HAEMOVIGILANCE REPORT 2015

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HAEMOVIGILANCE REPORT 2015

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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Abbreviations

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Abbreviations

AHTR	Acute Haemolytic Transfusion Reactions
ATR	Acute Transfusion Reactions
DAE	Donor Adverse Events
DAT	Direct Antiglobulin Test
DHTR	Delayed Haemolytic Transfusion Reactions
DSTR	Delayed Serological Transfusion Reactions
FFP	Fresh Frozen Plasma
FNHTR	Febrile Non-Haemolytic Transfusion Reactions
HBV	Hepatitis B Virus
HCV	Hepatitis C Virus
HIV	Human Immunodeficiency Virus
HLA	Human Leucocyte Antigens
IBCT	Incorrect Blood Component Transfused
ID-NAT	Individual Donation Nucleic Acid Amplification Test
IHN	International Haemovigilance Networks
ISBT	International Society of Blood Transfusion
ISTARE	International Surveillance of Transfusion-Associated Reactions and Events
PTP	Post-transfusion Purpura
SANBS	South African National Blood Service
SHOT	Serious Hazards of Transfusion
TA-GvHD	Transfusion-associated Graft versus Host Disease
TTI	Transfusion-transmissible Infections
TRALI	Transfusion-related Acute Lung Injury
TACO	Transfusion-associated Circulatory Overload
WPBTS	Western Province Blood Transfusion Service

Transfusion Reaction Classifications & Definitions

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Transfusion Reaction Classifications & 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 Hb, rise in LDH, positive DAT and positive cross match.
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 TRALI, TACO or severe allergic reaction (SAR) 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 4 of the following occurring within 6 hours of transfusion: • Acute respiratory distress. • Tachycardia. • Increased blood pressure. • Acute or worsening pulmonary oedema. • Evidence of positive fluid balance.
Transfusion-related Acute Lung Injury	Acute hypoxemia with PaO2 fraction of inspired oxygen [FIO2] ratio of 300mm Hg or less combined with chest x-ray showing bilateral infiltrates in the absence of left atrial hypertension (i.e. circulatory overload). There is abrupt onset in association with transfusion.

Transfusion Reaction Classifications & Definitions (continued)

Category	Definition
Anaphylactic Transfusion Reactions	Hypotension with one or more of: urticaria, rash, dyspnoea, angioedema, stridor, wheezing, pruritus, within 24 hours of transfusion.
Febrile Non-Haemolytic Transfusion Reactions	Isolated fever >39°C or equivalent or a change of >2°C from pre-transfusion value with or without minor rigors and chills but without haemolysis or features of an allergic reaction. The patient may have one or more of myalgia, nausea, changes in blood pressure or hypoxia. The most common cause is a reaction to passively transfused cytokines or a reaction to recipient antibodies and leukocytes in the donor's blood.
Delayed Transfusion Reactions	Transfusion-related reactions that occur after 24 hours following a transfusion of blood or components.
Delayed Haemolytic Transfusion Reactions	The recipient develops antibodies to RBC 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 to 28 days after a transfusion despite an adequate haemoglobin response to transfusion that is maintained. See Appendix D for common antibodies associated with DSTR.
Post-transfusion Purpura	Thrombocytopenia arising 5-12 days following transfusion of cellular blood components associated with the presence in the patient of alloantibodies directed against the HPA (Human Platelet Antigen) system.
Transfusion-associated Graft versus Host Disease	The introduction of immuno-competent lymphocytes into a susceptible host. The allogeneic lymphocytes engraft, proliferate and destroy host cells, develops within 30 days of transfusion; presenting with fever, rash, liver function abnormalities, diarrhea, pancytopenia and bone marrow hypoplasia.
Transfusion-transmitted Infections	Recipient has evidence of infection post-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 TTI, but specifically related to a virus. The most common viruses associated with TTVIs 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 TTBI include cases where the recipient has evidence of infection post-transfusion, and there was no evidence of infection prior to transfusion and no evidence of an alternative source of infection.

Transfusion Reaction Classifications & 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 which, if undetected, could result in the determination of a wrong blood group or issue, collection or administration of an incorrect, inappropriate or unsuitable component, but which was recognised before the transfusion took place.
Misidentification – Hospital error	Near miss events related to the misidentification of specimens, units or patients, which occurs outside of the blood bank.
Misidentification – Blood Bank error	Near miss events related to the misidentification of specimens, units or patients, which occurs 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 that have led to mistransfusions. It may or may not have led 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 ATE 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 which did not meet all of the stated requirements.
Near Miss	An adverse event that is discovered before the start of a transfusion.
Adverse Reaction	Undesirable response or effect temporally associated with the administration of blood or blood components: • May be the result of an incident, or • An interaction between a recipient and blood.

Foreword

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1. Foreword - Message from the Medical Directors

The South African National Blood Transfusion Services' Haemovigilance Report forms an integral part of the data used to guide the country's blood safety policies.

Haemovigilance has become a crucial part of the blood safety concept. It is defined as surveillance procedures covering the whole transfusion chain, from collection of blood and its components to follow-up of recipients, intended to collect and assess information on unexpected or undesirable effects resulting from the therapeutic use of labile blood products and to prevent their occurrence or recurrence (International Haemovigilance Network [IHN], 2012). Data is sourced from both private and public hospitals in South Africa. Increasingly, healthcare professionals in the public and private sectors search for evidence-based utilisation and improved patient outcomes for blood transfusions.

Since 2010, the annual Haemovigilance Report for the Blood Transfusion Services in South Africa has included a section on donor vigilance, detailing the adverse reactions of blood donors over and above the adverse reactions of recipients of blood transfusion which it has been covering since 2000. The inclusion of donor reactions improves donor care by tracking all adverse events associated with blood donation.

The risk of transfusion-transmitted infections (TTIs) in South Africa today is lower compared to before the implementation of Individual donation Nucleic acid testing (ID-NAT) in 2005 but, the supply of safe blood products remains subject to contamination with known and emerging or yet to be identified human pathogens. Only continuous improvement and implementation of donor selection, sensitive screening tests and effective inactivation procedures can ensure the elimination, or at least reduction, of the risk of acquiring TTIs. In addition, ongoing education and up-to-date information regarding potential TTI agents is necessary to promote the reporting of adverse events, an important component of transfusion-transmitted disease surveillance. Thus, the collaboration of all parties involved in transfusion medicine, including national haemovigilance systems, is crucial for protecting a secure blood product supply from known and emerging blood-borne pathogens.

The South African National Blood Service and Western Province Blood Transfusion Service (SANBS and WPBTS) would like to express our sincere gratitude and appreciation to the staff in the hospital blood banks, specialised laboratory services, the transfusion-transmissible infection (TTI), lookback and haemovigilance officers as well as the healthcare professionals in the hospitals for their contribution in providing information for the production of this 2015 Haemovigilance Report.

The principal objectives of this report are:

- To supply national data reported during 2015 on:
  - Adverse reactions associated with transfusion,
  - Data on serious adverse reactions associated with blood donation,
  - Analysis on the frequency of events (patient-related and donor-related) over the period from 2008 to 2015 (overall and per diagnosis); in order to identify areas where improvement is needed.

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Executive Summary 2015

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2. Executive Summary 2015

Despite significant improvements in product safety through careful donor selection and product screening, transfusion errors and reactions still occur in hospitals. Often, they result from human error and can lead to patients staying longer than anticipated in hospital and in some unfortunate cases, death. Analysing the Haemovigilance reports provides a picture of current transfusion risks, and may provide information about the causes of preventable transfusion events and show where improvements are necessary and possible.

In this the 16th annual national Haemovigilance Report we provide an overview of blood transfusion and donation-related adverse events in South Africa, and recent data and information on blood product issues and usage. This report represents data gathered between January and December 2015, by the two services providing blood transfusion in South Africa, i.e. the SANBS and the WPBTS.

2.1 Collections:

A total of 993 717 units of blood were collected by the two services and separated into various blood products. There was an increase in total collections by both services between 2014 and 2015 of about 2.7%.

2.2 Blood product issues and usage data:

There were **1 200 228** components of blood products issued in South Africa in 2015. Red blood cell (RBC) products accounted for about 80.2% of all products issued. The demand for blood products has been increasing over the last few years, issued blood products increased by ± 4% between 2014 and 2015.

2.3 Hospital participation:

In 2015, **239** of the 749 (32%) healthcare facilities in South Africa that we service reported transfusion adverse events to the Haemovigilance office. The participation increased from ± 26% in 2012 to ± 31% in 2015 which may indicate that the education provided to healthcare workers have created more awareness and understanding in the rationale and aim of haemovigilance resulting in better hospital participation.

2.4 Summary of recipient adverse events:

There were 961 adverse events reported to the National Haemovigilance Programme during 2015. The number of reports received decreased by 0.2% from 963 in 2014 to 961 in 2015 despite the intensified training conducted countrywide. The most frequently reported adverse events were allergic reactions (including minor, severe and anaphylactic) then followed by febrile non-haemolytic transfusion reactions (FNHTR), representing 36% and 35% of all reports respectively. Other significant adverse reactions reported included 77 cases of transfusion-associated dyspnoea (TAD) and 33 cases of hypotensive reaction representing 8% and 3% of all reports respectively.

A total of 34 **(3% of all transfusion reactions)** cases of incorrect blood component transfused (IBCT) were reported with errors originating from both the hospitals and the blood banks.

Twelve cases of mortalities were reported of which 5 cases were classified as potentially transfusion-related. This translates to an estimated risk of death from transfusion to be 1 in 243 205 components issued, compared to 1 in 128 205 in 2014 and 1 in 167 000 in 2013. However, in all the 12 cases, none was confirmed as a definitive cause of death, this is attributed to no post- transfusion samples obtained and no postmortem performed on the deceased patients.

There were no confirmed cases of transfusion-transmitted Hepatitis B, Hepatitis C or malaria infections reported in 2015. The South African Blood Transfusion Services implemented Individual donation Nucleic acid testing (ID-NAT) in 2005 and has subsequently screened approximately 9.2 million donations using this state of the art technology. Of the 16 248 donations tested during this period, 513 were confirmed HIV positive by ID-NAT.

One breakthrough HIV infection has been reported and confirmed during the period. (See lookback chapter for case summary)

2. Executive Summary 2015 (continued)

Seventy nine cases remained unclassified due to lack of sufficient transfusion reaction information supplied on the form and on follow-up.

The UK SHOT Report 2015 indicated that: "Once again, the majority of SHOT reports follow mistakes (often multiple) in the transfusion process (77.7%) related to human factors. We have observed a worrying number of adverse reactions and events related to poor communication and poor clinical decisions. Laboratory errors have increased and there are concerns that local investigations and root cause analyses are not being fully completed. The UK Transfusion Laboratory Collaborative survey completed in March 2015 confirmed that many laboratories are under pressure with vacancies (some very longstanding) and increased workloads.

Incorrect blood components transfused (IBCT) contributed 36% and wrong components transfused (WCT) were 41%. There were 26 deaths with 2 classified as definite, 9 as probably related and 15 possibly related. There was a risk of serious harm of 1 in 15 528 components issued and an overall risk of death where transfusion was contributory is 1 in 99 010 components issued, but the risk of death from an error is 1 in 322 581".[2]

2.5 Summary of platelet bacterial testing (SANBS data only):

Of the 14 208 apheresis platelet units collected in 2015, a total of 3 018 (21.2%) were tested for microbial growth and from 162 (5.4%) of these units various organisms were cultured. The Standards of Practice for Blood Transfusion in South Africa requires that, 1% or a minimum of 16 units per collection area, whichever is greatest, be tested monthly. This target was exceeded. Approximately 94.6% of all platelets tested met the required specifications and the target is to have 100% sterility on the platelet products.

2.6 Summary of donor adverse events:

Donor vigilance is the systematic monitoring of adverse reactions and incidents in blood donor care with a view to improving quality and safety of donated blood for further use.

During 2015, there were a total 993 717 collections, including 971 046 whole blood collections, 3 802 apheresis red cells; 1 964 plasma collections and 16 905 apheresis platelet donations.

There were 3 804 donor adverse events reported in 2015, an increase from 3 520 reported in 2014. The overall reported ratio of donation-related adverse events was 1: 261 collections in 2015, 1: 274 in 2014, 1: 272 in 2013, and 1: 212 reported in 2012 and is attributable to the change in the capturing procedure which needs to be reviewed as it resulted in underreporting for the SANBS.

Vasovagal events as a category accounted for about 80% of all adverse events, local symptoms accounted for 19% and other reactions made up 1%.

Introduction

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3. Introduction

This is the 16th annual haemovigilance report for South Africa; the first report was published in 2000. The SANBS and the WPBTS are working in collaboration towards a more integrated and electronic haemovigilance reporting system.

The South African Haemovigilance team collects data and reports on adverse events in blood donors and patients. Reporting of cases from hospitals is currently done manually, on forms obtainable from the blood banks. In order to ensure that the evaluations lead to significant conclusions, the transfusion form should be filled in by hospital personnel, as completely as possible containing all relevant clinical data.

Participation in haemovigilance is a legal requirement for all organisations undertaking activity in any part of the transfusion chain within South Africa, as envisaged in terms of **Section 68 of the National Health Act 61 of 2003** and read with Regulation R179 published in Government Gazette 35099 on 12 March 2012. According to the National Health Act, the blood transfusion service must inform the Director-General or a person specifically designated by him or her, verbally immediately of any report received in terms of Sub-regulation (3), of any serious or life threatening reaction or death and confirm such report in writing as soon as possible.

3.1 Previous reports into transfusion safety and quality in South Africa:

Every year, the SANBS together with the WPBTS, prepare a joint report regarding all the events that occurred in the past year. This document also contains an analysis of the trends regarding the evolution (since 2000) of the principal events featured in the report.

3.2 Haemovigilance Project Working Groups' progress and achievements to date:

South Africa is a participating member of the International Haemovigilance Network (IHN) since 2009 and the data is available on the ISTARE database by country. International peer review of our data takes place at the regular international meetings attended. Some of the other participating member countries include the United Kingdom, The Netherlands, Australia, Greece, Canada, Japan, Germany and many more.

The Objectives of IHN include:

- Exchange of valid information between members.
- Increase rapid alert/early warning between members.
- Encourage and undertake educational activities between members.

The SANBS took a leading role in the WHO haemovigilance core writing group in drafting WHO guidelines in the establishment of a national haemovigilance system. The guidelines are aimed to assist less developed countries without haemovigilance systems.

Overview of Product Issues 2015

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4. Overview of Product Issues 2015

A grand total of **1 200 228** blood and blood products were issued to patients in South Africa by the two supplying services (SANBS and WPBTS). SANBS issued a total of **1 026 862** (86%) while WPBTS issued **173 366** (14%) units of blood. **There was a 4% increase in issuing between 2014 and 2015.**

The SANBS has 2 donation testing centres in Constantia Kloof (Gauteng) and Pinetown (KZN), 7 processing centres, 84 blood banks and more than 400 emergency blood fridges (storing emergency Group O blood).

The WPBTS has 1 donation testing centre at the Head Office in Pinelands and; blood and blood components are distributed to 7 blood banks and 92 emergency blood fridges. Limited fractionation is pera Parow.

Donation testing for both services includes individual donation nucleic acid testing (ID-NAT) for HIV RNA, hepatitis B (HBV) DNA and hepatitis C (HCV) RNA; serology (anti-HIV, HBsAg and anti-HCV) and; Treponema pallium haemagglutination (TPHA) for syphilis.

Both services provide blood and blood products to an estimate of 749 hospitals and clinics countrywide.

Table 4.1 Component/Product Issues 2015

Products	SANBS	WPBTS	Total
Plasma products			
Cryo-Poor Plasma	24 987	1 296	**26 283**
Fresh Frozen Plasma	128 029	13 895	**141 924**
Totals	**153 016**	**15 191**	**168 207**
Platelet Products			
Apheresis Platelet	27 162	3 531	**30 693**
Pooled Platelet	32 997	5 149	**38 146**
Total	**60 159**	**8 680**	**68 839**
Red Cell Products			
Paediatric	38 668	2 956	**41 624**
Red Cells	740 355	132 415	**872 770**
Reserved	117	0	**117**
Emergency Units and Ward Stock	32 148	13 974	**46 122**
Whole Blood	2 399	150	**2 594**
Total Red Cell Products	**813 687**	**149 495**	**963 182**
Grand Total	**1 026 862**	**173 366**	**1 200 228**

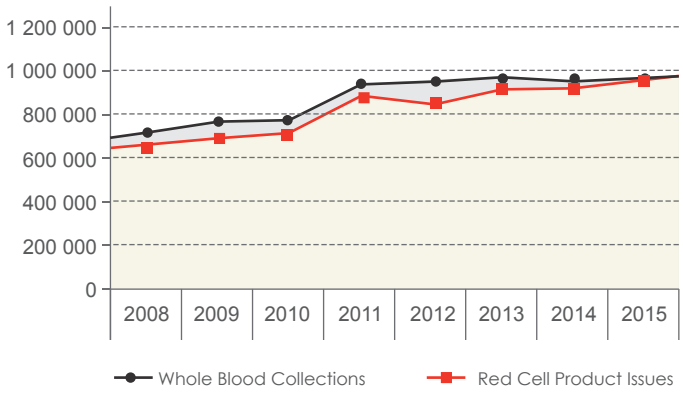
The percentage (%) difference between collections and usable red cell products units was 1% in 2015 as shown in the Table 4.2 and Figure 1 below.

Table 4.2 Collections and Issues (2008-2015)

	2008	2009	2010	2011	2012	2013	2014	2015
Whole Blood Collections	717 262	771 591	776 311	930 654	932 509	967 125	944 058	971 046
Red Cell Product Issues	661 342	700 529	714 515	873 353	858 760	902 063	917 199	963 182
% Difference	8%	9%	8%	6%	7%	7%	3%	1%

Red cell product issues continued to closely follow whole blood units collected and maintaining a percentage difference of around 1% compared to 3% in 2014. The risk margin is narrower i.e. decreased in terms of issuing and collections compared to the previous years.

Figure 1: Collections and Issues (2008-2015)



Transfusion Adverse Events 2015

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5. Transfusion Adverse Events 2015

5.1 Summary of Transfusion Adverse Events 2015

	Adverse Events	SANBS	WPBTS	South Africa Total	Percentage (%)
Acute Transfusion Reactions	Acute Haemolytic Transfusion Reactions (AHTR)	22	0	22	2.2
	Allergic Reactions	123	78	201	21.9
	Severe Allergic Reactions	48	11	59	6.1
	Anaphylactic Reactions	70	17	87	9.1
	Febrile Non-haemolytic Reactions (FNHTR)	275	59	334	35.0
	Transfusion-associated Circulatory Overload (TACO)	0	0	0	0
	Transfusion-related Acute Lung Injury (TRALI)	4	1	5	0.5
	Transfusion-associated Dyspnoea (TAD)	73	4	77	8.0
	Hypotensive Reactions	31	2	33	3.0
	Unclassifiable (Incomplete Information)	70	3	73	7.6
	Unclassifiable (No Forms)	2	4	6	0.6
	Total ATR (Acute Transfusion Reactions)	718	179	897	93.4
Delayed Transfusion Reactions	Delayed Haemolytic Transfusion Reactions (DHTR)	1	0	1	0.1
	Delayed Serological Reactions (DSTR)	0	0	0	0
	Total Delayed Reactions	1	0	1	0.1
Incorrect Blood Component Transfused (IBCT)	ABO + Rh Incompatible Transfusions	1	0	1	0.1
	ABO Incompatible Transfusions	3	3	6	0.6
	Misdirected Transfusions	13	1	14	1.5
	Antibodies Detected	10	0	10	1.0
	Patient Misidentifications	3	0	3	0.3
	Total IBCT	30	4	34	3.5
Other Reactions	Near Miss	7	8	15	1.6
	Transfusion-associated Graft versus Host Disease (TA-GvHD)	0	0	0	0
	Transfusion-transmitted Infections	0	0	0	0
	Post-transfusion Purpura	0	0	0	0
	Mortality	12	0	12	1.2
	Seizures	1	0	1	0.1
	Excluded	1	0	1	0.1
	Total Other	**21**	**8**	**29**	**3.0**
	GRAND TOTAL	**770**	**191**	**961**	**100**

As shown in table 5.1 above, a total of 961 cases were received and analysed by the Haemovigilance offices of both the **SANBS (80%)** and the **WPBTS (20%)** for 2015. Acute Transfusion reactions were the highest occurring at 93.4%.

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 IHN.

5. Transfusion Adverse Events 2015 (continued)

Table 5.2 Rates of transfusion adverse events per classification

Adverse Events		Total number per classification	Rates per 100 000 units issued
Acute Transfusion Reactions	Acute Haemolytic Transfusion Reactions (AHTR)	22	1.8
	Allergic Reactions	201	16.7
	Severe Allergic Reactions	59	4.9
	Anaphylactic Reactions	87	7.2
	Febrile Non-haemolytic Transfusion Reactions (FNHTR)	334	27.8
	Transfusion-associated Circulatory Overload (TACO)	0	0.0
	Transfusion-related Acute Lung Injury (TRALI)	5	0.4
	Transfusion-associated Dyspnoea (TAD)	77	6.4
	Hypotensive Reactions	33	2.7
	Unclassifiable (Incomplete information)	73	6.1
	Unclassifiable (No forms)	6	0.5
Total ATR		**897**	**74.7**
Delayed Reactions	Delayed Haemolytic Transfusion Reactions (DHTR)	1	0.1
	Delayed serological reactions (DSTR)	1	0.1
Incorrect Blood Component Transfused (IBCT)	ABO + Rh Incompatible Transfusions	1	0.1
	ABO Incompatible Transfusions	6	0.5
	Misdirected Transfusions	14	1.2
	Antibodies Detected	10	0.8
	Patient Misidentifications	3	0.2
Total IBCT		**34**	**2.8**
Other Reactions	Near Miss	15	1.2
	Transfusion-associated Graft versus Host Disease (TA-GvHD)	0	0.0
	Transfusion-transmitted Infections	0	0.0
	Post-transfusion Purpura	0	0.0
	Mortality	12	1.0
	Seizures	1	0.0
	Excluded	1	0.0
Total Other		**29**	**2.4**
GRAND TOTAL		**961**	**80.1**

Table 5.2 shows that in South Africa the rate of all transfusion adverse events reported in 2015 was 80.1 per 100 000 units issued compared to 83.5 per 100 000 in 2014, and 91.4 per 100 000 in 2013. Of all adverse events, ATRs were the most frequently reported at 74.7 per 100 000 units issued and IBCT at 2.8 per 100 000 units issued.

Within the ATR category, the most commonly reported adverse events were allergic reactions (including mild, severe and anaphylactic) at 28.8 per 100 000 units issued, followed by FNHTR at a rate of 27.8 per 100 000 units issued.

5. Transfusion Adverse Events 2015 (continued)

Table 5.3 and figure 2 below shows that the rates of adverse reactions reported between 2008 and 2013 have increased from 61.3 to 91.4 per 100 000 units issued, however there was a decrease from 83.5 to 80.1 in 2014 and 2015 respectively. This indicates that there are still challenges in the reporting of reactions despite the awareness of haemovigilance created through education of blood users and the establishment and maintenance of hospital transfusion committees.

Table 5.3 Adverse Reaction Rates (2008-2015)

	2008	2009	2010	2011	2012	2013	2014	2015
Issued	950 460	984 381	1 032 580	1 081 690	1 069 402	1 133 204	1 152 836	1 200 228
Adverse Reactions	583	682	688	763	879	1 036	963	961
Rates per 100 000 Issues	61.3	69.3	66.6	70.5	82.2	91.4	83.5	80.1

Figure 2: Adverse Reactions Rates (2008-2015)

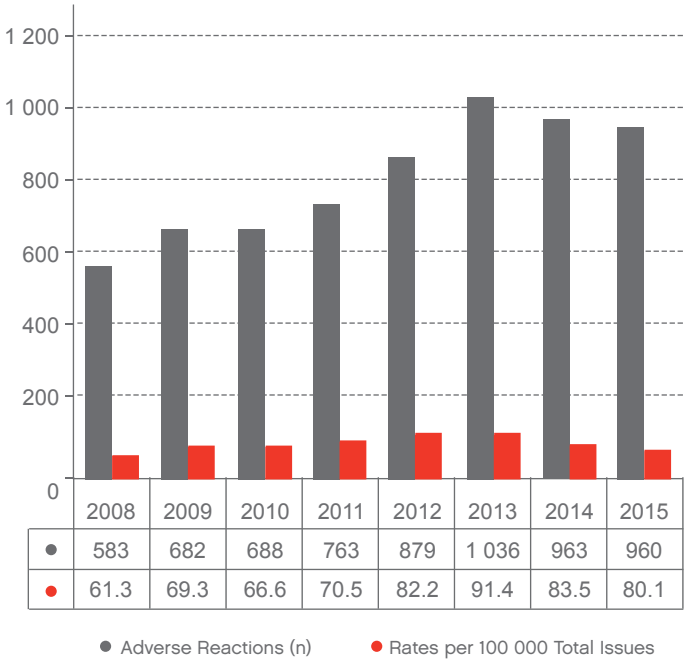

Table 5.4 below shows that over a period of 8 years, Acute Transfusion Reactions (ATRs) contributed more than 90% of all transfusion adverse reactions.

Table 5.4 Acute Transfusion Reactions (2008-2015)

Acute Reactions:	2008	2009	2010	2011	2012	2013	2014	2015	Totals
AHTR	13	15	15	4	4	52	10	22	**135**
ALLERGIC (INCLUDING SEVERE ALLERGIC)	177	222	231	221	274	297	251	260	**1 933**
ANAPHYLACTIC	11	5	6	16	26	64	53	87	**268**
TRALI	0	4	1	1	2	1	2	5	**16**
TACO	0	3	5	1	0	0	3	0	**12**
TAD	64	36	47	71	64	76	80	77	**515**
FNHTR	150	229	257	255	360	388	347	334	**2 320**
HYPOTENSIVE	25	12	51	54	40	52	57	33	**324**
UNCLASSIFIABLE	126	116	97	117	72	112	99	79	**818**
Totals	**566**	**642**	**710**	**740**	**842**	**1 042**	**902**	**897**	**6 341**

Acute Transfusion Reactions 2015: Case Discussions

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6. Acute Transfusion Reactions 2015: Case Discussions

The National Haemovigilance Office receives and follows-up confidential reports from hospitals and medical practitioners of serious adverse events/reactions to blood components following transfusion. Clinical data is collected using standardised forms where information on the reaction, in-hospital management and outcome is collected. Feedback is provided as appropriate. The reports are analysed, the findings are then disseminated and published in the form of an Annual Report, which makes recommendations for future practice.

Acute Haemolytic Transfusion Reactions (AHTR)
Allergic Transfusion Reactions
Anaphylactic Transfusion Reactions
Transfusion-related Acute Lung Injury (TRALI)
Transfusion-associated Circulatory Overload (TACO)
Transfusion-associated Dyspnoea (TAD)
Febrile Non-Haemolytic Transfusion Reaction (FNHTR)
Hypotensive Reactions
Unclassifiable Reactions

6.1 Acute Haemolytic Transfusion Reactions (AHTR)

2008	2009	2010	2011	2012	2013	2014	2015
13	14	15	1	4	4	10	22

22 cases of Acute Haemolytic Transfusion Reactions (AHTR) were reported in 2015.

An example of a case is described below.

Case: Acute Haemolytic Transfusion Reaction

- **A 9 day old male baby diagnosed** with acute respiratory distress syndrome and anaemia.
- Transfused with 1 unit of paediatric leucodepleted red cells.
- Three and a half hours after commencing the transfusion the patient developed skin reactions, tachycardia, cyanosis, dyspnoea, bronchospasms, a decrease in oxygen and haemoglobinuria.
- The transfusion was stopped immediately, and the patient was managed accordingly and stabilised.
- No further information was provided to the blood transfusion service on the clinical condition of the patient.

- **Conclusion:** This case was classified as an acute haemolytic transfusion reaction.

6.2 Allergic Transfusion Reactions

2008	2009	2010	2011	2012	2013	2014	2015
117	221	231	201	274	297	251	260

260 cases of combined mild and severe allergic reactions were reported in 2015.

An example of a case is described below.

Case: Allergic Reaction

- **A 4 month old male patient diagnosed** with pneumonia and severe anaemia.
- Transfused with 1 unit of leucodepleted red cells.
- In less than 6 hours the patient had a severe skin reaction.
- The transfusion was stopped immediately and the patient was given Hydrocortisone 21mg and stabilized.
- No further information was provided to the blood transfusion service on the clinical condition of the patient.

- **Conclusion:** This case was classified as an allergic reaction.

6.3 Anaphylactic Transfusion Reactions

2008	2009	2010	2011	2012	2013	2014	2015
15	5	6	16	26	64	53	87

87 cases of anaphylactic reactions were reported in 2015.

An example of a case is described below.

Case: Allergic Reaction

- **A 23 year old female patient diagnosed** with anaemia post-laparatomy for a perforated appendix, Hb of 8.6 g/dl on the 6th day post-surgery.
- 2 units of red cells were ordered and issued.
- Less than an hour into the transfusion of the first unit, with about 100ml of the product transfused, the patient experienced flushing/sweating, tachycardia, dyspnoea, a decrease in oxygen saturation, rigors and a hypotension.
- The transfusion was immediately stopped, oxygen administered by face mask, saline and adrenaline infusion administered and the patient stabilised.
- No further information was provided to the blood transfusion service on the clinical condition of the patient.

- **Conclusion:** This case was classified as an Anaphylactic Reaction.

6. Acute Transfusion Reactions 2015: Case Discussions (continued)

6.4 Transfusion-related Acute Lung Injury (TRALI)

Transfusion-related Acute Lung Injury (TRALI) is characterized by pulmonary oedema, hypoxemia, respiratory distress, and radiographic evidence of new bilateral pulmonary infiltrates (sometimes described as white lung) occurring within minutes to 6 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 the risk is increased with transfusion of blood products with high plasma content and blood products containing human leukocyte antigen (HLA) I and II.

2008	2009	2010	2011	2012	2013	2014	2015
0	1	1	1	2	1	2	5

5 cases of suspected/ possible TRALI were reported in 2015 but only 1 was confirmed and the other 4 as possible TRALI.

An example of a potential case is described below.

Case: TRALI

- **A 34 year old female patient, taken to theatre for exploratory laparotomy** with an Hb of 7.4 g/dl.
- The patient went into hypovolemic shock in theatre.
- 4 units of Red cells and 2 units of fresh frozen plasma were ordered and issued.
- After about 130ml transfused, the patient experienced dyspnoea, tachycardia, bronchospasm, cyanosis, oliguria, decrease in oxygen, and hypotension.
- According to the treating physician, the patient acutely crashed in the ward.
- Transfusion was stopped; patient was already intubated and oxygen was increased to 70%, Lasix administered intravenously and there was no improvement.
- The patient was bleeding acutely in the abdomen; she had to be taken to theater for a re-look.
- After the procedure chest X-rays were done and according to the treating physician the chest X-rays were demonstrative of clear diffused lung infiltrates and pulmonary oedema.
- Post-transfusion samples were taken and forwarded to the blood bank for investigation as the treating physician suspected TRALI.
- No further information was provided to the blood transfusion service on the clinical condition of the patient.

- **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 transfusions plus lack of response to diuretics.

6.5 Transfusion-associated Circulatory Overload (TACO)

2008	2009	2010	2011	2012	2013	2014	2015
7	3	5	1	0	0	3	0

No cases of Transfusion-associated circulatory overload were reported in 2015.

6.6 Transfusion-associated Dyspnoea (TAD)

2008	2009	2010	2011	2012	2013	2014	2015
64	36	47	71	64	76	80	77

There were **77 cases** of TAD reported in 2015.

An example of a case is described below.

Case: TAD

- **A 6 year old patient presented with symptomatic anaemia with a platelet count of 4 and Hb of 7.9 g/dl**
- The diagnosis was symptomatic anaemia, to investigate for immune thrombocytopenic purpura.
- The treating doctor ordered a unit of red cells.
- More than 6 hours into the transfusion, the patient had new onset dyspnoea only.
- As the doctor had suspected TRALI, a chest X-ray and arterial blood gases were done and no abnormality was detected.
- The baby was supported with nasal oxygen therapy and responded well to treatment.
- No further information was provided to the blood transfusion service on the clinical condition of the patient.

- **Conclusion:** The case was classified as transfusion-associated dyspnoea.

6. Acute Transfusion Reactions 2015: Case Discussions

6.7 Febrile Non-Haemolytic Transfusion Reactions (FNHTR)

2008	2009	2010	2011	2012	2013	2014	2015
150	229	257	255	360	388	347	334

334 cases of Febrile Non-Haemolytic transfusion reactions (FNHTR) were reported in 2015.

An example of a case is described below.

Case: FNHTR

- **A 51 year old female diagnosed** with Trypanosomiasis and anaemia, Hb of 8.4g/dl.
- Transfused with 1 unit of red cells. Between 1 and 2 hours into the transfusion, the patient presented with an elevated temperature from 37°C to 40°C, flushing/sweating, tachycardia 156bpm, rigors, increased blood pressure of 214/96 mmHg and a decrease in oxygen saturation.
- The transfusion was stopped; Solucortef® 100mg and Paracetamol were given and the patient stabilised.
- Blood culture tests and a chest X-ray were done by the treating doctor but results were not provided to the blood service.
- No further information was provided to the blood transfusion service on the clinical condition of the patient.

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

6.8 Hypotensive Reactions

2008	2009	2010	2011	2012	2013	2014	2015
12	17	257	54	40	52	57	33

33 cases of Hypotensive reactions were reported in 2015.

An example of a case is described below.

Case: Hypotensive reaction

- **A 20 day old male baby for an exchange transfusion.**
- A Group O negative unit of whole blood unit was used for this procedure.
- The blood was appropriately warmed with a blood warmer.
- After about 45ml transfused, in about 1-2 hours, the baby had new onset tachycardia and a drop in blood pressure.
- The transfusion was immediately stopped and 5mg of Solucortef administered intravenously and the baby's blood pressure improved.
- Post-transfusion samples were forwarded for testing together with the whole blood unit.
- The transfusion reaction investigation results found that the direct antiglobulin tests were negative.
- Irregular red cell antibodies i.e. anti-D were detected in the patient's post-transfusion sample.
- The unit tested negative for the D red cell antigen and no apparent cause was detected for the transfusion reaction.
- No further information was provided to the blood transfusion service on the clinical condition of the patient.

- **Conclusion:** This case was classified as a hypotensive reaction.

6.9 Unclassifiable Reactions

2008	2009	2010	2011	2012	2013	2014	2015
44	43	48	117	72	112	99	79

There were **79 cases** of Unclassifiable Reactions in 2015 **due to lack of sufficient transfusion reaction information submitted.**

Incorrect Blood Components Transfused (IBCT): Case Discussions

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7. Incorrect Blood Components Transfused (IBCT): Case Discussions

Incorrect Blood Components Transfused (IBCT)

- Incorrect blood components transfused (1 Rh, 6 ABO-incompatible units): **7 cases**
- Misdirected Transfusions **14 cases**
- Patient Misidentification **3 cases**
- Missed antibodies **10 cases**

Errors and incidences in this section, classified as IBCT are potentially preventable, particularly the misdirected and misidentification errors.

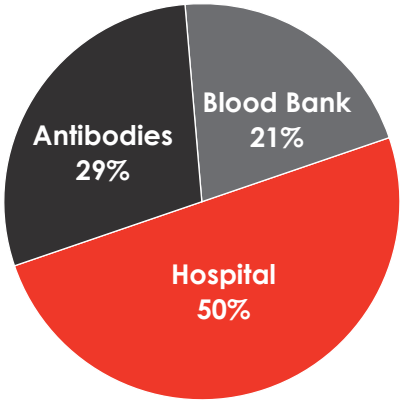
2008	2009	2010	2011	2012	2013	2014	2015
10	31	10	22	26	35	35	34

There were **34 cases** reported and captured in 2015. These cases include categories of ABO and Rh-incompatible transfusions, ABO-incompatible transfusions, Misdirected transfusions, Patient misidentifications and cases of antibodies detected on issued emergency units.

The personnel involved in these errors were:

Type of Error	Personnel Involved	Number of Cases	Percent-age (%)
ABO/Rh incompatibilities	Blood Bank Technicians Blood Bank errors.	7	20.6%
Patient Misidentification at Transfusion (Bedside/Theatre)	Doctors and Nurses Hospital Errors	27	50%
Antibodies detected – Emergency units	Neither a lab nor a hospital error	10	29.4%
Total IBCT		**34**	**100%**

Of the 34 errors reported 7 cases were committed in the blood bank, 17 cases in the hospitals and 10 cases had antibodies detected when units were already issued as emergency requests. Of the 7 errors committed in the blood bank, 6 cases were due to serological ABO-incompatibilities and 1 case due to Rh-incompatibility.



Currently 5 blood banks at the SANBS (Charlotte Maxeke Johannesburg Academic Hospital, Chris Hani Baragwanath Academic Hospital, Steve Biko Academic Hospital, Inkosi Albert Luthuli Academic Hospital and Universitas Hospital) of the 84 blood banks are automated. A strategic decision was taken to roll out automation to the remaining blood banks before implementing the electronic cross-match which will replace the serological cross-match.

Because the cross-match is performed manually, there are errors that occur that could compromise patients' lives. Automation has several advantages all of which ensures greater patient safety. It improves the quality and safety of blood products, improves the objectivity and reproducibility of tests, reduces human error in testing and transcription, ensures improved traceability of reagents and processes and allows for archiving of an image of the actual test results.

Of the 17 hospital errors that occurred, 4 cases were due to sample collection and the other 13 were due to wrong units transfused to wrong patients.

The WPBTS has already fully implemented blood bank automation since 2014.

Positive identification of the recipient at sample collection and prior to transfusion remains a concern and education needs to constantly highlight its importance.

7.1 Recommended interventions for reducing transfusion-related errors:

According to Pronovost PJ, Ravitz AD et al[1]. (2015) the WISH Patient Safety Forum, Transforming Patient Safety: ten steps to improve patient safety were identified and these are also applicable to transfusion safety:

- Policy and regulation to help rather than hinder safety improvementsPatient safety is a core value of the culture
- Leadership influences patient safety
- Education leads to informed decision-making and system resilience
- Transparency and open disclosure are professional expectations
- Metrics are used to evaluate progress and success
- Technology facilitates healthcare without constraining it
- Patient safety is sustainable
- Patients and their families are engaged partners in patient safety
- Patient safety research is transdisciplinary

The WISH forum concludes that these themes are enablers to move healthcare from its current state into one where preventable harm is eliminated. Recognising the human factors leading to transfusion errors will move transfusion safety closer to the ultimate goal of eliminating preventable harm.

According to the UK SHOT 2015 report[2], "the most dangerous steps in transfusion practice still continue to be the human interventions" and below are some of their recommendations to ensure a reduction in errors:

- Positive patient identification (ask the patient to state name and date of birth)
- Check identification of component against patient wristband
- Check the prescription: has this component been prescribed?
- Check the prescription: is this the correct component?
- Check for specific requirements – does the patient need irradiated components or specially selected units?

Other interventions recommended between transfusion services and hospitals in South Africa include:

- Focus on communication and collaboration between blood transfusion service and the hospitals where there's an easier end-to-end view of the blood value chain.
- Leadership commitment (not just at the start but consistent focus and commitment throughout the process).
- Shared accountability and openness (learning rather than blame).
- The Blood Transfusion Service to continue providing transfusion education and support to hospitals.

7.2 Misdirected transfusions:

An example of an ABO-incompatible case is outlined below. This case was a sample mix-error in the blood bank.

Case: Incorrect Blood Component Transfused (IBCT No reaction): Blood Bank error

- 28 year old man sustained a laceration to his brachial artery following a stab wound to the neck and required surgery (Hb 4.3g/dl).
- Four units of red cell concentrate and two units of FFP were ordered
- There was a patient sample mix-up in the blood bank resulting in four units of A Positive blood being issued for the patient who was type O-group Rh Positive. All four units were transfused to the patient.
- The error was only detected by the blood bank a day later during a clerical check.
- The clinician was informed immediately and the patient had daily blood tests and urine monitoring at the district hospital where he was admitted, but he developed no symptoms of acute haemolysis
- He was discharged from the hospital five days after receiving the transfusions and required regular follow-up to monitor for a delayed transfusion reaction, which did not occur.
- No further information was provided to the blood transfusion service on the clinical condition of the patient.

- **Conclusion:** This was classified as a misdirected transfusion reaction (Blood Bank error).

An example of a misdirected transfusion hospital error case is outlined below:

Case: Misdirected Transfusion – Hospital error

- A 73 year old woman admitted to the orthopaedic ward for work-up for a hip replacement.
- She was sent to the radiology department for a MRI scan but was returned to the incorrect ward by the hospital porter.
- In the ward she received approximately 150ml of A-group Rh positive blood that was intended for the patient in whose bed she was lying. She did not dispute the transfusion as she was mildly confused and the ward staff only identified the error after the start of the transfusion.
- She developed tachycardia, hypertension and sweating after the start of the transfusion and was transferred to the High Care Unit for further observation, where she was monitored for 24 hours and did not develop convincing symptoms of acute haemolysis.
- Her actual blood group could not be confirmed on the immediate post-transfusion sample due to the incompatible blood transfusion.

- **Conclusion:** This was classified as a misdirected transfusion (Hospital error).

Near Miss Events

Delayed Haemolytic Transfusion Reactions (DHTR)

Post-Transfusion Purpura (PTP)

Transfusion-Associated Graft Versus Host Disease (TA-GvHD)

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8. Near Miss Events

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

2008	2009	2010	2011	2012	2013	2014	2015
0	2	2	0	7	0	8	15

The 15 Near miss cases for 2015 were all hospital errors that occurred at sample collection. Wrong samples, not belonging to a patient intended to be transfused, were forwarded to the blood bank. Due to having the previous transfusion data of our patients, such potentially fatal discrepancies in blood groups were detected by the blood banks.

Case: Near miss

- A blood request was received in the blood bank for a patient and the indication for transfusion not indicated on the near miss report.
- The initial patient sample and the information on the request form correlated and the request was processed by the blood bank technician.
  2 units Red Cells were typed and crossmatched.
- During the process of entering the testing results on the Meditech system, the technician observed that the patient's blood group did not correlate with the blood group information on the Meditech system.
- The test results grouped the patient as Group A Rh positive and the information on Meditech was that the patient was B-Group Rh positive.
- The hospital was contacted to submit a new patient sample to confirm the patient's blood group.
- The first technician that worked on the case wrote a comment on the blood request form for the other blood bank staff not to issue blood until a new sample was received to confirm the patient's blood group.
- The same request form was then incorrectly put in the blood issuing rack.
- A second blood bank technician mistakenly issued the 2 units blood to the hospital as she did not read the comments on the request form.
- The ward sister that received the unit from the blood bank contacted the blood bank to inform them that they had ordered blood for a wrong patient.
- They had ordered for patient RS and wanted to order for patient RG.
- The blood was returned to the blood bank with a new request for the correct patient RG.
- Both patients had previously received blood and the blood groups on the system confirmed that patient RS was blood Group B Rh positive and patient RG was Group A Rh positive.

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

9. Delayed Haemolytic Transfusion Reactions (DHTR)

2008	2009	2010	2011	2012	2013	2014	2015
0	2	2	0	1	0	0	1

There was 1 case of Delayed Haemolytic Transfusion Reactions (DHTR) reported in 2015.

Case: DHTR

- An 18 year old patient diagnosed with multiple fractures, after a motor vehicle accident.
- The patient was transfused for anaemia post-splenectomy.
- 6 units Red Cells, Group B Rh Positive and 4 units of FFP were deemed compatible and issued.
- 5 Days later, another request was received for the same patient. On crossmatching and performing compatibility testing, the technician dealing with the case experienced difficulties with the grouping and the screen cells.
- Both the screen cells and grouping results were positive.
- The Direct antiglobulin test was positive and the Group O Rh positive.
- The technician then further requested a second confirmatory sample.
- The second sample was received, this sample was found to be Group O Rh positive and the screening was negative. Group O, Rh positive were crossmatched and issued.
- A transfusion reaction report for this patient was received 6 days after the initial transfusion episode. On the form the doctor indicated that the patient was jaundiced and had an elevated temperature.
- No further information was provided to the blood transfusion service on the clinical condition of the patient.

- **Conclusion:** This is an example of a delayed haemolytic transfusion reaction where ABO incompatible units of blood had been transfused to a patient.

10. Post-transfusion Purpura (PTP)

2008	2009	2010	2011	2012	2013	2014	2015
0	0	0	0	0	0	0	0

There were no cases of Post-transfusion Purpura (PTP) reported in 2015.

11. Transfusion-associated Graft versus Host Disease (TA-GvHD)

2008	2009	2010	2011	2012	2013	2014	2015
0	0	0	0	0	0	0	0

There were no cases of TA-GvHD reported in 2015.

Mortality Reports 2015

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12. Mortality Reports 2015

2008	2009	2010	2011	2012	2013	2014	2015
1	3	3	3	3	7	16	12

There were 12 reported cases of patient mortality forwarded to the blood services following transfusions in 2015.

In 1 case transfusion was excluded by the treating doctor as a cause of death, in 11 other cases the outcomes of the case were inconclusive to confirm if transfusion was a probable cause of the mortality.

It is important to note that if no post-transfusion samples are forwarded to the blood transfusion service and no postmortem performed on the deceased patients, we cannot conclusively associate the blood transfusion to the death of the patients. Blood transfusion will remain a possible contributing factor and not a confirmed or definitive cause of the reported deaths.

As the National office that receives reports of these cases, we are faced with a challenge of the hospital personnel discarding transfused units immediately after the reaction, thereby making it impossible for the blood service to investigate and conclude on such events. Through ongoing education and the intervention by the Department of Health, we are hoping to make it compulsory that post-transfusion samples and postmortems be done on all mortality cases.

A brief description of the 12 Mortality reports:

Case 1:

- **A 3 month old baby diagnosed** with Down's syndrome, endocardial cushion defect and a low haematocrit.
- The surgeon had requested 2 adult units of red blood cells not older than 5 days but due to the case being an emergency and a fresh unit unavailable at the blood bank, 2 units that were 10 and 17 days old were issued after discussion with the ward sister.
- The baby was transfused with about 60ml of leucodepleted RBCs following a cardiothoracic surgery.
- Between 1-2 hours into the transfusion, patient became hyperkalaemic with lactatic acidosis.
- The patient developed irreversible haemodynamic shock.
- The baby was resuscitated without success and demised.

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

Case 2:

- The blood service was notified of the case when the treating Haematologist was reporting on the unavailability of platelets in a particular hospital's blood bank when the doctors needed emergency platelets for a patient.
- The platelets were for a neonate with severe thrombocytopenia and septic shock.
- This was a twin baby who suddenly dropped the platelet count from 303 to 20/µl.
- The treating Haematologist requested to be issued with emergency units of platelets and was informed that platelets were unavailable at that blood bank at the time of request.
- On follow up the following morning platelets (apheresis and pooled) were still unavailable even at other nearby blood banks.
- The baby started bleeding from all puncture sites, the bleeding could not be stopped and the baby demised.
- The second twin also had sepsis with thrombocytopenia with a platelet count of 12/ µl.
- When the platelets finally arrived, they were transfused to the second twin who responded well and subsequently discharged.
- According to the doctor's report the most likely cause of the mortality was severe thrombocytopenia potentiated by the unavailability of platelets.

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

12. Mortality Reports 2015 (continued)

Case 3:

- **A premature baby diagnosed** with Necrotizing enterocolitis and anaemia.
- The paediatrician ordered 1 unit of red cells.
- One unit of Group O, Rh Positive red cell concentrate was crossmatched, deemed compatible and issued.
- 2 days after the unit was issued, the paediatrician went to the blood bank to enquire about results of the transfusion reaction of this baby.
- The doctor was informed by the blood bank staff that a transfusion reaction notification was never received by the blood bank. The enquiring doctor then agreed to follow up on the case and bring the required documents and specimen.
- What was later received was specimen without the transfused units and the transfusion reaction form. The unit in question was never returned by the doctor.
- Pre- and post-transfusion testing was carried out on the received patient samples and no blood group inconsistencies or irregular antibodies were detected.
- 5 days later a different doctor phoned the blood bank enquiring about the results of the previously queried transfusion investigation.
- She notified the blood bank technician about the baby's demise and stated that they suspected the cause of death was related to transfusion.
- What the doctor also stated was that the unit number was not recorded on the patient's file when the blood bank technicians requested for the unit number to confirm what is on the blood bank's records.
- On day 6 post transfusion, a different doctor also came personally to check on the results of the transfusion reaction. This doctor insisted that she had brought the reaction just before she knocked off on the day it occurred. No evidence of this was found. She then agreed to fill in a transfusion reaction form.

- **Comments:**
  A full transfusion reaction investigation could not be performed as the implicated unit was not forwarded to SANBS.
- As no pre- and post-transfusion compatibility testing or additional investigations could be performed, the serological testing for this case remained incomplete.
- No serological cause for the patient's transfusion reaction and subsequent death could be determined.

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

Case 4:

- **A 67 year old male diagnosed** with symptomatic anaemia and retroviral disease.
- He was transfused with a Group B, Rh positive red cell unit.
- After about 100ml of RBC transfused, the patient had a sudden cardiac arrest and demised.
- The treating doctor reported the mortality, indicated the condition was poor and that transfusion could have contributed to the demise.

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

Case 5:

- A 4 day old female baby with Down's syndrome, cardiac pathology and occult sepsis.
- Needed blood for exchange transfusion.
- The patient reportedly had a cardiac arrest after about 260ml transfused within the first hour.
- The mortality was reported to the blood bank by the treating doctor.

- **Comment:** No post-samples obtained for this patient and further testing could not be performed.
- No postmortem was conducted to conclude on the possible cause of mortality. This case was not forwarded for further testing and no paperwork was received to compile a detailed report.

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

12. Mortality Reports 2015 (continued)

Case 6:

- **A 5 year old female patient diagnosed** with Acute Lymphoblastic leukemia and a low platelet count.
- Transfused with a unit of apheresis platelets.
- After about 100ml transfused the patient had urticaria, flushing/sweating, tachycardia and an increase in blood pressure. Resuscitation was unsuccessful.
- The blood bank was informed of the patient's demise.
- A transfusion reaction investigation was initiated
- There were no post-transfusion specimen sent through and no abnormalities or blood group discrepancies were noticed on the pre-transfusion samples.

- **Comment:** No post-transfusion samples were forwarded and no postmortem was conducted.

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

Case 7:

- A preterm baby with sepsis and severe anaemia, Hb of 4.2 g/dl.
- The baby was transfused with a Group O, Rh positive leucodepleted paediatric unit of red cells.
- The unit was transfused and absorbed well by the baby.
- Around six hours into the transfusion it was documented that the patient had a decrease in oxygen saturation, hypotension and cyanosis.
- The baby was resuscitated with intravenous adrenaline, Calcium gluconate, Salbutamol, was intubated and stabilised.
- The treating paediatrician explained that the baby's deteriorating condition was discovered during a ward round.
- The doctors tried to resuscitate the baby but were unsuccessful.
- The baby was reported as having demised to the blood bank, the following day.

- **Comment:** No samples were submitted and no postmortem results were forwarded by the hospital.

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

Case 8:

- A 30 year old female with post-partum haemorrhage and anaemia with an Hb of4g/dl.
- Initially compatible red cell units could not be found and more samples were requested and sent to Red Cell Serology laboratory for testing.
- Plasma and platelet units were issued in the interim.
- After testing, compatible units were found and issued
- The patient was transfused with 3 units of RBCs.
- A report of the patient mortality was received by the blood bank the following morning.
- Suspected transfusion reactions symptoms were not indicated on the form.

- **Comment:** The treating doctor indicated on the transfusion reaction form that the death was not related to transfusion.
- No post-transfusion samples were forwarded to the blood bank and no postmortem conducted.

- **Conclusion:** Transfusion was excluded as a cause.

Case 9:

- A 77 year old male patient with respiratory failure transfused for blood loss from sacral wound.
- The patient was transfused with a Group O Rh positive unit of RBC. This unit was ordered and issued to the ward for the same patient 10 days prior to the unit being transfused.
- The patient reportedly had flushing/ sweating, cyanosis, dyspnoea, decrease in oxygen saturation and hypertension.
- The patient subsequently had a respiratory arrest, was intubated and transferred to the high care unit.
- The patient subsequently died and the treating doctor indicated respiratory failure as the cause of death.
- The transfusion reaction form and infused unit were sent to the blood bank.
- The unit was haemolysed and could not be tested. No post-transfusion samples were forwarded to the blood bank and no postmortem conducted.

- **Comment:** The treating doctor indicated that the death was not related to transfusion.

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

12. Mortality Reports 2015 (continued)

Case 10:

- **A 59 year old female diagnosed** with acute coronary syndrome and anaemia with Hb of 4.3g/dl
- The patient was transfused with Group O Rh positive unit of red cells.
- After about 250ml transfused patient had: urticaria, flushing/sweating, tachycardia and hypotension.
- According to the transfusion reaction report the patient demised before resuscitation could be commenced.

- **Comment:** No post-transfusion samples were forwarded to the blood bank and no postmortem conducted to conclude on the possible cause of mortality.

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

Case 11:

- A 23 year old male with congenital nephrotic syndrome and anaemia with Hb of 7.3g/dl.
- The patient was transfused with 1 Group O Rh positive leucodepleted red cell unit.
- After ± 5ml transfused patient had: tachycardia, vomiting, dyspnoea, bronchospasms and a decrease in oxygen saturation.
- The patient was intubated, resuscitated for 45 minutes without success and demised.

- **Comment:** No post-transfusion samples were forwarded to the blood bank and no postmortem conducted to conclude on the possible cause of mortality. The Doctor's report concluded that the cause of death was suspected transfusion related acute respiratory distress syndrome.

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

Case 12:

- **A 77 year old female diagnosed** with pleural effusion and anaemia
- Transfused with a Group B, Rh positive RBC unit.
- After about 250ml transfused the patient had tachycardia and sweating.
- The transfusion was stopped and patient sent for a brain CT scan.
- On the way back from the scan the patient had a cardiac arrest in the hospital lift.
- Resuscitation efforts failed and the patient demised.
- The treating doctor ordered a transfusion reaction investigation and blood samples were sent to the blood bank.
- The blood unit that was transfused was not sent for investigation as it was discarded in the biohazardous box.

- **Comment:**
- A full transfusion reaction investigation could not be performed as the implicated unit was not forwarded to the blood bank.
- As no pre- and post-transfusion compatibility testing or additional investigations could be performed, the serological testing for this case remained incomplete.
- No serological cause for the patient's transfusion reaction and subsequent death could be determined.
- A written report was never received from the treating doctor following several attempts to finalise this case.

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

Lookback Programme

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13. Lookback Programme

The Transfusion-transmissible Infection (TTI) Lookback Programme was established in 1986. It has been incorporated into the Haemovigilance Programme since 2005.

Blood Transfusion Services in South Africa screen all blood donations for HIV, hepatitis C and hepatitis B by both serological tests and by individual donor nucleic acid amplification testing (ID-NAT). 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.

Total number of lookbacks	SANBS	WPBTS	Total
HIV	499	29	**528**
HBV	202	7	**209**
HCV	13	1	**14**
HIV/HBV Co-Infections	8	0	**8**
HIV/HCV Co-Infections	1	0	**1**
Other	3	0	**3**
Total	**726**	**37**	**763**

In 2015, a total of 763 donors sero-converted and were investigated through the donor triggered donor-triggered lookback process, a 13.1% decrease compared to 863 in 2014. There was a 100% follow-up of all cases. Of the 763 cases, 69.2% of lookbacks were due to HIV, 27.4% HBV and 1.8% cases were due to HCV. Eight cases had HIV/HBV co-infection and 1 case HIV/HCV co-infection. For the other infections, 2 were investigated for Swine Flu and the other for Hepatitis A and; were all excluded.

Table 13.2 Investigation outcomes

Donor-triggered investigation outcome	SANBS	WPBTS	Total
Retest negative	52	8	**60**
Recipient positive before transfusion	42	0	**42**
HIV positive recipient/s – phylogenetic analysis	2	0	**2**
Recipient died between transfusion and initiation of lookback	97	12	**109**
Unresolved	733	14	**747**
Untraceable patient	10	4	**14**
Other	1	0	**1**
Refused/Declined testing	1	0	**1**
HBV Immune	0	0	**0**
HBV positive recipient - phylogenetic analysis	0	0	**0**
On dual therapy (HBV Ib)	0	0	**0**
Total	**938**	**38**	**976**

At the time of the report, 976 donor-triggered investigations were conducted from the 763 donors with previous donations. Two hundred and one (**20.1%) of the 976 cases were resolved/closed.** Of the 201 cases, 60 recipients were traced and tested negative while 42 cases were confirmed to have been positive before transfusion (confirmed on requisition form or by the treating doctor). There was a true closure rate of about 10.7% for 2015. Two cases of HIV phylogenetic testing were conducted and only 1 was confirmed as a transfusion transmission and the other excluded.

13. Lookback Programme (continued)

HIV Transmission case summary

Donor: A 23 year old male with 18 previous whole blood donations. He donated the implicated unit on the 19/09/2014 and tested negative for all viral markers by NAT and Abbott Prism.

The donor's subsequent donation on the 4/12/2014 tested positive for HIV by NAT and anti-HIV. A donor-triggered lookback investigation was initiated and the recipient of the unit was identified.

The Senior Clinical Manager of the hospital where the transfusion took place was notified and the recipient was contacted and referred for HIV testing.

The recipient: a 58 year old male who had been transfused for a septic below knee amputation on the 28/09/2014 tested HIV positive. Additional samples were taken from the recipient and were sent to the NICD for phylogenetic testing.

The phylogenetic testing confirmed that the infection in the recipient was transfusion-transmitted.

All engagements and counselling of the recipient have taken place.

The HTLV case reported in 2013 was confirmed by phylogenetic testing within 2016.

HTLV-1 Transmission case summary

During 2013, SANBS was notified of a blood recipient who had been diagnosed with HTLV-1 associated myelopathy. The recipient had been transfused with 6 units of red cell concentrate over the course of several weeks in 2011. The managing doctor of the patient initiated a recipient triggered lookback. All six donors of the transfused units were contacted and pre-test counselled for HTLV-1 serology testing. Five of six donors tested HTLV negative, a sixth donor tested HTLV positive. This donor was post-test counselled as per recommendations for HTLV, advised on future medical care and permanently deferred from donation. Both donor and recipient consented to blood samples being taken for HTLV phylogenetic testing which was completed by the Pasteur Institute in 2016. The phylogenetic test confirmed that a 772 base pair sequence in the env region of the genome of HTLV from both donor and recipient were strictly identical.

One hundred and nine recipients were confirmed to have died between the transfusion episode and the lookback investigation initiation period, 15 cases were untraceable because the patients were unreachable by the hospital or due to missing hospital files.

The other 747 of the 976 (76.5%) cases remained unresolved/ open at the time of the report but the investigations still continue. They remain unresolved/ open 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 responsible clinician but no further active follow-up is pursued.

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

Recipient-Triggered lookbacks 2015

A recipient-triggered lookback investigation is initiated when the Blood Service is 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 13.3 Recipient-triggered lookbacks 2015

	Resolved	Unresolved	Total
HIV	5	2	**7**
HBV	0	0	**0**
HCV	0	0	**0**
Other	1	4	**5**
Total	**6**	**6**	**12**

A total of 12 recipient-triggered lookback cases were reported and 6 (50%) of cases had been resolved or closed at the time of the report. Of the 6 cases that were resolved, 5 donors retested negative and the other case was information request from the treating doctor that subsequently informed the office to close the case.
Of the total 12 reported recipient-triggered lookback cases, 6 (50%) cases remain unresolved because no records were found due to time lapsed or the donors being untraceable.

13. Lookback Programme (continued)

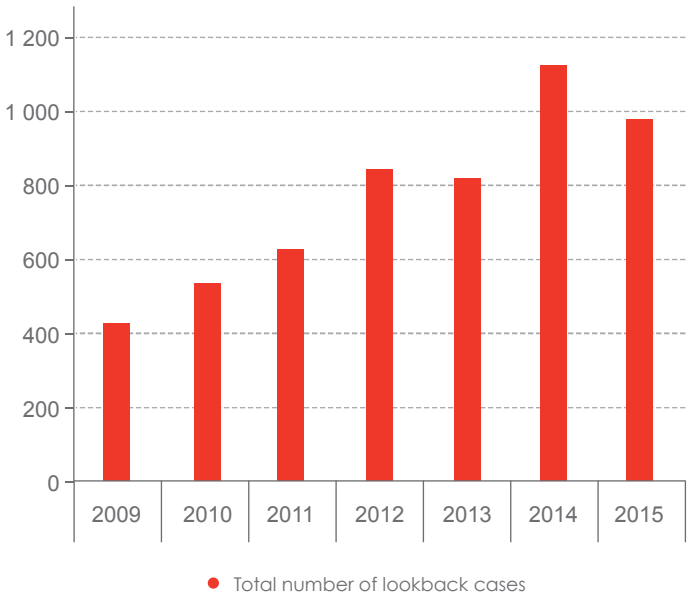
There has been a huge increase in the total number of all lookback cases (donor and recipient-triggered) from 447 in 2009 to 1 129 in 2014 with a slight decrease in 2015 to 976 as shown in table 13.4 and figure 3 below.

Table 13.4 Overview of lookback investigations (2009-2015)

	2009	2010	2011	2012	2013	2014	2015	Total
Total number of lookback cases	447	546	642	629	849	1 129	976	**5 218**

Nine hundred and seventy six of 1 200 228 (± 0.1%) transfused products resulted in a lookback investigation due to possible microbial contamination.

Figure 3: Lookback cases investigated (2009-2015)



Challenges to the lookback programme which results in the high number of unresolved cases:

- Blood requisition forms are not completed correctly and patient information is incomplete.
- Incorrect hospital number is entered and the patient cannot be traced in many provincial hospitals.
- Information on deceased patients or patients who were HIV+ before transfusion in the case of an HIV lookback is not always relayed timeously to the lookback officer.
- Retest results are not sent to the lookback officer as requested in the lookback notification.
- Numerous follow-up calls have to be made before a result is obtained from several major provincial hospitals and many doctors in private practice.
- Several hospitals and doctors consider it the duty of the SANBS to recall, counsel and retest the recipients of a possible window-period transfusion, but the Clinical Guidelines (Chapter 1: Legal obligations, page 1, fifth edition) clearly indicate that this is the duty of the attending doctor who prescribed the transfusion or designate at the hospital where the transfusion was administered.
- The cost of blood tests and tight hospital budgets has also been mentioned by several doctors and hospital managers.

Platelet Bacterial Testing (SANBS Only)

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14. Platelet Bacterial Testing (SANBS Only)

As part of the SANBS quality assurance programme and policy, 1% or a minimum of 16 platelets units/ collection sites, whichever is greatest, must be tested for bacterial contamination on a monthly basis. It is important that platelets are screened for bacterial contamination as these products are stored at room temperature; which is an ideal environment for bacterial growth.

All platelet components tested were screened for bacterial contamination using an automated culture system; incubating both aerobic and anaerobic culture bottles for 14 days at 35 - 39°C. All positive cultures are subjected to a Gram stain at the SANBS and this provides a preliminary result for patient management. Full identification to species level is performed by an accredited external referral laboratory.

The average sterility testing results for 2015 showed an annual contamination rate of 5.4% as demonstrated in Table 14.1 below. Table 14.2 provides a summary of the organisms cultured.

Table 14.1 Platelet Bacterial Testing 2015

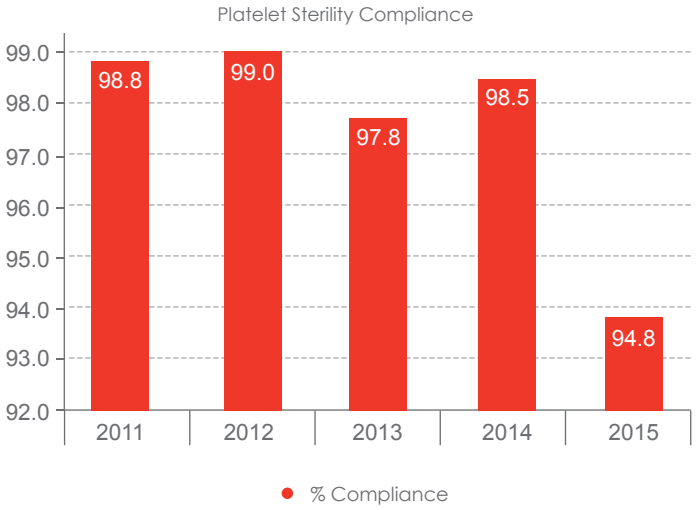
Products Tested	Number Tested	Number Positive & (%)
Apheresis Platelets	2 832	**147 (5.2%)**
Expired Platelets	186	**15 (8.1%)**
Total	**3 018**	**162 (5.4%)**

Table 14.2 Summary of Micro-organisms Isolated in Apheresis Platelets

Products Tested n=164 *	Cocci n = 76	Bacilli n = 80
Gram Positive Bacteria n = 152	76	76
Gram Negative Bacteria n= 4	0	4
Fungi n =1	1	N/A
No Bacterial Growth n=7	7	N/A

* Total number of organisms was more than the number of positive units as more than 1 organism was isolated in some units.

Average Monthly Apheresis Platelet Sterility Rates



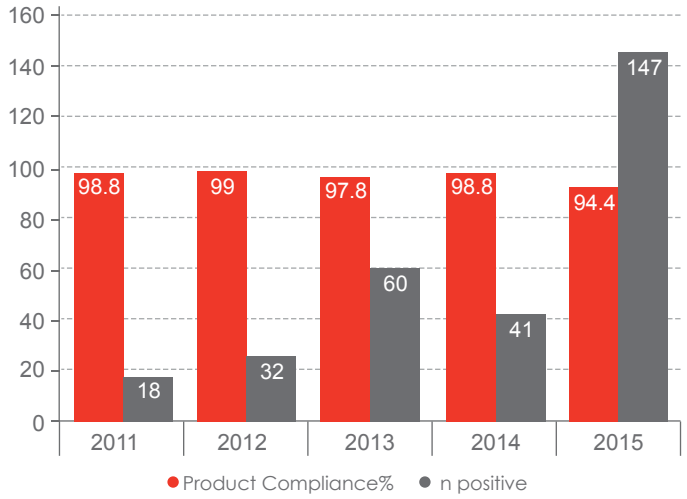
The average monthly compliance rate as demonstrated in the histogram above was 94.8 % for 2015 compared to 98.5% for 2014 and the target is to have 100% sterility on the platelet products.

Since platelets are usually transfused to severely ill and/ or immunocompromised patients, contaminated units at low bacterial count can cause bacteremia and potentially severe septicemia in recipients of these units. SANBS has a well-developed communication system in place allowing efficient communication between the sterility testing laboratory and the SANBS Medical Managers (MM). Once a positive culture and Gram stain are available the MMs are contacted immediately so that they can discuss the findings with the patients' treating doctors.

As the demand for platelets is high, recall of product is usually not possible as most would already be transfused to patients.

In 2015 no reported deaths or adverse events due to bacterial contamination have been reported. Although the risk is small and usually linked to virulent Gram negative bacteria, we suspect that "zero" reported adverse events are likely to reflect underreporting.

14. Platelet Bacterial Testing (SANBS Only) (continued)



In addition to platelet sterility testing, environmental monitoring is performed monthly in apheresis collection areas and bi-annually in processing centres.

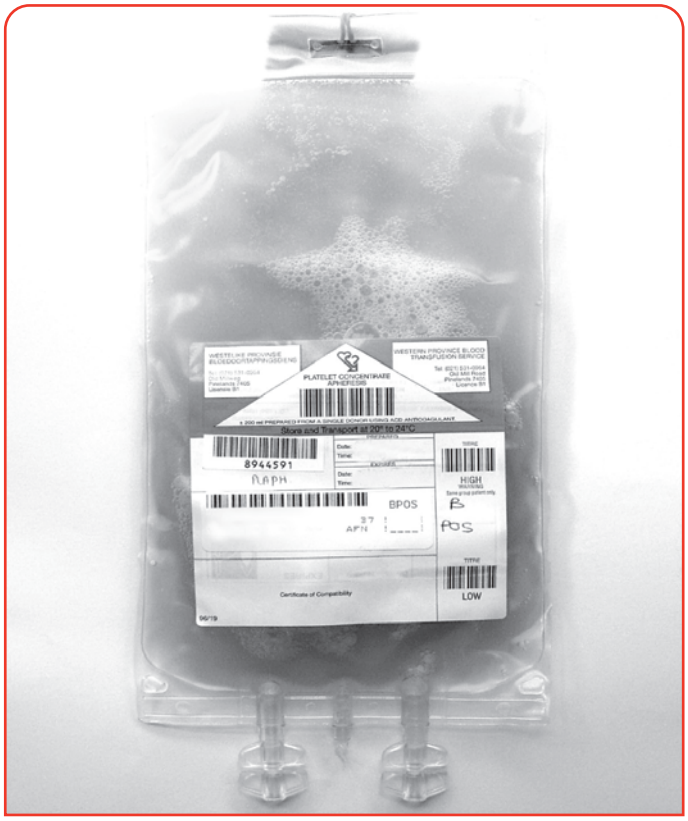


Table 14.4 Environmental Testing 2015

Number of tests (contact plates sampled)	Number compliant	Number not complying (>2+ Growth)	Most detected organisms
2 429	2 423 (98.8%)	2 pathogens	*Pseudomonas aeruginosa*
			Coagulase Negative Staph
		4 normal flora	*Micrococcus species*
			Bacillus species
			Fungal species

A significant increase in the number of contaminants was noted in 2015. As more than 90% of isolates were bacteria commonly residing on the skin, poor hand hygiene is the most likely cause of the increase seen. The following preventative actions were implemented in SANBS in order to try and improve sterility compliance:

- Enhanced awareness of aseptic technique and proper and consistent hand washing practice.
- Implementation of an Infection Control training programme.
- Enhanced awareness for blood products to be collected and processed according to aseptic standards and Good Laboratory Practice.
- Hand hygiene and environmental hygiene to be the responsibility of all staff involved in the value chain .
- Appropriate usage and validation of disinfectants used for work areas, bench tops, utensils and hand washing.

Donor Vigilance

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15. Donor Vigilance

15.1 Introduction

The mission of the blood transfusion services in South Africa is to collect and provide sufficient and safe blood for all patients in the country. While the advances in blood banking have substantially improved the safety of the blood supply over the past decades1 the provision of a constant and sufficient blood supply remains a challenge.

Research has shown that donors who suffer adverse events not only have lower return rates, but also take longer to return to donate. 5,7,8 It has also been noted that collections at the blood drives where these events occur decrease and take time to recover. Based on this, it is prudent to identify processes that have been demonstrated to reduce the incidence of adverse events related to blood donation.

In order to measure the effect of donor adverse events, the SANBS has developed an electronic database for the recording and reporting of these events. System development was completed in December 2009 and implemented on 1 January 2010. The systematic recording of donor adverse events (DAE) had not been part of standard procedures until this time and initial uptake was slow, but improved throughout the year. Further training was offered to the staff and standard operating procedures reviewed to enable continuous improvement of the reporting system.

Information obtained from interrogation of the DAE database is used internally to identify problem areas, perform a root cause analysis and implement corrective action. Trends are identified and this information is used to adapt and amend operations to ensure safe practices and continuous improvement. It is hoped that this information will be used to benchmark the SANBS's performance internationally.

When designing the DAE Electronic Database, a decision was made to base the system on the Standard for Surveillance of Complications Related to Blood Donation (2008) as compiled by the Working Group on Complications Related to Blood Donation, the International Society of Blood Transfusion (ISBT) Working Party on Haemovigilance, and the European Haemovigilance Network.

The adverse events are categorised according to whether the symptoms are localised to the donation/needle site or whether they are generalised in nature. Generalised symptoms are those associated with vasovagal reactions either experienced at the time of donation or after leaving the blood collection centre. There is a separate category for adverse events associated with apheresis procedures.

Categories of complications related to blood donation

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

15. Donor Vigilance (continued)

15.2 Classifications

Complications mainly with local symptoms	
These complications are directly caused by the insertion of the needle. Some of these are mainly characterised by occurrence of blood outside vessels, whereas others are mainly characterised by pain.	
Complications mainly characterised by the occurrence of blood outside the vessels.	
Adverse Event	**Definition**
Haematoma	An accumulation of blood in the tissues outside the vessels. Symptoms: Include bruising, discolouration, swelling and local pain.
Arterial Puncture	A puncture of the brachial artery or of one of its branches by the needle used for bleeding of the donor. Symptoms: There may be weak pain localised to the elbow region. Objectively a lighter red colour than usual of the collected blood can be seen and perhaps some movements of the needle caused by arterial pulsation; the bag fills very quickly. In uncomplicated cases there may be no haematoma. Complications: The risk of a large haematoma is increased and thereby risks such as Compartment Syndrome in the forearm, Brachial Artery Pseudo Aneurysm and arterio-venous fistula.
Delayed Bleeding	Spontaneous recommencement of bleeding from the venipuncture site, which occurs after the donor has left the donation site.
Complications mainly characterised by pain.	
Adverse Event	**Definition**
Nerve Irritation	Irritation of a nerve by pressure from a haematoma. Symptoms are nerve type as radiating pain and/or paraesthesia in association with a haematoma. The haematoma may not always be apparent at the time. Symptoms do not occur immediately on insertion of the needle but start when the haematoma has reached a sufficient size, sometime after insertion of the needle.
Nerve Injury	Injury of a nerve by the needle at insertion or withdrawal. Symptom is pain often associated with paraesthesia. The pain is severe and radiating. It arises immediately when the needle is inserted or withdrawn.
Tendon Injury	Injury of a tendon by the needle. Symptom is severe local non-radiating pain initiating immediately when the needle is inserted.
Painful Arm	Cases characterised mainly by severe local and radiating pain in the arm used for the donation and arising during or within hours following donation, but without further details to permit classification in one of the already more specific categories mentioned above.
Other kinds of categories with local symptoms	
Adverse Event	Definition
Thrombophlebitis	Inflammation in a vein associated with a thrombus. Symptoms are warmth, tenderness, local pain, redness and swelling. Thrombophlebitis in a superficial vein gives rise to a subcutaneous red, hard and tender cord. Thrombophlebitis in a deep vein gives more severe symptoms and may be associated with fever.
Allergy (local)	Allergic type skin reaction at the venipuncture site caused by allergens in solutions used for disinfection of the arm or allergens from the needle. Symptoms are rash, swelling and itching at venipuncture site.

15. Donor Vigilance (continued)

Complications mainly with generalised symptoms.	
Vasovagal reaction	
Adverse Event	**Definition**
Vasovagal Reaction (Faint)	A vasovagal reaction is a general feeling of discomfort and weakness with anxiety, dizziness and nausea, which may progress to loss of consciousness (faint). Most give only minor symptoms, but a few have a more severe course with symptoms like loss of consciousness and convulsions or incontinence. Symptoms are discomfort, weakness, anxiety, dizziness, nausea, sweating, vomiting, pallor, hyperventilation, convulsions, and loss of consciousness. 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.
Immediate Vasovagal Reaction	Symptoms occur before donor leaves the donation site.
Immediate Vasovagal Reaction with Injury	Injury caused by falls or accidents in donors with a vasovagal reaction and unconsciousness before the donors have left the donation site.
Delayed Vasovagal Reaction	Symptoms occur after donor has left the donation site.
Delayed Vasovagal Reaction with Injury	Injury caused by a fall or accident in a donor with a vasovagal reaction and unconsciousness after the donor has left the donation site.
Complications related to apheresis.	
Complications mainly characterised by pain.	
Adverse Event	**Definition**
Citrate Reaction	Symptoms and signs associated with the transient hypocalcaemia caused by citrate. Donors usually present with mild tingling around the mouth and on the lips, metallic taste in the mouth and peripheral paraesthesia. Severe cases are characterised by respiratory difficulty with nausea and vomiting.
Haemolysis	Destruction of the donor's red blood cells.
Generalised Allergic Reaction	The result of an interaction of an allergen with preformed antibodies. Minor allergic reaction: Reaction limited to the skin, with or without a rash. Severe allergic reaction: Reaction with risk to life, characterised by bronchospasm causing hypoxia, or angioedema causing respiratory distress.
Air Embolism	An air-lock that obstructs the outflow of blood from the right ventricle of the heart or air that lodges in the pulmonary or cerebral vasculature. Air may gain access to the circulation as a result of surgery, injury or intra-venous infusion.

15. Donor Vigilance (continued)

In 2015, a total of 993 717 blood products were collected by the SANBS and the WPBTS combined as shown in table 15.1. The SANBS contributed 84% and the WPBTS 16% of all collections which remained the same since 2013.

15.3 Summary of Collections and Donor Adverse Events 2015

Table 15.3.1 Collections

Collections 2015	SANBS	WPBTS	Total
Whole Blood	810	160 577	**971 046**
Apheresis Red Cells	3 802	0	**3 802**
Apheresis Platelets	14 208	2 687	**11 964**
Plasma	1 964	0	**2 202**
Totals	**830 443**	**163 274**	**993 717**

The SANBS collections were undertaken at **78 permanent** collection centres, approximately **71 mobile blood collection teams** and **14** fixed site apheresis collection centres.

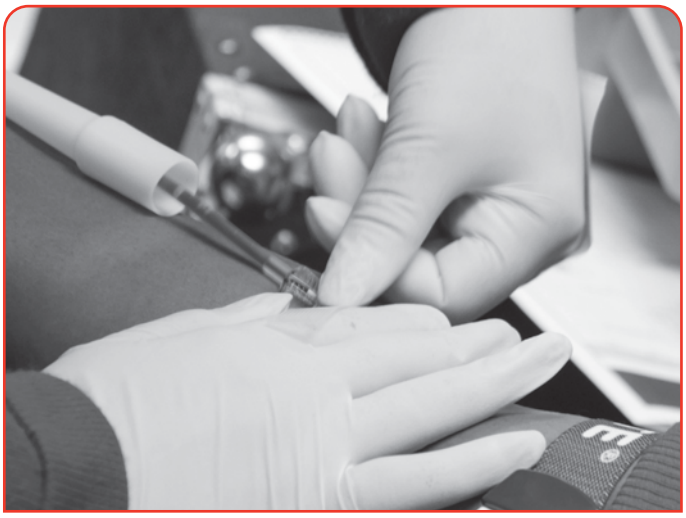
The WPBTS collection sites are located at **3** regional branches, (in Paarl, Worcester and George), **3** fixed site blood donor centres, **7** mobile units and an apheresis and autologous/ designated donation unit at the Head Quarters in Pinelands.

15. Donor Vigilance (continued)

15.3.2 Donor Adverse Events By Donation Type

Acute Reactions	Whole Blood	Apheresis	Unallocated	Totals
Haematoma	346	209	19	**574**
Arterial Puncture	1	0	0	**1**
Delayed Bleeding	16	1	0	**17**
Nerve Irritation	7	0	1	**8**
Tendon Injury	1	0	0	**1**
Nerve Injury	0	0	0	**0**
Painful Arm	96	23	2	**121**
Total Local Symptoms	**467**	**233**	**22**	**722**
Faint Immediate Type	2 333	33	12	**2 378**
Faint Immediate, Accident	59	3	1	**63**
Faint Delayed Type	537	6	12	**555**
Faint Delayed, Accident	45	0	4	**49**
Total no. Vasovagal Reactions	**2 974**	**42**	**29**	**3 045**
Citrate Reaction	0	33	0	**33**
Haemolysis	0	1	0	**1**
Generalised Allergic Reaction	1	1	1	**3**
Embolism	0	0	0	**0**
Others	0	0	0	**0**
Total	**1**	**35**	**1**	**37**
Grand Total	**3 442**	**310**	**52**	**3 804**

15. Donor Vigilance (continued)



In 2015, all donor adverse events reported contributed 0.38% (3 804 out of 993 717) of total collections compared to 3 520 in 2014. The adverse events have been categorised into whole blood, apheresis and unallocated donations. The main concern is with the unallocated category i.e. those that do not fall into either whole blood or apheresis donations. This indicates that the staff does not accurately capture/classify donor adverse events (DAE) according to donation type and strategies are being implemented to ensure correct capturing.

Based on tables 15.3.1 and 15.3.2, percentage of DAE from whole blood collections was 0.35% (3442/971046) and 1.5% from apheresis collections (310/20707).

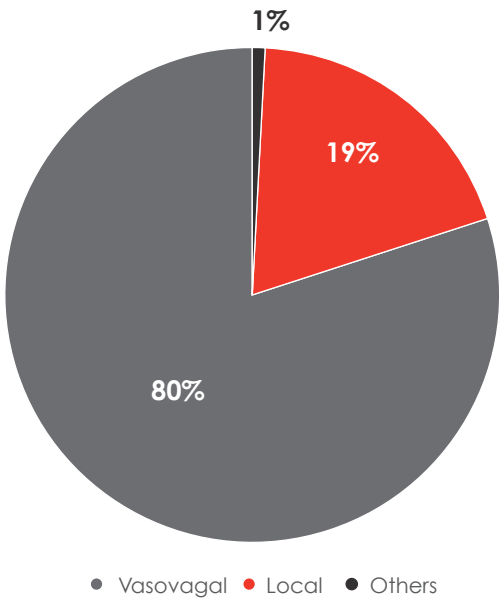
Table 15.3.3 Donor adverse events according to broad categories

	Local Symptoms	Vasovagal	Others	Total
SANBS	474	1 247	36	**1 757**
WPBTS	248	1 798	1	**2 047**
Total	**722**	**3 045**	**37**	**3 804**

The majority of donor adverse reactions were vasovagal (80.0%), local symptoms (19.0%) and others (1.0%) as shown in table 15.1.1 and figure 5. Of the vasovagal reactions, 96% were attributable to faints without accidents and 4% faints with accidents. Even though the majority of vasovagal events are without accidents, all events must be managed immediately and effectively by all staff involved.

In the local symptoms category, 80% events were due to haematomas followed by 17% of painful arm cases. Studies have shown that retention in donors who have had DAE is a challenge. Efforts to reduce the occurrences are investigated and controls must be in place to minimise all events.

Figure 5: Percentage Donor Adverse Events 2015



15. Donor Vigilance (continued)

Table 15.3.4 Analysis of Adverse Events by Severity

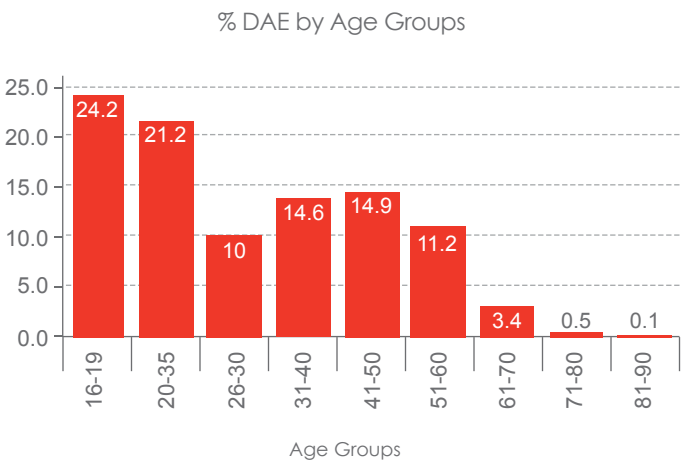
	Severity	Mild	Moderate	Severe	Subtotal
Local Adverse Events	Haematoma	561	51	7	**574**
	Arterial Puncture	0	1	0	**1**
	Delayed Bleeding	14	2	1	**17**
	Nerve Irritation	4	3	1	**8**
	Tendon Injury	1	0	0	**1**
	Nerve Injury	0	0	0	**0**
	Painful Arm	86	28	7	**121**
	Total Local Symptoms	**621**	**85**	**16**	**722**
Vasovagal	Faint Immediate Type	2 092	201	85	**2 738**
	Faint Immediate, Accident	42	17	4	**63**
	Faint Delayed Type	420	102	33	**555**
	Faint Delayed, Accident	27	11	11	**49**
	Total no. Vasovagal Reactions	**2 581**	**331**	**133**	**3 045**
Others	Citrate Reaction	31	1	1	**33**
	Haemolysis	1	0	0	**0**
	Generalised Allergic Reaction	1	1	1	**3**
	Embolism	0	0	0	**0**
	Others	0	0	0	**0**
	Total	**33**	**2**	**2**	**37**
	Grand Total	**3 235**	**418**	**151**	**3 804**

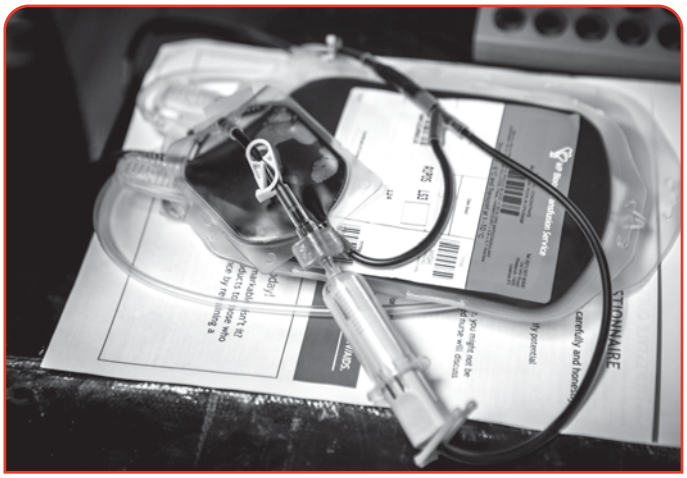
15. Donor Vigilance (continued)

15.4 Analysis of Adverse Events by Age group

As shown in figure 6 below, donors 16-19 years had the most donor adverse events at 24.2% followed by donors 20-25 years at 21.2%, 41-50 years at 14.9%, followed by 31-40 years at 14.6%, then 51-60 years at 11.2%, donors 26-30 years at 10%, 61-70 years at 3.4% and the elderly group above 71+ years had the least events at 0.6%. The results are similar for the past 5 years.

Figure 6





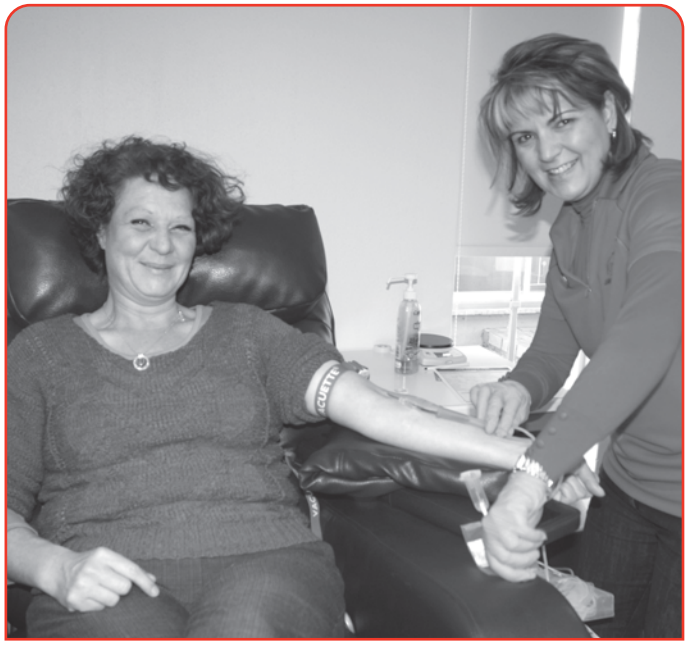
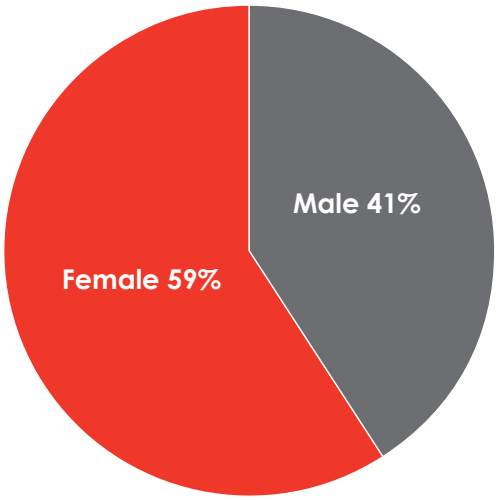


Figure 7 below illustrates that 59% of females had donor adverse events as compared to 41% of males. The finding is in keeping with literature that females are more prone to reactions than males.

Figure 7



International Corner

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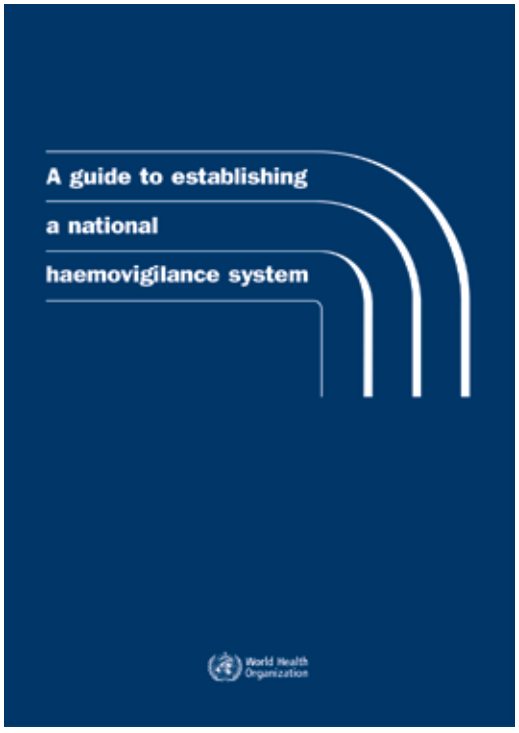
16. International Corner

16.1 International Haemovigilance participation

SANBS continues to be an active member of the International Haemovigilance Network (IHN) and SANBS staff attended and presented at the Annual Haemovigilance Seminar held in Paris on the 9th to the 11th March 2016. The top issues that were presented on were iron deficiency amongst blood donors, human factors and transfusion errors, Ebola outbreaks and the blood transfusion setting and; pathogen inactivation. It became evident that all countries experience similar challenges only at different magnitudes.

16.2 World health Organisation (WHO) Haemovigilance guidelines

The document that SANBS participated in its drafting, has now been published and is on the WHO website: "A guide to establishing a national haemovigilance system" www.who.int/bloodsafety/haemovigilance/haemovigilance-guide/en/. Language editions in French, Portuguese and Russian are being developed and should be published soon.



Conclusion

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17. Conclusion

The WPBTS and the SANBS are committed to continue ensuring blood safety, supporting healthcare givers when reporting transfusion adverse events, investigating and identifying system failures and; identifying processes which will prevent recurrence.

Collaborations and enforcement by the Department of Health towards hospitals in performing postmortems and submitting the required post-transfusion samples will assist the blood services in confirming or excluding transfusion-related mortalities reported.

Haemovigilance will continuously highlight and educate the healthcare providers on the importance of monitoring, evaluating and reporting of transfusion adverse events. Human error rates remain a concern that all parties involved need to address along with the appropriate management of patients that experience adverse events.

Ongoing surveillance and review of donor adverse events is vital and enables the blood services to monitor and minimise risks related to blood donation and implement corrective systems. The blood services aim for continuous improvement in an environment that is not perfect.

References

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Notes