

HAEMOVIGILANCE REPORT

2016

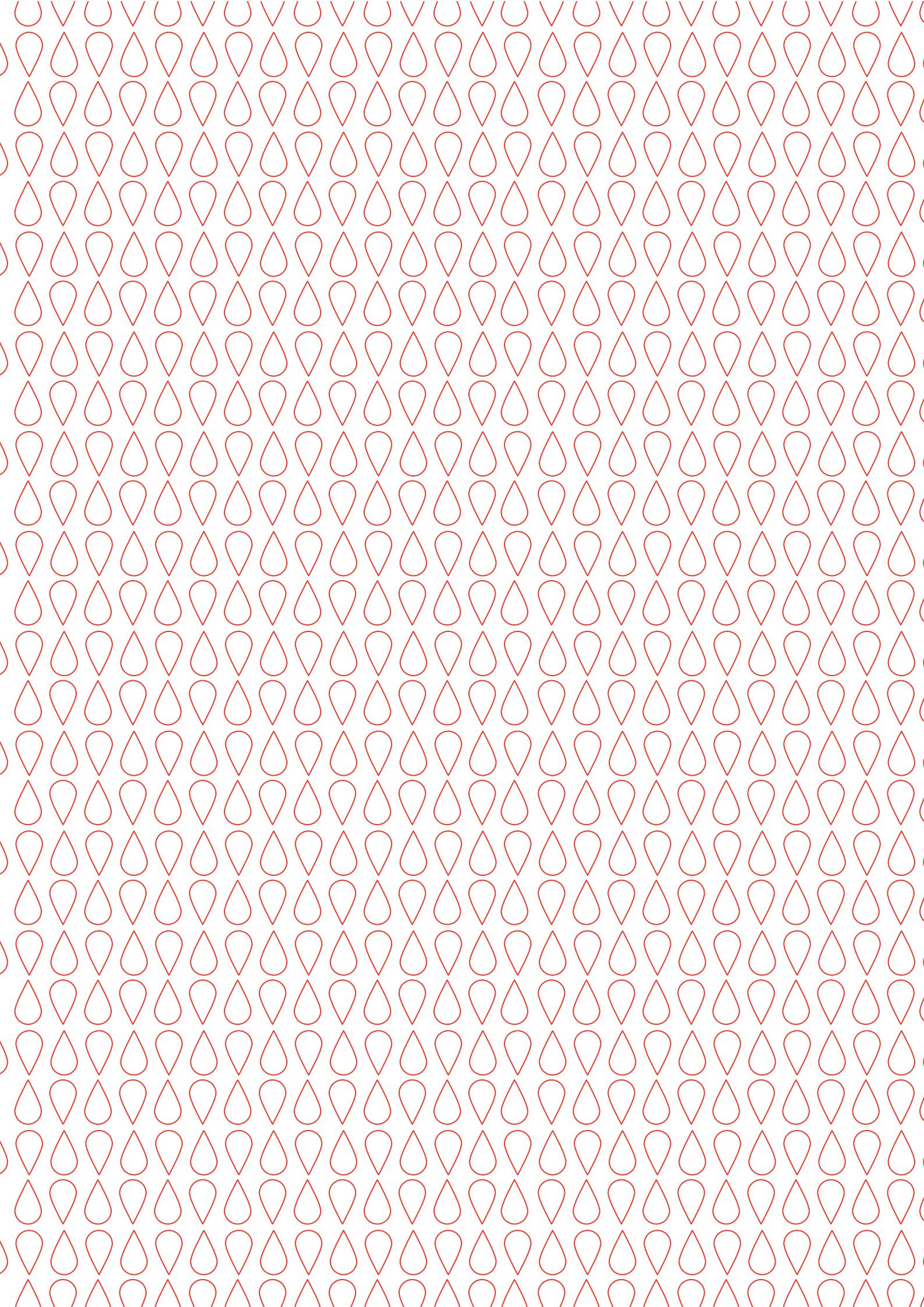


WP Blood Transfusion Service
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SANBS

South African National Blood Service



HAEMOVIGILANCE REPORT

2016

PRIVACY STATEMENT

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

DISCLAIMER

This document is a general report only. The data, analysis and conclusions contained herein are intended to provide healthcare professionals and the public with general information only on transfusion-related adverse events in South African hospitals. This report is a snapshot of currently available data, which have been obtained from limited resources.

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ACKNOWLEDGEMENTS

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

A special note of thanks goes to all the laboratories staff who assisted in data collection. We acknowledge Red Cell Serology Laboratories' efforts in ensuring that laboratory reports are sent to the relevant reporting hospitals.

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Title: South African National Haemovigilance Report
ISBN: 978-0-620-78428-3 (Print)
978-0-620-78429-0 (e-book)

UK English has been used in this report.

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

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CONTENTS

Abbreviations	Page 4
Classifications and definitions	Page 5
Foreword – message from the medical directors	Page 9
Introduction	Page 11
Chapter 1	Page 13
Executive summary	
Blood product collections and issues	
Hospital participation	
Transfusion reactions	
Patient mortalities	
Donor reactions	
Lookback	
Platelet bacterial testing	
Chapter 2	Page 16
Overview of product issues 2016	
Chapter 3	Page 20
Overview of transfusion reactions 2016	
Chapter 4	Page 26
Acute transfusion reactions: case discussions	
Acute haemolytic transfusion reactions	
Allergic transfusion reactions	
Anaphylactic transfusion reactions	
Transfusion-related acute lung injury	
Transfusion-associated circulatory overload	
Transfusion-associated dyspnoea	
Febrile non-haemolytic transfusion reaction	
Hypotensive reactions	
Chapter 5	Page 30
Incorrect blood components transfused (IBCT): case discussions	
Misdirected transfusions	
Misidentification	

CONTENTS

Chapter 6

Near miss events
Delayed haemolytic transfusion reactions (DHTR)
Post-transfusion purpura (PTP)
Transfusion-associated graft-versus-host disease (TA-GvHD)

Chapter 7

Mortality reports

Chapter 8

Lookback programme

Chapter 9

Platelet bacterial testing

Chapter 10

Donor vigilance
Classifications and definitions
Product collections 2016
Summary of donor adverse events by type
Analysis of adverse events by age and gender
Analysis of adverse events by donation type
Analysis of adverse events by severity

Chapter 11

Conclusion

Chapter 12

References

Page 35

Page 37

Page 42

Page 47

Page 51

Page 58

Page 60

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.

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 PaO_2 fraction of inspired oxygen [FiO_2] 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.

Transfusion reaction classifications and definitions (continued)

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 $>39^{\circ}\text{C}$ or equivalent, or a change of $>2^{\circ}\text{C}$ 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, and develops 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 and either at least one component received by the infected recipient was 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 and there was no evidence of infection before transfusion and no 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 a 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 mistransfusions. 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.

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: <ul style="list-style-type: none"> • An incident • An interaction between a recipient and blood

Forward – message from the medical directors



Foreword – message from the medical directors

The importance of the South African blood transfusion services' *Haemovigilance Report*, cannot be underestimated, as it is a platform where nurses and doctors can report adverse events that help us monitor the safety of our operations and products.

The value of this information guides us in our decision-making on current and future strategies to ensure that we meet our mandate of supplying safe and sufficient blood to patients in South Africa.

We endeavour to continuously improve this system by educating medical staff regarding the importance of reporting, by automating our systems and by working towards creating an electronic platform in future.

We would like to express our sincere gratitude to all the staff involved in the identification of reactions, investigation and the reporting thereof. If not for your continuous commitment to haemovigilance, we would not have been able to function as ethical blood services.

Thank you.



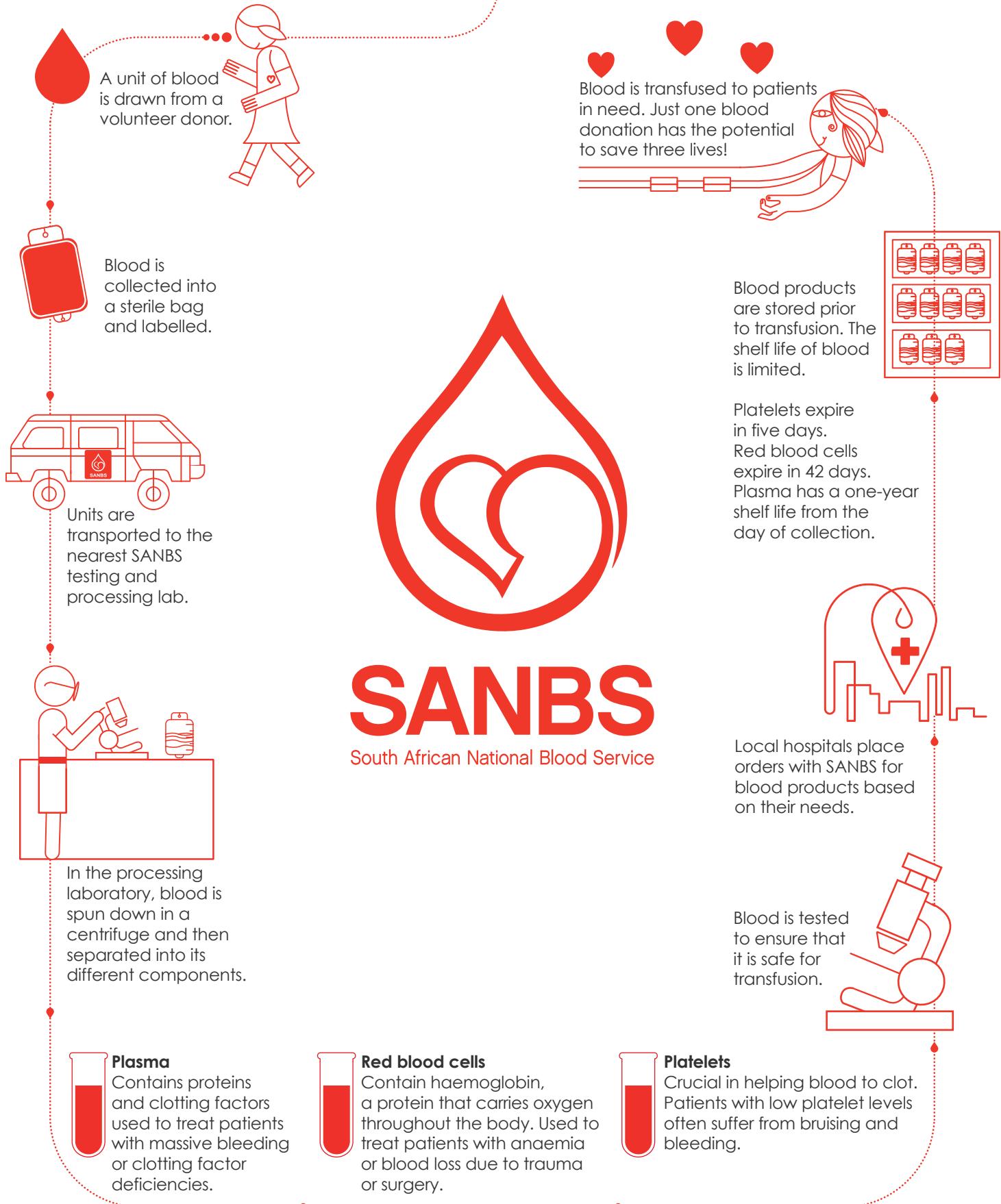
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Journey of blood



Introduction

This is the 17th annual *Haemovigilance Report for South Africa*; the first report was published in 2000.

Haemovigilance is widely defined as “a set of surveillance procedures covering the entire transfusion chain, from donation and processing of blood and its components to provision and transfusion to patients and 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 actions to prevent their occurrence or recurrence” (World Health Organization [WHO], 2016). Haemovigilance is an important tool to ensure safety, effective supply, appropriate utilisation and overall management of blood and blood products.

To be truly effective, a haemovigilance system needs to traverse the entire transfusion value chain; from collection of blood products through to transfusion (or discard) of the units. The WHO provides guidelines on prerequisites for an effective national haemovigilance system. One of the key requirements is ownership by the government through the ministry or Department of Health. It stipulates that the government is responsible for ensuring safe, sufficient and cost-effective supply of blood, as well as promoting safe, high-quality use and management of blood and blood products.

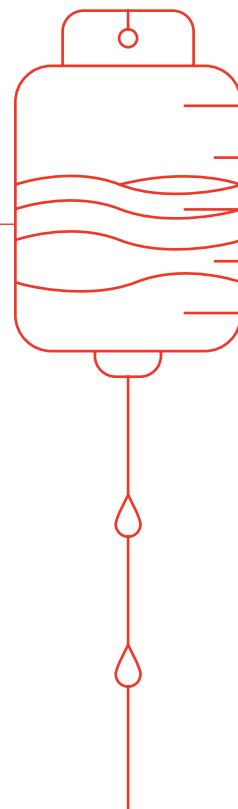
This is achieved through establishment of a national blood commission with the main responsibility of developing a national blood policy. The national blood policy should provide guidance on the ideal haemovigilance system (in line with the country’s health system), resource allocation, coordination of all transfusion stakeholders from blood services through to healthcare workers, monitoring and reporting, as well as legislative requirements.

Stakeholder collaboration is an essential tool to ensure the success of haemovigilance systems. To achieve the necessary stakeholder engagement, an authoritative body is essential. Although the WHO stipulates that government ownership is essential, it does recognise that this is not feasible in all countries. In the absence of the recommended governmental support, it is within the blood transfusion service’s reasonable remit to explore options for a national haemovigilance system that fulfils the requirements of an effective haemovigilance system.

Options include appointment of an independent body non-affiliated to the blood services to oversee a national haemovigilance system, or coordination of the national haemovigilance system by the blood services. The cumulative knowledge and experience of the blood services in South Africa is ideally suited to support the further development of a national haemovigilance system.

The current South African haemovigilance system is funded, operated and coordinated by the two blood transfusion services in South Africa, namely the South African National Blood Service (SANBS) and the Western Province Blood Transfusion Service (WPBTS). It employs passive surveillance. Units are tracked from collection to issue. Once issued (by the blood banks), they are presumed transfused.

The programme relies on hospitals to provide feedback on adverse reactions experienced by recipients. To achieve a more effective haemovigilance system, South Africa needs to transition towards an active surveillance system with tracking of units up to transfusion or discard.



Internationally, countries implement active surveillance to varying degrees, depending on resource availability. Some countries employ transfusion officers to monitor each transfusion and record adverse reactions. In other countries, follow-up is retrospective through review of each transfusion record to establish adverse reaction occurrence. Either way, active surveillance requires additional resources, both human and financial. It is in view of the above that various potential approaches to implementing a more effective national haemovigilance system in South Africa (as per WHO guidelines) will be investigated with key stakeholders. This also entails strengthening the existing system.

This year's report provides an analysis of the trends in the programme to year-end 2016. It also highlights areas of improvement and lays the foundation for the changes envisioned through improvement of the current system.

Executive summary 2016

1



Executive summary 2016

With an estimated HIV prevalence of 12.7% of the total population (Statistics South Africa, 2016), South Africa falls among the 10 countries with the highest prevalence of HIV in the world. This, along with other high-ranking diseases such as tuberculosis, trauma and cancer, places significant pressure on the country's demand for blood. Although improvements in medical care have resulted in reduced demand for blood in most countries in Europe, the United States, Australia and Canada, high disease burden and health disparities in South Africa have kept blood-demand levels elevated.

Supply of this valuable resource depends on the availability and retention of safe blood donors. The challenge is that less than 1% of the population donates blood. Of the total eligible blood donors that presented at SANBS clinics, 19.19% were deferred from donation in 2016 for various health reasons. Haemoglobin (Hb) failure was the most common reason for deferral, affecting up to 37.2% of black donors.

The high rate of donor deferral due to Hb failure poses a significant challenge to donor retention and safety. To address the potential risk of iron deficiency, donation patterns of donors at high risk of anaemia were reviewed and changed. The donation frequency for donors over 65 was reduced from six times a year to four times, while the frequency of blood collection from schools was reduced to no more than three times a year. Additional measures, such as targeted ferritin testing, donor iron supplementation and increasing male Hb cut-off from 12.5 g/dl to at least 13.5 g/dl are planned for 2018.

Since its inception in 2000, the South African haemovigilance programme has focused on monitoring, analysis, investigation and reporting of adverse events experienced by blood recipients and donors.

The information gathered has informed changes in the quality system, from collection and processing to issuing of blood. Included in the changes were improvements in donor selection and the reporting of adverse reactions. In addition, SANBS introduced apheresis platelet sterility testing, infection control and prevention, as well as blood-bank automation. The latter improves patient safety during blood crossmatching by improving sensitivity and turn-around times (through batch testing), and reducing errors, as there is minimal human intervention in the process.

Following implementation of blood-bank automation, significant reduction in blood-bank errors was observed: they decreased from seven reported cases in 2015 to one case in 2016.

Pooled platelet pathogen inactivation or reduction was assessed at WPBTS and feasibility processes are underway in SANBS. This technology will inactivate known and unknown pathogens in the pooled platelet products. In addition to improving the safety of pooled platelets, pathogen inactivation will help mitigate the shortage of apheresis platelets, which has been an ongoing challenge.

This 17th annual national Haemovigilance Report is an overview of data collected by the two blood transfusion services from January to December 2016. It covers blood product collections and issues; transfusion and donor-adverse reactions; patient mortalities; apheresis platelet sterility testing; and look-back data.

Blood product collections and issues

A total of 985 310 units of blood were collected and separated into various components, with 8 407 fewer units collected in 2016 than in 2015. SANBS collections decreased by 2.1%, while WPBTS collections decreased by 4.8%. A total of 1 201 291 blood components were issued. Product issues by WPBTS increased by 14 041, while issues by SANBS decreased by 12 978. The largest decrease in SANBS issues was in red cell products, which decreased by 14 353. Red cell issues accounted for 79% of all product issues.



Executive summary 2016

Hospital participation

273 of 749 health care facilities that are supplied with blood and blood products reported transfusion reactions. The participation increased by 34 facilities in 2016 compared to 2015. Although hospital reporting of transfusion reactions increased slightly, the rates of transfusion errors also increased as discussed below.

Transfusion adverse reactions

The haemovigilance offices of SANBS and WPBTS received and analysed 986 cases of suspected transfusion reactions. The transfusion-adverse reaction reporting rate for 2016 was 0.82 adverse reactions per 1 000 units issued. This is a low reporting rate, compared with countries such as the United Kingdom and Canada. The latter, for example, report 3 to 3.5 adverse reactions per 1 000 units issued.

Acute transfusion reactions were the most commonly reported reactions, at 93.0%. This was followed by incorrect blood component transfused (IBCT), at 3.8%. Of the acute reactions, febrile non-haemolytic reactions (FNHTRs) were the most common, followed by allergic reactions.

Incorrect blood component transfused and near misses accounted for 5.3% of all reactions. These occur due to errors by hospital and blood-bank staff. Blood-bank errors dropped from 21% in 2015 to 2.6% in 2016. The marked decrease is attributed to the SANBS's introduction of blood-bank automation.

Hospital errors increased significantly from 50% in 2015 to 81.6% in 2016. The high incidence of hospital-related transfusion errors highlights the need for improved hospital-based mitigation strategies.

Patient mortalities

The hospitals reported 14 cases of transfusion-related patient deaths. Of the 14 cases, only three were accompanied by the complete documentation required to conduct post-transfusion investigations. Most of the cases were reported verbally by hospital personnel, without completing transfusion reaction forms. Seven of the cases were classified as probably unrelated to transfusion, as the treating doctors reported that the deaths were more likely a consequence of the patients' baseline illness. One case was accompanied by delayed issuing of fresh frozen plasma.

Donor adverse reactions

In 2016, SANBS and WPBTS collected blood from 80 fixed donor centres and more than 24 282 mobile drives. Overall, reporting of donor adverse reactions improved, but underreporting has not been eliminated. In 2016, 4 870 donor adverse reactions were reported, compared with 3 804 in 2015. Reported cases increased from 0.38% in 2015 to 0.49% in 2016. The overall reported ratio of donor adverse reactions was 1:202 in 2016, 1:261 in 2015 and 1:274 in 2014. Donors aged 16 to 19 had the highest frequency of reactions at 28.9% followed by ages 20 to 25, at 17.2%. More females (59%) than males (41%) developed adverse reactions. Vasovagal reactions were the highest at 75%, while local reactions were 19%.

Lookback

Of the total donors that seroconverted in 2016, 702 were investigated through the donor-triggered lookback process. This was a decrease of 8% from 2015. There was a 100% follow-up of all cases. Of the 702 cases, 74.9% of lookbacks were due to HIV, 21.5% HBV and 2.3% HCV. Five cases had HIV/HBV co-infection and two cases HIV/HCV co-infection.

A human T-cell leukemia virus type 1 (HTLV-1) lookback investigation started in 2013 was concluded in 2016.

A total of 11 recipient-triggered lookback cases were reported and six had been resolved at the time of the report. Of these, four donors retested negative. Four of the 11 recipient-triggered cases remain unresolved, because no records were found due to the time lapse or the donors were untraceable, while one was a pending malaria case.

Platelet bacterial testing (SANBS only)

Bacterial contamination of platelet products is a major post-transfusion risk, which has remained static at a rate of 1/3 000 for the last 30 years globally. As apheresis platelets are in limited supply in South Africa, SANBS only tests a percentage of apheresis platelets for sterility, using a US Food and Drug Administration-approved bacterial culture system. Of the 13 980 apheresis platelet units collected in 2016, 2 860 (20.5%) were tested for microbial growth and 4.9% tested positive.

Compared to 2015, the apheresis platelet sterility rate improved marginally from 94.8% to 95.1%. In addition, only a small number of expired platelets were tested, as most of SANBS's platelets are used within three days of production. The positivity rate in expired platelets was 5.3%.

Overview of product issues 2016

2



Overview of product issues 2016

South Africa's two blood transfusion services issued a grand total of 1 201 291 blood and blood products in 2016. SANBS issued 1 013 884 products, while WPBTS issued 187 407 products.

Overall products issued increased by 1 063 in 2016 compared with 2015. Total product issues by the WPBTS increased by 14 041, while total issues by the SANBS decreased by 12 978. The largest decrease in SANBS issues was in red cell products, which decreased by 14 353. Red cell issues accounted for 79% of all issues. Total platelet issues increased by 1 593 units, while total plasma issues increased by 11 075.

In 2015, the two blood services issued blood products to 749 health facilities. This increased slightly in 2016. Supply of red cell products through emergency blood fridges (emergency stock) located in various public and private health facilities decreased from 46 122 in 2015 to 42 333 in 2016.

The paucity of, and high demand for, group O blood is a major challenge facing blood services with regard to emergency stock. To address the challenge, SANBS group O issues from emergency fridges were decreased and replaced with group to group issues from blood banks. Blood bank operational hours were extended for some of the blood banks. In addition, SANBS introduced a blood conservation officer (BCO) at each of the four busiest zones. The BCO's main role is to monitor and address blood wastage and use of emergency blood stocks.

Table 2.1: Overall product issues (2016)

Products	SANBS	WPBTS	Total
Plasma products			
Cryo-plasma	26 541	1 881	28 422
Fresh frozen plasma	127 045	23 815	150 860
Totals	153 586	25 696	179 282
Apheresis platelet			
Apheresis platelet	26 810	4 251	31 061
Pooled platelet	34 154	5 217	39 371
Total	60 964	9 468	70 432
Paediatric			
Paediatric	36 281	2 887	39 168
Red cells			
Red cells	728 880	138 863	867 743
Reserved	150	28	178
Emergency units and ward stock	32 077	10 256	42 333
Whole blood	1 946	209	2 155
Total red cell products	799 334	152 243	951 577
Grand total	1 013 884	187 407	1 201 291

Overview of product issues 2016 (continued)

The South African haemovigilance system follows a passive surveillance system. Once issued, units are not tracked to determine transfusion; therefore, units issued and unreturned to blood banks are presumed transfused.

Figure 2.1: SANBS red cell product issues (2016)

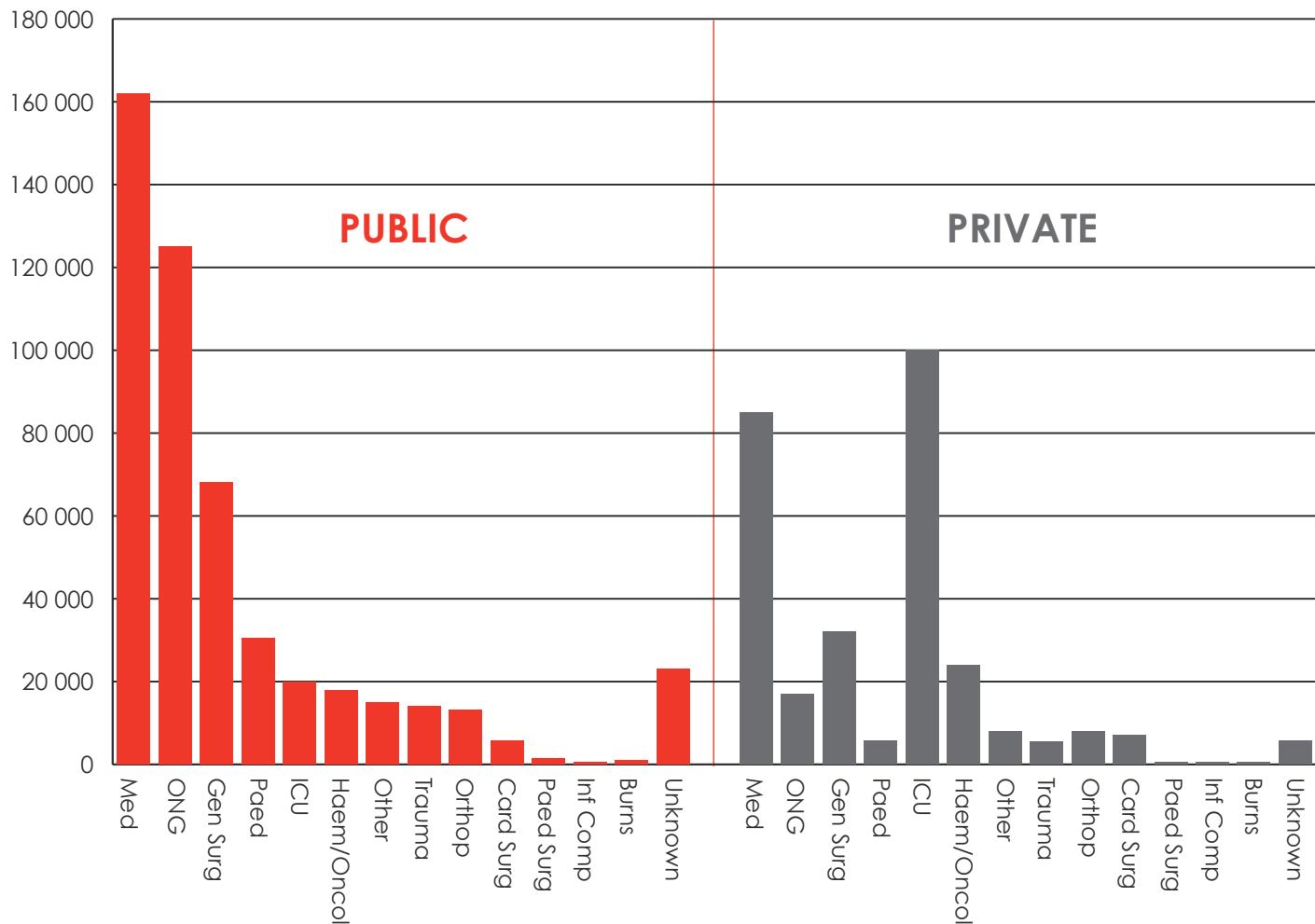


Figure 2.1 illustrates the SANBS red cell issue profile of the public compared with the private health sector. The biggest public-sector user was medical departments at 20.2%, followed by gynaecology and obstetrics at 15.7% and general surgery at 8.6%. In the private sector, the biggest user was intensive care units at 12.4%. This was followed by medical departments at 10.6% and general surgery at 4.1%.

Both SANBS and WPBTS conduct the following tests on all products prior to issue: HIV (individual donor nucleic acid testing [ID-NAT] and serology), Hepatitis B and C (ID-NAT and serology), as well as syphilis (TPHA and VDRL). With the introduction of ID-NAT testing for the viruses in 2005, the window period for the viruses improved as follows:

- HIV – from 19 to 4.6 days
- Hepatitis B – from 38 to 15.3 days
- Hepatitis C – from 65 to 2.5 days

Overview of product issues 2016 (continued)

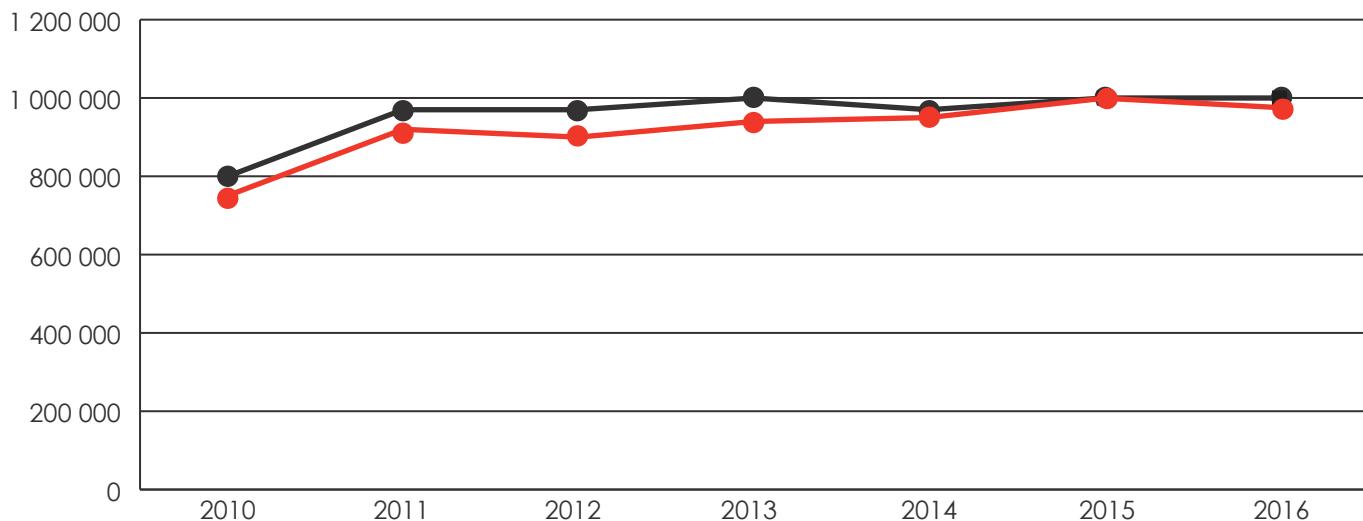
Table 2.2: Collections and issues (2010 to 2016)

Collection types	2010	2011	2012	2013	2014	2015	2016
Whole blood collections	776 311	930 654	932 509	967 125	944 058	971 046	963 146
Red cell product issues	714 515	873 353	858 760	902 063	917 199	963 182	925 465*
Percentage difference	8%	6%	7%	7%	3%	1%	4%

*Adjusted for paediatric units.

A review of Table 2.2 reflects a steady decrease in percentage difference between whole blood collections versus red cell product issues. A slight increase was, however, observed in 2016. Overall, red cell issues continued to closely resemble whole blood collections.

Figure 2.2: Collections and issues (2010 to 2016)



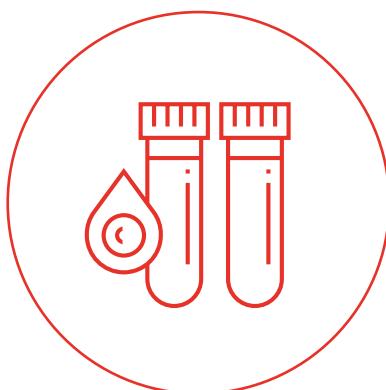
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Overview of transfusion reactions 2016



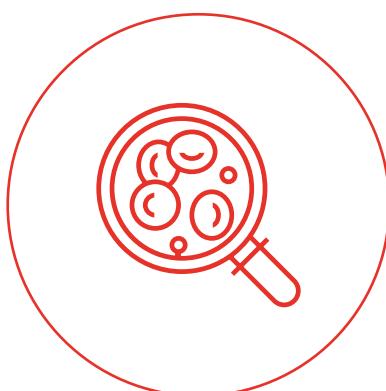
Overview of transfusion reactions 2016

"The transfusion of blood and blood products is a life-saving intervention. However, there are risks of adverse events associated with the donation of blood and its components, and with the transfusion of blood and blood products to patients. Adverse events include all reactions, incidents, near misses, errors, deviations from standard operating procedures and accidents associated with blood donation and transfusion." (WHO *Aide-mémoire for ministries of health*, 2014).

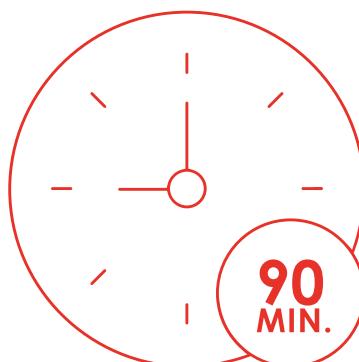


On a daily basis, SANBS and WPBTS receive reports of transfusion reactions that occurred in hospitals and clinics. The reports are analysed, investigated and classified. Where necessary, clinical advice on reaction management is provided. This is followed by feedback to the hospital or clinic on probable cause of reaction.

In South Africa, it is a statutory requirement that adverse reactions are reported. In practice, however, a patient's managing clinician determines whether a reaction has occurred and should be reported to the blood service. This implies that under-reporting does occur, the extent of which cannot be quantified.



In 2016, SANBS and WPBTS Haemovigilance offices received and analysed 986 suspected transfusion reaction cases. Of these, SANBS reported 782 (79.3%) and the WPBTS 204 (20.7%).



Overview of transfusion reactions 2016 (continued)

Table 3.1: Summary of transfusion adverse events (2016)

	Adverse events	SANBS	WPBTS	South Africa	(%)
Acute transfusion reactions (ATRs)	Acute haemolytic transfusion reactions (AHTR)	4	1	5	0.5
	Allergic reactions	146	87	233	23.6
	Severe allergic reactions	44	10	54	5.4
	Anaphylactic reactions	25	8	33	3.3
	Febrile non-haemolytic reactions (FNHTR)	246	60	306	31.0
	Transfusion-associated circulatory overload (TACO)	3	2	5	0.5
	Transfusion-related acute lung injury (TRALI)	1	0	1	1.2
	Transfusion-associated dyspnoea (TAD)	71	3	74	7.5
	Hypotensive reactions	24	4	28	2.8
	Unclassifiable (incomplete information)	160	15	175	17.7
	Unclassifiable (no forms)	3	0	3	0.3
Total acute transfusion reactions (ATR)		727	190	917	93.0
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
Incorrect blood component transfused (IBCT)	Rh incompatible transfusions	1	0	1	0.1
	ABO incompatible transfusions	10	1	11	1.11
	Misdirected transfusions	16	3	19	1.9
	Antibodies detected	6	0	6	0.6
	Patient misidentifications	1	0	1	0.1
	Total IBCT	34	4	38	3.8
Other reactions	Near miss	6	8	14	1.4
	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	2	14	1.4
	Seizures	3	0	3	0.3
	Excluded	13	0	13	1.3
	Total other	34	10	44	4.4
GRAND TOTAL		782	204	986	100

Note: Thirteen cases from December 2015 were* excluded from the grand total as they fell outside the year under analysis.

Table 3.1 shows that, at 93%, acute transfusion reactions were the most commonly reported reactions. This was followed by other reactions at 4.4% and incorrect blood component transfused at 3.8%. No delayed reactions, nor transfusion transmissible infections, were reported in 2016.

A large majority of IBCT reactions are due to transfusion errors. Transfusion errors (ABO incompatibility; misdirected transfusions, patient misidentifications) and near misses account for 5.3% of all reported reactions. Of the reported errors, 2.6% occurred in blood banks, while 81.6 % were clinical.

Overview of transfusion reactions 2016 (continued)

Table 3.2: Rates of transfusion adverse events per classification

	Adverse events	Total number per classification	Rates per 100 000 units issued
Acute transfusion reactions (ATRs)	Acute haemolytic transfusion reactions (AHTR)	5	0.4
	Allergic reactions	233	19.4
	Severe allergic reactions	54	4.4
	Anaphylactic reactions	33	2.7
	Febrile non-haemolytic reactions (FNHTR)	306	25.4
	Transfusion-associated circulatory overload (TACO)	5	0.4
	Transfusion-related acute lung injury (TRALI)	1	0.08
	Transfusion-associated dyspnoea (TAD)	74	6.1
	Hypotensive reactions	28	2.3
	Unclassifiable (incomplete information)	175	14.5
	Unclassifiable (no forms)	3	0.2
Total acute transfusion reactions (ATR)		917	75.8
Delayed transfusion reactions	Delayed haemolytic transfusion reactions (DHTR)	0	0
	Delayed serological transfusion reactions (DSTR)	0	0
	Total delayed reactions	0	0
Incorrect blood component transfused (IBCT)	Rh incompatible transfusions	1	0.08
	ABO incompatible transfusions	11	0.9
	Misdirected transfusions	19	1.5
	Antibodies detected	6	0.5
	Patient misidentifications	1	0.08
Total IBCT		38	2.9
Other reactions	Near miss	14	1.1
	Transfusion-associated graft-versus-host disease (TA-GvHD)	0	0
	Transfusion-transmitted infections	0	0
	Post-transfusion purpura	0	0
	Mortality	14	1.1
	Seizures	3	0.2
	Excluded	13	1.0
Total other		44	3.4
GRAND TOTAL		986	82.1

The rates of adverse events are calculated per 100 000 units issued as per the international surveillance of transfusion-associated reactions and events (ISTARE) database used by members of the International Haemovigilance Network (IHN).

Table 3.2 above shows that in 2016 the South African transfusion rate per 100 000 units was 82.1. This translates to 0.82 reactions per 1 000 units issued. The transfusion reaction rate for SANBS was 0.77, while the WPBTS rate was 1.09.

Overview of product issues 2016 (continued)

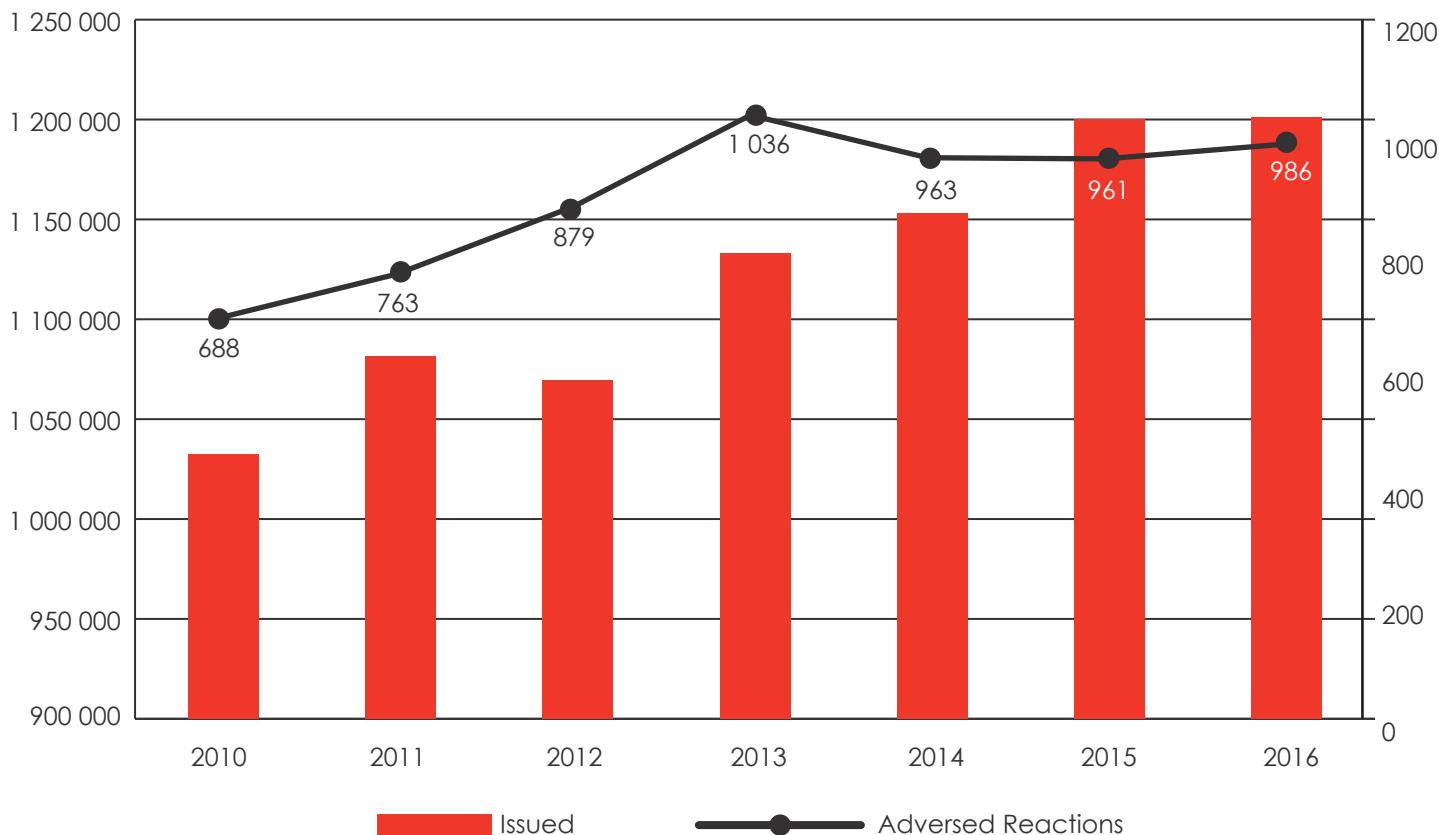
Rates of transfusion adverse events (2010 to 2016)

Table 3.3 below shows the rates of transfusion adverse reactions per 100 000 (units) over a seven-year period. There was a steady increase in reported cases from 2010 to 2013. However, 2014 saw a decline in reported cases. This trend persisted in 2015 with a slight increase in 2016. The decrease in number of cases reported is likely due to under-reporting as opposed to a reduction in reaction occurrence.

Table 3.3: Adverse reaction rates per 100 000 issues (2010 to 2016)

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

Figure 3.1: Adverse reactions (2010 to 2016)



Overview of product issues 2016 (continued)

Table 3.4: Acute transfusion reactions (2010 to 2016)

Acute reactions	2010	2011	2012	2013	2014	2015	2016	Total
AHTR	15	4	4	52	10	22	5	140
Allergic (including severe allergic)	231	221	274	297	251	260	87	2 020
Anaphylactic	6	16	26	64	53	87	33	301
TRALI	1	1	2	1	2	5	1	17
TACO	5	1	0	0	3	0	5	17
TAD	47	71	64	76	80	77	74	589
FNHTR	257	255	360	338	347	334	306	2 626
Hypotensive	51	54	40	52	57	33	28	352
Unclassifiable	97	117	72	112	99	79	178	996
Total	710	740	842	1 042	902	897	717	7 058

Figure 3.2: Acute transfusion reactions (2010 to 2016)

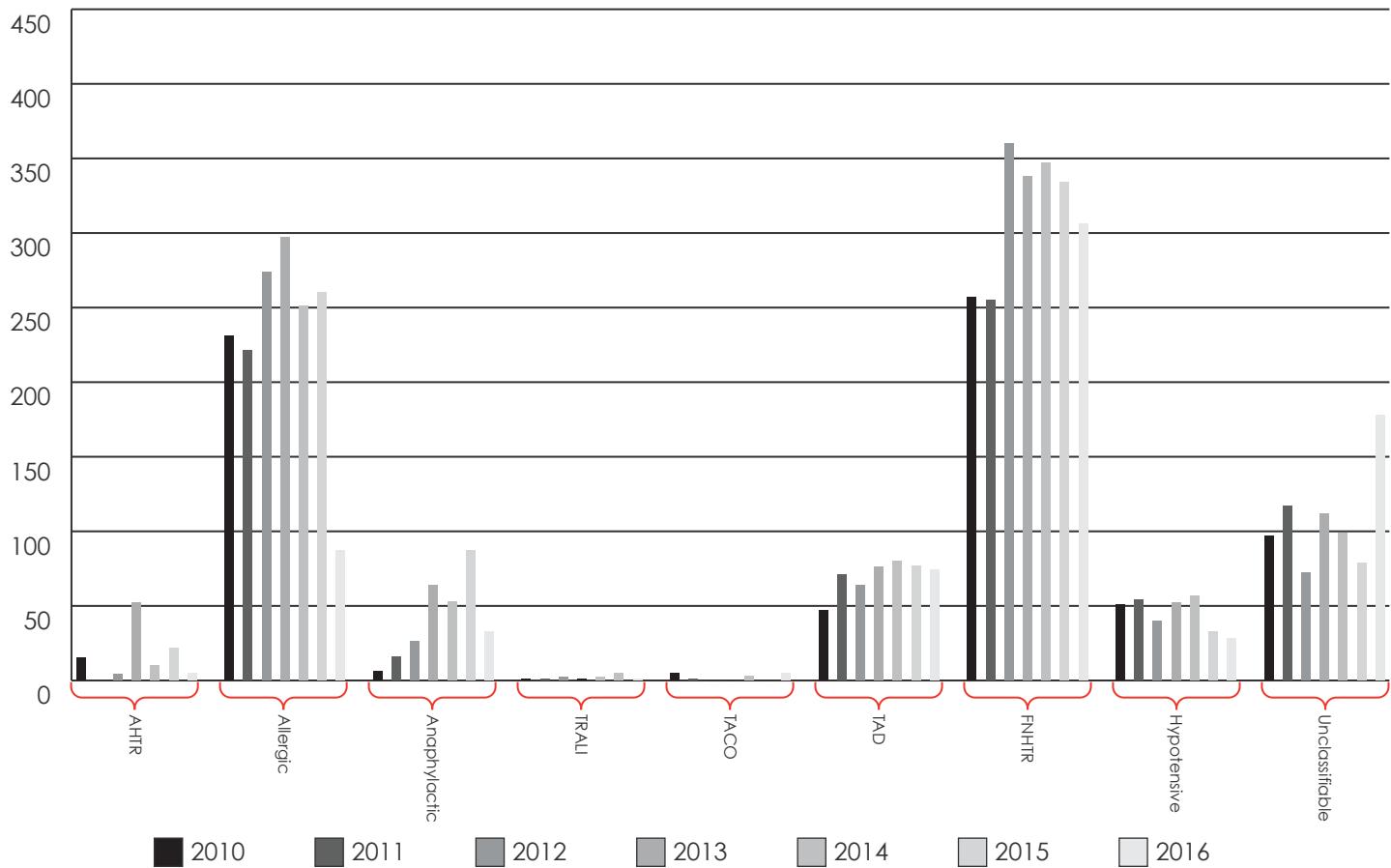


Figure 3.2 shows the frequency of occurrence of the different types of acute transfusion reactions over a period of seven years. Febrile non-haemolytic reactions (FNHTR) occurred the most frequently, followed by unclassified and allergic reactions. The main contributory factor to the high frequency of unclassified reactions was insufficient information received from hospital staff with regard to patients' clinical histories, as well as clinical changes experienced during transfusion reactions. In most of these cases, the transfusion reaction form was either incompletely filled or post-transfusion specimens were not submitted to the blood bank for further investigation.

4

Acute transfusion reactions: case discussions



Acute transfusion reactions: case discussions

Acute transfusion reactions present as adverse signs and symptoms during or within 24 hours of blood transfusion. Common symptoms are fever, pruritis, nausea, vomiting, tachycardia or restlessness. Severe reactions are often accompanied by dyspnoea, haemoglobinuria, oliguria, shock or loss of consciousness.

Early recognition of potential transfusion reaction is essential to patient safety. This requires high levels of vigilance. Recognising acute transfusion reactions is often complicated by changes in signs and symptoms of underlying disease that occur concurrent to transfusion.

In order to accurately capture data and advise on clinical management of patients who develop transfusion reactions, the blood services depend on reports from patients' treating doctors. Importantly, the likelihood that reactions are reported depends

on the extent to which clinical signs and symptoms are recognised as related to transfusion, as well as clinician's willingness to comply with reporting requirements.

Although acute transfusion reactions are the most frequently reported type of reaction in South Africa, they almost entirely consist of allergic and FNHTR reactions, with very few reported cases of TRALI, TACO, acute haemolytic reactions, and no cases of bacterial infection. This is in contrast to the US, for example, which reported TRALI, TACO, acute haemolytic

reactions and bacterial infections as the four leading causes of transfusion related deaths in 2013 (Bolton M, Cohen H, Paula H, 2013).

In order to improve patient safety with regard to transfusion, collaborative effort by both the hospitals and the blood transfusion services is needed. This partly depends on improved support from the Department of Health in highlighting the significance of transfusion safety awareness among practitioners.

Acute transfusion reactions 2016 – case studies

2009	2010	2011	2012	2013	2014	2015	2016
14	15	1	4	4	10	22	4

Four cases of acute haemolytic transfusion reactions (AHTR) were reported in 2016.

Allergic transfusion reactions

2009	2010	2011	2012	2013	2014	2015	2016
221	231	201	274	297	251	260	146

146 cases of both mild and severe allergic reactions were reported.

Case 1:

Acute haemolytic transfusion reaction

- Two-year-old male baby diagnosed with severe malaria and anaemia
- History of travel to malaria area
- On return, the patient developed vomiting, diarrhoea and fever
- Two units of Group O, Rh-positive, leucodepleted red cells were ordered, tested for compatibility and issued for the patient
- Within one to two hours of commencement of transfusion, the patient developed haematuria and hypotension
- Transfusion was immediately stopped and the patient stabilised
- Full serological investigations were conducted on the pre- and post-transfusion samples from the patient, as well as from the suspected blood unit
- No abnormalities or incompatibilities were detected in any of the specimens tested
- No further information was provided to the blood transfusion service on the clinical condition of the patient

Conclusion: The case was classified as an allergic reaction.

Case 2:

Allergic reaction

- Ten-year-old female patient diagnosed with thrombocytopenia and severe anaemia
- Patient was transfused with two units of leucodepleted red cells
- The patient immediately developed a severe skin reaction
- The transfusion was stopped
- Intravenous hydrocortisone was reportedly commenced
- No further information provided to the blood transfusion service on the clinical condition of the patient

Conclusion: The case was classified as a possible acute haemolytic transfusion reaction; however, malaria-induced haemolysis could not be excluded.

Acute transfusion reactions: case discussions (continued)

Anaphylactic transfusion reactions

2009	2010	2011	2012	2013	2014	2015	2016
5	6	16	26	64	54	87	87

Of the 87 reported cases in this category, 33 were classified as anaphylactic and 54 as severe allergic reactions.

Case 3:

Anaphylactic reaction

- Two-month-old female patient treated for apnoea and chronic lung disease (haemoglobin 6.1 g/dl)
- One unit of pediatric leucodepleted red cells was ordered and issued for the patient
- Within one hour of commencement of transfusion (about 20ml of product transfused) patient experienced dyspnoea, facial and tongue swelling
- The transfusion was stopped immediately, oxygen administered by face mask and patient stabilised

Conclusion: The case was classified as an anaphylactic reaction.

Transfusion-related acute lung injury

Transfusion-related acute lung injury (TRALI) is characterised by pulmonary oedema, hypoxemia, respiratory distress and radiographic evidence of new bilateral pulmonary infiltrates (sometimes described as white lung) occurring within minutes to six hours after transfusion.

Signs and symptoms may also include fever, tachycardia, cyanosis, hypotension and frothy sputum. TRALI can be triggered by the transfusion of any blood product, but transfusion of blood products with high plasma content and blood products containing human leukocyte antigen (HLA) I and II increase the risk.

2009	2010	2011	2012	2013	2014	2015	2016
1	1	1	2	1	2	5	1

One case of suspected/possible TRALI was reported in 2016.

Case 4:

Transfusion-related acute lung injury

- Forty-seven-year-old male with diabetes and hypertension admitted for surgical debridement of diabetic foot (haemoglobin 7.6 g/dl)
- Four units of red cells and two units of fresh frozen plasma were ordered for patient
- Four units of Group O, Rh-positive red cells and fresh frozen plasma were issued for patient
- Within one to two hours of transfusion, the patient developed fever, flushing, restlessness, tachycardia, shock and collapsed
- According to the managing doctor, the patient "crashed" acutely while in theatre
- The managing doctor also reported acute onset of pulmonary oedema and suspected TRALI
- Transfusion was stopped, a transfusion reaction form and post-transfusion specimens were forwarded to the blood bank for further investigations
- No further information was provided to the blood transfusion service on the clinical condition of the patient

Red cell laboratory testing results:

- Patient's pre-transfusion specimen: Group A (weak), Rh-positive. The direct antiglobulin test was negative
- Patient's post-transfusion specimen: Group A (weak), Rh positive. The direct antiglobulin test was negative
- Fresh frozen plasma unit: known Group O, Rh-positive
- Minor crossmatch: no incompatibility was demonstrable when the patient's red cell sample was tested against the plasma donation

Red cell antibody screen:

- Patient's sample: no irregular antibodies detected
- Fresh frozen plasma unit: no irregular antibodies detected

HLA antibody screen:

- Donor's sample: a DQA1*03:02 HLA antibody was weakly demonstrable in the plasma sample of the tested unit

Conclusion: This case was classified as a definite transfusion-related acute lung injury based on typical findings on chest X-ray, the development of dyspnoea, bronchospasms and other symptoms following blood product transfusion, plus lack of response to diuretics.

Acute transfusion reactions: case discussions (continued)

Transfusion-associated circulatory overload

2009	2010	2011	2012	2013	2014	2015	2016
3	5	1	0	0	3	0	5

Five cases of transfusion-associated circulatory overload (TACO) were reported in 2016. TACO usually indicates a temporal association with blood transfusion. Patients with TACO manifest respiratory system-related signs and symptoms, typically during the transfusion or within 12 hours afterwards.

Case 5:

Transfusion-associated circulatory overload

- Thirty-three-year-old female with post-partum haemorrhage secondary to uterine tear (haemoglobin 6.2 g/dl)
- Three units of Group A, Rh-positive red cells were ordered and issued for patient
- Less than an hour into transfusion of the first unit (about 100ml of blood transfused) the patient developed headache, dyspnoea, dizziness, fever, hypertension, tachycardia and decrease in oxygen saturation
- Full serological investigation was performed on patient's pre- and post-transfusion samples, as well as the suspected unit
- No serological incompatibilities found
- No further information provided to the blood transfusion service on the clinical condition of the patient

Conclusion: The case was classified as TACO.

Transfusion-associated dyspnoea

2009	2010	2011	2012	2013	2014	2015	2016
36	47	71	64	76	80	77	74

74 cases of transfusion-associated dyspnoea (TAD) were reported in 2016.

Case 6:

Transfusion-associated dyspnoea

- Eighteen-day-old neonate diagnosed with pneumonia and anaemia (haemoglobin 8.5 g/dl)
- History of symptomatic anaemia; referred for immune thrombocytopenic purpura investigation
- One unit of leucodepleted paediatric red cell unit was ordered and issued for the patient
- Within minutes of initiation of transfusion, the patient developed dyspnoea and cyanosis
- Chest X-ray and blood gas tests were performed
- No abnormalities found
- Patient was provided supportive oxygen
- Clinical condition improved

Conclusion: The case was classified as transfusion-associated dyspnoea (TAD).

Febrile non-haemolytic transfusion reactions

2009	2010	2011	2012	2013	2014	2015	2016
229	257	255	360	388	347	334	306

306 cases of febrile non-haemolytic transfusion reaction (FNHTR) were reported.

Case 7:

Febrile non-haemolytic transfusion reaction

- Twenty-day-old premature male neonate diagnosed with pneumonia, renal impairment and anaemia (haemoglobin 8 g/dl)
- One unit of leucodepleted paediatric red cells was ordered and issued for the patient
- Within six hours of transfusion, the patient developed flushing, decrease in oxygen saturation, fever (temperature increase from 36.4°C to 38°C), tachycardia (pulse increase from 169 to 226 bpm)
- The transfusion was stopped
- The patient was stabilised

Conclusion: The case was classified as a febrile non-haemolytic transfusion reaction (FNHTR).

Hypotensive reactions

2009	2010	2011	2012	2013	2014	2015	2016
17	257	54	40	52	57	33	28

28 cases of hypotensive reaction were reported in 2016.

Case 8:

Hypotensive reaction

- Five-month-old male baby diagnosed with thrombocytopenia and chronic renal failure
- History of previous left nephrectomy, sepsis and severe electrolyte abnormalities
- One unit of emergency, leucodepleted, paediatric red cells ordered and issued for the patient
- Within one hour of initiation of transfusion, the patient developed hypotension and decreased oxygen saturation
- On further follow-up by the haemovigilance office, the patient was reported to have stabilised

Conclusion: The case was classified as a hypotensive reaction.

Unclassifiable reactions

2009	2010	2011	2012	2013	2014	2015	2016
43	48	117	72	112	99	79	178

178 of the received cases could not be classified due to lack of supportive documentation. Three were due to non-submission of the transfusion reaction form, while 175 were due to incomplete information and/or specimens submitted to the blood banks.

5

Incorrect blood components transfused (IBCT): case discussions



Incorrect blood components transfused (IBCT): case discussions

Incorrect blood components transfused (IBCT) reactions occur due to transfusion errors. In most cases, transfusion errors are related to staff practice and/or education. Insufficient staff education and/or poor practice can result in errors that otherwise could have been avoided.

Examples include failure to follow existing transfusion protocols; failure to correctly identify the patient before initiation of transfusion; not labeling samples at the bedside or pre-labeled compact specimen tubes.

At blood bank level, errors can occur due to sample mix-up during the crossmatch process, incorrect labeling of blood bags and incorrect product issued for specific request.

According to the independent UK haemovigilance scheme Serious Hazards of Transfusion (SHOT, 2013), the reasons for transfusion errors remain the same now as they were in 1967. This highlights the need to maintain safety basics in transfusion practice. Although the number of SANBS- and WPBTS-reported transfusion errors is low compared to other types of reactions, the errors are preventable, therefore mitigation strategies to reduce them are essential.

Mitigation processes for transfusion errors

Current mitigation strategies within SANBS and WPBTS include the transfusion error being reported to the blood service, after which the haemovigilance office carries out an analysis and investigation of the incident to determine the source and cause of the error.

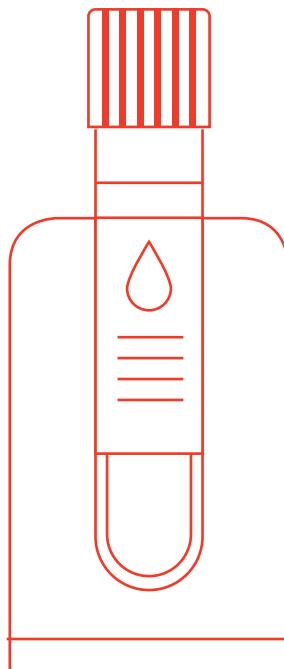
Part of the investigation involves antibody and serological compatibility tests conducted by the red cell serology lab. Once investigations are complete, a feedback letter is sent to the hospital clinical manager.

In addition, if the error occurred at hospital level, the blood transfusion service staff (hospital liaison officer at the SANBS; marketing officer at the WPBTS) communicate this to the hospital, either directly to ward staff or via the hospital transfusion committee (HTC).

The HTC comprises representatives from hospital management, clinical department heads, nursing department heads, the finance department, the transport department, the blood service medical team and, in some hospitals, the pharmaceutical department.

Currently, more than 80% of public hospitals have a functional HTC. The committee's duty is to ensure appropriate and safe use of blood and blood products. This is achieved through developing transfusion protocols; monitoring hospital compliance with the protocols; preventing wastage; monitoring use of blood and blood products; educating staff on transfusion matters; identifying gaps in transfusion processes; and developing measures to address gaps identified.

Where transfusion error is identified, the committee needs to ensure that implicated hospital staff members receive the necessary support, for



example through education. If nursing staff education is necessary, the hospital liaison officer (HLO) or marketing officer is responsible for arranging and providing it. If education involves clinicians, the blood transfusion zone medical manager (SANBS) or blood transfusion specialist (WPBTS) provides the education.

If the error occurs at blood-bank level, the blood-bank supervisor is informed and responsible for ensuring that the staff members receive the necessary training to prevent future error.

Incorrect blood components transfused (IBCT): case discussions

Challenges and plans

Challenges related to the strategy include poor dissemination of 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 addition, follow-up of transfusion errors by HLOs has not been consistent. In some areas, feedback on errors is a standing agenda item at HTC meetings; in others it is not. Education to address transfusion errors is usually brief, lasting between 15 and 20 minutes. This poses a challenge for outlying hospitals. If

transfusion error-related training is not aligned with pre-existing staff training, it is difficult for the HLO to travel distances (e.g. 800km), to provide a 15-minute training session. This is compounded by the recurrent poor attendance of hospital personnel at such trainings.

Although the bulk of reaction data is currently electronically collated, there are gaps with respect to case follow up. The HLOs often have to rely on verbal or email communication from the haemovigilance office on case status.

Feedback to hospitals is currently directed to hospital clinical managers

and this often implies it does not reach the patient's clinician. In view of this, plans are underway to fully digitalise the process of reporting cases from the blood bank to the patient's clinician. This will enable HLOs to follow case status and provide timely feedback to clinicians.

In addition, feedback on transfusion reactions and errors has been incorporated as standing agenda item at HTC meetings. Plans are underway to develop a formal system to improve dissemination of information from HTC meetings to ward staff, including empowering HTC members in outlying hospitals to provide corrective training to staff.

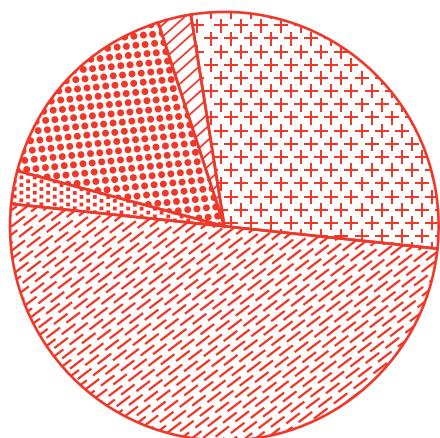
Table 5.1: IBCT cases reported in 2016

IBCT type	Number of cases
ABO, Rhesus (Rh) incompatibilities	12
Misdirected transfusions	19
Patient misidentifications	1
Antibodies detected on emergency unit	6
Total	38

A total of 38 IBCT cases were reported in 2016. These cases included ABO- and Rh-incompatible transfusions, misdirected transfusions, patient misidentifications and cases of antibodies detected on issued emergency units. The bulk of IBCT reactions were due to misdirected transfusions, followed by ABO and Rh incompatibilities.

The diagram below depicts the proportion of each IBCT category:

Figure 5.1: IBCT data category 2016



- Rh incompatible transfusions
- ABO incompatible transfusions
- Misdirected transfusions
- Patient misidentifications
- Antibodies detected

Incorrect blood components transfused (IBCT): case discussions

Table 5.2: IBCT error source

Type of error	Source	Number of cases
ABO/Rh incompatibility	Hospital staff	11
ABO/Rh incompatibility	Blood bank staff	1
Patient misidentifications at bedside	Hospital staff	20
Antibodies detected – emergency units	Neither lab nor hospital error	6
Total		38

Of the 38 reported cases, one was attributed to human error at the blood bank. The number is significantly lower than the seven reported cases of blood-bank errors in 2015. The reduction in SANBS blood-bank errors has been attributed to the introduction of blood-bank automation.

Of the reported ICBT cases, 31 were due to errors by hospital personnel, while six were due to antibodies detected from units issued as an emergency, and therefore not the result of omission or error by blood-bank or hospital staff. The bulk of errors occurred in hospitals and for this reason, error-reduction efforts will focus mostly on hospital-based interventions.

Figure 5.2: IBCT source 2016

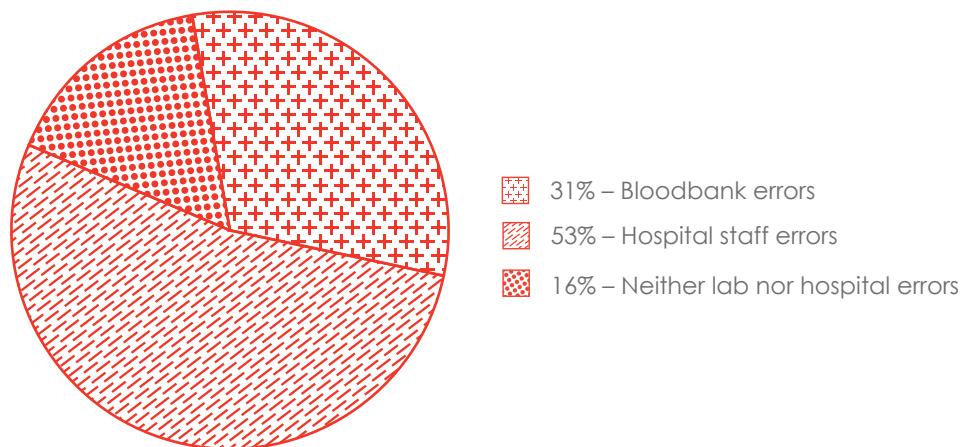
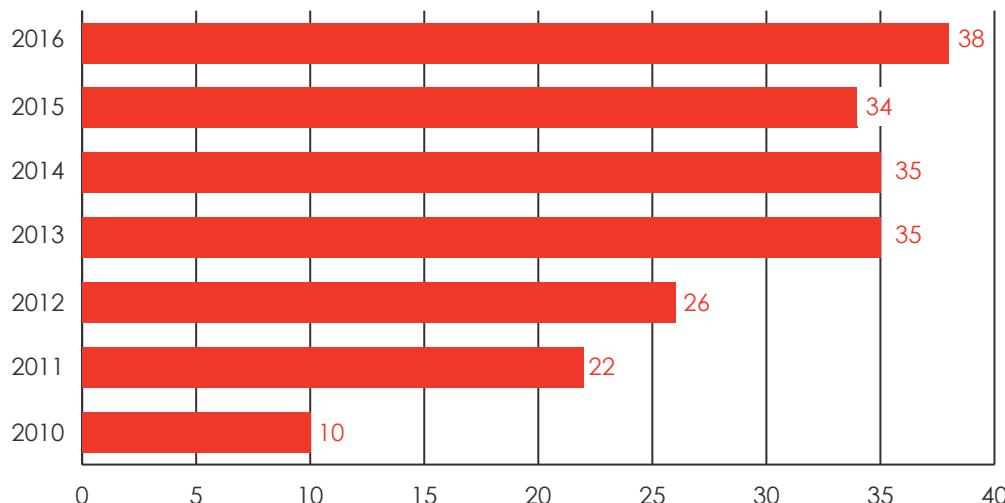


Figure 5.3: Total IBCT cases reported (2010 to 2016)



The number of reported IBCT cases increased from 2010 to 2014, declined slightly in 2015 and then rose in 2016. The rise in 2016 could indicate increased reporting, but on the other hand could also indicate an increased error rate. The trend highlights the urgent need for improved mitigation procedures to be implemented, as discussed above.

Incorrect blood components transfused (IBCT): case discussions

IBCT case studies

Misdirected transfusions

Case 1:

Misdirected transfusion – hospital error

- Forty-year-old male patient with a history of non-Hodgkin's lymphoma
- One unit of group-specific apheresis platelet (single donor) was ordered for the patient
- Patient was typed blood group AB positive
- Hospital ward staff reported that instead of the single donor (group AB) platelet, the patient was accidentally transfused with about 20ml of pooled (group A) platelet that was meant for another patient
- No adverse effects were reported
- Post-transfusion testing on the patient's sample demonstrated the presence of anti-B antibodies from the transfused unit

Conclusion: The case was classified as a misdirected transfusion event (hospital error).

Incorrect blood component transfused

Case 2:

Incorrect blood component transfused – blood bank error

- Twenty-eight-year-old male with brachial artery laceration following a stab wound to the neck
- Patient was due for surgery (haemoglobin 4.3 g/dl)
- Four units of red cell concentrate and two units of fresh frozen plasma were ordered for the patient
- Patient was typed blood group O, Rh-positive, by the blood bank
- Instead of issuing four units of group O, Rh-positive red cells, the blood bank mistakenly issued four units of group A, Rh-positive red cells for the patient
- All four units were transfused to the patient
- The error was detected by the blood bank the following day during clerical check
- The patient's managing clinician was informed immediately
- Patient was monitored daily for signs of haemolysis; including daily blood and urine tests.
- No abnormalities detected
- Patient was discharged from hospital five days post transfusion in a stable condition and booked for follow-up to monitor for delayed transfusion reaction signs
- No further information was provided to the blood transfusion service on subsequent clinical condition of the patient

Conclusion: The case was classified as a misdirected transfusion reaction (blood bank error).



6

1. Near miss events
2. Delayed haemolytic transfusion reactions
3. Post-transfusion purpura
4. Transfusion-associated graft-versus-host disease



1. 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, 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
3	5	1	0	0	3	0	5

A total of 14 near miss cases were reported in 2016. These originated in hospitals and occurred during specimen collection. It is both a legal and transfusion-standards requirement that information pertaining to units collected and issued be captured on the blood transfusions' electronic system.

Prior to issuing blood for a patient, the blood banks need to compare, among other factors, key identifying parameters of a patient request against existing information on the electronic database. This prevents progression of aforementioned errors beyond the near miss stage. This also highlights the importance of adhering to quality standards at each step of the value chain to ensure safe transfusions.

An example of a near miss is outlined below:

Case 1:

Near miss

- Seven-day-old baby girl with anaemia admitted following acute blood loss intra-operatively (haemoglobin 8.4 g/dl)
- Request for blood was sent to the blood bank
- The initial patient sample and information on the blood request form correlated and the request was processed by the blood bank
- The patient's sample was typed blood group A, Rh-positive
- According to the blood bank's electronic records, the patient had previously been typed a blood group B, RH-positive on cord blood investigations
- The blood bank did not issue the blood but brought the discrepancy to the attention of the treating doctor
- A retest of a previous sample of the patient's cord blood tested group A, Rh-positive
- A further repeat sample was requested by the blood bank from the ward
- On the same day, a repeat sample was received at the blood bank
- The sample typed as group A, Rh-positive
- A unit of Group A, Rh-negative, leucodepleted red cell was crossmatched and deemed compatible
- The case was forwarded to red cell serology for further verification and investigation
- The results were as follows:

Pre-transfusion – specimen 1

- Blood type: Group A, Rh-positive
- Direct antiglobulin test: negative
- Irregular antibody screen: negative

Pre-transfusion – specimen 2

- Blood type: Group A, Rh-positive
- Direct antiglobulin test: sample insufficient (baby)
- Irregular antibody screen: not tested (sample was insufficient)
- The test results implied that the cord sample could have been collected from a patient other than the above-mentioned baby
- It is not clear if the baby was transfused with the initial Group B Rh-positive unit from the initial laboratory history
- A transfusion reaction notification was never received from this initial episode.

Conclusion: This is an example of a near-miss incident where incompatible blood could have been transfused to the patient because the initial sample received was taken from a different patient.

2. Delayed haemolytic transfusion reactions (DHTR)

2009	2010	2011	2012	2013	2014	2015	2016
2	2	0	1	0	0	1	0

There were no cases of delayed haemolytic transfusion reactions (DHTR) reported in 2016.

3. Post-transfusion purpura (PTP)

2009	2010	2011	2012	2013	2014	2015	2016
0	0	0	0	0	0	0	0

There were no cases of post-transfusion purpura (PTP) reported in 2016.

4. Transfusion-associated graft-versus-host disease (TA-GvHD)

2009	2010	2011	2012	2013	2014	2015	2016
0	0	0	0	0	0	0	0

There were no cases of TA-GvHD reported in 2016.

Mortality reports 2016

7



Mortality reports 2016

"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). According to this definition, deaths due to blood product delays or insufficient products should be reported as transfusion related.

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.

As mentioned earlier in this report, poor submission rate of required documents by hospital personnel is a major challenge for South African blood services. Consequently, most cases are either unclassifiable or inconclusive as far as the contribution of blood transfusion to death is concerned.

The blood services received reports of 14 cases of suspected transfusion-related mortality in 2016. The patients' treating doctors excluded blood transfusion as probable cause of death in seven of the 14 cases.

One case was accompanied by delay in issuing fresh frozen plasma. Transfusion reaction forms were submitted for eight of the 14 cases. Six cases were reported verbally; therefore, further investigations could not be conducted.

More efforts to obtain the necessary documentation are vital to ensure that all cases of death related to transfusion are reported as such. The lack of appropriate classification and reporting in this regard potentially masks awareness to hazards of transfusion, which should in essence be brought to the fore.

An additional set of mortality data received by SANBS is units requested for patients and cancelled due to death. These cases are currently not reported under haemovigilance data as the hospitals do not report them to the blood services. Granted majority of these deaths are likely due to severity of underlying illness, leading to patient death prior to transfusion initiation.

Decision has been reached by the blood service to undertake case reviews of such deaths, to try to establish likely causes. This will enable blood transfusion services to identify gaps, for example in supportive services such as the hospital transport system, which has been reported as a concern for some outlying hospitals.

Once gaps have been identified, mitigation procedures will be developed where possible. These will be published in the 2018 Haemovigilance Report.

Total transfusion mortalities reported from 2010 to 2016

2009	2010	2011	2012	2013	2014	2015	2016
3	3	3	3	7	16	12	14

All 14 transfusion mortality cases reported in 2016 are detailed below.

Case 1:

- Twenty-four-year-old woman with acute leukaemia
- She was admitted with symptomatic anaemia and abnormal uterine bleeding secondary to multifibroid uterus
- Patient was transfused with three units of red cell concentrate
- The managing doctor reported verbally that the patient demised six hours after initiation of transfusion
- No paperwork or post-transfusion samples received by the blood bank
- No post-transfusion investigations conducted
- A detailed report could therefore not be compiled

Conclusion: Supportive documentation was not submitted. Transfusion could therefore not be excluded as contributory to the patient's death.

Case 2:

- Male patient with severe upper GIT bleeding
- Patient required blood transfusion while awaiting transfer to higher-level hospital for care and gastroscopy
- Patient received a unit of red blood cells from the emergency fridge
- During transfusion, the nurse in charge of patient noticed oozing from venous access
- The transfused unit was discovered to have expired seven days prior
- The patient's managing doctor contacted the blood service's on-call doctor for advice on further patient management
- The patient's clinical condition had worsened, according to his managing doctor
- However, there were no signs of acute haemolysis or bacterial contamination
- The patient was transferred to a higher-level hospital and received an additional two units of red cells
- The blood bank thereafter received verbal notification of the patient's death
- No additional information was received from hospital regarding the expired red cell unit

Conclusion: Inconclusive case outcome. Blood transfusion could not be excluded or confirmed as contributory to mortality.

Mortality reports 2016 (continued)

Case 3:

- Trauma patient transferred from peripheral hospital with multiple fractures, ruptured spleen and kidney
- The case was initially reported as a patient misidentification as previous laboratory history indicated blood group as A, Rh-positive
- Second sample received for patient was found to be discrepant, as it was typed group O, Rh-positive
- Due to the discrepancy, a further specimen was requested
- This was found to be group O, Rh-positive
- Two units of group O, Rh-positive red cells were issued
- This implied that the first sample was likely taken from a different patient
- Patient was taken to theatre
- He was haemodynamically unstable and required IVI adrenaline
- Condition eventually improved
- Patient fairly stable post operation but required haemodialysis (post-op haemoglobin 10g/dl)
- Patient dialysed with two units of group O, Rh-positive red cells
- Patient reportedly "crashed" while being transfused on dialysis
- Resuscitation was reportedly initiated but patient demised
- Treating doctor indicated that patient had developed severe hyperkalaemia; cause unclear
- Treating doctor reported that patient tolerated transfusion well and complications did not appear to be related to the transfusion, therefore excluded blood transfusion as cause of death

Conclusion: Blood transfusion could not conclusively be excluded as cause of death since post-transfusion testing could not be conducted.

Case 4:

- Twenty-nine-year-old woman admitted with a history of complications following post-partum sepsis
- Patient also had anaemia (haemoglobin 6.1 g/dl)
- One unit of Group A, Rh-positive red blood cells was crossmatched, found compatible and issued for the patient
- Report from patient's managing doctor indicated that the patient developed hypertension, fever (temperature 39.2 °C) and tachycardia six hours after initiation of transfusion
- Patient went into cardiac arrest; resuscitation was initiated but she demised
- The patient's treating doctor excluded transfusion as a cause of mortality as no definite association could be determined
- The blood transfusion service did not receive a post-mortem report

Conclusion: Blood transfusion could not conclusively be excluded as cause of death since post-transfusion testing could not be conducted.

Case 5:

- Thirty-nine-year-old male (patient A) with gunshot wound to the abdomen
- Clinical condition very unstable
- Two units of red cell concentrate and fresh frozen plasma were requested for patient
- The blood bank had also received a request for two units of emergency red cells for another patient (B)
- Patient A was typed group A, Rh-positive
- Patient B was typed group AB, Rh-positive
- Red cell units for patient B were ready for collection 15 minutes post processing of units for patient A
- The doctor in charge of patient A mistakenly collected units intended for patient B from the blood bank
- Patient B's red cell units were then transfused to patient A
- Patient A subsequently demised
- No serological cause for the patient's death could be determined
- On follow-up, the treating doctor verbally reported that blood transfusion was not the cause for patient demise as the prognosis was poor
- Complete transfusion reaction investigations could not be performed, as the implicated unit was not returned to the blood bank
- No written report was received from treating doctor despite multiple requests from the blood service

Conclusion: Blood transfusion could not be conclusively excluded as contributory to the death due to insufficient documentation submitted.

Case 6:

- A twenty-five-year-old female diagnosed with disseminated TB
- Two units of Group O, Rh-negative red cell units were requested and issued for the patient
- According to a (verbal) report from the patient's treating doctor, patient developed respiratory distress six hours post transfusion and demised a day later
- The blood bank received a transfusion reaction form indicating patient mortality two days later
- None of the transfused unit bags were submitted to the blood bank for further investigations
- No post-transfusion samples were submitted to the blood bank
- The treating doctor indicated that the patient was critically ill
- Transfusion was not suspected as cause of death

Conclusion: Blood transfusion could not conclusively be excluded as cause of death since post-transfusion testing could not be conducted.

Mortality reports 2016 (continued)

Case 7:

- Four-month-old male baby
- Admission diagnosis was severe acute malnutrition, generalised oedema and possible herbal intoxication (haemoglobin 5.7 g/dl)
- Patient was transfused with one unit of compatible leucodepleted paediatric red cell unit
- According to a verbal report by the treating doctor, the clinical condition deteriorated an hour into transfusion (about 5ml blood transfused)
- Patient developed tachycardia and decrease in oxygen saturation
- Transfusion was stopped
- Intravenous furosemide and nebulized adrenalin were administered
- The clinical condition improved
- Patient was transferred to a level two hospital, but demised en route
- The implicated unit was submitted to the blood bank
- Post-transfusion samples were, however, not submitted
- No serological incompatibility demonstrable on pre-transfusion specimen and implicated unit

Conclusion: The outcome was inconclusive and it was not confirmed whether transfusion was a probable cause of death.

Case 8:

- Twenty-eight-year-old patient diagnosed with miliary tuberculosis, retroviral disease (in virological failure) and anaemia (Hb 3.4 g/dl)
- Clinically unstable with dyspnoea and confusion
- One unit of group A, Rh-positive red cells ordered and issued for the patient as an emergency
- Patient's clinical condition deteriorated about six hours following transfusion
- Resuscitation attempts failed and patient demised
- Treating doctor reported the mortality to the blood bank
- Treating doctor reported that patient presented with serious complications
- Post-transfusion samples were submitted; however, they were collected in unsuitable tubes

Conclusion: Blood transfusion could not conclusively be excluded as cause of death since post-transfusion testing could not be conducted.

Case 9:

- Forty-four-year-old male diagnosed with pancytopenia, extra-pulmonary tuberculosis and anaemia (haemoglobin 5.4 g/dl)
- Patient was transfused with a group A, Rh-positive red cell unit
- The patient reportedly developed fever, headache, dizziness, nausea, vomiting and rigors immediately after commencement of the transfusion
- Patient subsequently developed respiratory distress and demised
- The transfusion reaction form and infused unit were submitted to the blood bank
- Transfusion reaction preliminary investigations were performed on patient's pre-transfusion specimen only and no irregular antibodies capable of causing a haemolytic reaction were detected
- No post-transfusion samples forwarded to the blood bank
- No serological incompatibility detected on pre sample
- No post-mortem results forwarded to the blood transfusion service

Conclusion: The outcome of the case was inconclusive to confirm whether transfusion was a probable cause of the mortality.

Case 10:

- Forty-two-day-old premature, low-birth weight (900g) baby with nosocomial infection (haemoglobin 8.5g/dl)
- The baby received a blood transfusion
- The baby was found to have collapsed in the early hours of the next morning
- No transfusion reaction form or post-transfusion specimens were submitted to the blood bank
- The treating doctor reported that since the time of demise and transfusion were so closely linked, transfusion as a possible cause needed to be ruled out, but could not provide sufficient information regarding the incident

Conclusion: The outcome of the case was inconclusive to confirm if transfusion was a probable cause of the mortality.

Case 11:

- Eighteen-month-old male baby admitted with severe malnutrition, hypoglycemia and anaemia (haemoglobin 2.4 g/dl)
- Two units of leucodepleted, group O, Rh-negative units were ordered and issued for the patient
- According to the treating doctor's report, the baby demised after transfusion with 15ml of the red cells
- No post-transfusion specimens submitted to the blood bank
- Preliminary transfusion reaction investigations on pre-specimens were negative
- The treating doctor reported that the death was not related to transfusion as the patient's clinical condition was critical on admission

Conclusion: Blood transfusion could not conclusively be excluded as cause of death since post-transfusion testing could not be conducted.

Mortality reports 2016 (continued)

Case 12:

- Four-day-old female baby with Down syndrome, cardiac pathology and occult sepsis
- Patient needed blood for exchange transfusion
- Patient reportedly went into cardiac arrest within one hour of transfusion
- The treating doctor reported the mortality to the blood bank
- No post-transfusion samples or transfusion reaction form submitted to the blood bank; therefore, additional investigations could not be performed
- No post-mortem performed

Conclusion: Transfusion could not be confirmed or excluded as cause of death.

Case 13:

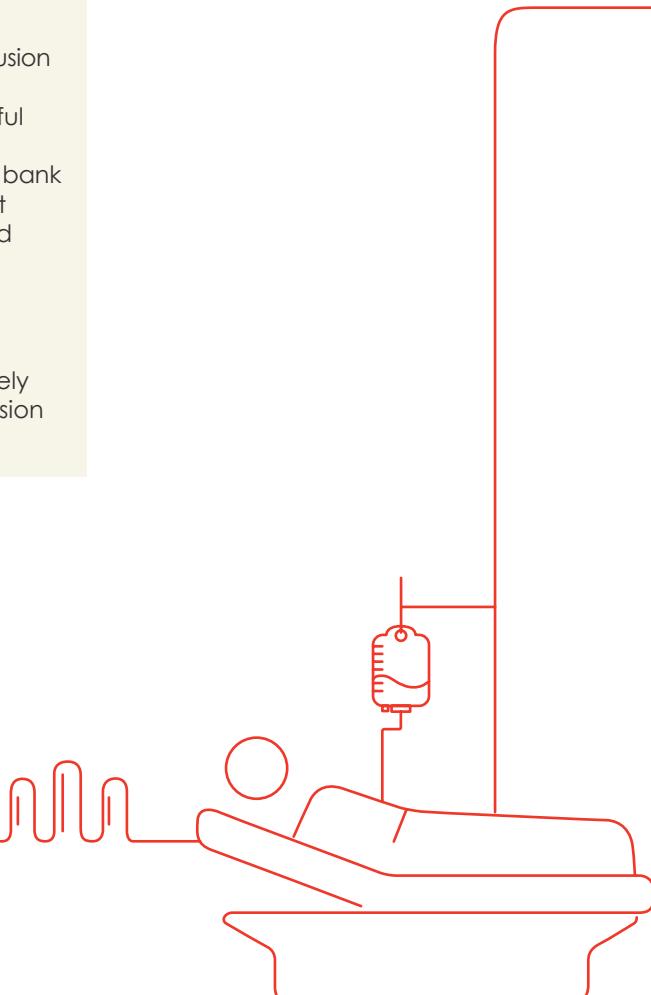
- Sixty-year-old male with benign prostatic hyperplasia, pulmonary TB and frank haematuria (haemoglobin 5.7 g/dl)
- Two units of group O, Rh-positive red cells were ordered and issued for the patient
- Patient developed severe renal failure and hyperkalaemia
- Patient's vitals were not monitored during transfusion
- Patient collapsed mid-transfusion
- Resuscitation was commenced but unsuccessful and patient demised
- Treating doctor reported mortality to the blood bank
- Treating doctor reported that mortality was not directly due to blood transfusion as patient had multiple complications
- No post-transfusion samples submitted to the blood bank

Conclusion: Blood transfusion could not conclusively be excluded as cause of death since post-transfusion testing could not be conducted.

Case 14:

- Twenty-seven-year-old female with septic abortion (haemoglobin 7g/dl)
- Two units of group A, Rh-positive red cells and three units of fresh frozen plasma were ordered as an emergency
- Fresh frozen plasma could not be issued immediately as it was out of stock
- The patient meanwhile developed disseminated intravascular coagulopathy (DIC) with uncontrollable bleeding, requiring massive transfusion
- An additional four red cell units and one platelet unit were ordered for the patient the following day
- Fresh frozen plasma also became available on the following day
- On arrival of the fresh frozen plasma, the blood service was notified of the patient's death

Conclusion: Due to the absence of treating doctor's report, delay in issuing fresh frozen plasma could not be excluded as contributory to the mortality.



Lookback Programme

8



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 (2016)

Donor-triggered lookbacks	SANBS	WPBTS	Total
HIV	496	30	526
HBV	145	6	151
HCV	15	1	16
HIV/HBV co-infections	5	0	5
HIV/HCV co-infections	2	0	2
Other	2	0	2
Total	665	37	702

Of the total donors that seroconverted in 2016, 702 were investigated through the donor-triggered lookback process. This was a decrease of 8% from 2015. There was a 100% follow-up of all cases. Of the 702 cases, 74.9% of lookbacks were due to HIV, 21.5% were due to HBV and 2.3% were due to HCV. Five cases had HIV/HBV co-infection and two cases HIV/HCV co-infection.

Lookback Programme (continued)

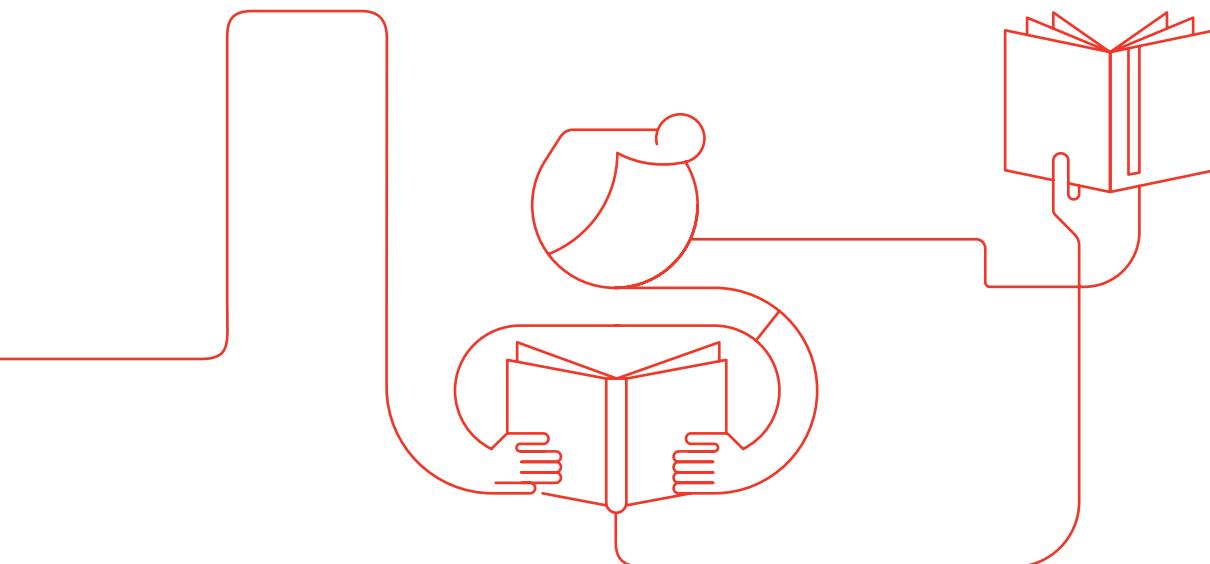
Table 7.2 Investigation outcomes

Donor-triggered investigation outcomes	SANBS	WPBTS	Total
Retest negative	45	12	526
Recipient positive before transfusion	51	0	151
Recipient positive before transfusion	2	0	16
Recipient died between transfusion and initiation of lookback	129	6	5
Unresolved	663	10	2
Untraceable patient	40	4	2
Other	8	5	702
Refused/declined testing	2	0	16
HBV immune	2	0	0
HBV positive recipient – phylogenetic analysis	0	0	0
On dual therapy (HBV Ib)	0	0	0
Total	942	37	979

At the time of the report, 979 donor-triggered investigations were conducted, and 306 (31.3%) were resolved/closed. Of the 306 cases, 57 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 11.2% for 2016 – 135 recipients were confirmed to have died between the transfusion and the initiation of the lookback investigation, and 44 cases were untraceable because the hospital could not reach the patients or the hospital files were missing.

The remaining 673 of the 979 donor-triggered investigations (68.7%) 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 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.



Lookback Programme (continued)

Recipient-triggered lookbacks 2016

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 2016

Recipient-triggered lookbacks	Resolved	Unresolved	Total
HIV	4	3	7
HBV	0	0	0
HCV	0	0	0
Other	2	2	4
Total	6	5	11

A total of 11 recipient-triggered lookback cases were reported, of which six (54.5%) had been resolved or closed at the time of the report. Of these six, four donors retested negative. Two cases classified as “other” were suspected to be cytomegalovirus infections. One was resolved and the other is still pending. Four of the 11 recipient-triggered cases (45.5%) remained unresolved, because no records were found due to time lapsed or the donors could not be traced, and one was a case of malaria.

Lookback Programme (continued)

There has been a significant increase in the total number of lookback cases (donor and recipient-triggered), from 546 in 2010 to 979 in 2016, as shown in Table 7.4 below.

Table 7.4 Overview of lookback investigations (2009 to 2016)

Year	2009	2010	2011	2012	2013	2014	2015	2016	Total
Total number of lookbacks	447	546	642	629	849	1 129	976	979	6 197

Of 1 201 291 issued products, 979 (0.08%) resulted in lookback investigations due to possible microbial contamination. This percentage is the same as the previous year.

The lookback programme faces a number of challenges, resulting in the high number of unresolved cases. These include:

- 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 timely to the lookback officer
- Retest results are not sent to the lookback officer as requested in the lookback notification
- A number of 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, but 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

9

Platelet bacterial testing (SANBS)

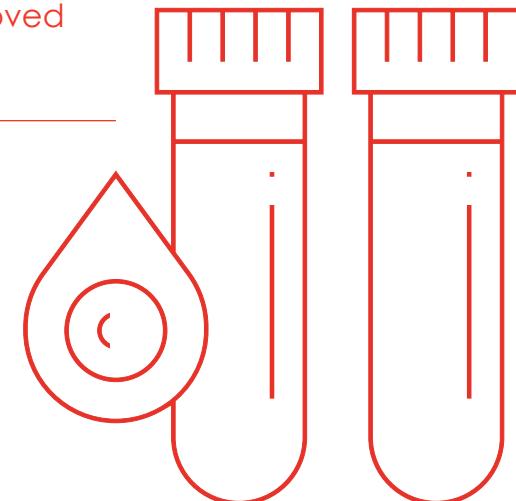


Platelet bacterial testing (SANBS)

Despite many preventative interventions, bacterial contamination of platelet products is a major post-transfusion risk and, globally, the rate has remained static at about one platelet unit in 3 000 for the last 30 years. As there is a limited supply of apheresis platelets (AP) in South Africa, SANBS only tests a percentage of the platelets for sterility, using the US Food and Drug Administration-approved bacterial culture system.

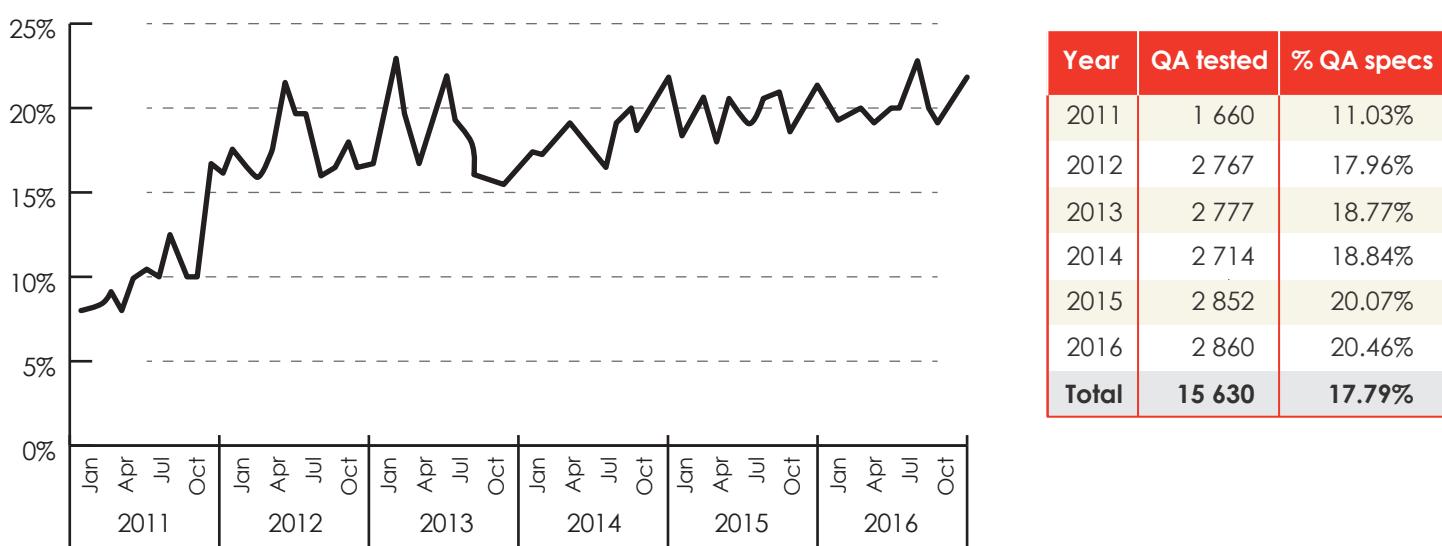
The SANBS microbiology department analysed the AP sterility data for the period from 2011 to 2016. The data presented here is predominantly for 2016, but the trends over the last six years are also included.

Sterility samples were collected aseptically in a sterile docked pouch, 2ml to 4ml of platelet product equally divided between aerobic and anaerobic culture bottles, and tested using the bioMérieux BacT/ALERT microbial identification system or the BD BACTEC blood culture system for 14 days. Bacterial identification was done at an accredited laboratory using the Beckman Coulter MicroScan system.



Over the last six years, 87 843 units were collected, with annual collections ranging between 15 049 in 2011 and 13 981 units in 2016, indicating a downward trend. The monthly AP-procedure numbers ranged from 1 058 to 1 402. The average percentage of AP platelets tested annually was 18%; however, the percentage increased from 11% to 20% from 2011 to 2016.

Figure 8.1: Proportion of apheresis collections submitted for sterility testing



The average positive sterility rate was 2.74% (429 out of 87 843 specimens) with annual rates ranging from 0.6% in 2011 to 5.22 % in 2015. The positive rates were consistently higher: 3.3% to 4.5% in October to January compared to 1.2% to 2.3% from February to July.

Platelet bacterial testing (SANBS) (continued)

Table 8.1: Percentage positive cultures per year

Year	Plat Coll	QA tested	Ster Poss	% Ster Pos
2011	15 049	1 660	10	0.60%
2012	15 408	2 767	26	0.94%
2013	14 794	2 777	61	2.20%
2014	14 402	2 714	42	1.55%
2015	14 209	2 852	149	5.22%
2016	13 981	2 860	141	4.93%
Grand Total	87 843	15 630	429	2.74%

Table 8.2: Frequency of most common bacterial isolates

Bacterial Isolates	2011 to 2016
<i>Propionibacterium acnes</i>	30%
<i>Staphylococcus epidermidis</i>	24%
<i>Bacillus</i> spp	8%
<i>Corynebacteria</i> spp	7%
<i>Micrococcus</i> spp	6%
<i>Streptococci</i> spp	4%
True pathogens	3%

The most common bacterial isolates were: *Propionibacterium acnes* (30%), coagulase-negative *Staphylococci* (24%), *Bacillus* spp (8%), *Corynebacteria* spp (7%), *Micrococcus* spp (6%) and *Streptococci* spp (4%). Nine (3%) pathogenic organisms were isolated, of which five were Gram-negative bacteria: *Acinetobacter* spp (n=2); *Enterobacter* spp, *Serratia* spp and *Klebsiella* spp (n=1 each), three *Listeria* spp and one *Staphylococcus aureus*.

Sterility results 2016

Compared to 2015, the AP sterility rate improved marginally from 94.8% to 95.1%. In addition, only a small number of expired platelets were tested, as most SANBS platelets are used within three days of production. It is expected that expired platelets will have a higher percentage contamination rate and this information is useful as a quality-control marker (see Table 8.3).

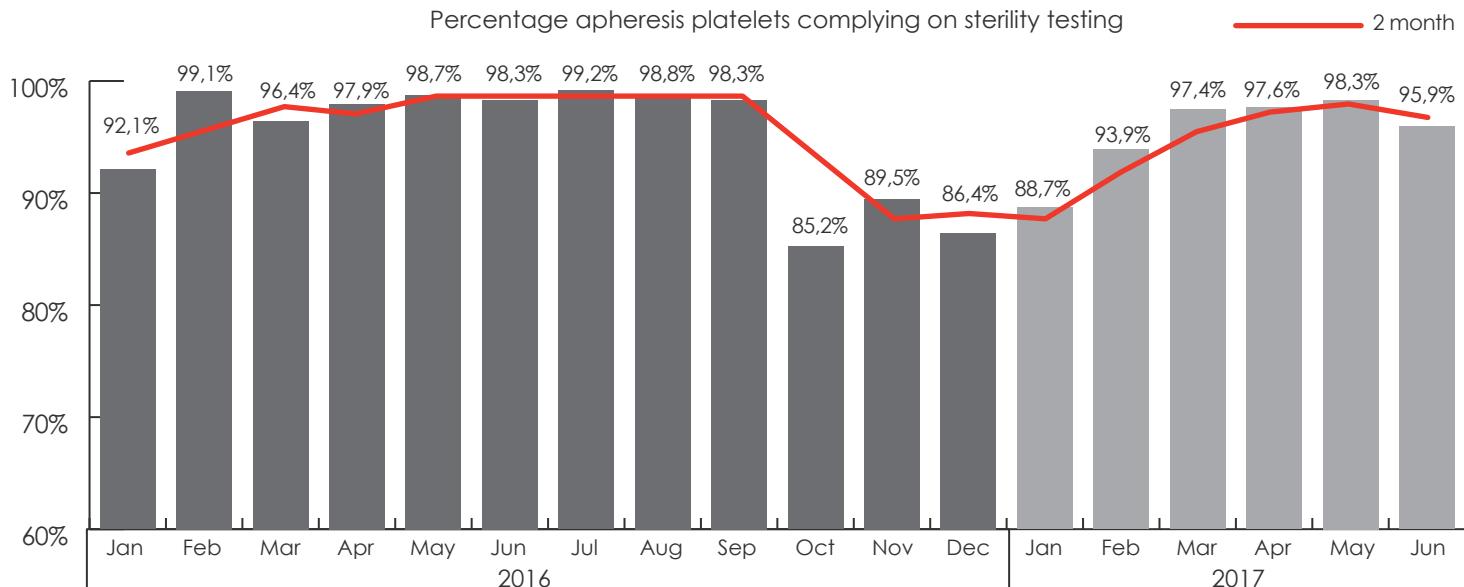
Table 8.3: Frequency table demonstrating positive sterilities

Product tested	Number tested (2015)	Number positive and percentage	Number tested (2016)	Number positive and percentage
Apheresis platelets	2 852	149 (5.2%)	2 860	150 (4.9%)
Expired platelets	182	17 (9.3%)	149	8 (5.3 %)

Platelet bacterial testing (SANBS) (continued)

The monthly trends indicate that the positive sterility rate increased between October 2016 and February 2017 – this was due to a contamination problem, with *Propionibacterium acnes* and *Micrococcus spp* in the laboratory introduced into quality-control AP samples (see Figure 8.2). This event was addressed and the necessary corrective action taken.

Figure 8.2: Monthly sterility trend



All apheresis clinics are routinely sampled for environmental contamination. According to SANBS standards, clinics should demonstrate < 2+ growth (< 25 CFUs). During 2016, 0.7% of all samples did not comply with the expected results and affected clinics had to implement corrective action. (This was up from 0.3% in 2015.)

Table 8.4: Environmental testing – apheresis-platelets collection clinics (2016)

Number of tests (contact plates sampled)	Number compliant	Number not compliant (>2+ growth)	Most frequently detected organisms
2 899	2 864 (98.8%)	21 (0.7%)	Bacillus species and coagulase-negative <i>Staphylococcus</i>

Conclusion

The trend of increasing positive sterility rates between 2011 and 2015 seems to have stabilised in 2016. In agreement with other publications, Gram-positive skin commensal bacteria account for 80% of all bacteria isolated; highlighting the importance of proper aseptic technique during the collection of blood donations, including apheresis platelets. The SANBS did not receive any reports of sepsis or death in this time, but assumes such events may be underreported.

In the last year, infection prevention and control (IPC) practises have been strengthened, which includes increased awareness of hand and environmental hygiene across the SANBS, the development of an IPC manual and procedures, as well as IPC training and regular tracking of sterility data at collection sites.

The sterility-testing practices have been optimised to allow higher-volume sample culturing (to achieve a higher testing sensitivity) and to reduce the incubation time to the lifetime of the platelet products.

In addition, the clean area in the microbiology laboratory has been improved by including an anteroom to ensure better access control to the processing area and safety hood. Interventions such as pathogen inactivation and rapid on-site testing are under investigation to produce safer platelet products for South African patients.

10

Donor vigilance



Donor vigilance

In general, blood donation is a safe process and most blood donors tolerate donation well. Occasionally, adverse reactions occur during or following donation. These vary from mild to severe. Although rare, some severe reactions are potentially life-threatening.

The blood transfusion services have therefore developed systems to ensure prevention, early detection and management of adverse reactions in order to reduce the likelihood of long-term sequelae. In addition, preventing donor-adverse reactions is an essential component of donor retention. Multiple local and international studies have documented the loss of donors resulting from adverse reactions, regardless of severity.

Donation-adverse reactions are broadly categorised into local and systemic reactions. Local reactions are primarily the result of problems related to venous access, the bulk being haematomas. These occur due to extravasation of blood from veins because of incorrect placement of needles during venipuncture. Although most local reactions are mild and resolve within a week or two, some can lead to long-term complications, such as nerve irritation, chronic arm pain and compartment syndrome.

Most systemic reactions are vasovagal in nature. Vasovagal reactions occur due to nervous-system malfunction, following a trigger such as pain, anxiety, or sight of blood. If untreated, a vasovagal reaction can lead to fainting and convulsions. A potential complication of vasovagal reactions is accidents and injury. Prevention is therefore critical.

Both whole-blood and apheresis donation can lead to local and systemic adverse reactions. Apheresis donations, in particular, can be accompanied by reactions resulting from citrate anticoagulant. Some systemic reactions, such as air embolism, can be severe from the outset.

Risk factors for the development of adverse donor reactions include low weight, age and first-time donor status. Women are also more at risk than men.

Donor-adverse reaction management begins with measures to prevent occurrence. These include appropriate donor selection and detection of potential risks. If a reaction does occur, it is vital that blood-service staff are well informed on how to initiate immediate and definite management. Care of the donor should supersede other concerns.

Implementation of staff-education sessions on adverse-reaction management is under investigation. The plan is to provide baseline training for all collection staff, followed by on-going, periodic training. It is envisioned that this additional support will improve staff awareness, adverse-reaction management and event reporting.

Categories of complications related to blood donation

Local symptoms	Blood outside vessels	Haematoma
		Arterial puncture
		Delayed bleeding
	Pain	Nerve irritation
		Nerve injury
		Tendon injury
		Painful arm
	Others	Thrombophlebitis
		Allergy (local)
	Generalised symptoms	Immediate
		Immediate with injury
		Delayed
		Delayed with injury
Related to apheresis	Vasovagal reaction	Citrate reaction
		Haemolysis
		Generalised allergic reaction
		Air embolism

Donor vigilance (continued)

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. <u>Symptoms:</u> 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. <u>Symptoms:</u> 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. <u>Complications:</u> There is an increased risk of a large haematoma, combined with risks such as compartment syndrome in the forearm, brachial artery pseudoaneurysm 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. <u>Symptoms:</u> 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. <u>Symptom:</u> 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. <u>Symptom:</u> 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 kinds of 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. <u>Symptoms:</u> 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. <u>Symptoms:</u> Rash, swelling and itching at venipuncture site.

Donor vigilance (continued)

Classifications

Complications mainly with generalised symptoms.	
Vasovagal reaction	
Adverse event	Definition
Vasovagal reaction (fainting)	<p>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.</p> <p>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.</p> <p><u>Symptoms:</u> Discomfort, weakness, anxiety, dizziness, nausea, sweating, vomiting, pallor, hyperventilation, convulsions and loss of consciousness.</p>
Immediate vasovagal reaction	<u>Symptoms</u> 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	<u>Symptoms</u> 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	<p><u>Symptoms</u> 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.</p>
Haemolysis	Destruction of the donor's red blood cells.
Generalised allergic reaction	<p>The result of an interaction of an allergen with preformed antibodies.</p> <p>A minor allergic reaction is limited to the skin, with or without a rash.</p> <p>A severe allergic reaction poses risk to life, characterised by bronchospasm causing hypoxia or angioedema causing respiratory distress.</p>
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.

Donor vigilance (continued)

Summary of collections and donor-adverse events (2016)

In 2016, total blood collections for SANBS and WPBTS were 985 310 units. Of these, 155 376 (15.77%) units were collected by WPBTS, while 829 934 (84.23%) were collected by SANBS. Both services experienced a decrease in collected blood. SANBS collections decreased by 2.1%, while WPBTS collections decreased by 4.8%.

Table 9.1: Collections (2016)

Collection	SANBS 2015	SANBS 2016	WPBTS 2015	WPBTS 2016	Total
Whole blood	828 530	810 721	160 577	152 475	963 196
Apheresis red cells	3 802	3 468	0	0	3 468
Apheresis platelets	14 208	13 980	2 697	2 901	16 881
Plasma	1 964	1 765	0	0	1 765
Totals	848 504	829 934	163 274	155 376	985 310

Table 9.2: Donor-adverse events according to broad categories (2015 to 2016)

Reaction	SANBS 2015	SANBS 2016	WPBTS 2015	WPBTS 2016	Total
Local	474	588	248	314	902
Vasovagal	1 747	1 762	1 798	1 908	3 670
Other	36	291	1	7	298
Totals	1 757	2 641	2 047	2 229	4 870

Total SANBS and WPBTS donor-adverse reactions as a percentage of collected units increased from 0.38% in 2015 to 0.49% in 2016. The SANBS reported a significant 50.3% increase in adverse events in 2016. This was likely due to efforts to combat underreporting, which has been an ongoing challenge for the service. In 2015, SANBS reported a donor-adverse reaction percentage of 0.32%, while WPBTS reported a percentage of 1.25%. The WPBTS reported cases increased by 8.9% in 2016.

The likelihood of development of donor-adverse reactions is determined by a number of factors, the most common reported factors being the age of the donor – younger donors are at higher risk of adverse reactions than older donors.

Table 9.3: Donor-adverse events by age group (2016)

Age (years)	16-19	20-25	26-30	31-40	41-50	51-60	61-70	71-80	81-90
Reactions	764	453	277	365	336	238	117	90	1
Percentage	28.9%	17.2%	10.5%	13.8%	12.7%	9.0%	4.4%	3.4%	0.4%

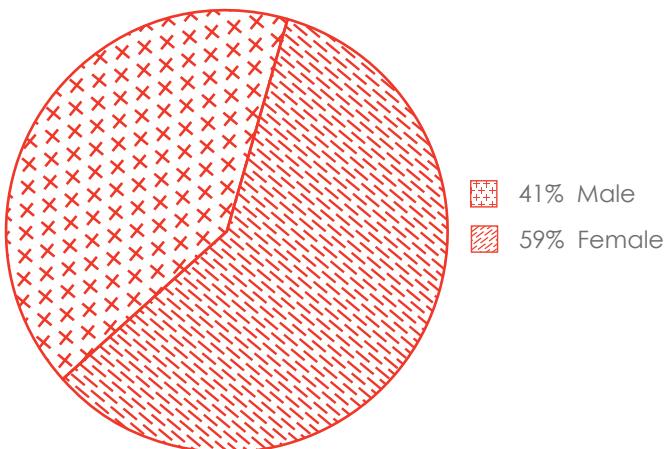
As shown in Table 9.3, donors aged 16 to 19 experienced the highest frequency of adverse events (28.9%), followed by those aged 20 to 25 (17.2%). The frequency of reactions was lower for the 26 to 30 age group, but increased for donors aged 31 to 50. Donors aged 60 and above had the lowest frequency of adverse reactions, indicating a steady decline in the likelihood of reactions with increasing age.

This trend has remained unchanged for five years and is consistent with the literature on risk factors for development of adverse events related to blood donation.

Donor vigilance (continued)

Female donors are reportedly at higher risk of donor-adverse reactions than males. In 2016, female donors experienced 59% of all donor-adverse events. This picture is similar to the trend observed over the years among South African donors (see Figure 9.1 below).

Figure 9.1: Donor-adverse events – males vs females (2016)



The most common reaction type was vasovagal reactions, followed by local adverse events such as haematomas. Risk factors for vasovagal reactions include age below 30 years, low blood volume and first-time donors with low weight. Figure 9.2 shows the prevalence of each category of adverse reaction.

Figure 9.2: Donor-adverse events by percentage (2016)

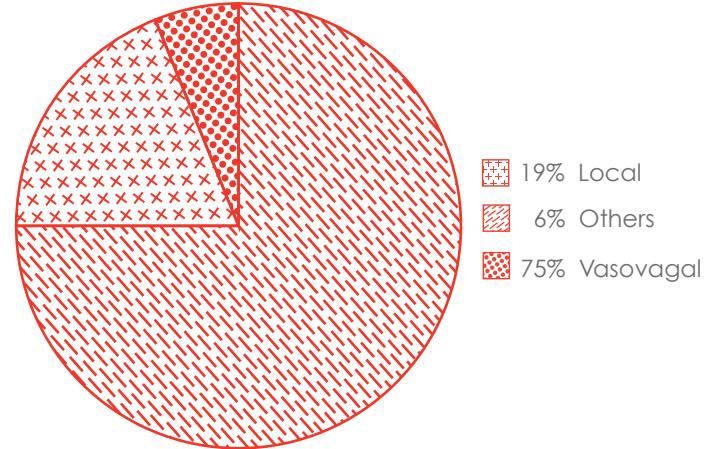


Table 9.4: Donor-adverse events by donation type (2016)

Acute reactions	Whole blood	Apheresis	Unallocated	Total
Haematoma	961	271	26	1 268
Arterial puncture	3	0	0	3
Delayed bleeding	14	0	0	14
Nerve irritation	10	0	1	11
Tendon injury	0	0	0	0
Nerve injury	0	0	0	0
Painful arm	84	9	5	97
Total local symptoms	1 072	279	32	1 383
Fainting – immediate	2 398	231	35	2 564
Fainting – immediate, accident	406	2	6	414
Fainting – delayed	206	2	21	229
Fainting – delayed, accident	52	0	1	153
Total vasovagal reactions	3 062	235	63	3 360
Citrate reaction	0	8	3	11
Haemolysis	5	0	0	5
Generalised allergic reaction	42	0	1	5
Embolism	0	0	0	5
Others	64	12	9	85
Total	111	4	12	127
Grand total	4 245	518	107	4 870

Donor vigilance (continued)

Vasovagal reactions were prevalent in both whole-blood and apheresis donations. Although the bulk of collections consists of whole blood, apheresis donors experienced more adverse reactions, at 2.5% compared to whole blood donors at 0.44%.

Of the vasovagal reactions, faints without accidents comprised 85%, while faints with accidents comprised 15%. The percentage of faints with accidents increased significantly compared to 2015 (3.5%). This highlights the need for improved measures to prevent occurrence, as well as measures to ensure appropriate management of each case.

Most faints occurred immediately after blood donation. Haematomas comprised the most commonly reported local adverse reaction. This was followed by painful arm. 2.2% of reported reactions were unallocated therefore could not be classified according to donation type.

Table 9.5: Analysis of adverse events by severity (2016)

	Severity	Mild	Moderate	Severe	Subtotal
Local adverse events	Haematoma	705	237	112	1 054
	Arterial puncture	2	1	0	3
	Delayed bleeding	17	4	0	21
	Nerve irritation	8	3	1	11
	Tendon injury	1	0	0	1
	Nerve injury	0	0	0	0
	Painful arm	68	42	16	126
	Total local symptoms	801	287	128	1 216
Vasovagal	Faint – immediate	187	476	26	2 089
	Faint – immediate, accident	0	2	10	12
	Faint – delayed	703	121	45	869
	Faint – delayed, accident	30	22	10	62
	Total vasovagal reactions	2 320	621	91	3 032
Others	Citrate reaction	357	11	1	369
	Haemolysis	10	3	0	13
	Generalised allergic reaction	10	3	0	13
	Embolism	0	0	0	0
	Other	207	16	4	227
	Total	584	33	5	622
Grand total		3 705	941	224	4 870

As illustrated on Table 9.5 above, 76.1% of reported adverse reactions were mild, 19.3% moderate and 4.6% severe.

Conclusion

11

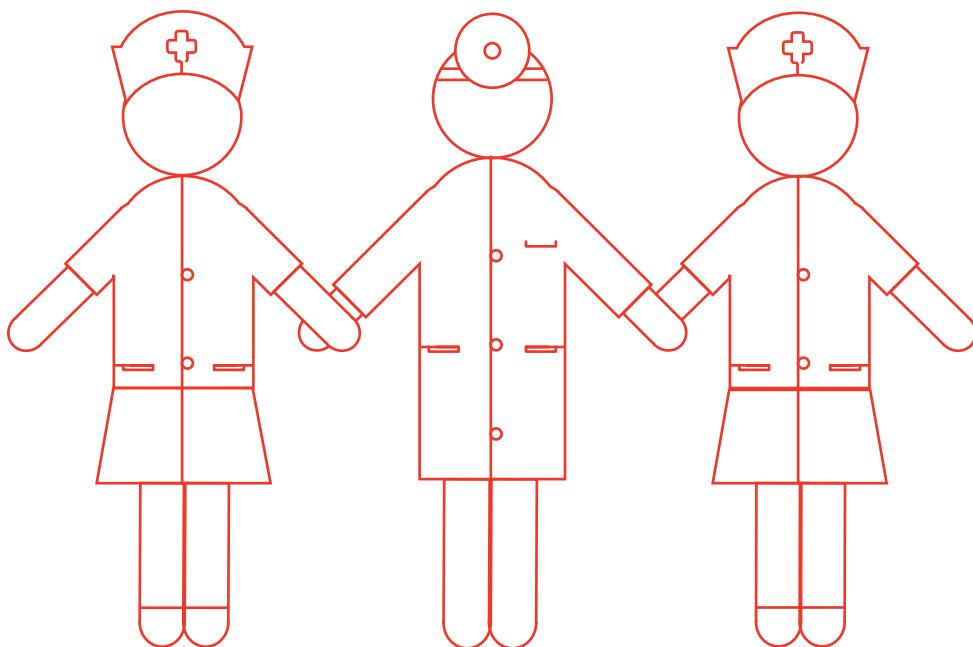


Conclusion

The safety and wellbeing of blood donors and patients are a key focus for both blood transfusion services in South Africa. Through the haemovigilance programme, the blood services can monitor progress and identify opportunities for improvements in donor and patient care.

Overall reporting rates for recipient- and donor-adverse reactions have continued to improve. However, compared to other countries, there is much room for improvement. The increasing number of reported transfusion errors implies that measures to prevent these through directed hospital staff training, inclusion in HTC meetings, as well as corrective staff training needs to improve. Active surveillance is needed to accurately capture all reactions experienced by blood recipients.

Many of the gaps in reporting, lookback tracing of recipients and submission of necessary documentation for reactions and mortalities are due to the lack of legal enforcement with regard to management of patient-adverse reactions and TTIs. Efforts to improve support from, and ownership by, the Department of Health need to be ongoing.



12

References



References

1. Amsler L, Jutzi M. *Haemovigilance Annual Report 2014*. Swiss medic. 2014.
2. Ashish J, Ravneet K. Haemovigilance and blood safety. *Asian Journal of Transfusion Science*. 2012 Jul-Dec; 6(2): 137-138.
3. Badami K. et al. National haemovigilance programme. New Zealand Blood Service; 2015.
4. Bolton-Maggs P et al. Serious Hazards of Transfusion (SHOT). Haemovigilance and progress is improving transfusion safety. *British Journal of Haematology*. 2013; 163: 303-314
5. Chrisostomou E, Karabini F, Tzolou A, Xanthi E, Zervou EK, Ziciadis K. Vasovagal reactions in blood donors during or immediately after blood donation. *Transfusion Medicine*. 2005 Oct; 15(5):389-94.
6. Joseph P, Neelesh J, Sarkar RS. A single-center study of vasovagal reaction in blood donors: Influence of age, sex, donation status, weight, total blood volume and volume of blood collected. *Asian Journal of Transfusion Science*. 2014 Jan-Jun; 8(1): 43-46.
7. Australian National Blood Authority. Strategic framework for the national haemovigilance program. September 2014.
8. PHB Bolton-Maggs P et al. on behalf of Serious Hazards of Transfusion (SHOT) Steering Group. The 2015 annual SHOT Report. 2016.
9. PHB Bolton- Maggs (Ed), Poles D. et al. on behalf of Serious Hazards of Transfusion (SHOT) Steering Group. The 2016 annual SHOT Report. 2017.
10. <http://www.ihn-org.com/haemovigilance-databases/istare-2/>
11. <http://www.sanbs.org.za>
12. <http://www.wpblood.org.za>
13. <http://www.who.int/bloodsafety/haemovigilance/en/>
14. <http://emedicine.medscape.com/article/206885-overview>

