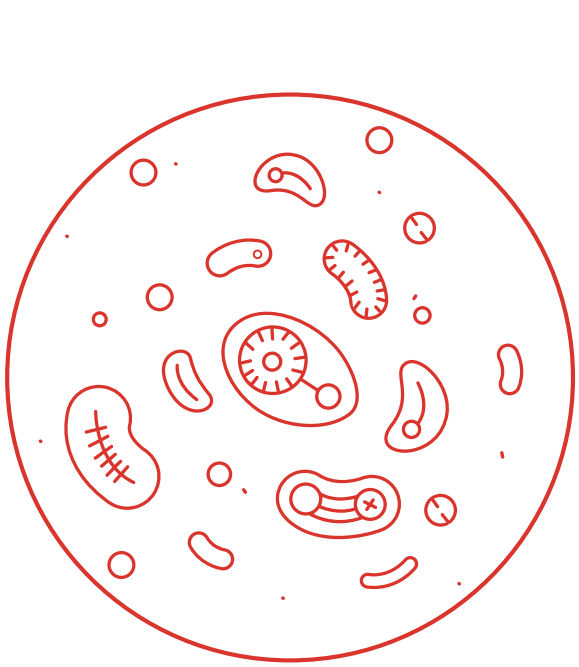
The percentage bacterial contamination of SDP products was 1%, and just under 1% for random donor platelet products. This is a reduction of more than half the rate of the previous year (2.5%). This indicates that SANBS is maintaining infection control prevention awareness and interventions. In the last year, bacterial surveillance was extended to include pooled platelets. Environmental screening was introduced into processing sites and will be rolled out to blood banks in the near future. In addition, detergent and alcohol wipes have been introduced to optimise environmental hygiene.

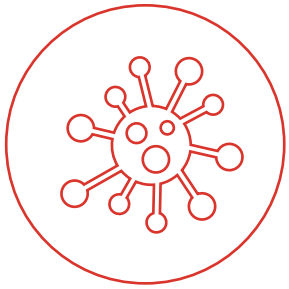
	Cocci n = 29				Bacilli n = 7			
	Quarter 1	**Quarter 2**	**Quarter 3**	**Quarter 4**	**Quarter 1**	**Quarter 2**	**Quarter 3**	**Quarter 4**
Gram-positive bacteria	12	9	2	6	3	2	0	0
Gram-negative bacteria	0	0	0	0	2	0	0	0
Fungi n = 0	0			0	0			0
No bacterial growth	0			0	0			0
Top three organisms	Quarter 1		Quarter 2		Quarter 3		Quarter 4	
	Micrococcus spp		Staphylococcus capitis		Staphylococcus epidermidis		Staphylococcus epidermidis	

(Table 5.3. Summary of microorganisms isolated per quarter from platelets products.)

	Cocci n = 29		Bacilli n = 7	
Top three organisms	**Quarter 1**	**Quarter 2**	**Quarter 3**	**Quarter 4**
	Micrococcus spp	Staphylococcus capitis	Staphylococcus epidermidis	Staphylococcus epidermidis
	Staphylococcus spp	Micrococcus spp	Corynebacterium jeikeium	Staphylococcus hominis
	Bacillus spp	Corynebacterium spp		
True pathogens	1-Pseudomonas aeruginosa	0	0	1 - Staphylococcus aureus

(Table 5.3. Summary of microorganisms isolated per quarter from platelets products.)





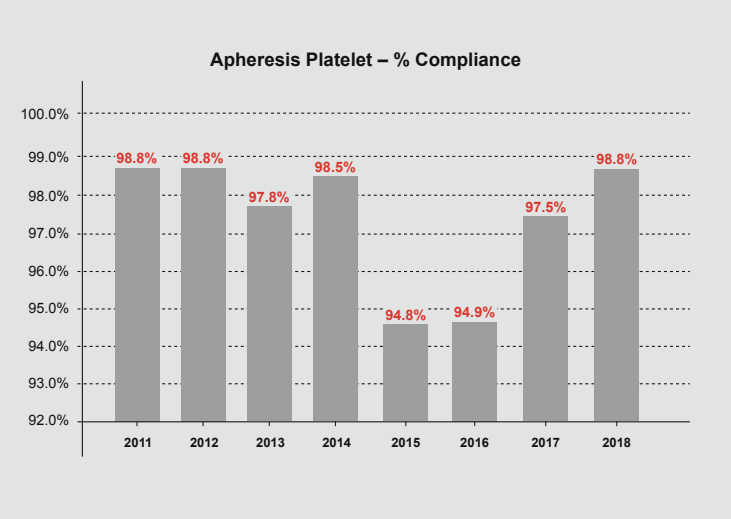
Microorganisms
from platelets products

Thirty-six bacteria were isolated – 34/36 were gram positive bacteria, indicating that skin and environmental commensals remain the most common isolates in platelet products. Two typical pathogens were isolated, one each of *Pseudomonas aeruginosa* and *Staphylococcus aureus*.

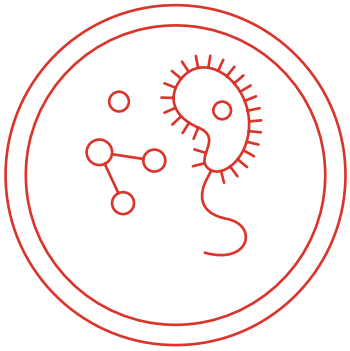
% Compliance	(Negative samples/total environmental samples) % positive
Quarter 1	(818/827) 1.1%
Quarter 2	(979/987) 0.2%
Quarter 3	(893/894) 0.1%
Quarter 4	(922/922) 0%
Total	**3/933 (0.3%)**

(Table 5.4. Environmental testing.)

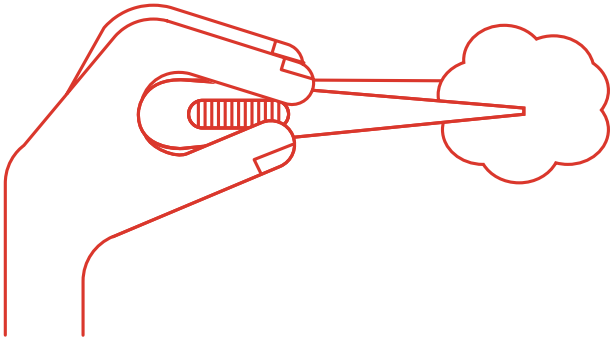
Environmental samples from apheresis clinics are collected monthly and include samples from benches, air, hands and utensils/equipment. The unacceptable rate has stayed constant. The most common isolates are gram-positive cocci and *Bacillus spp.*



(Figure 5.4. Annual trends of platelet sterilities.)



Bacterial Contamination of Apheresis Platelets Declining



It is evident and encouraging that the rate of bacterial contamination of Apheresis Platelets compared to previous years is still declining. Although significant improvements have been made and infection control prevention is now well established at SANBS, the risk of bacterially contaminated platelets remains. Culture is not 100% sensitive and SANBS is not able to test all Apheresis platelets due to insufficient availability.

To reduce the residual risk further, the 70% infection prevention antiseptic swabs for cleaning of donor skin will be changed to 2% Chlorhexidine gluconate (CHX) as this is superior to alcohol alone. In addition, SANBS must continue to explore the feasibility of introducing pathogen reduction/inactivation to reduce the residual risk even further.

6. Donor Vigilance Data 2018

Approximately 107 million units of blood donations are collected globally every year. In high-income countries, the rate is 39.2 donations per 1 000 population; 12.6 donations in middle-income and only 4.0 donations in low-income countries (3). 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, recognized donor complications can occur. Donor vigilance is the systematic monitoring of adverse reactions and incidents in blood donor care to improve quality and safety for blood donors. Donor haemovigilance systems permit monitoring of donor safety and evaluation of the impact of changes in donation procedures and of the success of interventions designed to further improve donor safety.

There were 5 569 donor adverse events reported in 2018. The overall reported rate of donation-related adverse events seems to have increased since 2014, which probably reflects improved capture and reporting of incidents, rather than deterioration in donor safety.

The most frequently reported donation adverse events were vasovagal reactions at 3 287 (59.03%). 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 or up to eight hours after the donation. Events that occur in the donor centre are immediate events, and those that occur after the donor has left the donor centre are delayed events.

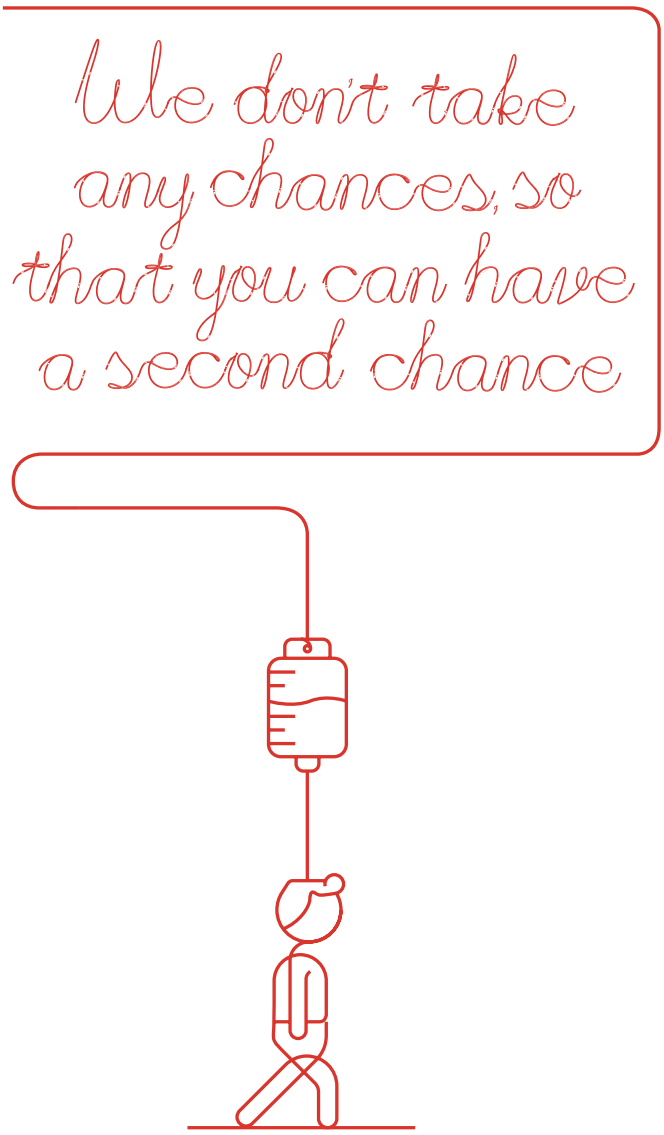
The other major category of donor adverse events is caused by venipuncture, most frequently manifesting in bruising and local arm pain, with less frequent local complications including local thrombosis and arterial puncture.

% Compliance					
Year	2014	2015	2016	2017	2018
Local symptoms	688	818	1 327	1 119	1 111
Arterial puncture	3	1	2	7	0
Delayed bleeding	18	32	77	46	32
Haematoma	538	540	885	788	822
Nerve injury	2	16	0	1	13
Nerve irritation	4	8	18	16	1
Painful arm	122	219	344	260	241
Tendon injury	1	2	1	1	2
Other	33	94	170	768	721
Citrate reaction	30	80	158	764	596
Generalised allergic reaction	3	13	6	3	124
Haemolysis	0	1	6	1	1

(Table 6.1. Donor adverse events reported in 2018. continued…)

% Compliance					
Year	**2014**	**2015**	**2016**	**2017**	**2018**
Vasovagal reactions	3 439	3 746	2 633	3557	3 827
Faint delayed type	1 187	1 658	1 145	1 651	1 407
Faint delayed, accident	183	133	135	101	188
Faint Immediate type	1 920	1 704	1 232	1 654	1 856
Faint immediate, accident	149	251	121	151	376
Grand total	**4 160**	**4 658**	**4 130**	**5 444**	**5 659**

(Table 6.1. Donor adverse events reported in 2018. continued…)

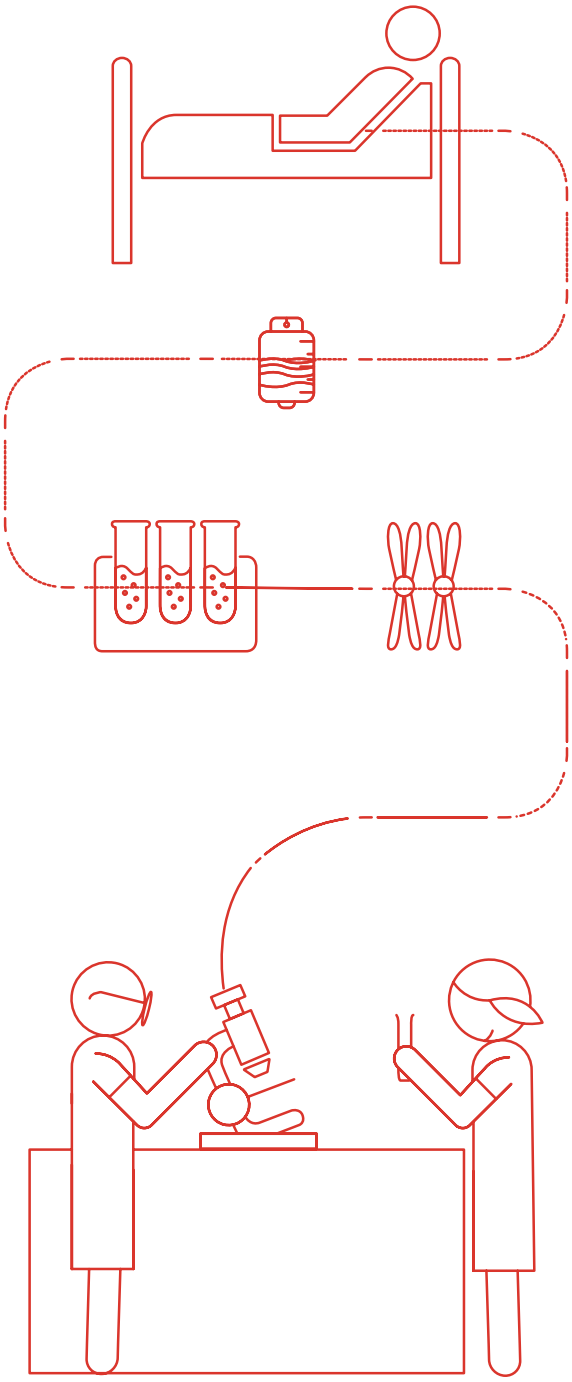


At SANBS we pride ourselves in using the healthiest blood from the healthiest donors and every aspect of the transfusion process is meticulously monitored to ensure the absolute safety of our donors and recipients. Your blood saves lives.

7. Conclusion

The South African Haemovigilance Programme endeavours continuously to highlight and 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 and patients who experience adverse events must be appropriately managed.

The two blood transfusion services in South Africa continue their commitment to ensuring blood safety, supporting healthcare givers when reporting transfusion adverse events, investigating and identifying system failures, and identifying processes that will prevent recurrence. Ongoing surveillance and review of donor adverse events is vital and enables the blood services to monitor and minimise risks related to blood donation and implement corrective systems. The blood services aim for continuous improvement in an environment that is not perfect.



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