HAEMOVIGILANCE REPORT

2017

WP Blood Transfusion Service
Do something remarkable

SANBS
South African National Blood Service

HAEMOVIGILANCE REPORT 2017

Privacy statement

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

Disclaimer

This document is a general report. The data, analysis and conclusions contained herein are intended to provide healthcare professionals and the public with general information on transfusion and donor related adverse events in South Africa. The report is a snapshot of currently available data.

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Abbreviations

AHTR	Acute haemolytic transfusion reactions
ATR	Acute transfusion reactions
DAE	Donor adverse events
DAT	Direct antiglobulin test
DHTR	Delayed haemolytic transfusion reactions
DSTR	Delayed serological transfusion reactions
FFP	Fresh frozen plasma
FNHTR	Febrile non-haemolytic transfusion reactions
HBV	Hepatitis B virus
HCV	Hepatitis C virus
HIV	Human immunodeficiency virus
HLA	Human leucocyte antigens
IBCT	Incorrect blood component transfused
ID-NAT	Individual donation nucleic acid amplification test
IHN	International Haemovigilance Networks
ISBT	International Society of Blood Transfusion
ISTARE	International Surveillance of Transfusion-Associated Reactions and Events
PTP	Post-transfusion purpura
SANBS	South African National Blood Service
SHOT	Serious hazards of transfusion
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

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.

Transfusion reaction classifications and definitions (continued)

Category	Definition
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 together 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 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.
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 a reaction 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. 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 after 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. Developing 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 and no clinical or laboratory evidence of infection prior to transfusion. At least one component received by the infected recipient donated by a donor who had 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 of the same bacterial strain in the recipient's blood and in the transfused blood product by approved techniques. Probable cases of transfusion-transmitted bacterial infection include instances where the recipient has evidence of infection following a transfusion with neither evidence of infection before transfusion nor evidence of an alternative source of infection.

Transfusion reaction classifications and definitions (continued)

Category	Definition
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 appropriate requirements or that was intended for another patient.
Near miss	An error or deviation from standard procedures or policies that, if undetected, could have resulted in the determination of a wrong blood group or issue, collection or administration of an incorrect, inappropriate or unsuitable component, but that was recognised before the transfusion took place.
Misidentification – hospital error	Near-miss events related to the misidentification of specimens, units or patients that occur outside the blood bank.
Misidentification – blood bank error	Near-miss events related to the misidentification of specimens, units or patients that occur at the blood bank.
Misdirected transfusion incidents	A misdirected transfusion incident is a case where the patient is transfused with blood that was intended for another patient. It thus comprises transfusion errors and deviations from standard operating procedures or hospital policies and/or practices that have led to mis-transfusions. It may or may not lead to an adverse reaction.
Unclassifiable complication of transfusion	Occurrence of an adverse event or reaction temporally related to transfusion, which cannot be classified according to an already defined Acute Transfusion Event and with no risk factor other than transfusion.
Transfusion-transmitted parasitic infections	Detection of the same parasite in the recipient's blood and parasite or specific antibodies in the donor blood.
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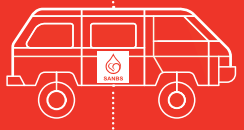
Unclassifiable complication of transfusion	Occurrence of an adverse event or reaction temporally related to transfusion, which cannot be classified according to an already defined Acute Transfusion Event and with no risk factor other than transfusion.

Basic definitions in adverse events (ISBT and IHN)	
Adverse event	Undesirable and unintended occurrences associated with transfusion.
Incident	Patient transfused with a blood component that did not meet all the stated requirements.
Near miss	An adverse event that is discovered before the start of a transfusion.
Adverse reaction	Undesirable response or effect temporally associated with the administration of blood, or blood components. May be the result of: • An incident • An interaction between a recipient and blood

Journey of blood

A unit of blood is drawn from a volunteer donor.

Blood is collected into a sterile bag and labelled.



Units are transported to the nearest SANBS testing and processing lab.

In the processing laboratory, blood is spun down in a centrifuge and then separated into its different components.

Plasma
Contains proteins and clotting factors used to treat patients with massive bleeding or clotting factor deficiencies.

Red blood cells
Contain haemoglobin, a protein which carries oxygen throughout the body. Used to treat patients with anaemia or blood loss due to trauma or surgery.

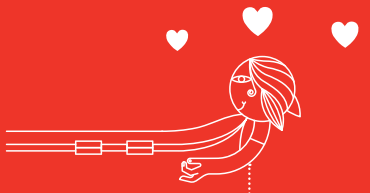
Platelets
Crucial in helping blood clot. Patients with low platelet levels often suffer from bruising and bleeding.

Blood is tested to ensure that it is safe for transfusion.

Local hospitals place orders with the SANBS for blood products based on their needs.

Blood products are stored prior to transfusion. The shelf life of blood is limited.

Platelets expire in five days. Red blood cells expire in 42 days. Frozen plasma has a one-year shelf life from the day of collection.



Blood is transfused to a patient in need. Just one blood donation has the potential to save three lives.

SANBS
South African National Blood Service

Your blood saves lives.

FOREWORD
MESSAGE FROM THE MEDICAL DIRECTORS

Dr Gregory Bellairs
Director and CEO
WPBTS

Dr Jackie Thomson
Medical Director, SANBS

This year the focus of the Haemovigillance team was to introduce the concept of Patient Blood Management to all our stakeholders.

Patient blood management is an evidence based bundle of care that optimises patients' outcome through managing and preserving their own blood. It will lead to a paradigm shift within the service from product focus to a patient focus.

Traditionally, it has been assumed that blood transfusion benefits patients; however the potential side effects related to transfusion, need to be considered prior to each transfusion. In South-Africa the risk of Transfusion Transmitted Infections (TTI) is of particular concern. Furthermore, international data suggests that serious non-viral adverse events such as Transfusion-Associated Circulatory Overload (TACO) or Transfusion-Related Acute Lung Injury (TRALI), are more common than previously thought; although still not commonly reported in South Africa. More recently identified conditions such as Transfusion-related immunomodulation may cause patient harm.

Although the risk of transfusion transmissible infections has declined significantly in recent years, through improved manufacturing and laboratory processes, the potential for transfusion of an unrecognized infectious agent remains a concern.

Despite improvements in systems management, there remains a risk of transfusion-related harm due to administrative errors. Such an error has the potential to result in Acute hemolytic reactions from ABO incompatibility, which may be fatal. Misdirected transfusions is the number one risk of transfusion.

Therefore if a patient requires therapy for anemia, transfusion should not be a default decision. Instead, the decision on whether to transfuse should be carefully considered, and should:

- take into account the full range of available therapies including iron replacement
- balance the evidence for efficacy and improved clinical outcome against the risks
- take into account patient values and choices.

AS ONE OF OUR 500 000 DONORS A YEAR,
EVERY DROP YOU DONATE SAVES LIVES. SO THANK YOU.
YOU ARE A TRUE HERO.

sanbs.org.za

Donate today. Your blood saves lives.

SANBS
South African National Blood Service

1

EXECUTIVE **SUMMARY**

EXECUTIVE SUMMARY

Since the successful release of our first annual haemovigilance report for South Africa in 2000, we are pleased to publish our 18th annual report.

The objective of a haemovigilance system is to detect risks and trigger preventative measures. Key recommendations from the 2016 report included the need for improved reporting from hospitals, improvements in report quality and supporting documentation, reduced transfusion errors as well as stakeholder accountability. Various recommendations were proposed to achieve these. A key proposal was improved collaboration with the Department of Health through the Patient Blood Management programme. Although the programme was still in planning stages in 2017, it is envisaged that implementation will strengthen stakeholder collaboration and ultimately trigger the necessary actions towards effective reporting of transfusion adverse events and prevention of errors.

This report provides an overview of data collected by the South African National Blood Service (SANBS) and Western Province Blood Transfusion Service (WPBTS) from January to December 2017. It covers blood product collections and issues, transfusion and donor-adverse reactions, patient mortalities, apheresis platelet sterility testing and look-back data.

Blood product issuing

In 2017, a total of 1 193 132 blood products were issued to patients across the country. SANBS issued 1 018 444 products, while WPBTS issued 174 688 products. Overall products issued decreased by 8 159 in 2017 compared to 2016. Total product issues by SANBS increased by 4 560, while total issues by WPBTS decreased by 12 719. Although overall red cell issues decreased in 2017, the proportion of red cell products issued remained the same at 79%. Total plasma issues increased by 1 474 units, while platelet issues increased minimally by 102 units.

Hospital participation

The number of hospitals reporting transfusion-adverse events declined from 273 to 249 in 2017. Health facilities supplied with blood and blood products increased from 749 in 2016 to 768 in 2017.

Transfusion-adverse reactions

A total of 1030 transfusion-adverse events were reported from different hospitals nationally. Of these, 840 (81.6%) were reported to SANBS while 189 (18.4.7%) were reported to WPBTS. Although fewer blood products were issued in 2017 compared to 2016, the rate of transfusion adverse events reported per 100 000 units issued increased from 82.1 in 2016 to 86.3 in 2017.

In line with previous years' data, the bulk of reported events were Febrile Non-Haemolytic and allergic reactions at 31.20% and 23.42% respectively. The incidence of incorrect blood components transfused decreased slightly from 3.80% in 2016 to 3.58% in 2017. The primary cause of these is human error. As such, prevention remains a priority. There were zero reported cases of Transfusion-Related Acute Lung Injury (TRALI), Delayed Hemolytic Transfusion Reaction (DHTR), Delayed Serologic Transfusion Reactions (DSTR) and Transfusion-Associated Graft-versus-Host Disease (TA-GvHD). 0.97% of Transfusion Associated Circulatory Overload (TACO) were reported. The TRALI and TACO data indicates potential under-reporting of these events. There were no reported cases of transfusion transmitted infections.

Patient mortalities

Twelve cases of patient deaths within 24 hours of transfusion were reported to the blood services. Serological incompatibility was excluded in 10 of the 12 cases. Insufficient documentation continues to pose a challenge to classification of transfusion associated mortalities. Of the 12 reported cases, only two were accompanied by reports from the managing doctors. This is a significant decline from seven out of 14 cases in 2016. No post-mortem reports were received.

Blood collections and Donor adverse reactions

In 2017 there were 984 730 successful donations. Of these, 152 739 (15.51%) units were collected by WPBTS, while 831 991 (84.49%) were collected by SANBS. SANBS collections increased by 0.25% while WPBTS collections decreased by 1.69%.

0.55% of donations resulted in adverse reactions. Total reported adverse reactions increased by 0.07% compared to 2016. The overall frequency of reported donation adverse reactions was 1:177. Adverse events were more commonly reported with whole blood donations than apheresis procedures. Vasovagal reactions and haematomas were the most common events associated with all types of donations

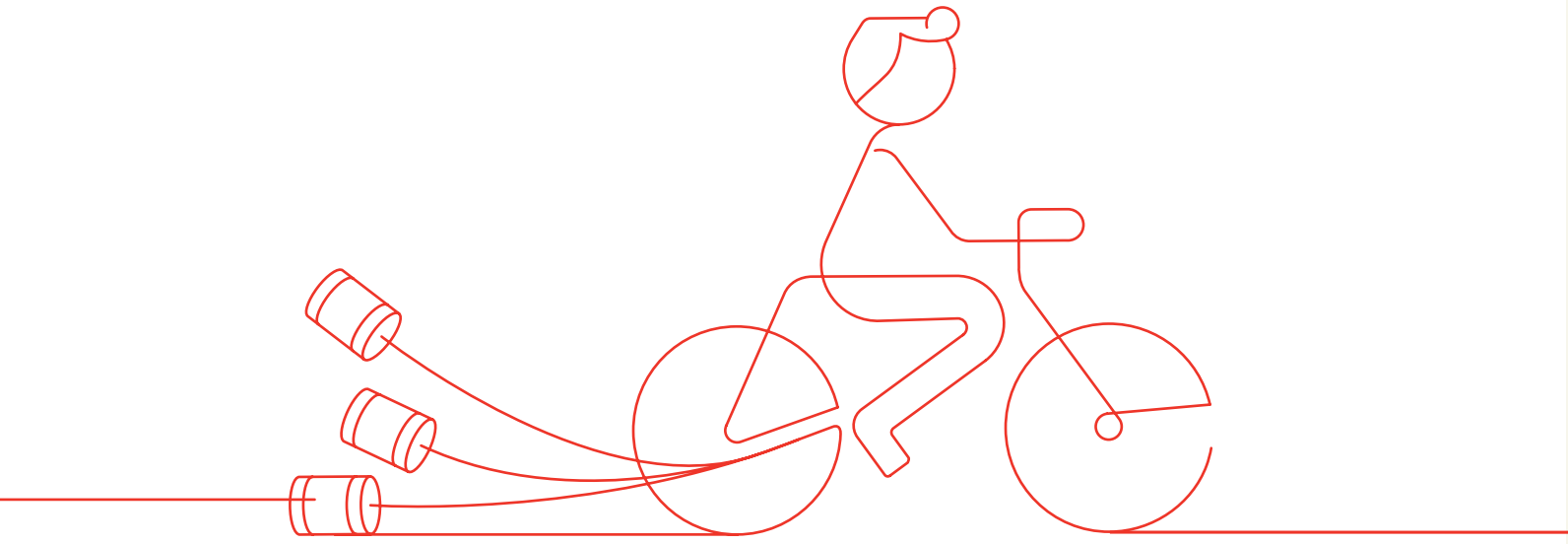
Look-back investigations

Of the total donors that seroconverted in 2017, 754 were investigated through the donor triggered lookback process. This is a 6.5% increase from 2016 cases. Case follow up was 100%. Of the 754 seroconverted donors, 68.7% were due to HIV, 27.0% HBV and 2.1% were due to HCV. Seven donors had HIV/HBV co-infection, two had HIV/HCV co-infection while another two were a result of HBV/HCV co-infection.

Ten recipient-triggered lookback cases were received. Of these six (60.0%) were resolved. Four of the resolved cases retested negative. Two cases were classified as "other". The first case was a suspected Malaria (resolved); all donors tested negative. The second was a CMV; unresolved as the Doctor did not complete the required forms to initiate the look-back investigation. In one case (HIV/HBV co-infection) it was determined that the patient in question had not received any transfusions. Three of the ten recipient-triggered cases (30.0%) remained unresolved due to unsuccessful attempts to trace and retest the implicated donors.

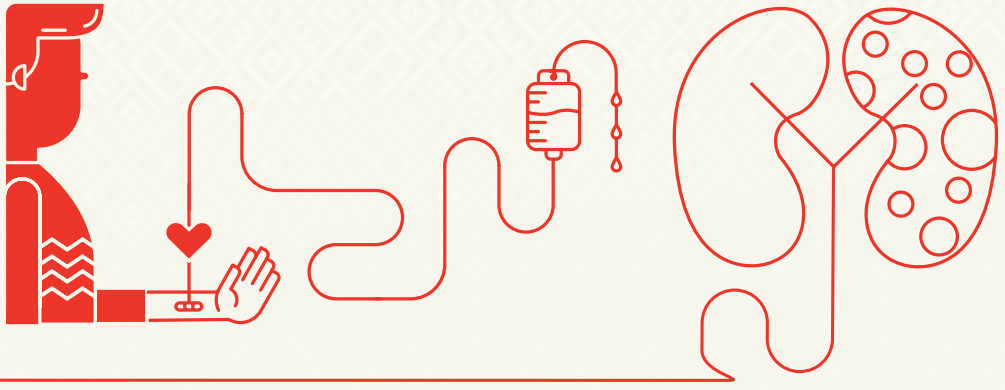
Platelet bacterial testing (SANBS only)

The percentage bacterial contamination of Apheresis platelets was 2.5%, which is approximately half the rate of the previous year, indicating that interventions to address the risk are benefiting platelet safety. Improvements include optimisation of bacterial testing facilities and processes. This involved culturing a larger volume (minimum 4 ml) of Apheresis platelet sample in aerobic bottles to enhance culture sensitivity while also reducing the incubation time to seven days. Infection and prevention control (IPC) awareness has also been increased. Hand and environmental hygiene have improved.



2

OVERVIEW OF **PRODUCT ISSUES**



OVERVIEW OF PRODUCT ISSUES

In 2017 SANBS and WPBTS issued a total of 1 193 132 blood products. SANBS issued 1 018 444 products, while WPBTS issued 174 688.

Overall products issued decreased by 8 159 in 2017 compared to 2016. Total product issues by SANBS increased by 4 560, while total issues by WPBTS decreased by 12 719. Although overall red cell issues decreased in 2017, the proportion of red cell products issued remained the same at 79%. Total plasma issues increased by 1 474 units, while platelet issues increased minimally by 102 units.

The number of health facilities supplied with blood and blood products increased from 749 in 2016 to 768 in 2017. Emergency red blood cells were supplied through 449 fridges located in various public and private sector health facilities. Supply of emergency blood however decreased from 42 333 to 39 535 units. As new hospitals emerge, the demand for Group O red cell products continues to increase. This remains a challenge as the demand outstrips current supply. The problem is further exacerbated by inappropriate utilisation of emergency stock red cell products for non-emergency cases as well as poor documentation of used products.

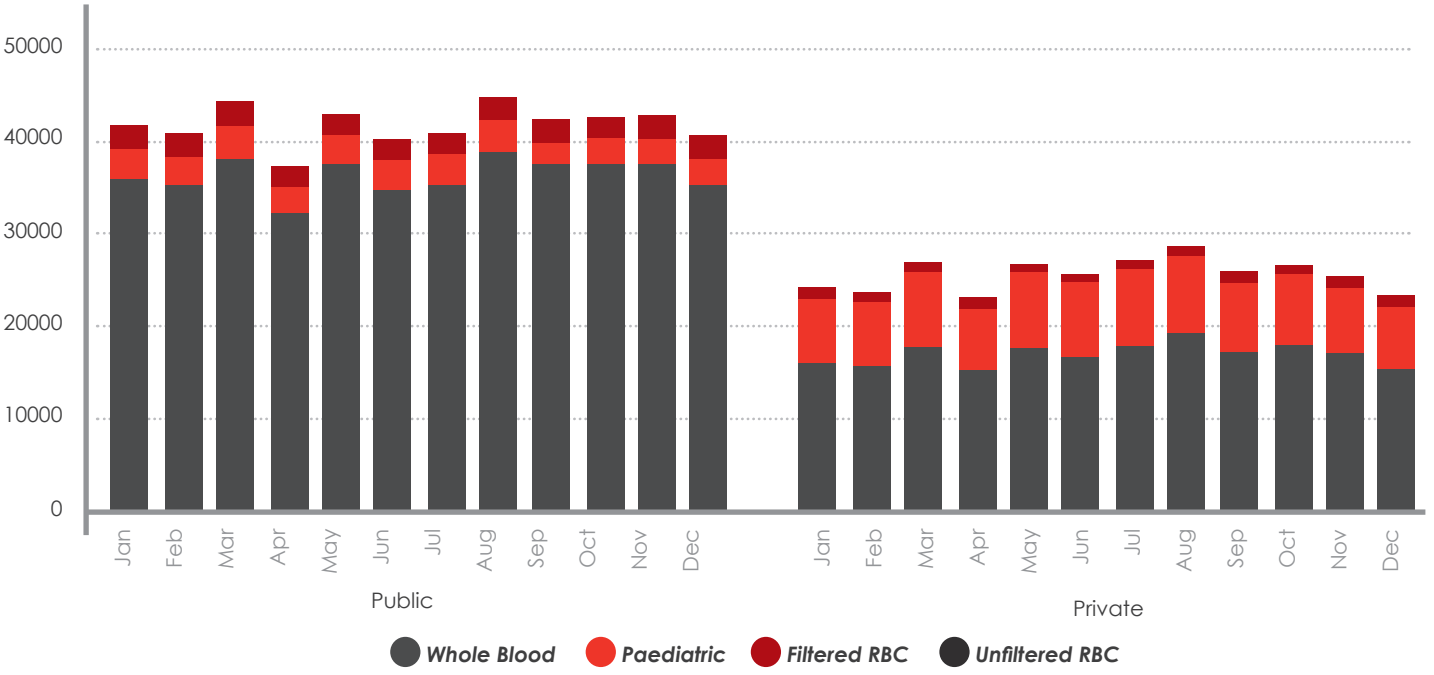
Table 2.1: Overall product issues 2017

Products	SANBS 2017	WPBTS 2017	TOTAL 2017
Cryo-plasma	28 755	1220	29 975
Fresh frozen plasma	127 529	23252	150 781
Totals	**156 284**	**24472**	**180 756**
Apheresis Platelet	24 668	4654	29 322
Pooled platelet	35 824	5388	41 212
Total	**60 492**	**10042**	**70 534**
Paediatric	36 958	2466	39 424
Red cells	732 406	128772	861 178
Reserved	144	70	214
Emergency units and ward stock	30 939	8596	39 535
Whole blood	1 221	270	1 491
Total red cell products	**801 668**	**140 174**	**941 842**
Grand Total	**1 0 18 444**	**174 688**	**1 193 132**

SANBS Red cell product issues

SANBS issued 801 668 red cell products of which 62% went to public institutions and 38% private institutions. Seventy-nine per cent of the products were issued as unfiltered products. Figure 2.1 displays the monthly RBC issues during 2017 by product type for public and private institutions. On average, 30% of the red blood cells in the private sector were filtered products, compared to 7% in the public sector.

Figure 2.1: SANBS Red cell product issues Public Vs Private sector



Collections and Issues

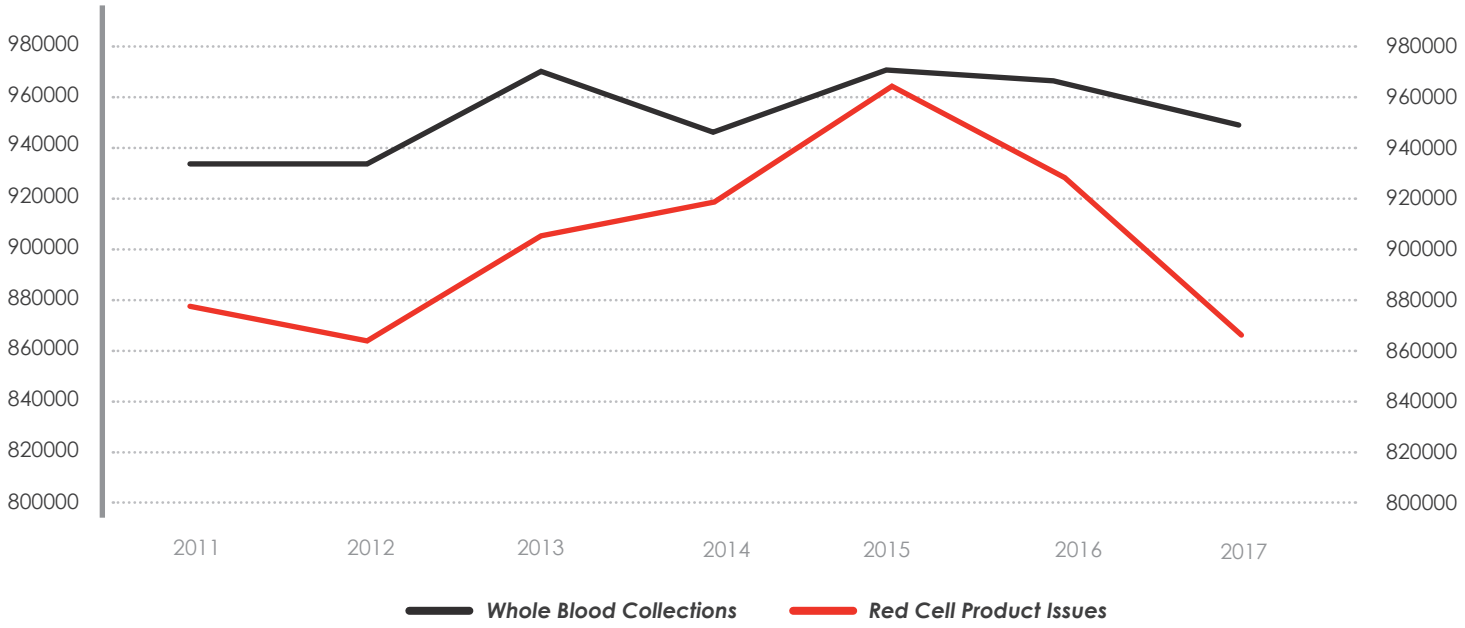
A review of Table and figure 2.2 reflects a steady decrease in percentage difference between whole blood collections versus red cell product issues from 2012 through to 2016. 2017 experienced a significant increase in percentage difference between whole blood collections and issues.

Table 2.2: Collections and issues

Collection types	2011	2012	2013	2014	2015	2016	2017
Whole blood collections	930 654	932 509	967 125	944 058	971 046	966 674	965 666
Red cell product issues	873 353	858 760	902 063	917 199	963 182	925 465	861 178*
Percentage difference	6%	7%	7%	3%	1%	4%	11%

*Adjusted for paediatric units.

Figure 2.2: Collections and issues (2010 to 2017)



Transfusion transmissible infections and blood safety

Although HIV, Hepatitis B and Hepatitis C serology testing and Individual Donor Nucleic Acid Amplification testing (ID-NAT) is conducted on all donated units, the presence of a window period poses some transfusion transmissible infection risks.

HIV residual risk

During the year 2017 blood donor HIV rate decreased from 0.21% to 0.19%, continuing the downward trend seen over the past five years. This decrease was mainly seen in first-time donors which decreased from 1.19% in 2013 to 0.93% in 2017. The decrease was seen in both genders and all age groups over 20 years old. However, HIV NAT yields and HIV positives in repeat donors represent incident infections and impact on the residual risk of obtaining a transfusion transmitted HIV infection. The HIV NAT yields increased from 7/100 000 in 2016 to 9/100 000 in 2017 in regular donors and first-time donors. Residual risk using the NAT yield ratio model uses NAT yields to impute incidence. The residual risk in 2017 was 1 in 35 143 donations when a worst-case scenario of 1 virion is deemed to be the 50% minimum infectious dose (MID_{50}). Using the risk day equivalent model and repeat donors to impute incidence the residual risk was 1 in 53 326 when the MID_{50} of 1 virion is used, or 1 in 1 756 693 transfusions when the MID_{50} of 316 virions is used.

Emerging infectious diseases (EID)

Untested transfusion transmissible infections pose additional risk to issued blood safety. In view of this, in July 2017 the Blood safety committee decided to implement an Emerging Infectious Disease (EID) subcommittee that would comprise of SANBS, WPBTS, National Bio-Institute (NBI) and National Institute for Communicable Diseases (NICD). The subcommittee is responsible for ongoing surveillance of diseases that require testing by the blood services. It also develops communication channels with NICD for reporting of outbreaks such as haemorrhagic fever. In order to establish a baseline, the subcommittee investigated the following diseases; Hepatitis E virus (HEV), West Nile virus (WNV), Cytomegalovirus (CMV), Hepatitis A virus (HAV), Human T-cell Lymphotropic virus (HTLV1), Dengue virus, Chikungunya virus, Malaria, Epstein-Barr virus (EBV), Parvo virus B19 and Human Herpesvirus 8 (HHV8).

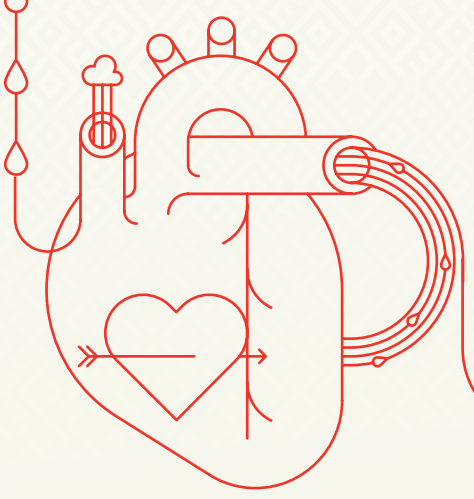
In quarter three of 2017, it was agreed to review in depth HEV, HHV8, WNV, HTLV1, CMV and HAV. In quarter 4 the following recommendations were approved by the Blood safety committee:

- perform a molecular and sero-prevalence study of HEV during the 2019/2020 financial year
- rewrite Clinical Guidelines for use of blood products in South Africa to be explicit around "those at risk" for CMV infection
- perform risk modelling for HAV and issuing of older donors' blood to young recipients
- extrapolate the HTLV data to the current demographic profile of blood donors

These measures constitute ongoing initiatives to improve the safety of blood with regard to untested and emerging transfusion transmissible pathogens.

3

OVERVIEW OF TRANSFUSION **ADVERSE EVENTS**



OVERVIEW OF TRANSFUSION ADVERSE EVENTS

"An adverse event is an undesirable and unintended occurrence before, during or after transfusion of blood or blood component which may be related to the administration of the blood or component. It may be the result of an error or an incident and it may or may not result in a reaction in a recipient. An incident is a case where the patient is transfused with a blood component which did not meet all the requirements for a suitable transfusion for that patient, or that was intended for another patient. It thus comprises transfusion errors and deviations from standard operating procedures or hospital policies that lead to mis-transfusions. It may or may not lead to an adverse reaction. An adverse reaction is an undesirable response or effect in a patient temporally associated with the administration of blood or blood component. It may, but need not, be the result of an incident" (ISBT, 2013).

During 2017 a total of 1030 transfusion adverse events were reported to SANBS and WPBTS from different hospitals nationally. Of these 840 (81.6%) were reported to SANBS while 189 (18.4%) were reported to WPBTS. Although fewer blood products were issued in 2017 compared to 2016, the rate of transfusion adverse events reported per 100 000 units issued increased from 82.1 in 2016 to 86.3 in 2017.

Table 3.1 provides a breakdown of types of reactions reported for the years 2016 and 2017. In line with previous years' data, the bulk of reported events were febrile non-haemolytic and allergic reactions at 31.20% and 23.42% respectively. The incidence of incorrect blood components transfused decreased slightly from 3.80% in 2016 to 3.58% in 2017. The primary cause of these is human error. As such, prevention remains a priority. There were zero reported cases of TRALI, DHTR, DSTR and TA-GvHD. The TRALI and TACO data indicates potential under-reporting of these events. There were no reported cases of transfusion transmitted infections.

Table 3.1: Summary of transfusion adverse events 2017

	Adverse events	SANBS 2017	WPBTS 2017	South Africa 2017	%
Acute transfusion reactions (ATRs)	Acute haemolytic transfusion reactions (AHTR)	0	0	0	0
	Allergic reactions	168	73	241	23.39
	Severe allergic reactions	37	8	45	4.37
	Anaphylactic reactions	38	8	46	4.47
	Febrile non-haemolytic Reactions (FNHTR)	250	71	321	31.17
	Transfusion-associated circulatory overload (TACO)	8	2	10	0.97
	Transfusion-related acute lung injury (TRALI)	0	0	0	0
	Transfusion-associated dyspnoea (TAD)	72	1	73	7.09
	Hypotensive reactions	34	2	36	3.50
	Unclassifiable (incomplete information and no forms)	184	15	199	19.32
	Total acute transfusion reactions (ATR)	**791**	**180**	**971**	**94.36**
Delayed transfusion reactions	Delayed haemolytic transfusion reactions (DHTR)	0	0	0	0
	Delayed serological transfusion reactions (DSTR)	0	0	0	0
	Total delayed reactions	**0**	**0**	**0**	**0**

Table 3.1: Summary of transfusion adverse events 2017 (continued)

	Adverse events	SANBS 2017	WPBTS 2017	South Africa 2017	%
Incorrect blood component transfused (IBCT)	Rh incompatible transfusions	3	0	3	0.29
	ABO incompatible transfusions	9	1	10	0.97
	Misdirected transfusions (with and Without ABO Incompatibility)	18	4	22	2.14
	Antibodies detected	2	0	2	0.19
	Total IBCT	**32**	**5**	**37**	**3.59**
Other reactions	Near miss	6	4	10	0.97
	Transfusion-associated graft-versus-host disease (TA-GvHD)	0	0	0	0
	Transfusion-transmitted infections	0	0	0	0
	Post-transfusion purpura	0	0	0	0
	Mortality	12	0	12	1.17
	Total other	**18**	**4**	**22**	**2.14**
	GRAND TOTAL	**840**	**189**	**1030**	**100**

Transfusion adverse events rate

The transfusion adverse event rate in South Africa was 86.3 units per 100 000 units transfused. This translates to 0.86 reactions per 1 000 units transfused. The SANBS transfusion adverse reaction rate was 0.82 while the WPBTS was 1.08 per 1000 units issued.

Table 3.2: Rates of transfusion adverse events per classification

Adverse events	Total number per classification 2017	Rates per 100 000 units issued 2017
Acute haemolytic transfusion reactions (AHTR)	0	0
Allergic reactions	241	23.4
Severe allergic reactions	45	4.3
Anaphylactic reactions	46	4.4
Febrile non-haemolytic transfusion reactions (FNHTR)	321	31.1
Transfusion-associated circulatory overload (TACO)	10	0.9
Transfusion-related acute lung injury (TRALI)	0	0
Transfusion-associated dyspnoea	73	7.0
Hypotensive reactions	36	3.4
Unclassifiable (incomplete information)	199	19.3
Total ATR	**971**	**81.3**
Delayed haemolytic transfusion reactions (DHTR)	0	0
Delayed serological reactions (DSTR)	0	0
Rh incompatible transfusion	3	0.2
ABO incompatible transfusion	10	0.9
Misdirected transfusions	22	2.1
Antibodies detected	2	0.1
Total IBCT	**37**	**3.1**
Near miss	10	0.9
Transfusion-associated graft-versus-host disease (TA-GvHD)	0	0

Table 3.2: Rates of transfusion adverse events per classification (continued)

Adverse events	Total number per classification 2017	Rates per 100 000 units issued 2017
Transfusion-transmitted infections	0	0
Post-transfusion purpura	0	0
Mortality	12	1.0
Total other	**22**	**1.8**
Grand total	**1030**	**86.3**

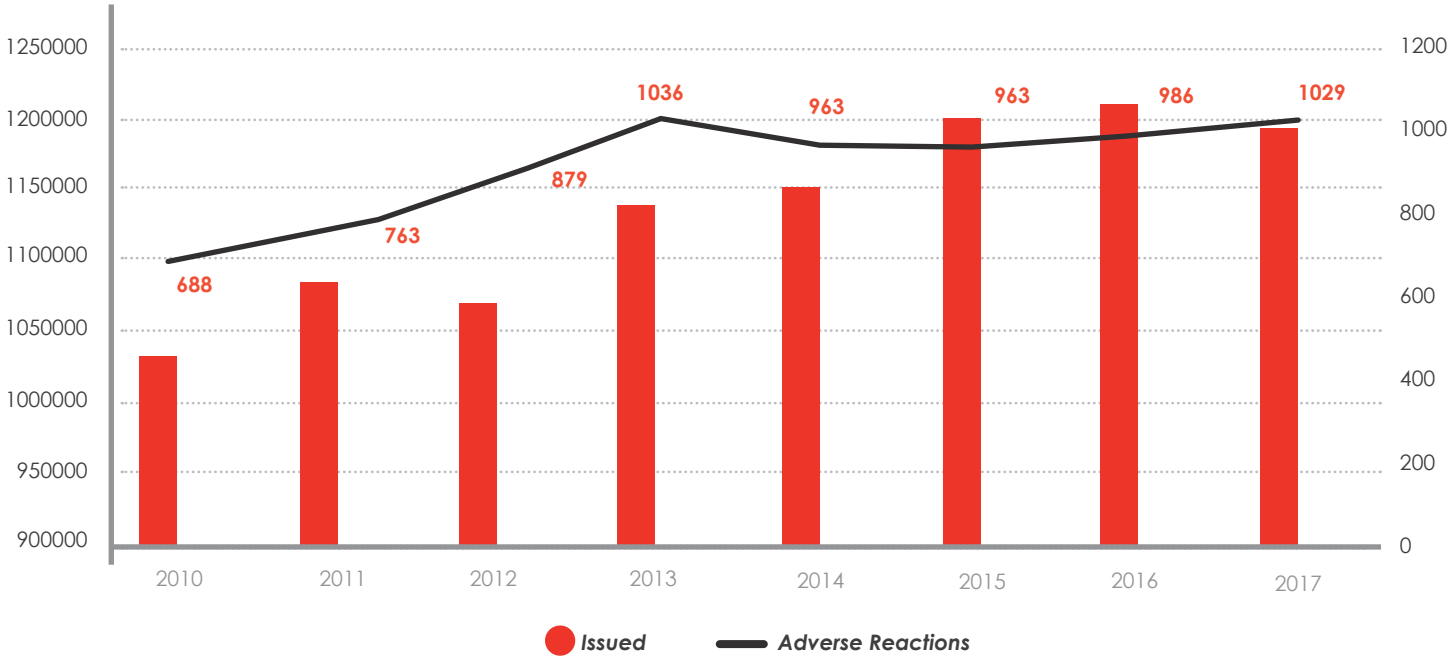
The rates of adverse events are calculated per 100 000 units issued. This is in line with the International Surveillance of Transfusion-Associated Reactions and Events (ISTARE) database used by members of the International Haemovigilance Network (IHN).

Table 3.3 shows the rates of transfusion adverse events per 100 000 units over an eight-year period. The rates increased steadily from 2010 to 2013. However, 2014 and 2015 saw a decline with an increase again from 2016.

Table 3.3: Adverse events rates per 100 000 issues (2010 to 2017)

	2010	2011	2012	2013	2014	2015	2016	2017
Issued	1 032 580	1 081 690	1 069 402	1 133 204	1 152 836	1 200 228	1 201 291	1 193 132
Adverse reactions	688	763	879	1 036	963	961	986	1 029
Rates per 100 000 issues	66.6	70.5	82.2	91.4	83.5	80.1	82.1	86.3

Figure 3.1: Adverse reactions rates – 2010 to 2017



ACUTE TRANSFUSION REACTIONS

Acute transfusion reactions remain the most commonly reported events at 94.36% of all reported cases. Of these Febrile Non-Hemolytic Transfusion Reactions (FNHTR), allergic and unclassifiable reactions are the most common.

Table 3.4: Acute transfusion reactions (2011 to 2017)

Acute reactions:	2011	2012	2013	2014	2015	2016	2017
AHTR	4	4	52	10	22	5	0
Allergic (including severe allergic)	221	274	297	251	260	87	286
Anaphylactic	16	26	64	53	87	33	46
TRALI	1	2	1	2	5	1	0
TACO	1	0	0	3	0	5	10
TAD	71	64	76	80	77	74	73
FNHTR	255	360	388	347	334	306	321
Hypotensive	54	40	52	57	33	28	36
Unclassifiable	117	72	112	99	79	178	199
Total	**740**	**842**	**1042**	**902**	**897**	**717**	**971**

Figure 3.2: Acute transfusion reactions

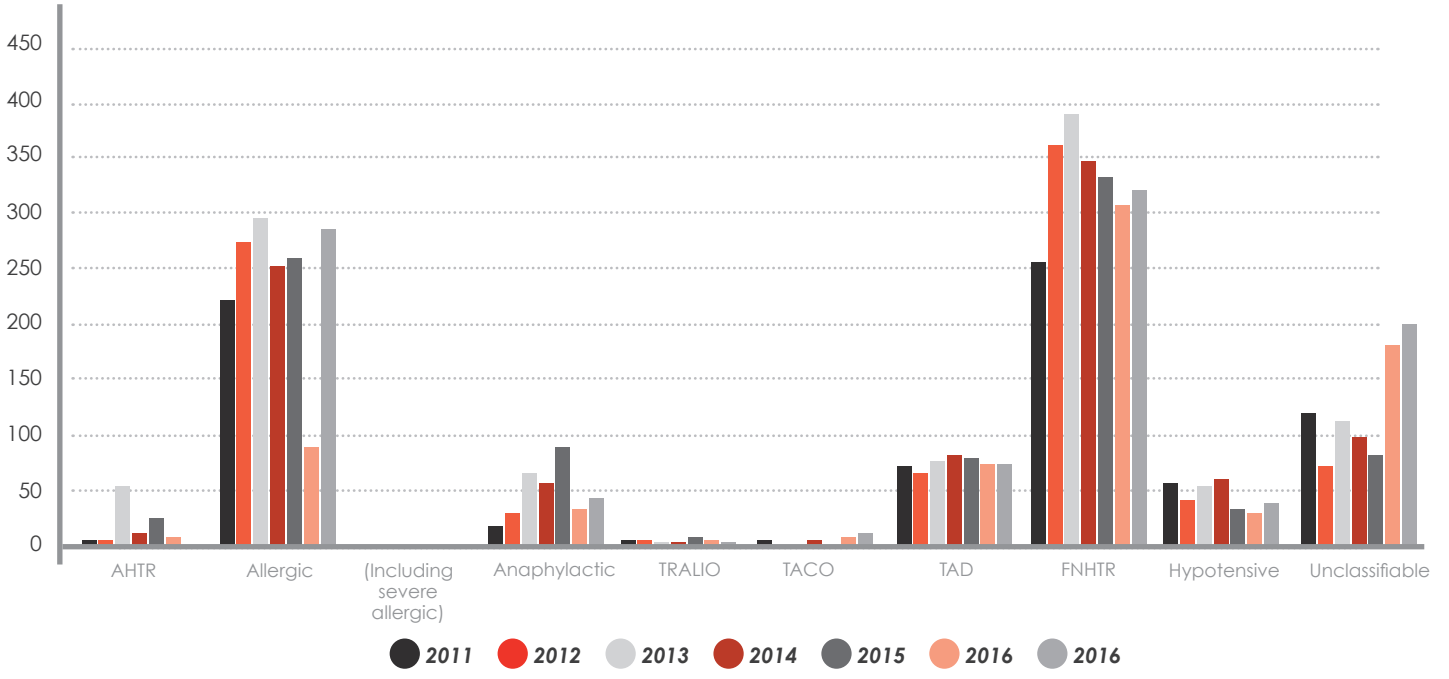
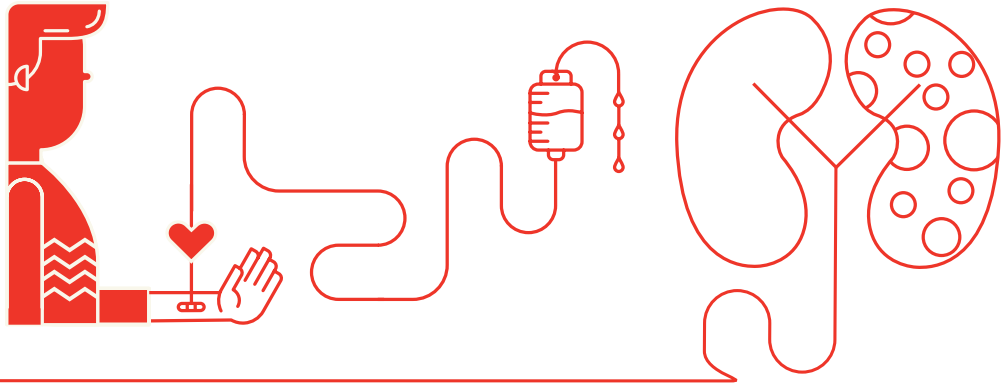


Table 3.5: Targeted treatment for febrile and allergic reactions

Reaction	Treatment	Prevention of recurrent reactions
FNHTR	Paracetamol	Paracetamol 60 minutes before anticipated time of reaction
Allergic	Antihistamine (steroid should not be used routinely) If anaphylaxis adrenaline is essential	If previous reaction with apheresis platelets try pooled platelets in PAS. If reactions continue, give pre-transfusion antihistamine If reactions continue, consider washed red cells; for FFP try a pooled component.

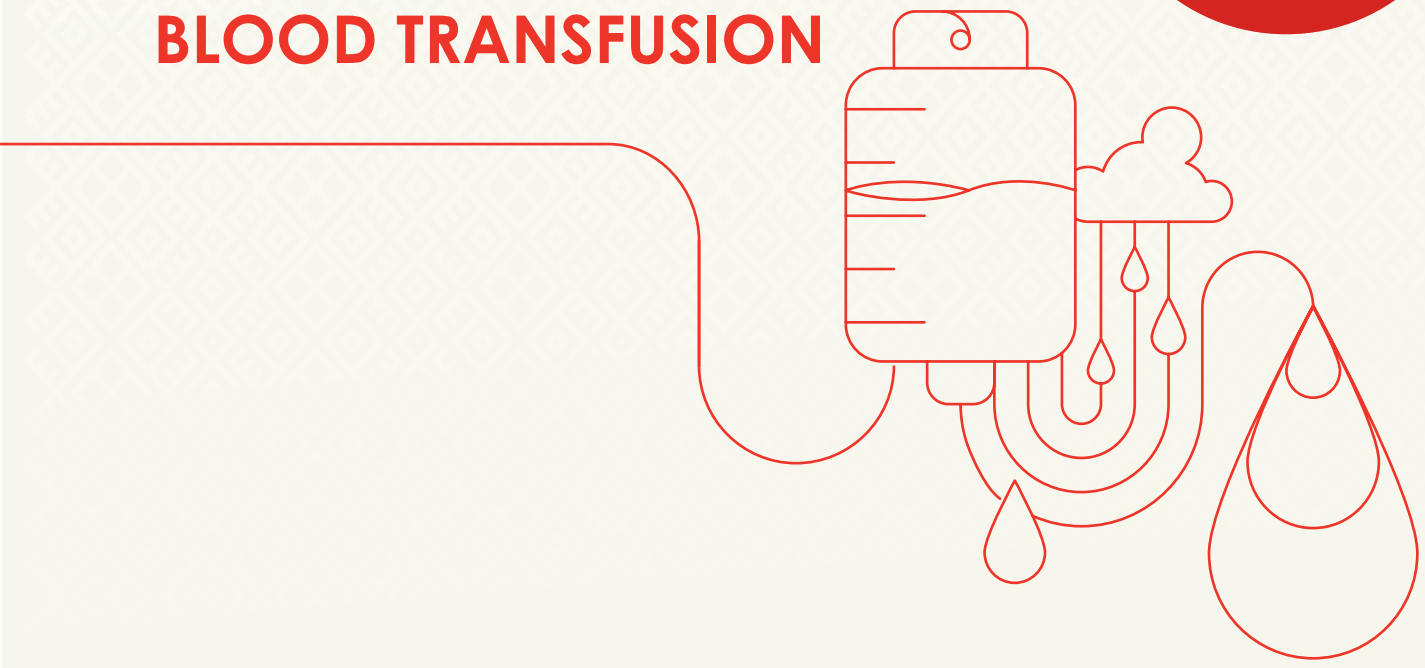
Source: SHOT, 2017

Table 3.5 provides a summary of recommended interventions for management and prevention of FNHTR and allergic reactions.



4

ERRORS IN **BLOOD TRANSFUSION**



ERRORS IN BLOOD TRANSFUSION

Transfusion errors are classified into two main categories; near misses, and misdirected transfusions. Transfusion of antibody positive blood from emergency fridges is also classified under transfusion errors. Human error is the most common underlying cause for transfusion errors.

"Human error is a nearly constant component of human involvement in any complicated task. In clinical and laboratory medicine, considerable time and expense is invested in instituting policies and procedures, including detailed and often redundant patient and specimen identification and test result verification, for the specific purpose of minimizing human error. Despite such intensive measures, human errors continue to occur at a seemingly irreducibly small rate in medical practice, sometimes with catastrophic results. Transfusion medicine is unique among clinical laboratory services in that the result is the delivery of a biologic product that may be both life-saving and capable of causing death" (Sauer D.A. et al, 2001).

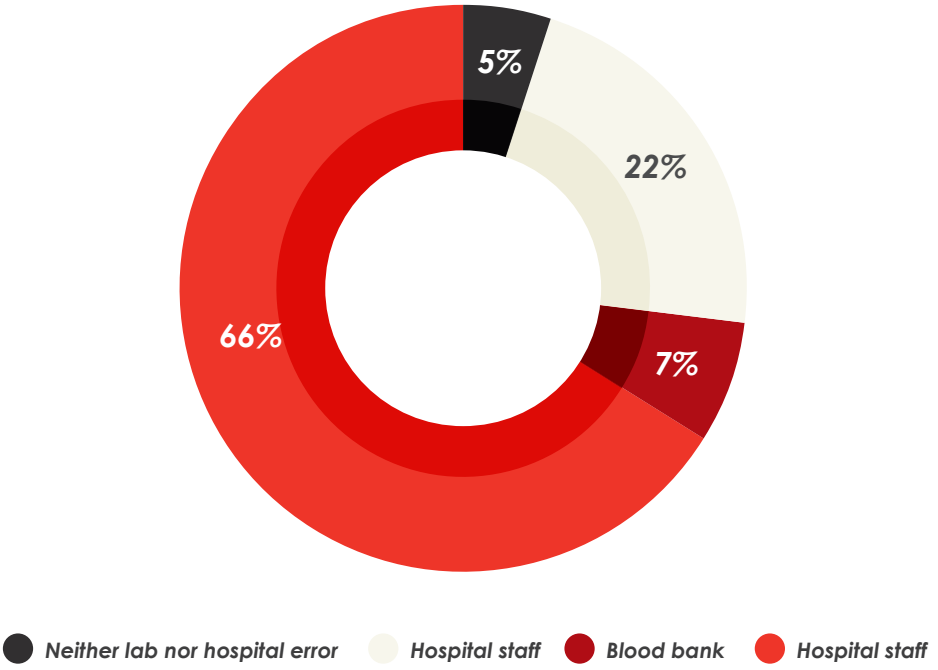
Blood transfusion is the end point in a process chain that involves multiple people in various areas of the blood services and hospitals. At blood bank level the process includes compatibility testing, checking product quality, matching a request to the right recipient and issuing the product within required timelines. At hospital level the initial step is decision by the Clinician to transfuse. This is followed by selection of product, completion of blood request form, patient identification, checking of product prior to transfusion and patient monitoring during transfusion. Failure to adhere to any of the associated quality assurance steps can result in transfusion errors. To mitigate this, check points have been placed at multiple stages of the chain. Failure to enforce these however continues to contribute to transfusion errors.

Consistent with previous years' reports, most errors reported in 2017 occurred in hospitals. In 2016 transfusion errors were added as a standing agenda item in monthly and/or quarterly Hospital Transfusion Committee (HTC) meetings. The aim is to raise awareness amongst hospital staff, primarily, hospital management. In addition, Hospital Liaison Officers (HLOs) from SANBS conduct root cause analyses on reported errors and arrange corrective training of implicated hospital personnel. The most common root cause is poor patient identification at the bedside. Despite corrective measures, the number of reported errors increased from 38 in 2016 to 41 in 2017. Patient misidentifications increased from 20 to 27. Table 4.1 provides a summary of reported transfusion errors in 2017 including their source.

Table 4.1: Transfusion errors and source

Error	Source	Number of errors 2016	Number of errors 2017
ABO/Rh incompatibility errors	Hospital staff	11	9
Rhesus (Rh) incompatibility	Blood bank staff	1	3
Patient misidentifications (bedside errors)	Hospital staff	20	27
Antibodies detected –emergency units	Neither lab nor hospital error	6	2
Total cases		**38**	**41**

Figure 4.1 Sources of error



With the introduction of blood bank automation in 2015, the number of Blood bank errors declined significantly. However, in 2017 Rhesus (Rh) incompatibility errors from blood banks increased to 3 compared to only 1 case in 2016. The number of antibody positive transfusions from emergency fridges decreased from 6 to 2 cases in 2017. Unlike the other transfusion errors, antibody positive transfusions with emergency fridge blood are not a consequence of human error. To mitigate these, hospital staff are educated to use emergency fridge blood for emergency cases only. Blood from the emergency fridges is to be used during initial stages of patient resuscitation while awaiting cross-matched blood from the blood bank. The challenge is, this is not always adhered to.

The 48 errors reported in 2017 resulted from 37 cases of incorrect blood component transfused (IBCT).

Table 4.2: IBCT cases reported 2016 and 2017

IBCT type	Number of cases 2016	Number of cases 2017
Rhesus (Rh) incompatible transfusions	2	3
Abo incompatible transfusions	10	10
Misdirected transfusions (with and without ABO Incompatibility)	19	22
Antibodies detected on emergency unit	6	2
Total	**37**	**37**

Figure 4.2: IBCT cases reported 2016 and 2017

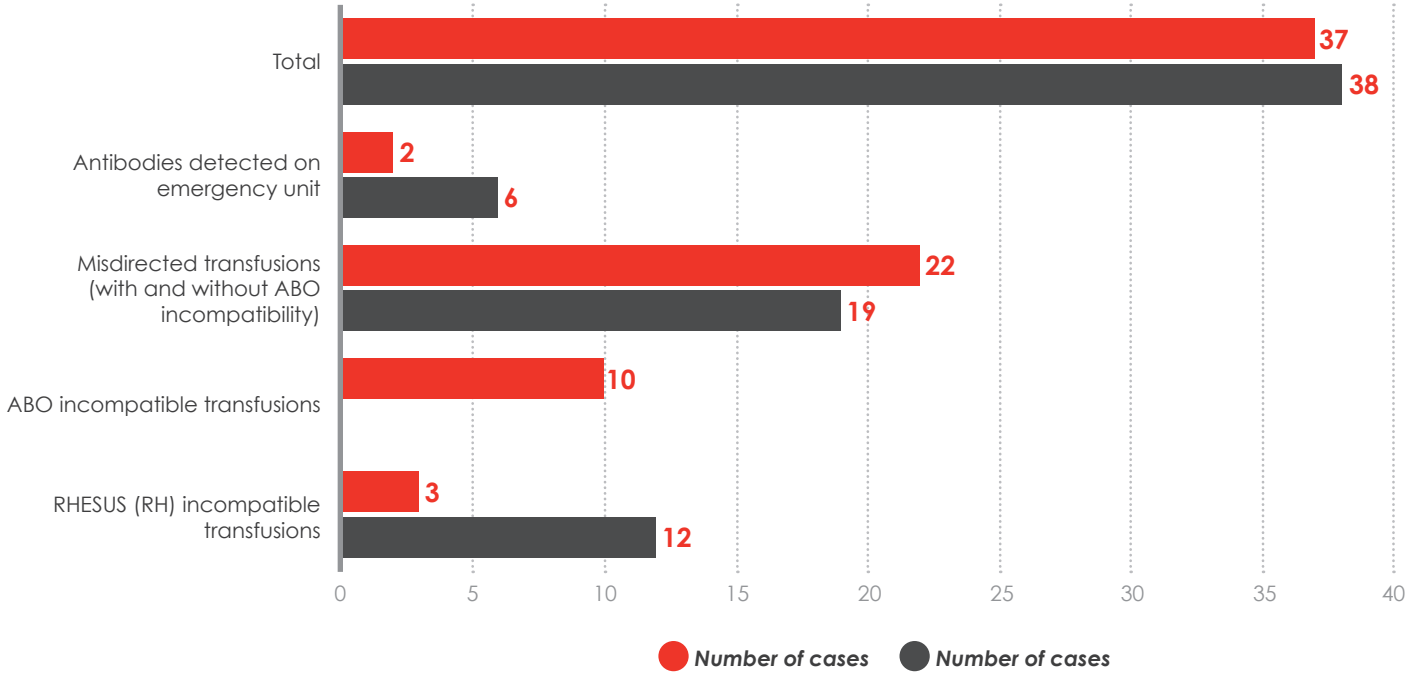
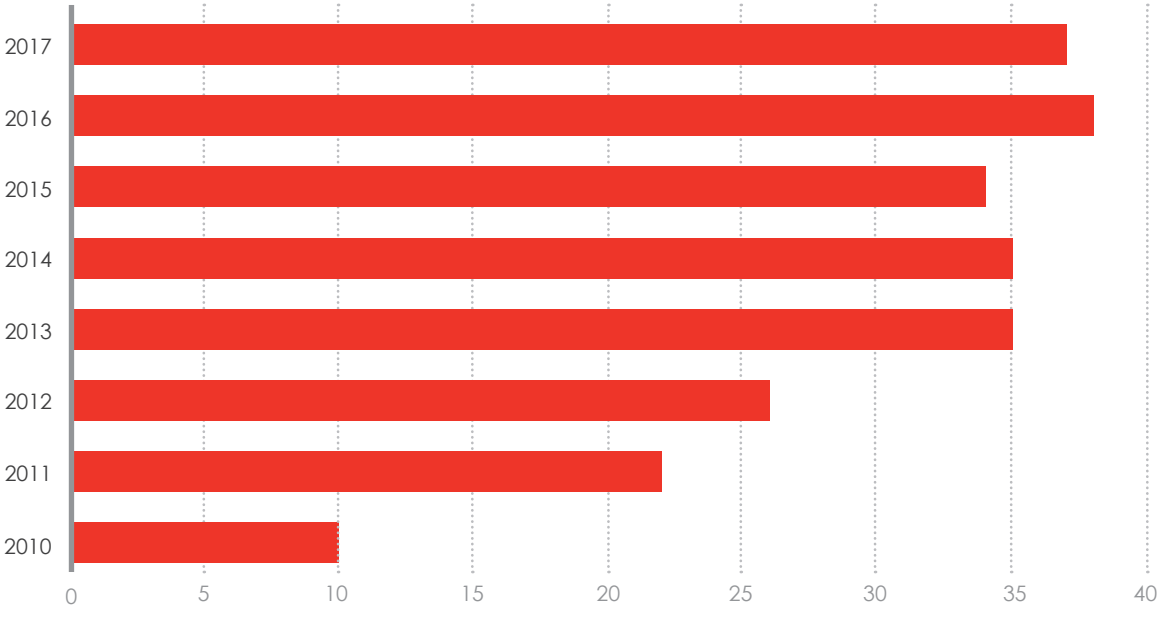


Figure 5.3 depicts the total number of IBCT from 2010 to 2017. Transfusion errors increased significantly from 2010 to 2017. One of the reasons for the increase is improvements in reporting rates. On the other hand, error increases require improved mitigation strategies.

Figure 4.3: Total IBCT cases reported (2010 to 2017)



While no mortalities were reported from transfusion errors in 2016 and 2017, errors can result in patient deaths. Reasons for the ongoing high rate of transfusion errors are poor dissemination of error-related information by the HTC to hospital ward staff; reluctance of hospital management to approve staff education; poor training attendance by hospital staff and cancellation of scheduled trainings. In a nutshell, the blood services have developed mechanisms for reduction of hospital related transfusion errors. Without sufficient collaboration and commitment from hospital management and personnel, these measures will not yield results. Hospital buy-in has been identified as the missing link to addressing transfusion errors.

In addition to transfusion errors, hospital buy-in is integral to the implementation of effective haemovigilance systems in hospitals. To be effective, haemovigilance needs to become a standard accreditation requirement for blood transfusion in hospitals. This is part of the planned Patient blood management programme for South Africa. One of the requirements for Patient blood management is active follow-up and management of transfusion related errors. It is therefore envisaged that through Patient blood management, prevention and management of transfusion errors will improve.

Below are examples of 2017 transfusion error cases:

Case 1: Rhesus incompatible transfusion- blood bank error

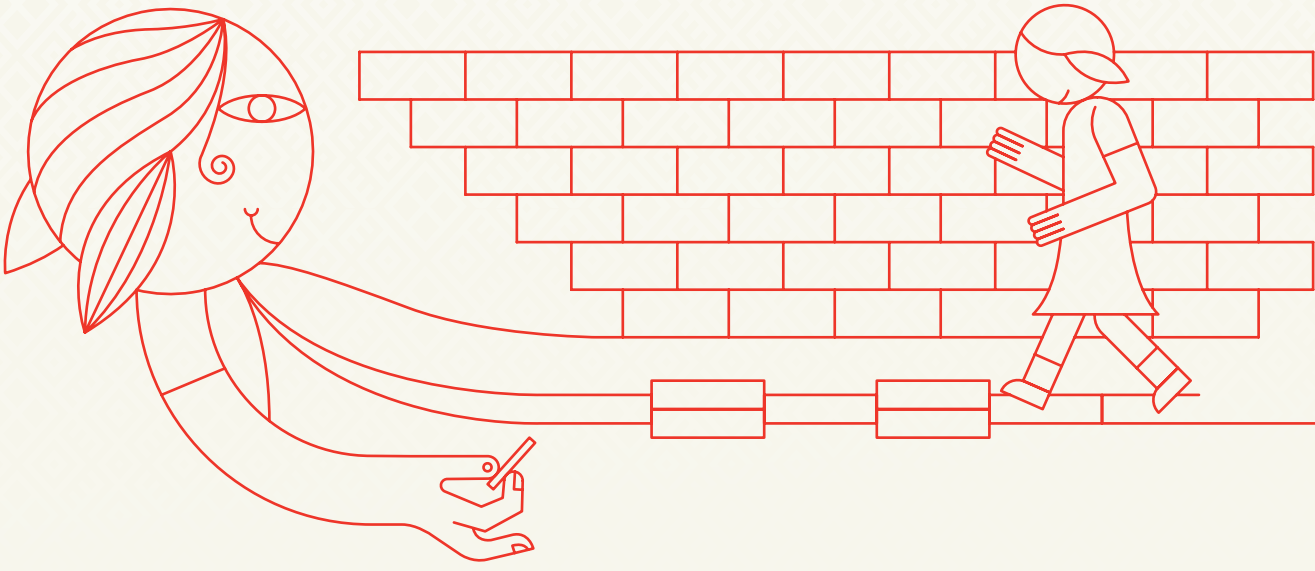
- The Blood bank received a request for a unit of leucodepleted paediatric red blood cells for patient M (age 2 weeks)
- The patient's sample was typed blood group O, Rh negative by the blood bank
- A Group O, Rh positive leucodepeted paediatric red cell unit was issued for the patient
- The following day the blood bank supervisor picked up the discrepancy in Rh status between patient sample and issued unit
- The discrepancy was reported to the blood bank manager and Zone medical manager
- The Zone medical manager informed the patient's treating doctor of the error
- The doctor reported that he would administer anti-D to the baby to mitigate potential adverse effects from the Rh positive unit
- The doctor subsequently reported that the patient had not developed any adverse reaction to the unit
- The patient's parents were informed of the error
- Corrective measures were instituted by the Blood bank supervisor

Case 2: Patient misidentification- hospital error

- A cross-match request was received at the blood bank for patient A for two units of red blood cells
- This was a standby request for the following day
- On the same day the blood bank received a standard request, for patient B who was in a different ward
- Blood was cross-matched and issued for patient B
- The following day a telephonic request was received from the ward for patient A's red cell units to be sent to the ward
- As it was a remotely located hospital a driver had to be dispatched to deliver the unit to the hospital
- An agency nurse was delegated to collect the units for patient A from the driver.
- The nurse incorrectly gave the driver a blood request form for patient B
- This form was filled out incompletely and the blood bank could not proceed with the request although this request was later canceled telephonically by the ward nurse
- On day three a different ward nurse phoned the blood bank enquiring about blood units for Patient A stating that it never reached the ward
- Upon investigation, units for Patient A were confirmed to have been dispatched and signed for by the ward
- The enquiring sister reported that the ward received Patient B's units which had been transfused
- The unit numbers however confirmed that these units had been issued for Patient A
- Both patients were confirmed to be Group-O Rh-Positive
- The units issued were Group O, Rh positive

5

NEAR MISS **EVENTS**



NEAR MISS EVENTS

A near miss event is defined as an error or deviation from standard procedures or policies that, if undetected, could result in the determination of a wrong blood group or issue, collection or administration of an incorrect, inappropriate or unsuitable component, but that was recognised before the transfusion took place.

2009	2010	2011	2012	2013	2014	2015	2016	2017
2	2	0	7	0	8	15	14	10

Ten near miss cases were reported in 2017. These originated in hospitals and occurred during specimen collection.

A near miss case is outlined below:

- A cross-match request was received at the blood bank for a patient AB
- The initial sample received from the hospital typed Group AB, Rh Positive
- On the same day, a second cross-match request was received at the blood bank for the same patient
- The second sample typed Group O, Rh Positive
- Blood bank personnel recognized the discrepancy and requested a fresh specimen for the patient
- The third specimen typed Group O, Rh Positive
- The case was forwarded to Red Cell Serology Laboratory for further investigation and the results were as follows:

Specimen 1:

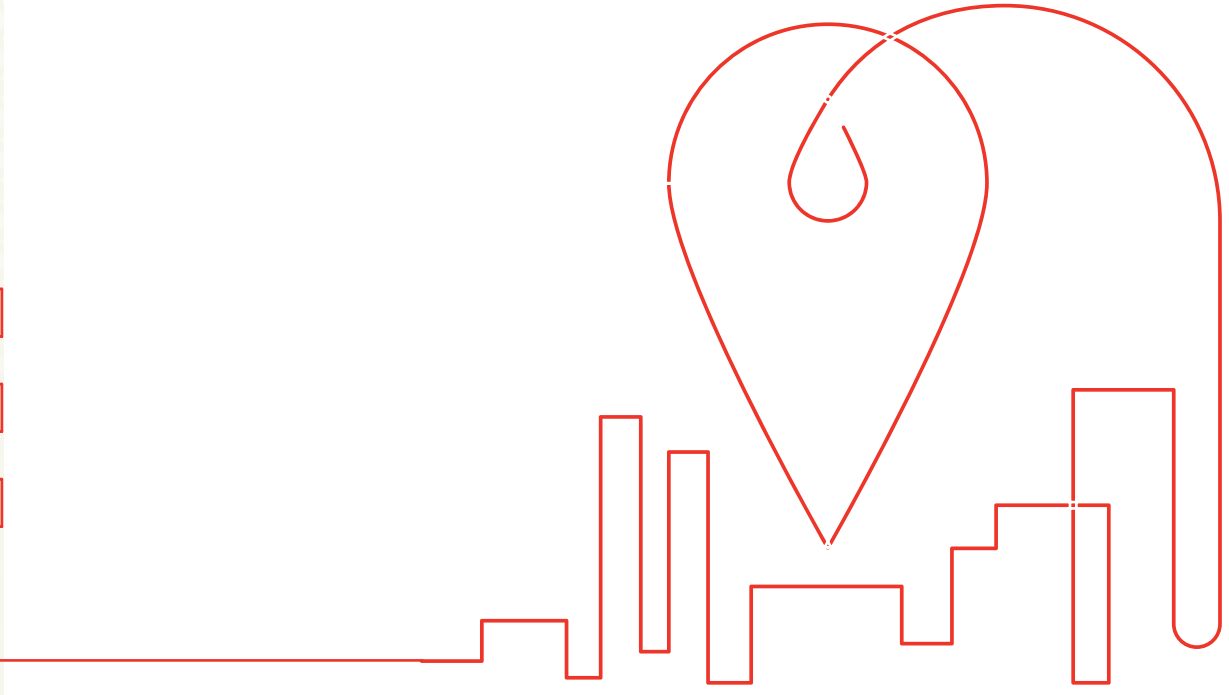
- Blood type: Group AB, Rh Positive
- Direct antiglobulin Test: Negative
- Irregular antibody screen: Not Tested (insufficient serum for testing)

Specimen 2:

- Blood Type: Group O Rh Positive
- Direct Antiglobulin Test: Negative
- Irregular antibody screen: Negative

Comments

The initial sample was not collected from patient AB. This resulted in an incompatible unit being issued to the patient. No transfusion reaction was reported from the incompatible transfusion.



6

PATIENT **MORTALITY REPORTS**

PATIENT MORTALITY REPORTS

"Transfusion mortality is any death that occurs secondary to an adverse reaction to a blood or blood product or due to insufficiency in quality of blood product or unavailability of blood." (SHOT, 2013). Patient deaths due to blood product delays or insufficient products should be reported as transfusion related. According to the Health Profession Amendment Act (Act 29 of 2007), "The death of a person undergoing, or as a result of, procedure of a therapeutic, diagnostic or palliative nature, or of which any aspect of such a procedure has been a contributory cause, shall not be deemed to be a death from natural causes as contemplated in the Inquests Act, 1959 (Act 58 of 1959)." Such deaths are therefore to be reported to the National Department of Health.

In 2017 twelve cases of patient deaths within 24 hours of blood transfusion were reported to the blood services. Classifying patient deaths as transfusion related depends on the clinical history provided by the treating doctor, serological investigations conducted on the patient's pre- and post-transfusion specimens, a report from the treating doctor on the probable cause of death, as well as a post-mortem report.

The blood services are responsible for conducting serological investigations on all reported cases. Findings of the tests along with any available information on the case are submitted to the Department of Health. Serological incompatibility was excluded in ten of the 12 reported patient mortality cases. Serological investigations could not be conducted on two of the 12 cases. One case could not be tested as it was reported 14 days post transfusion and no post transfusion specimens were submitted to the blood service for investigation. Another case involved positive allo-antibodies identified at the blood bank. Antigen negative whole blood and AB plasma had to be sourced from inventory for the patient. By the time the blood arrived from inventory the patient's condition had deteriorated significantly resulting in death. The patient's managing doctor reported that the patient's death was likely due to rapid progression of the underlying clinical condition.

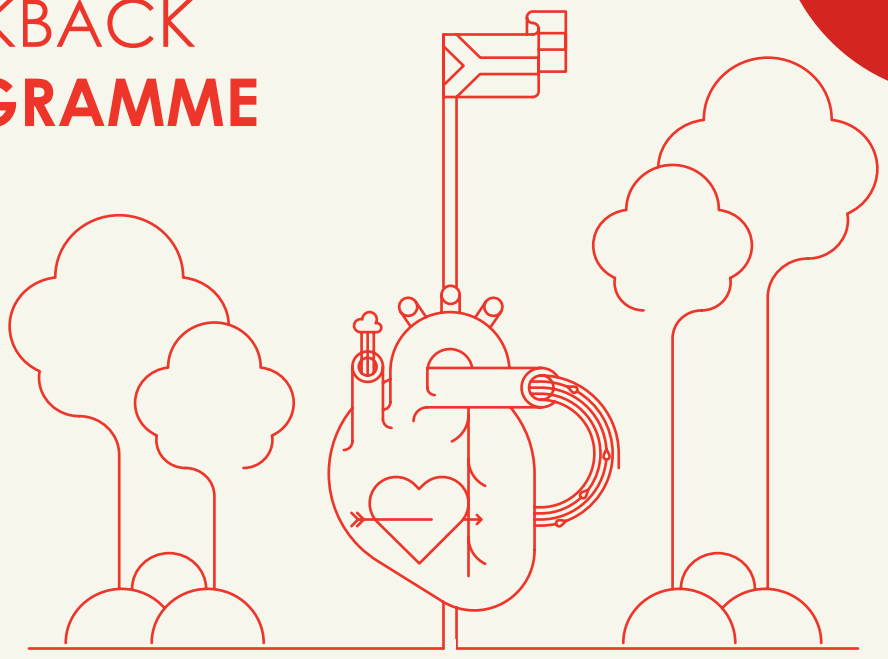
Insufficient documentation continues to pose a challenge to classification of transfusion associated mortalities. Of the 12 reported cases, only two were accompanied by reports from the managing doctors. This is a significant decline from seven out of 14 cases in 2016. No post-mortem reports were received in 2017. The insufficient documentation on patient mortalities results in inability of the haemovigilance teams to determine or entirely exclude blood transfusion as contributory to patient mortalities.

Total transfusion mortalities reported from 2010 to 2017

2010	2011	2012	2013	2014	2015	2016	2017
3	3	3	7	16	12	14	12

7

LOOKBACK **PROGRAMME**



LOOKBACK PROGRAMME

The Transfusion-Transmissible Infection (TTI) Lookback Programme was established in 1986 and incorporated into the Haemovigilance Programme since 2005.

Blood transfusion services in South Africa screen all blood donations for HIV, hepatitis C and hepatitis B using both serological tests and individual-donor Nucleic Acid Amplification (NAT) testing. The Lookback Programme aims to trace all patients who are identified as recipients of blood from donors who test positive for a transfusion-transmissible infection on a subsequent donation, where the previous negative unit may possibly have been donated in a window period.

In a donor-triggered lookback investigation, the recipient/s of the previous negative units are identified and their treating doctor notified. As far as possible, the patient is recalled, counselled and tested for the relevant viral marker and the result reported to the blood service.

Table 7.1 Number of donors investigated for TTI markers

Total number of lookbacks	SANBS	WPBTS	Total
HIV	482	36	518
HBV	196	8	204
HCV	14	2	16
HIV/HBV Co-Infections	7	0	7
HIV/HCV Co-Infections	2	0	2
HBV/HCV Co-Infections	2	0	2
Other	5	0	5
Total	**708**	**46**	**754**

Of the total donors that seroconverted in 2017, 754 were investigated through the donor triggered lookback process. This is a 6.5% increase from cases investigated in 2016. Case follow up was100%. Of the 754 seroconverted donors, 68.7% were due to HIV, 27.0% HBV and 2.1% were due to HCV. Seven donors had HIV/HBV co-infection, two had HIV/HCV co-infection while another two were a result of HBV/HCV co-infection.

Table 7.2 Investigation outcomes

Donor-triggered investigation outcome	SANBS	WPBTS	Total
Retest negative	50	10	60
Recipient positive before transfusion	51	0	51
HIV-positive recipient/s – phylogenetic analysis	2	0	2
Recipient died between transfusion and initiation of lookback	87	6	93
Unresolved	653	16	669
Untraceable patient	48	14	62
Other	2	0	2
Refused/declined testing	2	0	2
HCV Positive	1	0	1
HBV immune	3	0	3
HBV positive recipient – phylogenetic analysis	0	0	0
On dual therapy (HBV IB)	0	0	0
Total	**899**	**46**	**945**

At the time of the report, 945 donor-triggered investigations were conducted, and 276 (29.0%) were resolved/closed. Of the 276 cases, 60 recipients were traced and tested negative, while 51 cases were confirmed (on requisition form or by the treating doctor in writing) to have been positive before transfusion. There was a true closure rate of about 11.7%. Ninety-three recipients were confirmed to have died between the transfusion and initiation of the lookback investigation, and 62 cases were untraceable because either the hospital could not reach the patients, or the hospital files were missing.

The remaining 669 of the 945 donor-triggered investigations (70.7%) were unresolved at the time of the report, because there was no response from the doctor or hospital after 12 months of active follow-up by the blood services. The cases are kept open in the event of a response from the responsible clinician, but no further active follow-up is pursued.

Although the introduction of individual-donor NAT testing in 2005 has significantly enhanced the safety of the blood supply, the careful recruitment and selection of low-risk donors remains crucial to preventing transfusion-transmitted infections.

Recipient-triggered lookbacks

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

Table 7.3 Recipient-triggered lookbacks

	Resolved	Unresolved	Total
HIV	3	2	5
HBV	0	1	1
HCV	1	0	1
HIV/HBV Co-infection	1	0	1
Other	1	1	2
Total	**6**	**4**	**10**

Ten recipient-triggered lookback cases were received. Of these six (60.0%) were resolved. Four of the resolved cases retested negative. Two cases were classified as "other". The first case was a Malaria (resolved); all donors tested negative. The second was a CMV; unresolved as the Doctor did not complete the required forms to initiate the look-back investigation. In one case (HIV/HBV co-infection) it was determined that the patient in question had not received any transfusions. Three of the ten recipient-triggered cases (30.0%) remained unresolved due to unsuccessful attempts to trace and retest the implicated donors.

Table 7.4 Overview of lookback investigations

	2010	2011	2012	2013	2014	2015	2016	2017	Total
Total number of lookback cases	**546**	**642**	**629**	**849**	**1 129**	**976**	**979**	**945**	**6695**

There has been a significant increase in the total number of lookback cases (donor and recipient-triggered), from 546 in 2010 to 945 in 2017, as shown in table 7.4.

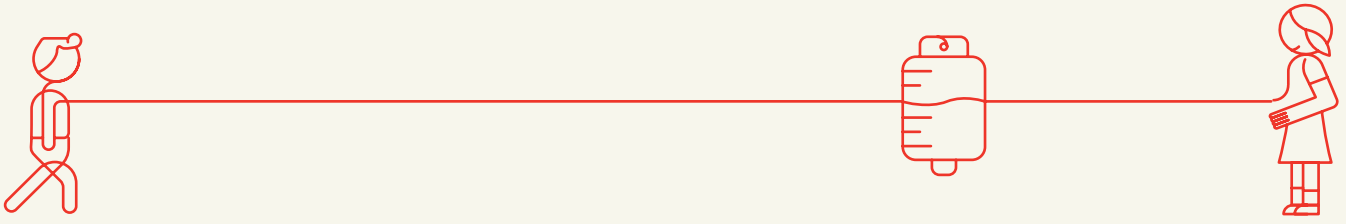
Of the 1 193 132 products issued in 2017, 945 (0.08%) resulted in lookback investigations due to possible microbial contamination. This percentage is the same as the previous year.

The Lookback Programme challenges have remained the same over the years. The challenges result in high number of unresolved cases. They are:

- Blood requisition forms are not completed correctly and patient information is incomplete
- In many provincial hospitals, incorrect hospital numbers are entered and patients cannot be traced
- Information on deceased patients – or patients who were HIV positive before transfusion, in the case of an HIV lookback – is not always relayed timeously to the lookback officer
- Retest results are not sent to the lookback officer as requested in the lookback notification
- Several major provincial hospitals and many doctors in private practice only provide results after numerous follow-up calls
- Hospitals and doctors often consider it the duty of the SANBS to recall, counsel and retest the recipients of a possible window-period transfusion. The Clinical Guidelines for the Use of Blood Products in South Africa, 5th edition (Chapter 1: Legal aspects of blood transfusion) clearly indicate that this is the duty of the doctor who prescribed the transfusion or the designate at the hospital where it was administered
- Doctors and hospital managers also cite the cost of blood tests and tight hospital budgets as challenges

8

PLATELET BACTERIAL **SURVEILLANCE (SANBS)**



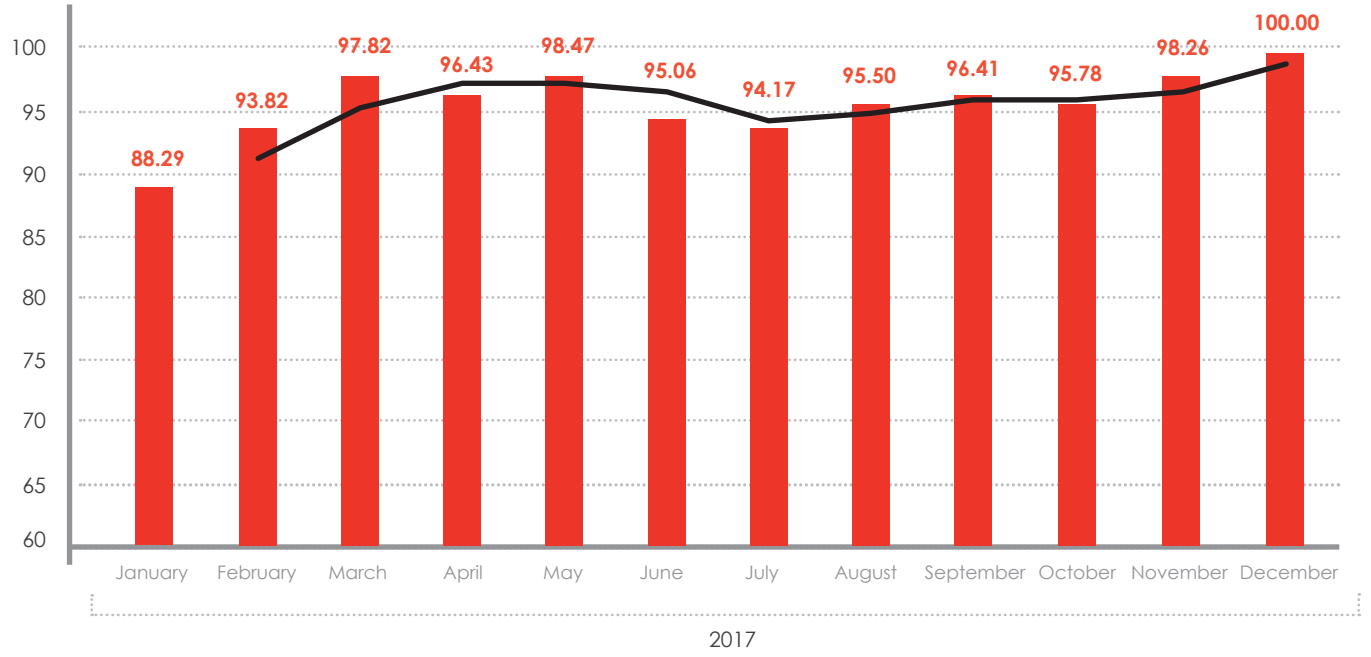
PLATELET BACTERIAL SURVEILLANCE (SANBS)

Bacterial surveillance of Apheresis platelets (AP) in SANBS is indicated on a quarterly and monthly basis. Over 3000 Apheresis platelet quality control (QC) samples were tested in 2017. This constitutes 16% of all SANBS Apheresis platelet collections in 2017.

Table 8.1 Apheresis Platelet (AP) Bacterial testing 2017

% Compliance	Apheresis PLT tested (compliant / total tested) % positive	Expired PLT (compliant / total tested) % positive
Quarter 1	(682/701) 3%	(11/12) 8.3%
Quarter 2	(695/729) 4.7%	(26/32) 18.7%
Quarter 3	(735/750) 2%	(21/21) 0%
Quarter 4	(888/898) 1%	(45/46) 1%
Total	**(3000/3078)** **2.5%**	**(103/111)** **7%**

Figure 8.1: Average of Sterility Products Complying



The percentage bacterial contamination of apheresis platelets was 2.5%, which is approximately half the rate of the previous year, indicating that interventions to address the risk are benefiting platelet safety. Improvements include optimisation of bacterial testing facilities and processes. This involved culturing a larger volume (minimum 4 ml) of AP sample in aerobic bottles to enhance culture sensitivity while also reducing the incubation time to seven days. Infection and prevention control (IPC) awareness has also been increased. Hand and environmental hygiene have improved.

Table 8.2 Summary of micro-organisms isolated per quarter

	Cocci n =52				Bacilli n = 23			
Gram Positive Bacteria	Q1: 12	Q2: 19	Q3: 13	Q4: 8	Q1: 5	Q2: 14	Q3: 2	Q4: 2
Gram Negative Bacteria	0	0	0	0	0	0	0	0
Fungi n = 0			0	0			0	0
No Bacterial Growth (NBG)			0	0			0	0

Top three organisms	Q1	Q2	Q3	Q4
	*Staphylococcus spp *(CNS)*	*Staphylococcus spp (CNS)*	*Micrococcus spp*	*Staphylococcus spp (CNS)*
	Micrococcus spp	*Micrococcus spp*	*Staphylococcus epi*	*Corynebacterium urelyticus*
	Propionibacterium spp.	*Corynebacterium spp*	*Staphylococcus spp (CNS)*	*Bacillus spp and Streptococcus salivanus*
True Pathogens	*0*	*Staph. aureus (n=1)*	*Staph. aureus (n=1)*	*0*

*CNS Coagulase negative Staphylococci

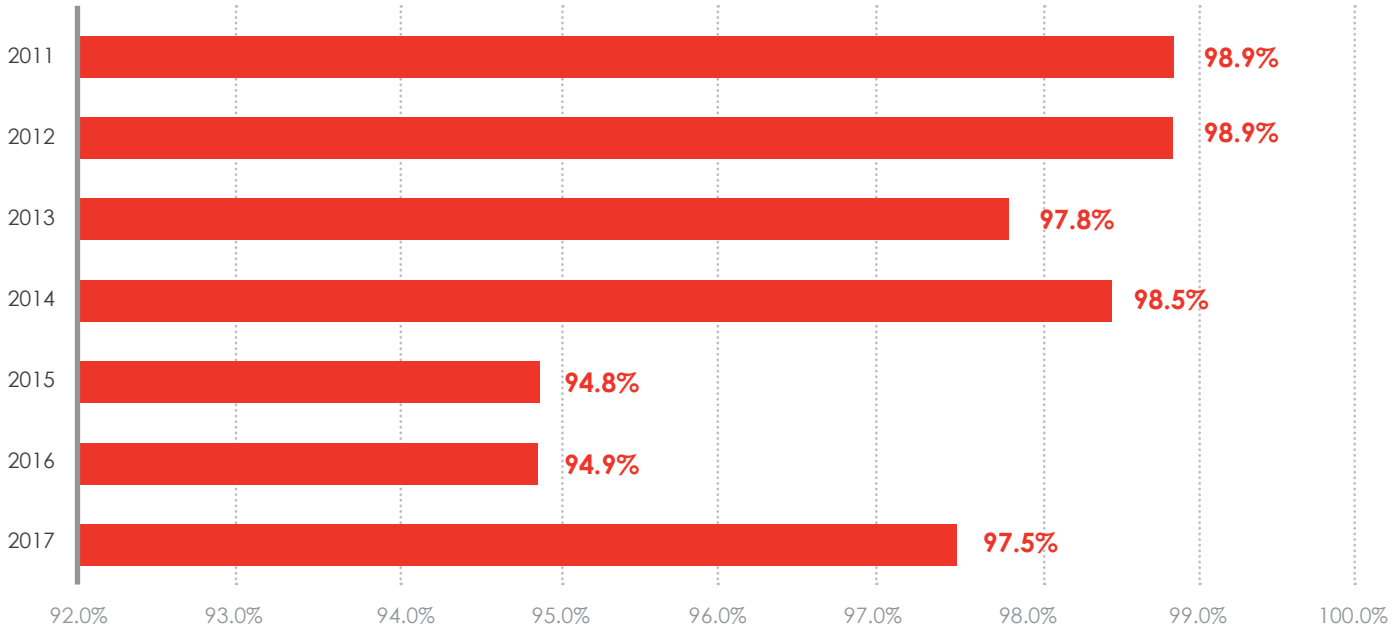
A total of 75 bacteria were isolated, all of which were gram positive cocci and bacilli. Gram positive skin commensals remain the most common isolates of AP QC samples. Ongoing efforts to sustain good hand hygiene and antiseptic donor procedures must be maintained.
Two typical pathogens were isolated; both were cloxacillin sensitive *Staph. aureus.*

Table 8.3 Environmental Testing

% Compliance	(Negative samples / total environmental samples) % positive
Quarter 1	(685/685) 0%
Quarter 2	(761/766) 0.7%%
Quarter 3	(810/810) 0%
Quarter 4	(235/252) 1%
Total	**(2491/2513) 1%**

Environmental samples from Apheresis clinics are collected monthly and include samples from benches, air, hands and utensils/equipment.

Figure 8.2 Annual trends of platelet sterilities



It is evident that there is significantly less bacterial contamination of AP compared to previous years across all apheresis clinics. This is due to; enhanced awareness of hand and environmental hygiene, the availability of improved antiseptics using 2% chlorhexidine / 70% isopropyl alcohol (2% CHX/IPA), improvements made in sample processing, and the addition of a clean area within the QC Lab / Microbiology Lab.

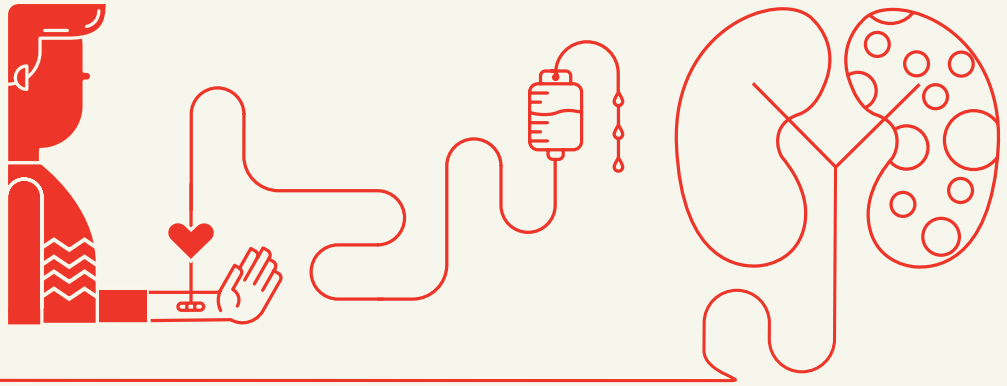
It has also been recommended to change the 70% IPA antiseptic swabs for cleaning of donor skin to 2% CHX/ IPA as this is superior to alcohol alone. This should reduce the residual risk further. It is early days, but the bacterial contamination rates have reduced significantly from 2017 to date and are being monitored closely.

Looking ahead, although significant improvements have been made, the risk of bacterially contaminated platelets remain as SANBS is not able to test all AP due to insufficient availability. SANBS must continue to explore the introduction of pathogen reduction / inactivation to produce safer pooled platelets which will also address availability. The SANBS QC department is currently busy with a bacterial surveillance study testing pooled platelets to establish a baseline for bacterial contamination of pooled platelets.

Chapter compiled by: Dr Ute Jentsch

9

DONOR
VIGILANCE



DONOR VIGILANCE

Blood donation saves lives. Adverse events associated with blood donation can impact on donor experience and likelihood of return. Donation adverse events can occur during or following collection of blood. Acute complications occur during or immediately following blood donation. Delayed complications occur after the donor has left the donation site. The blood services receive notification of delayed complications either by telephone, personal visit or email.

Categories of complications related to blood donation

Local symptoms	Blood outside vessels		Haematoma
			Arterial puncture
			Delayed bleeding
	Pain	Specified as:	Nerve irritation
			Nerve injury
		or not specified	Tendon injury
			Painful arm
	Others		Thrombophlebitis
			Allergy (local)
Generalised symptoms	Vasovagal reaction		Immediate
			Immediate with injury
			Delayed
			Delayed with injury
Related to apheresis			Citrate reaction
			Haemolysis
			Generalised allergic reaction
			Air embolism

CLASSIFICATIONS

Complications mainly with local symptoms

These complications are directly caused by the insertion of the needle. Some of these are mainly characterised by occurrence of blood outside vessels, whereas others are mainly characterised by pain.

Complications mainly characterised by the occurrence of blood outside the vessels.

Adverse event	Definition
Haematoma	An accumulation of blood in the tissues outside the vessels. Symptoms: Bruising, discolouration, swelling and local pain.
Arterial puncture	A puncture of the brachial artery or of one of its branches by the needle used for bleeding of the donor. Symptoms: There may be weak pain in the elbow region. The collected blood may appear a lighter red colour than usual, and there may be some movement of the needle caused by arterial pulsation. The bag will fill very quickly. In uncomplicated cases there may be no haematoma. Complications: There is an increased risk of a large haematoma, combined with risks such as compartment syndrome in the forearm, brachial artery pseudo aneurysm and arteriovenous fistula.
Delayed bleeding	Spontaneous recommencement of bleeding from the venipuncture site after the donor has left the donation site.

Complications mainly characterised by pain.

Adverse event	Definition
Nerve irritation	Irritation of a nerve by pressure from a haematoma. Symptoms: Radiating pain and/or paraesthesia in association with a haematoma. The haematoma may not always be apparent at the time. Symptoms do not occur immediately on insertion of the needle but start when the haematoma has reached a sufficient size, sometime after insertion of the needle.
Nerve injury	Injury of a nerve by the needle at insertion or withdrawal. Symptom: Severe and radiating pain, often associated with paraesthesia. The pain arises immediately after the needle is inserted or withdrawn.
Tendon injury	Injury of a tendon by the needle. Symptom: Severe local non-radiating pain, starting immediately when the needle is inserted.
Painful arm	This refers to cases characterised mainly by severe local and radiating pain in the arm used for the donation, arising during the donation or within hours afterwards, but without further details that allows for classification as one of the specific categories above.

Other categories with local symptoms

Adverse event	Definition
Thrombophlebitis	Inflammation in a vein associated with a thrombus. Thrombophlebitis in a superficial vein gives rise to a subcutaneous red, hard and tender cord-like mass. Thrombophlebitis in a deep vein results in more severe symptoms and may be associated with fever. Symptoms: Warmth, tenderness, local pain, redness and swelling.
Allergy (local)	Allergic type skin reaction at the venipuncture site caused by allergens in solutions used for disinfection of the arm or allergens from the needle. Symptoms: Rash, swelling and itching at venipuncture site.

CLASSIFICATIONS

Complications mainly with generalised symptoms.	
Vasovagal reaction	
Adverse Event	**Definition**
Vasovagal reaction (fainting)	A vasovagal reaction is a general feeling of discomfort and weakness with anxiety, dizziness and nausea, which may progress to loss of consciousness (fainting). In most cases, symptoms are minor, but in a small number of cases they are more severe, such as loss of consciousness and convulsions or incontinence. The reaction is generated by the autonomic nervous system and further stimulated by psychological factors and the volume of blood removed relative to the donor's total blood volume. Symptoms: Discomfort, weakness, anxiety, dizziness, nausea, sweating, vomiting, pallor, hyperventilation, convulsions and loss of consciousness.
Immediate vasovagal reaction	Symptoms occur before the donor leaves the donation site.
Immediate vasovagal reaction with injury	This refers to injury when a donor with a vasovagal reaction falls or has an accident before leaving the donation site and loses consciousness.
Delayed vasovagal reaction	Symptoms occur after donor has left the donation site.
Delayed vasovagal reaction with injury	This refers to injury when a donor with a vasovagal reaction falls or has an accident after leaving the donation site and loses consciousness.

Complications related to apheresis.	
Complications mainly characterised by pain.	
Adverse Event	**Definition**
Citrate reaction	Symptoms and signs associated with the transient hypocalcaemia caused by citrate. Donors usually present with mild tingling around the mouth and on the lips, metallic taste in the mouth and peripheral paraesthesia. Severe cases are characterised by respiratory difficulty, with nausea and vomiting.
Haemolysis	Destruction of the donor's red blood cells.
Generalised allergic reaction	The result of an interaction of an allergen with preformed antibodies. A minor allergic reaction is limited to the skin, with or without a rash. A severe allergic reaction poses risk to life, characterised by bronchospasm causing hypoxia or angioedema causing respiratory distress.
Air embolism	An air lock that obstructs the outflow of blood from the right ventricle of the heart or air that lodges in the pulmonary or cerebral vasculature. Air may gain access to the circulation as a result of surgery, injury or intravenous infusion.

SUMMARY OF COLLECTIONS AND DONOR-ADVERSE EVENTS

In 2017 there were 984 730 successful donations. Of these, 152 739 (15.78%) blood products were collected by WPBTS, while 831 991 (84.49%) were collected by SANBS. SANBS collections increased by 0.25% while WPBTS collections decreased by 1.69%.

Table 9.1: Collections (2016 to 2017)

Collection	SANBS 2016	SANBS 2017	WPBTS 2016	WPBTS 2017	TOTAL 2017
Whole blood	810 721	815 435	152 475	148958	964 393
Apheresis red Cells	3 468	1 273	0	0	1273
Apheresis platelets	13 980	13 475	2 901	3781	17 256
Plasma	1 765	1 808	0	0	1 808
Totals	**829 934**	**831 991**	**155 376**	**152 739**	**948 730**

0.55% of donations resulted in adverse reactions. Total reported adverse reactions increased by 0.07% compared to 2016. The overall frequency of reported donation adverse reactions was 1:177. Adverse events are more commonly reported with whole blood donations than apheresis procedures. Vasovagal reactions and haematomas were the most common events associated with all types of donations. Donor adverse events according to broad category are shown on table 9.2.

Table 9.2: Donor adverse events according to broad categories

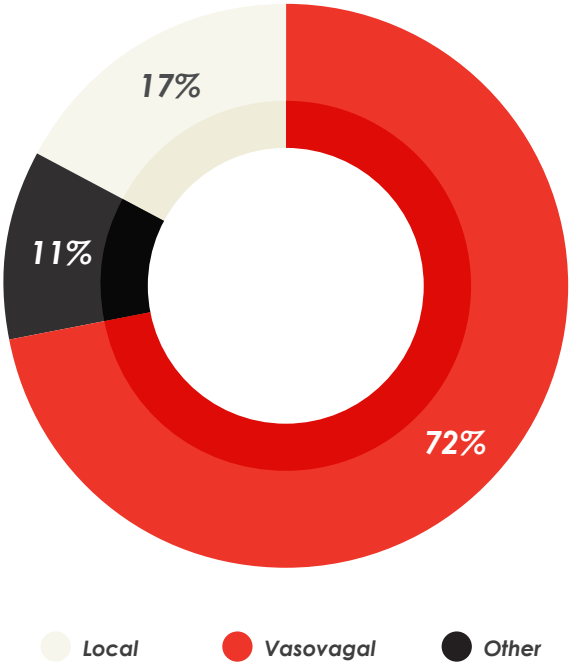
Reaction	SANBS		WPBTS		Total: 2017
	2016	2017	2016	2017	
Local	588	584	314	339	923
Vasovagal	1762	2099	1908	1829	3928
Other	291	581	7	6	587
Total	**2641**	**3264**	**2229**	**2174**	**5438**

SANBS reported donor adverse events increased by 23.6% in 2017 while the WPBTS adverse events decreased by 2.53%.

The likelihood of developing adverse reactions is multifactorial and includes donor age. Younger donors are at higher risk of reactions.

Risk factors for vasovagal reactions include age below 30 years, low blood volume and low weight first-time donors. Figure 9.1 shows the proportion of each adverse reaction type.

Figure 9.1 Donor adverse proportion by type



Female donors are reportedly at higher risk of donor-adverse reactions than males. In 2017, female donors experienced 59% of all donor adverse events. This picture is similar to international trends.

Figure 9.2: Donor-adverse events – male vs females

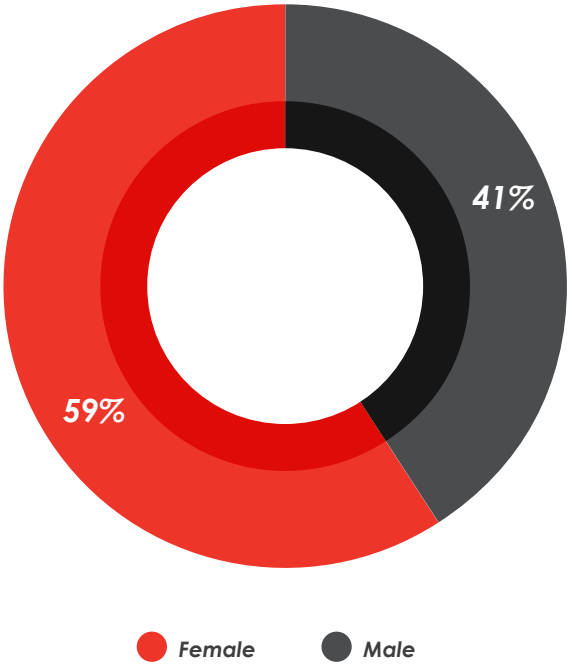


Table 9.3: Donor-adverse events by donation type

Acute reactions	Whole blood	Apheresis	Unallocated	Total
Haematoma	652	105	0	757
Arterial puncture	2	0	0	2
Delayed bleeding	23	0	0	23
Nerve irritation	7	0	0	7
Tendon injury	1	0	0	1
Nerve injury	2	0	0	2
Painful arm	138	6	0	144
Total local symptoms	**825**	**111**	**0**	**936**
Fainting – immediate	2844	17	0	2861
Fainting – immediate, accident	154	0	1	155
Fainting – delayed	970	1	0	971
Fainting – delayed, accident	78	0	0	78
Total vasovagal reactions	**4046**	**18**	**1**	**4065**
Citrate reaction	426	6	0	432
Haemolysis	1	0	0	1
Generalised allergic reaction	3	0	0	3
Embolism	0	0	0	0
Others	0	1	0	1
Total	**430**	**7**	**0**	**437**
Grand total	**5301**	**136**	**1**	**5438**

Vasovagal reactions were prevalent in both whole-blood and apheresis donations. 97.5% of all adverse reactions originated from whole blood.

Of the vasovagal reactions, faints without accidents comprised 94.3%, while faints with accidents comprised 5.7%. The percentage of faints with accidents decreased significantly compared to 2016 (15.0%). Fewer accidents contribute to improved donor return post adverse reaction.

As observed in 2016, immediate faints and haematomas were most common. This was followed by painful arm. Overall reporting of adverse events improved as evidenced by the significant reduction in unallocated cases from 12 cases in 2016 to one in 2017.

Table 9.4: Analysis of adverse events by severity

	Severity	Mild	Moderate	Severe	Subtotal
Local Adverse events	Haematoma	616	105	29	750
	Arterial puncture	1	1	0	2
	Delayed Bleeding	19	3	1	23
	Nerve irritation	4	2	1	7
	Tendon injury	0	1	0	1
	Nerve injury	1	0	1	2
	Painful arm	88	42	8	138
	Total local symptoms	**729**	**154**	**40**	**923**
Vasovagal	Faint – immediate	2516	211	150	2877
	Faint –immediate, accident	123	28	3	154
	Faint –delayed type	756	182	32	970
	Faint – delayed, accident	45	25	8	78
	Total vasovagal reactions	**3440**	**446**	**193**	**4079**
Others	Citrate reaction	429	3	0	432
	Haemolysis	1	0	0	1
	Generalised allergic reaction	3	0	0	3
	Embolism	0	0	0	0
	Other	0	0	0	0
	Total	**433**	**3**	**0**	**436**
	Grand total	**4602**	**603**	**233**	**5438**

The proportion of mild adverse events increased to 84.6% compared to 76.1% in 2016. Severe events, however, remained unchanged at 4.3 %.

CONCLUSION

Over the years reporting of transfusion and donor-adverse reactions as evidenced by the number of cases has improved. Hospital participation has, however, declined. Patient mortalities have remained stable. On the other hand, despite measures from the blood services to address errors, hospital-related transfusion errors have not improved.

Total reported donor-adverse reactions have increased. While reporting donor-adverse reactions is encouraged and critical to improving donor care, the ultimate aim is to reduce occurrence as much as possible and empower staff to effect excellent management of these. In view of this, phase one of the Donor adverse reaction management project will be initiated in 2018.

The role of stakeholder collaboration in improving the South African haemovigilance system has been highlighted in this and previous reports. A different approach through Patient blood management is to be trialed out in 2018.

While Patient blood management will potentially assist in addressing the key challenges, additional effort is required to improve outcomes.

10

CONCLUSION

His first steps were made possible by

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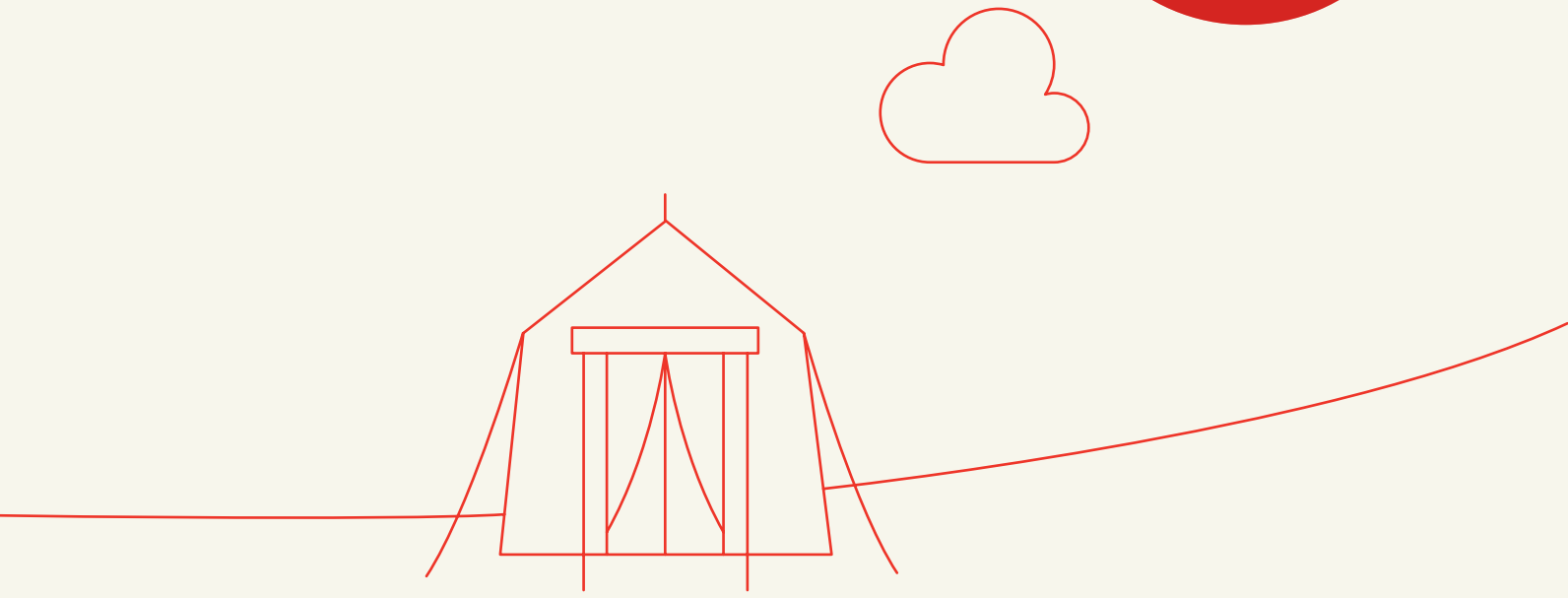

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