

Haemovigilance Report 2014



WP Blood Transfusion Service
Do something remarkable



SANBS
South African National Blood Service

Haemovigilance Report 2014

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.

List of Authors & Contributors

Compiled by:

- **Dr Neo Moleli**
Lead Consultant Donor Services and Haemovigilance
- **Sr Francis Ledwaba**
National Haemovigilance Officer
- **Dr Tshilidzi Muthivhi**
Research & Development Specialist

Contributors:

- **Dr Charlotte Ingram** (Medical Director SANBS)
- **Dr Gregory Bellairs** (Medical Director WPBTS)
- **Dr Caroline Hilton** (Transfusion Medical Doctor WPBTS)
- **Dr Karin van den Berg** (Medical Officer Eastern Cape SANBS)
- **Dr Ute Jentsch** (Lead Consultant Virology/Pathology & Education SANBS)
- **Sr Cindy Sims** (Specialised Donation Professional Nurse WPBTS)
- **Sr Kim Strutt** (Clinic Co-coordinator WPBTS)
- **Vangie Walker** (National TTI Lookback Officer SANBS)
- **Medical Officers** (SANBS)
- **Marion Vermeulen** (National Manager Donation Testing SANBS)
- **Michael Lennards** (National Manager Processing & Issuing)
- **Moses Moloi** (Laboratory Supervisor Red Cell Serology)
- **Kuben Vather** (Specialised Laboratory Services Manager SANBS)
- **Angie Moloi** (Red cell Supervisor SANBS)
- **Red cell serology staff** (SANBS)
- **Truscha Niekerk** (National Manager: Quality Control SANBS)
- **Xoliswa Mpumlwana** (Quality Control Specialist SANBS)
- **Anna Raselomane** (Graphic Design & Multimedia Specialist SANBS)

Acknowledgements

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

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

Contact Details

National Haemovigilance Office
South African National Blood Service
Private Bag X14
Weltevreden Park
1715
Telephone: +27 11 761 9371
Website: www.sanbs.org.za

ISBN 978-0-620-64607-9

UK English has been used in this report.

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

Design & Layout: Chapter 3 - Design & Advertising
tania@chapter3.co.za

Table of Contents

Abbreviations

Classifications and Definitions

Chapter 1 | 12 |

Foreword and message from the Medical directors

Chapter 2 | 14 |

Executive summary

2.1 Blood product issues and usage data

2.2 Collections and issues

2.3 Hospital participation

2.3 Summary of transfusion adverse events

2.4 Summary of platelet bacterial testing

2.5 Summary of donor adverse events

Chapter 3 | 17 |

Introduction

3.1 Previous reports into transfusion safety and quality in South Africa

3.2 Haemovigilance Project Working Groups (IHN) progress and achievements to date

Chapter 4 | 19 |

Overview of Product Issues

Chapter 5 | 21 |

Transfusion Adverse Reactions

Chapter 6 | 25 |

Acute Transfusion Reactions: Case Discussions

Acute Haemolytic Transfusion Reactions

Allergic Transfusion Reactions

Anaphylactic Transfusion Reactions

Transfusion Related Acute Lung Injury

Transfusion Associated Circulatory Overload

Transfusion Associated Dyspnoea

Febrile Non-Haemolytic transfusion reaction

Hypotensive Reactions

Unclassifiable Reactions

Chapter 7 | 29 |

Incorrect Blood Components Transfused (IBCT)

Misdirected transfusions

Misidentification

Table of Contents continued

Chapter 8 Near Miss Events	32
Chapter 9 Delayed Transfusion Reactions: Case Discussion	32
Chapter 10 Post Transfusion Purpura (PTP)	32
Chapter 11 Transfusion Associated Graft versus Host Disease (TA-GvHD)	32
Chapter 12 Mortality Cases	34
Chapter 13 Lookback Programme	39
Chapter 14 Platelets Bacterial Testing	42
Chapter 15 Donor Vigilance Introduction Classification Summary of Adverse Events 2013 Analysis of Adverse Events by Donation Type Analysis of Adverse Events by Severity Analysis of Adverse Events by Age Groups Donor care and health - Iron study	45
Chapter 16 International Corner	55
Chapter 17 Conclusion	57
Chapter 18 References	59

Abbreviations



WP Blood Transfusion Service
Do something remarkable



SANBS
South African National Blood Service

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



WP Blood Transfusion Service
Do something remarkable



SANBS
South African National Blood Service

Transfusion Reaction Classification & 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, pruritis, 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: <ul style="list-style-type: none"> • Acute respiratory distress. • Tachycardia. • Increased blood pressure. • Acute or worsening pulmonary oedema. • Evidence of positive fluid balance.
Transfusion Related Acute Lung Injury	Acute hypoxemia with PaO ₂ fraction of inspired oxygen [FIO ₂] ratio of 300 mm 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 Classification & Definitions

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 $>39^{\circ}\text{C}$ or equivalent or a change of $>2^{\circ}\text{C}$ from pre-transfusion value with or without minor rigors and chills but without haemolysis or features of an allergic reaction. The patient may have one or more of myalgia, nausea, changes in blood pressure or hypoxia. The most common cause is a reaction to passively transfused cytokines or a reaction to recipient antibodies and leukocytes in the donor's blood.
Delayed Transfusion Reactions	Transfusion related reactions that occur after 24 hours following a transfusion of blood or components.
Delayed Haemolytic Transfusion Reactions	The recipient develops antibodies to 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 Classification & Definitions

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. <i>It may or may not have led to an adverse reaction.</i>
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: <ul style="list-style-type: none"> • May be the result of an incident, or • An interaction between a recipient and blood.

Foreword



WP Blood Transfusion Service
Do something remarkable



SANBS
South African National Blood Service

1. Foreword - Message from the Medical Directors



Dr Charlotte Ingram
National Medical Director | SANBS



Dr Greg Bellairs
Director/CEO | WPBTS

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

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 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 is an effort to improve donor care by tracking all adverse events associated with blood donation.

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 2014 Haemovigilance Report.

The principal objectives of this report are:

- To supply national data on the adverse events reported during 2014:
- Adverse reactions associated with transfusion,
- Data on serious adverse reactions associated with blood donation,
- To analyse the frequency of events (patient related and donor related) over the period from 2008 to 2014 (overall and per diagnosis); and
- To pinpoint the issues requiring further analysis.

Executive Summary

2014



WP Blood Transfusion Service
Do something remarkable



SANBS
South African National Blood Service

2. Executive Summary 2014

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 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.

This is the fifteenth annual national Haemovigilance Report. It provides 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 is compiled from data gathered between January and December 2014, by the two services providing blood transfusion in South Africa, i.e. the SANBS and the WPBTS.

2.1 Collections:

A total of **967 272** units of blood were collected by the two services and separated into various blood products. There was no increase in total collections by both services between 2013 and 2014.

2.2 Blood product issues and usage data:

There were 1 152 836 components of blood products issued in South Africa in 2014. Red blood cells (RBC) products accounted for about 80% of all products issued. The demand for blood products has been increasing over the last few years, issued blood products increased from 1 069 407 in 2012, 1 133 204 in 2013 to 1 152 836 in 2014 (2% increase).

2.3 Hospital participation:

In 2014, **222** of the 749 (30%) healthcare facilities in South Africa that we service reported transfusion adverse events to the Haemovigilance office. The participation remained at $\pm 26\%$ between 2012 and 2013 but increased to $\pm 30\%$ in 2014 which indicates that the education provided to healthcare workers seems to 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 963 adverse events reported to the National Haemovigilance Programme for 2014. The number of reports received decreased by 7.05% from 1 036 in 2013 to 963 in 2014 despite the intensified training conducted country wide.

The most frequently reported adverse events were febrile non-haemolytic transfusion reactions (FNHTR) and allergic reactions (including minor, severe and anaphylactic), representing 36% and 32% of all reports respectively. Other significant adverse reactions reported included 80 accounts of transfusion associated dyspnoea (TAD) cases and 57 hypotensive reaction cases representing 8% and 6% of all reports respectively.

A total of **35 (3.6% of all transfusion reactions)** cases of incorrect blood component transfused (IBCT) were reported with errors originating from both the hospitals and the blood banks. The UK SHOT 2014 report recorded errors to have contributed 77.8% of all transfusion reactions¹. The UK includes under errors, any mistake occurring within the process i.e. avoidable, delayed or under-transfusions, handling and storage errors, Anti-D immunoglobulin errors and incorrect blood components transfused, thus the high percentage.

Sixteen cases of mortalities were reported with only 9 classified as potentially transfusion related fatalities. This translates to an estimated risk of death from transfusion to be 1 in 128 205 components issued, a 30% increase compared to 1 in 167 000 in 2013. However, in all the 16 cases, no case was confirmed indicating transfusion as a definitive cause of death, since no post transfusion samples were obtained and no post mortem performed on the deceased patients.

The risk of death from transfusion as estimated from SHOT data in 2012 is 1 in 322 580 components issued and 1 in 357 143 reported by FDA in 2013.^{2,3}

No cases of confirmed transfusion transmitted Hepatitis B, Hepatitis C or malaria infections were reported in 2014. SANBS implemented Individual donation Nucleic acid testing (ID-NAT) in October 2005 and has subsequently screened approximately 7,5 million donations using this state of the art technology. During this period 14 202 donations have tested confirmed HIV positive of which 440 were only detected by ID-NAT. One breakthrough HIV infection has been reported during the period.

Ninety nine cases remained unclassified due to lack of sufficient transfusion reaction data.

2. Executive Summary 2014 continued

2.5 Summary of testing platelets for bacterial contamination (SANBS data only):

Of the 24 457 apheresis platelet units collected in 2014, a total of 2 726 (11.1%) were tested for microbial growth and from 41 (1.4%) 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 98.5% of all platelets tested met the required specifications.



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 2014, there were a total 967 272 collections, including 944 058 whole blood collections, 3 929 apheresis red cells; 2 202 plasma collections and 17 083 apheresis platelet donations.

There were 3 520 donor adverse events reported in 2014, a slight decrease from 3 550 reported in 2013. The overall reported ratio of donation-related adverse events was 1: 274 collections in 2014, 1: 272 in 2013, a decrease from 1: 212 reported in 2012 and is attributable to the change in the capturing procedure which needs to be reviewed as it resulted in under-reporting for the SANBS.

Vasovagal events as a category accounted for about 81% of all adverse events, local symptoms accounted for 18.5% and other reactions made up 0.5%.

Introduction



WP Blood Transfusion Service
Do something remarkable



SANBS
South African National Blood Service

3. Introduction

This is the fifteenth 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.

The 2014 report shows that adverse events related to blood transfusion have increased in most of South African hospitals. This is due to an improved collaboration between the South African Blood Services, blood banks, the clinicians and hospital personnel.



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 ISTAR data base 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, 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 is taking 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 for 2014



WP Blood Transfusion Service
Do something remarkable



SANBS
South African National Blood Service

4. Overview of Product Issues for 2014

A collective total of **1 152 836** blood and blood products were issued to patients in South Africa by the two supplying services (SANBS and WPBTS). SANBS issued a total of **981 905 (85%)** while WPBTS issued **170 931 (15%)** units of blood. **There was no change in the issuing statistics between 2013 and 2014.**

The SANBS has 2 donation testing centres (Constantia Kloof and Pinetown), 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 performed at the fractionation plant in Beaconvale, Parow.

Donation testing for both services includes individual donation nucleic acid testing (ID-NAT) for HIV, hepatitis B (HBV) and hepatitis C (HCV); serology (HIV, HBV and HCV) and; syphilis.

Both services provide blood and blood products to \pm 749 hospitals and clinics country wide.

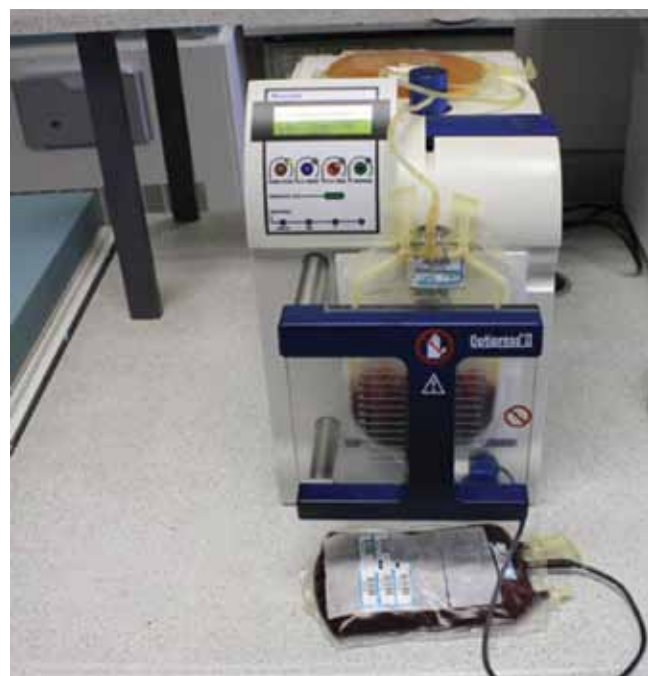
Table 4.1 Component/ Product Issues 2014 (SANBS and WPBTS)

Products	SANBS	WPBTS	Total
Plasma products			
Cryo-Poor Plasma	22 874	2 220	25 094
Fresh Frozen Plasma	117 626	25 176	142 802
Totals	140 500	27 396	167 896
Platelet Products			
Apheresis Platelet	27 951	3 375	31 326
Pooled Platelet	31 3693	5 046	36 415
Total	59 320	8 421	67 741
Red Cell Products			
Paediatric	38 473	3 372	41 845
Red Cells	709 228	129 693	838 921
Reserved	130	0	130
Emergency Units and Ward Stock	31 236	1 872	33 108
Whole Blood	3 018	177	3 195
Total Red Cell Products	782 085	135 114	917 199
Grand Total	981 905	170 347	1 152 836

The percentage (%) difference between collections and usable red cell products units was 3% in 2014 as shown in the Table 4.2 and Figure 1 below.

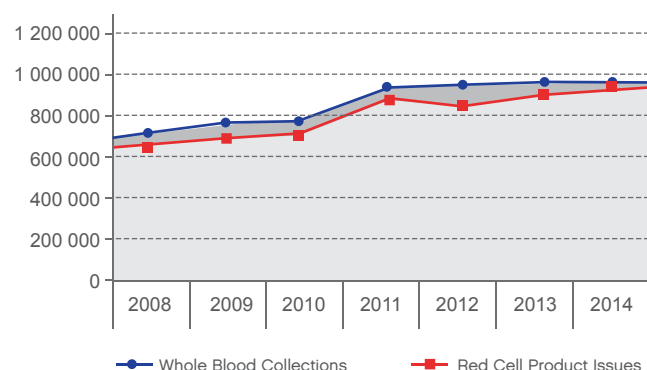
Table 4.2 Collections and Issues (2008-2013)

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



Red cell product issues continued to closely follow whole blood units collected and maintaining a percentage difference of around 3% compared to 7% in 2012 and 2013. The risk margin is narrower i.e. decreased in terms of issuing and collections compared to the previous years.

Figure 1: Collections and Issues (2008-2014)



Transfusion Adverse Events 2014



WP Blood Transfusion Service
Do something remarkable



SANBS
South African National Blood Service

5. Transfusion Adverse Events 2014

5.1 Summary of transfusion adverse events 2014

	Adverse Events	SANBS	WPBTS	South Africa Total
Acute Transfusion Reactions	Acute Haemolytic Transfusion Reactions (AHTR)	9	1	10
	Allergic Reactions	142	86	228
	Severe Allergic Reactions	23	0	23
	Anaphylactic Reactions	31	22	53
	Febrile Non-haemolytic Reactions (FNHTR)	284	63	347
	Transfusion Associated Circulatory Overload (TACO)	3	0	3
	Transfusion Related Acute Lung Injury (TRALI)	2	0	2
	Transfusion Associated Dyspnoea (TAD)	79	1	80
	Hypotensive Reactions	49	8	57
	Unclassifiable (Incomplete Information)	89	7	96
	Unclassifiable (No Forms)	3	0	3
	Total ATR (Acute Transfusion Reactions)	714	188	902
Delayed Transfusion Reactions	Delayed Haemolytic Transfusion Reactions (DHTR)	0	0	0
	Delayed Serological Reactions (DSTR)	0	0	0
Incorrect Blood Component Transfused (IBCT)	ABO + Rh Incompatible Transfusions	11	1	12
	ABO Incompatible Transfusions	7	0	7
	Misdirected Transfusions	10	0	10
	Patient Misidentifications	3	3	6
	Total IBCT	31	4	35
Other Reactions	Near Miss	5	3	8
	Transfusion Associated Graft versus Host Disease (TA-GvHD)	0	0	0
	Transfusion Transmitted Infections	2	0	2
	Post Transfusion Purpura	0	0	0
	Mortality	15	1	16
	Total Other	22	4	26
	GRAND TOTAL	767	196	963

As shown in table 5.1 above, a total of **963** cases were received and analysed by the Haemovigilance offices of both the **SANBS (80%)** and the **WPBTS (20%)** for 2014.

Of the **963**, a total of **347** cases were febrile non-haemolytic transfusion reactions (FNHTR) and they remain the most frequently reported, contributing to about **36.0%** of all reactions.

Allergic reactions were the second most frequently reported reactions with **304** cases (including mild, severe and anaphylactic) accounting for **31.6%** of all reactions.

A total of **80** cases (**8.3%**) of transfusion associated dyspnea (TAD) were received.

Fifty seven cases (**5.9%**) of hypotensive reactions, **35** cases (**3.6%**) of incorrect blood components transfused (IBCT), **16 (0.6%)** mortality cases, **10** cases (**1.0%**) of acute haemolysis, **8 (0.8%)** near miss cases, **2** cases (**0.2%**) of transfusion related acute lung injury (TRALI) one definite and one possible and, **2** cases (**0.2%**) of transfusion transmitted infections (TTI) one HTLV and one HIV were reported to the haemovigilance office.

No "delayed haemolytic transfusion reactions" were reported to the blood transfusion services.

A total of **96** cases (**10.0%**) were unclassifiable due to incomplete information and **3** other cases (**0.6%**) unclassifiable because no transfusion reaction forms were submitted to the office. All **99** cases could not be classified into any definite category but had to be recorded since the patients were transfused and samples sent for investigations.

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 2014 continued

Table 5.2 Rates of transfusion adverse events per classification

Adverse Events		Total number per cases	Rates per 100 000 units issued
Acute Transfusion Reactions	Acute Haemolytic Transfusion Reactions (AHTR)	10	0.9
	Allergic Reactions	228	19.8
	Severe Allergic Reactions	23	2.0
	Anaphylactic Reactions	53	4.6
	Febrile Non-haemolytic Transfusion Reactions (FNHTR)	347	30.1
	Transfusion Associated Circulatory Overload (TACO)	3	0.3
	Transfusion Related Acute Lung Injury (TRALI)	2	0.2
	Transfusion Associated Dyspnoea (TAD)	80	6.9
	Hypotensive Reactions	57	4.9
	Unclassifiable (Incomplete information)	96	8.3
	Unclassifiable (No forms)	3	0.3
Total ATR		902	78.2
Delayed Reactions	Delayed Haemolytic Transfusion Reactions (DHTR)	0	0.0
Total Delayed	Delayed serological reactions (DSTR)	0	0.0
Incorrect Blood Component Transfused (IBCT)	ABO + Rh Incompatible Transfusions	12	1.0
	ABO Incompatible Transfusions	7	0.6
	Misdirected Transfusions	10	0.9
	Patient Misidentifications	6	0.5
Total IBCT		35	3.0
Other Reactions	Near Miss	8	0.7
	Transfusion Associated Graft versus Host Disease (TA-GvHD)	0	0.0
	Transfusion Transmitted Infections	2	0.2
	Post Transfusion Purpura	0	0.0
	Mortality	16	1.4
Total Other		26	2.3
GRAND TOTAL		963	83.5



Table 5.2 shows that in South Africa the rate of all transfusion adverse events reported in 2014 was 83.5 per 100 000 units issued compared to 91.4 per 100 000 in 2013, an increase from 82.20 in 2012. Of all adverse events, ATRs were the most frequently reported at 78.2 per 100 000 units issued and IBCT at 3.0 per 100 000 units issued.

Within the ATR category, the most commonly reported adverse events were FNHTR at a rate of 30.1 per 100 000 units issued, followed by allergic reactions (including mild, severe and anaphylactic) at 26.4 per 100 000 units issued.

5. Transfusion Adverse Events 2014 continued

Table 5.3 and figure 2 below shows that the rates of adverse reactions reported between 2008 and 2014 have increased from 61.3 to 91.4 per 100 000 units issued. This indicates that there is an improvement in the reporting year after year and this could be attributable to various factors including amongst others awareness of haemovigilance created through education of blood users and the establishment and maintenance of hospital transfusion committees.

Table 5.3 Adverse Reaction Rates (2008-2014)

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

Figure 2: Adverse Reactions Rates (2008-2014)

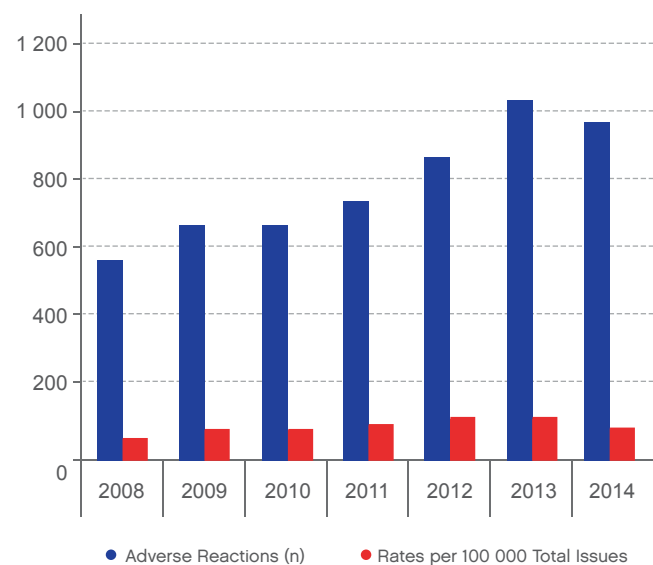


Table 5.4 below shows that over a period of 6 years there has been an increase in the number of reported adverse events. There has been an upward trend in the reporting of ATRs from 566 in 2008 to 994 in 2013. The increase was two-fold for both allergic reactions (188 in 2008 to 361 in 2013) and FNHTR (150 in 2008 to 388 in 2013).

Table 5.4 Acute Transfusion Reactions (2008-2013) (National Data)

Acute Reactions:	2008	2009	2010	2011	2012	2013	2014	Totals
AHTR	13	15	15	1	4	4	10	62
ALLERGIC (INCLUDING SEVERE ALLERGIC)	177	222	231	221	274	297	251	1 673
ANAPHYLACTIC	11	5	6	16	26	64	53	181
TRALI	0	4	1	1	2	1	2	11
TACO	0	3	5	1	0	0	3	12
TAD	64	36	47	71	64	76	80	438
FNHTR	150	229	257	255	360	388	347	1 986
HYPOTENSIVE	25	12	51	54	40	52	57	291
UNCLASSIFIABLE	126	116	97	117	72	112	99	739
Totals	566	642	710	737	842	994	902	5 393

Acute Transfusion Reactions 2014: Case Discussions



WP Blood Transfusion Service
Do something remarkable



SANBS
South African National Blood Service

6. Acute Transfusion Reactions 2014: 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 Transfusion Reactions: Case Discussions

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
13	14	15	1	4	4	10

10 cases of Acute Haemolytic Transfusion Reactions (AHTR) were reported in 2014.

An example of a case is described below.

Case: Acute Haemolytic Transfusion Reactions (AHTR)

- ◆ **A 20 day old male baby diagnosed** with Hyaline membrane disease, Patent Ductus Arteriosus and anaemia.
- ◆ Transfused with 1 unit of paediatric leucodepleted red cells.
- ◆ Immediately after commencing the transfusion the patient developed nausea and vomiting, increase in blood pressure, haemoglobinuria and oliguria.
- ◆ The transfusion was stopped and the patient was managed accordingly and stabilised.
- ◆ **Conclusion:** This case was classified as an acute haemolytic transfusion reaction.

6.2 Allergic Transfusion Reactions

2008	2009	2010	2011	2012	2013	2014
177	221	231	201	274	297	251

251 cases of combined mild and severe allergic reactions were reported in 2014.

An example of a case is described below.

Case: Allergic Reaction

- ◆ **A 9 year old female patient diagnosed** with HIV infection and Aplastic anaemia.
- ◆ Transfused with 1 unit of leucodepleted red cells.
- ◆ Between 1 and 2 hours later the patient had a skin reaction.
- ◆ The transfusion was stopped immediately and the patient was given antihistamines and stabilised.
- ◆ **Conclusion:** This case was classified as an allergic reaction.

6.3 Anaphylactic Transfusion Reactions

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

53 cases of anaphylactic reactions were reported in 2014.

An example of a case is described below.

Case: Anaphylactic reactions

- ◆ **A 51 year old female patient presented** with Red Cell Aplasia and severe anaemia, Hb of 3.2 g/dl.
- ◆ Four units of red cells were ordered and issued.
- ◆ 1-2 hours into the transfusion, with about 350 ml of product transfused, the patient experienced flushing/sweating, tachycardia, nausea/vomiting, dyspnoea, bronchospasm, a drop in blood pressure, fever, oliguria and collapsed.
- ◆ The transfusion was immediately stopped, Phenergan® and Solucortef® given and the patient stabilised.
- ◆ **Conclusion:** This case was classified as an Anaphylactic Reaction.

6. Acute Transfusion Reactions 2014: Case Discussions

6.4 Transfusion Related Acute Lung Injury (TRALI)

Transfusion Related Acute Lung Injury (**TRALI**) is characterised by pulmonary edema, 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
0	1	1	1	2	1	2

2 cases of possible TRALI were reported in 2014.

An example of a potential case is described below.

Case: TRALI Case Study

- ◆ **An 11 year old male patient** with Nasopharyngeal Cancer and Thrombocytopenia, platelet count of $41 \times 10^9/L$
- ◆ Two units of apheresis platelets were ordered and issued.
- ◆ After about 253 ml were transfused, the patient experienced dyspnoea and tachycardia.
- ◆ The transfusion was stopped; Phenergan®, hydrocortisone and oxygen were administered.
- ◆ Chest x-rays were done but results were not available for SANBS. Post transfusion samples were taken and forwarded to the blood bank for investigation as the treating physician suspected TRALI.
- ◆ The donor and patient samples were sent for HLA antibody testing.
- ◆ Donor: The results showed multiple weak antibodies to Class 1, Human Leucocyte Antigens (HLA) and anti- Cw17 detected in platelets.
- ◆ Patient: The sample results had corresponding HLA Class 1 antigens to the Human Leucocyte Antigens (HLA) and Cw17 antigens were detected in the donor platelets.
- ◆ **Conclusion:** This case was classified as a potential Transfusion Related Acute Lung Injury.

6.5 Transfusion Associated Circulatory Overload (TACO)

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

3 cases of Transfusion associated circulatory overload were reported in 2014.



An example of a case is described below.

Case: Transfusion Associated Circulatory Overload (TACO)

- ◆ **A 63 year old female diagnosed** with cardiac failure and severe iron deficiency anaemia.
- ◆ Three units of red cells were ordered and issued.
- ◆ More than 6 hours later the patient presented with dyspnoea, flushing/sweating, tachycardia, cyanosis, a decrease in oxygen saturation and an increase in blood pressure.
- ◆ The transfusion was stopped and the patient given oxygen, Lasix® and Paracetamol.
- ◆ The physician indicated that slight pulmonary oedema was observed on chest x-rays and since the patient responded well to Lasix, TRALI was excluded.
- ◆ He confirmed the transfusion reaction to being a Transfusion Associated Circulatory Overload (TACO).
- ◆ **Conclusion:** This case was classified as TACO.

6. Acute Transfusion Reactions 2014: Case Discussions

6.6 Transfusion Associated Dyspnoea (TAD)

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

There were **80 cases** of TAD reported in 2014.

An example of a case is described below.

Case: Transfusion Associated Dyspnoea

- ◆ **A 48 year old man presented** to hospital with epistaxis.
- ◆ Transfused with 1 unit of red cells.
- ◆ He developed sweating, flushing, hyperventilation and desaturated following the start of the transfusion (no allergic nor anaphylactic symptoms were reported).
- ◆ The symptoms ceased soon after the transfusion was stopped and an x-ray was not performed
- ◆ **Conclusion:** The case was classified as transfusion-associated dyspnoea.

6.7 Febrile Non-Haemolytic Transfusion Reactions (FNHTR)

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

347 cases of Febrile Non-Haemolytic transfusion reactions (FNHTR) were reported in 2014.

An example of a case is described below.

Case: Febrile Non-Haemolytic transfusion reaction (FNHTR) (JTR 501)

- ◆ **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 156 bpm, rigors, increased blood pressure of 214/96 mmHg and a decrease in oxygen saturation.
- ◆ The transfusion was stopped; Solucortef® 100 mg and Paracetamol were given and the patient stabilised.
- ◆ Blood culture tests and a chest x-ray were done but results are not available.

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

6.8 Hypotensive Reactions

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

57 cases of Hypotensive reactions were reported in 2014.

An example of a case is described below.

Case: Hypotensive reaction JTR 412

- ◆ **A 24 year old male patient diagnosed** with disseminated Tuberculosis and symptomatic anaemia.
- ◆ Transfused with 1 unit of red cells.
- ◆ In less than an hour with about 30 ml transfused, the patient presented with a sudden drop in blood pressure to 90/50 mmHg, flushing/sweating and dyspnoea.
- ◆ Oxygen 40 percent; Phenergan® 25 mg and Voluven® were administered.
- ◆ **Conclusion:** This case was classified as a hypotensive reaction.



6.9 Unclassifiable Reactions

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

There were **99 cases** of Unclassifiable Reactions in 2014 **due to lack of sufficient transfusion reaction data submitted.**

Incorrect Blood Components Transfused (IBCT): Case Discussions



WP Blood Transfusion Service
Do something remarkable



SANBS
South African National Blood Service

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

Incorrect Blood Components Transfused (IBCT): Case Discussions

- ♦ Incorrect blood components transfused and ABO Incompatible units: **19 cases**
- ♦ Misdirected Transfusions **10 cases**
- ♦ Patient Misidentification **6 cases**

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

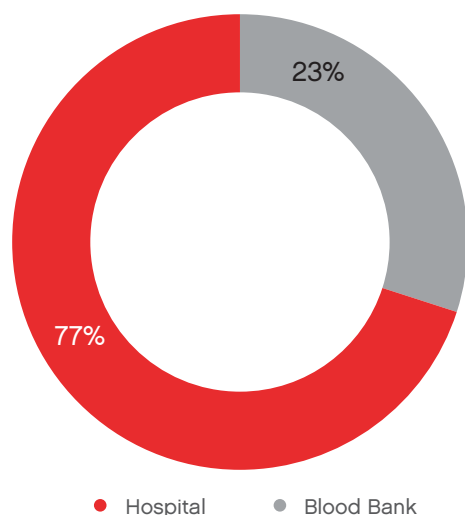
2008	2009	2010	2011	2012	2013	2014
31	36	10	22	26	35	35

There were **35 cases** captured in 2014. These cases include categories of ABO and Rh incompatible transfusions, ABO incompatible transfusions, Misdirected transfusions and Patient misidentifications.

The personnel involved in these errors were:

Type of Error	Personnel Involved	Number of Cases	Percentage (%)
Incompatible blood issued/	Blood Bank Technicians Blood Bank errors.	8	23%
Patient Misidentification at Transfusion (Bedside/Theatre)	Clinical Staff (Doctors and Nurses) Hospital errors	27	77%
Total ATR		35	100%

Of the 35 errors reported 8 cases were committed in the blood bank and 27 cases in the hospitals. Of the 8 errors committed in the blood bank, 6 cases were due to serological incompatibilities, 2 cases were due to ABO incompatibilities. No cases of Rh incompatibilities were reported.



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. The first blood bank will be automated in October 2015 in a phased-in approach.

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.

The WPBTS has already fully implemented blood bank automation and that explains why they had only one blood bank error in 2014.

Of the 27 hospital errors that occurred, 4 cases were due to sample collection errors and the other 23 were due to wrong units transfused to wrong patients.

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 the UK SHOT 2013 report¹, "the most dangerous steps in transfusion practice 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?

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

Other interventions recommended between transfusion services and hospitals include:

- ◆ Collaboration between blood transfusion service and the hospitals where there's an easier end-to-end view of the blood value chain.
- ◆ Assist hospitals in drafting and implementing policies on the use and management of blood and blood products.
- ◆ Internal training of blood bank staff to ensure prevention of errors.
- ◆ The Blood Transfusion Service to continue providing transfusion education and support to hospitals.

An example of an ABO incompatible case is outlined below. This case was a clerical error in the blood bank where a blood unit was dispatched to a wrong patient with an identical surname.



Incorrect Blood Component Transfused (IBCT No reaction): Blood bank Error Case Study

- ◆ Red cell concentrates were ordered for two different patients in the same ward with the same surname
Patient 1 – **Group O Positive**
Patient 2 – **Group A Positive**
- ◆ A porter came to collect the unit of blood for Patient 2, but the blood bank staff member erroneously issued the blood cross-matched for Patient 1.
- ◆ The requesting doctor came to collect the blood for Patient 1 shortly thereafter and the mistake was detected by the blood bank staff before issuing to the doctor.
- ◆ The ward was contacted immediately and instructed to stop the transfusion for Patient 2 (about 50 ml had already been transfused).
- ◆ No adverse symptoms were reported as Patient 2 had received a compatible blood type (O Positive blood crossmatched for Patient 1)
- ◆ **Conclusion:** This was classified as an incorrect blood component transfused.

7.2 Misdirected transfusions:

An example of a misdirected transfusion case is outlined below:

Case study: Misdirected Transfusion – Hospital error

- ◆ A 26 year old female (patient 1).
- ◆ Admitted for an incomplete abortion with haemoglobin of 6.9 g/dl.
- ◆ A crossmatch request was received by the blood bank for two units of red cells.
- ◆ The blood specimen was typed Group O, Rh Positive.
- ◆ **Three units of Group O Rh Positive blood were cross matched and deemed to be compatible.**
- ◆ Two of these units were issued to patient 1.
- ◆ Later on the same day, a crossmatch request was received, at the same blood bank for a different patient (patient 2).
- ◆ Patient 2 had a similar surname and blood group as patient 1.
- ◆ Two units of Group O, Rh Positive blood were cross matched and deemed to be compatible and were issued to patient 2.
- ◆ The following day, the blood bank was notified of a misdirected transfusion.
- ◆ The one unit that was initially issued for patient 2 was mistakenly, partially transfused to patient 1.
- ◆ A post transfusion sample from patient 1, the partially transfused unit of blood as well as a transfusion reaction form were received by the blood bank for investigation.
- ◆ No untoward reaction was noted in patient 1 as reported by the healthcare worker, following the misdirected transfusion.
- ◆ A preliminary transfusion reaction investigation was performed by the blood bank.

Patient 1

- ◆ Blood typing testing performed on patient 1's pre and post transfusion samples confirmed the patient was partially transfused with a Group O, Rh Positive.
- ◆ No serological incompatibility was found and the results were as follows:

Pre transfusion specimen:

- ◆ Direct Antiglobulin Test was Negative
- ◆ Irregular antibody screen : Negative

Post transfusion specimen:

- ◆ Direct Antiglobulin Test was Negative
- ◆ Irregular antibody screen : Negative

Blood Unit:

- ◆ Direct Antiglobulin Test was Negative

Comment: Positive verification of patient identity must be carried out prior to the transfusion of blood or blood products.

- ◆ **Conclusion:** This case was classified as a Misdirected transfusion.

Near Miss Events

**Delayed Haemolytic
Transfusion Reactions (DHTR)**

Post Transfusion Purpura (PTP)

**Transfusion Associated Graft
versus Host Disease (TA-GvHD)**



WP Blood Transfusion Service
Do something remarkable



SANBS
South African National Blood Service

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 recognised before the transfusion took place.

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

The 8 Near miss cases for 2014 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.

Near miss Case Study

- ◆ A crossmatch sample was received in the blood bank for Patient J who had an upper-gastro intestinal bleed.
- ◆ The sample was grouped as **AB Group Rh Positive**.
- ◆ Patient J had previously received blood in 2006 and the database had record of him being **A Group Rh Positive**.
- ◆ The requesting doctor did not include his contact details on the form, so the ward staff nurse was contacted to provide another crossmatch sample for Patient J.
- ◆ The second specimen received confirmed that he was type **A Group Rh Positive** and the correct blood group unit was issued.
- ◆ **Conclusion:** This is an example of a near miss incident where incompatible blood may have been issued to a patient had the error not been detected by previous blood bank records.

9. Delayed Haemolytic Transfusion Reactions (DHTR)

9.1 Delayed Haemolytic Transfusion Reactions (DHTR)

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

- ◆ There were no cases of Delayed Haemolytic Transfusion Reactions (DHTR) reported in 2014.

10. Post Transfusion Purpura (PTP)

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

- ◆ There were no cases of Post Transfusion Purpura (PTP) reported in 2014.

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

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

- ◆ There were no cases of Transfusion Associated Graft versus Host Disease (TA-GvHD) reported in 2014.



Mortality Reports

2014



WP Blood Transfusion Service
Do something remarkable



SANBS
South African National Blood Service

12. Mortality Reports 2014

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

Relation to the transfusion was inconclusive.

There were **16** reported cases of patient mortality forwarded to the blood services following transfusions in 2014. In 7 cases transfusion was excluded as a cause of death, in 7 cases transfusion was a possible cause and, in the other 2 cases transfusion classified as a contributing factor to the death.

It is important to note that if no post transfusion samples are forwarded to the blood service and no post mortem 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 post mortems be done on all mortality cases.

A brief description of the 16 Mortality reports:

Case 1:

- 2 month old male patient with jaundice required exchange transfusion.
- O Positive unit was used for exchange transfusion.
- Patient experienced dyspnoea, cyanosis, a decrease in oxygen saturation, a drop in blood pressure, was resuscitated without a response and demised.
- Findings: Calcium gluconate was introduced into the blood product that led to haemolysis and raised potassium levels. Blood gas results showed increased potassium levels.
- Red Cell Serology (RCS) Results: No serological incompatibility.
- Comment:** No post transfusion specimens were submitted and no post mortem conducted.
- Conclusion:** Transfusion was excluded as a cause.

Case 2:

- 73 year old female patient with Abdominal Aortic Aneurysm and anaemia, Haemoglobin level of 7.3g/dl.
- Transfused with 1 unit of Group B, Rh Negative Red Blood Cells.
- After about 150 ml were transfused, the patient experienced nausea/vomiting, dyspnoea and collapsed.
- Patient passed away a few hours post transfusion.
- Blood bank was informed the following day about patient's demise.
- Red Cell Serology results: No serological incompatibility demonstrable.
- Comment:** No post transfusion samples forwarded and no post mortem conducted.
- Conclusion:** Transfusion was a possible contributing factor but not a definite cause.

Case 3:

- 44 year old female patient with Pneumonia and anaemia, haemoglobin of 6.7 g/dl.
- Transfused with 2 B Positive red cell units.
- Incident: patient started gasping halfway into the second unit as was reported by the ward personnel, resuscitated without response and demised.
- Red Cell Serology results: No serological incompatibility demonstrable.
- Comment:** No post transfusion sample forwarded to the blood bank and no post mortem conducted. The treating doctor indicated that the demise was not due to transfusion but the underlying condition.
- Conclusion:** Transfusion was excluded as a cause.

12. Mortality Reports 2014 continued

Case 4:

- ◆ **21 year old female** patient with anaemia in pregnancy, Hb 5.8g/dl
- ◆ 3 units B Positive red cells ordered and issued.
- ◆ After about 150 ml transfused, the patient experienced tachycardia, flushing/sweating, skin reactions, dyspnoea, bronchospasm, a decrease in oxygen saturation, a drop in blood pressure, rigors, collapse, oliguria/anuria and back pain.
- ◆ The blood bank was informed 3 days later of the transfusion reaction and the demise of the patient.
- ◆ The transfused pack and post transfusion samples were not forwarded to the blood bank and no post mortem was conducted.
- ◆ Red Cell Serology Results: No serological incompatibility demonstrable.

◆ **Conclusion:** Transfusion was a possible contributing factor but not a definite cause.

Case 5:

- ◆ **A 4 year old male** patient with leukaemia and anaemia.
- ◆ Transfused with 1 unit B Positive leucodepleted red cells.
- ◆ The patient experienced nausea and vomiting.
- ◆ Blood bank was notified of the demise 18 hours post transfusion.
- ◆ Red Cell Serology results: No serological incompatibility demonstrable.
- ◆ **Comment:** No post transfusion samples were forwarded and no post mortem conducted. The treating physician indicated that they were uncertain of the cause of death but suspected transfusion as a possible cause of the death.
- ◆ **Conclusion:** Transfusion was a possible contributing factor but not a definite cause.

Case 6:

- ◆ **61 year old female** with fractured humerus and anaemia.
- ◆ Transfused with 2 units O Positive red cells.
- ◆ The doctor reported that during transfusion, while under anaesthesia in theatre the patient had arrhythmias and high potassium levels. The patient was transferred to another hospital for emergency management and care where she passed away on arrival.
- ◆ Red Cell Serology results: No serological incompatibility demonstrable in the pre-transfusion samples.
- ◆ **Comment:** No post transfusion samples were forwarded and no post mortem was conducted.
- ◆ **Conclusion:** Transfusion was a possible contributing factor but not a definite cause.

Case 7:

- ◆ **18 year old female** with leukaemia with pancytopenia.
- ◆ Transfused with 1 unit O Positive leucodepleted and irradiated red cells.
- ◆ After 311 ml transfused the patient had haemoglobinuria and collapsed. The treating physician reported that the patient was resuscitated without a response and demised.
- ◆ The demise was immediately reported to blood bank.
- ◆ **Comment:** The treating physician informed the blood bank that *Clostridium perfringens* had been cultured in the blood. The empty blood pack was forwarded to the Quality Control department for further testing and the results indicated no bacterial growth.
- ◆ Red Cell Serology results: No serological incompatibility.
- ◆ **Comment:** no samples were submitted and no post mortem done.
- ◆ **Conclusion:** Transfusion was a possible cause but could not be confirmed as definite.

12. Mortality Reports 2014 continued

Case 8:

- ◆ **47 year old male** patient with anaemia post bilateral lung transplant.
- ◆ Transfused with 1 unit B Negative red cells.
- ◆ The patient experienced sweating, a decrease in oxygen saturation and a drop in blood pressure.
- ◆ **Comment:** A day later the mortality case was reported to the blood bank by the nursing sister and the treating doctor had 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 post mortem conducted.
- ◆ **Conclusion:** Transfusion was excluded as a cause.

Case 9:

- ◆ **21 year old female** patient with Leukaemia and anaemia.
- ◆ Transfused with 1 unit O Positive red cells.
- ◆ The patient experienced flushing/sweating, tachycardia, increase in blood pressure and collapsed.
- ◆ This case was reported to the blood bank as a normal transfusion reaction for investigation and was later reported that the patient demised.
- ◆ **Comment:** The treating doctor indicated that the death was not related to transfusion.
- ◆ No post transfusion samples were forwarded to the blood bank and no post mortem conducted.
- ◆ **Conclusion:** Transfusion was excluded as a cause.

Case 10:

- ◆ **87 year old female** patient with Cholecystitis for pre-Operative optimisation.
- ◆ Patient had 2 units of FFP ordered and reacted immediately to the 1st unit.
- ◆ The patient experienced tachypnoea and crepitations suggestive of pulmonary oedema.
- ◆ Patient was transferred to ICU, resuscitated without any response and demised.
- ◆ Red Cell Serology results: No serological incompatibility demonstrable on the pre-transfusion samples.
- ◆ No post transfusion samples were forwarded to the blood bank and no post mortem conducted.
- ◆ **Conclusion:** Transfusion is a possible cause but could not be confirmed as definite.

Case 11:

- ◆ **24 year old female** with post-partum haemorrhage, post caesarean section and anaemia.
- ◆ Transfused with 2 units O Positive red cells and 4 units fresh frozen plasma.
- ◆ The patient reacted while in theatre after 1 red cell unit was warmed in hot water and apparently haemolysed.
- ◆ The patient experienced a decrease in oxygen saturations, hypotension, collapsed and was resuscitated in theatre before being transferred to ICU.
- ◆ The doctor reported that patient demised on arrival in ICU.
- ◆ Doctor's report indicated that there was increased potassium (K+) level in the patient's blood sample from laboratory results and he suspected that as possibly being the cause of the patient's demise.
- ◆ **Comment:** No post samples were forwarded to the blood bank and no post mortem conducted to conclude on the possible cause of mortality.
- ◆ **Conclusion:** Transfusion was excluded as a cause.

Case 12:

- ◆ **A 2 year old male** patient with burns for skin graft and acute blood loss.
- ◆ Transfused with 1 unit O Positive red cells.
- ◆ After about 100 ml transfused the patient experienced flushing/sweating, a decrease in oxygen saturation, and a drop in blood pressure and collapsed.
- ◆ Resuscitation was commenced without any response and demised.
- ◆ The doctor's report indicated that there was progressive hyperkalaemia.
- ◆ **Comment:** No post transfusion samples were forwarded to the blood bank and no post mortem conducted to conclude on the possible cause of mortality.
- ◆ **Conclusion:** Transfusion was excluded as a cause.

12. Mortality Reports 2014 continued

Case 13:

- ◆ **A 57 year old male** patient with a bleeding peptic ulcer and anaemia, Hb 4.7g/dl.
- ◆ Transfused with 3 emergency O Positive red cell units.
- ◆ The patient was then taken to theatre due to the acutely bleeding peptic ulcer.
- ◆ Another requisition for 4 units FFP, 9 units cryoprecipitate and 2 units of red cells was later received.
- ◆ The Anaesthetist reported telephonically to the blood bank that the patient passed away in theatre, after resuscitation efforts failed.
- ◆ The doctor informed the blood bank that they suspected the cause of death to be due to TRALI/TACO as the patient developed pulmonary oedema after being transfused with the first unit of Plasma.
- ◆ No post transfusion samples were forwarded to the blood bank and no post mortem conducted to conclude on the possible cause of mortality.
- ◆ **Conclusion:** Transfusion is a contributing factor due to the number of products received but not the cause.

Case 14:

- ◆ **A 10 year old female** patient with acute blood loss.
- ◆ Transfused with 2 units of red cells.
- ◆ After about 150 ml into the second unit the patient experienced cyanosis, dyspnoea, a decrease in oxygen saturation, a drop in blood pressure and collapsed.
- ◆ The doctor's report indicated that the patient was resuscitated for about 26 cycles, for about 60 minutes.
- ◆ The resuscitation was unsuccessful and the patient demised.
- ◆ No post transfusion samples were forwarded to the blood bank and no post mortem conducted to conclude on the possible cause of mortality.
- ◆ **Conclusion:** Transfusion is a possible cause but could not be confirmed as definite.

Case 15:

- ◆ **A 24 year old female** patient with post-partum haemorrhage.
- ◆ 2 units of O Positive red cell units and 1 unit of fresh frozen plasma were ordered and issued.
- ◆ Between 1 to 2 hours into the transfusion, the patient experienced flushing/ sweating, tachycardia, cyanosis, dyspnoea, rigors and a decrease in oxygen saturation.
- ◆ Solucortef® 200 mg was administered intravenously.
- ◆ Based on the initial report, the case was classified as a transfusion associated dyspnoea.
- ◆ This case came in as an investigation 6 months post transfusion by the Department of Health enquiring about the cause of death.
- ◆ **Important to note:** This case was not reported to the blood service by the hospital as a mortality case.
- ◆ No further testing could be initiated upon receiving the enquiry.
- ◆ **Conclusion:** Transfusion was excluded as a cause.

Case 16:

- ◆ **A female** patient sustained multiple stab wounds to the left axilla, neck and back.
- ◆ Bilateral intercostal drains were inserted and the patient transfused with two units of emergency blood.
- ◆ She was transferred to a tertiary hospital two hours away for vascular surgery due to pulmonary artery damage.
- ◆ Multiple blood products were transfused during the surgery (red cell concentrates, fresh frozen plasma, cryoprecipitate and pooled platelets).
- ◆ Her condition deteriorated in theatre – she became difficult to ventilate and developed DIC.
- ◆ She arrested several times and died on the third arrest despite aggressive resuscitatory efforts.
- ◆ The cause of her death was attributed to severe acute respiratory distress syndrome (ARDS) secondary either to severe chest trauma or transfusion associated acute lung injury (TRALI).
- ◆ An autopsy was performed that confirmed the presence of ARDS, the cause of which could not be established.
- ◆ **Conclusion:** It is possible that the cause of death was due to TRALI, although this cannot be confirmed with certainty due to comorbid trauma.

Lookback Programme



WP Blood Transfusion Service
Do something remarkable



SANBS
South African National Blood Service

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.



Table 13.1 Number of donors investigated for TTI markers (2014)

Total number of lookbacks	SANBS	WPBTS	Total
HIV	522	46	568
HBV	243	15	258
HCV	15	1	16
HIV/HBV Co-Infections	13	0	13
Other	8	0	8
Total	801	62	863

In 2014, a total of 863 donors sero-converted and were investigated through the donor triggered lookback process, an increase compared to 566 cases in 2012 and 678 cases in 2013. There was a 100% follow up of all cases. Of the 863 cases, 65.8% of lookbacks were due to HIV, 29.9% HBV and 2.8% cases were due to HCV. Thirteen cases had HIV/HBV co-infection and the 8 other cases were investigated for infections such as/including Malaria, HTLV-1, Rubella and Rickettsia.

Table 13.2 Investigation outcomes

Donor-triggered investigation outcome	SANBS	WPBTS	Total
Retest negative	58	13	71
Recipient positive before transfusion	41	2	43
HIV positive recipient/s – phylogenetic analysis	1	0	1
Recipient died - between transfusion and initiation of lookback	116	9	125
Unresolved	831	24	855
Untraceable patient	8	14	22
Other	7	0	7
Refused/Declined testing	0	0	0
HBV Immune	5	0	5
HBV positive recipient - phylogenetic analysis	0	0	0
On dual therapy (HBV lb)	0	0	0
Total	1 067	62	1 129

At the time of the report, 1 129 donor-triggered investigations were conducted from the 863 donors with previous donations. Two hundred and forty (**21.3%**) of the **1 129 cases were resolved/closed**. Of the 240 cases, 71 recipients were traced and tested negative while 43 cases were confirmed to have been positive before transfusion (confirmed on requisition form or by the treating doctor). One breakthrough HIV infection has been reported in 2014 and another of HTLV that is in the final stages of phylogenetic testing.

One hundred and twenty five recipients were confirmed to have died between the transfusion episode and the lookback investigation initiation period, 22 cases were untraceable because the patients were unreachable by the hospital or due to missing hospital files, in the other 7 cases the hospital clinical managers refused to investigate lookbacks that were more than 6 months old and 5 cases were HBV immune.

The other **855 of the 1 129 (75.7%) cases remained unresolved/open** at the time of the report but the investigations still continue. They remain unresolved because there was no response from the doctor or hospital after 6 months of being contacted by the blood services.

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

13. Lookback Programme

Recipient-Triggered lookbacks 2014

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 2014

	Resolved	Unresolved	Total
HIV	7	3	10
HBV	2	1	3
HCV	0	0	0
Other	2	2	4
Total	11	6	17

A total of 17 recipient-triggered lookback cases were reported and 11 (64.7%) of cases had been resolved or closed at the time of the report. Of the 11 cases that were resolved, 9 donors re-tested negative and the other 2 cases were information requests from treating doctors that subsequently informed the office to close the cases. Of the total 17 reported recipient-triggered lookback cases, 6 (35.3%) cases remain unresolved because no records were found due to time lapsed or the donors being untraceable.

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 as shown in table 13.4 and figure 3 below.

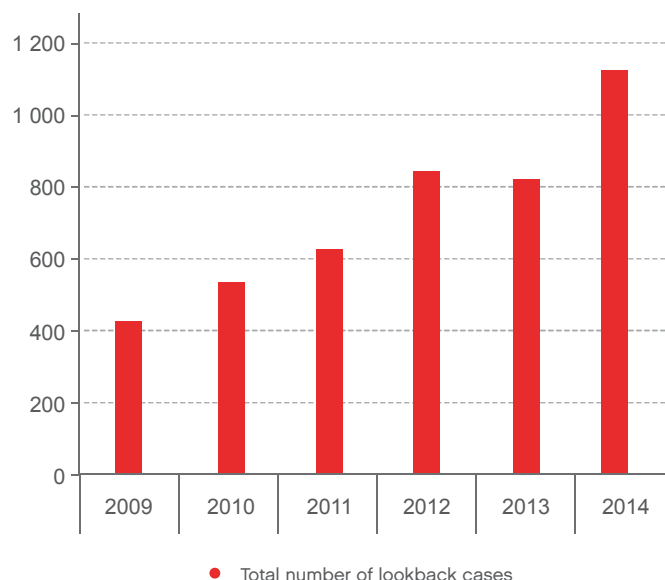
Table 13.4 Overview of lookback investigations (2009-2014)

	2009	2010	2011	2012	2013	2014	Total
Total number of lookback cases	447	546	642	629	849	1 129	4 242

One thousand one hundred and twenty nine of 1 152 836 ($\pm 0.1\%$) transfused products resulted in a lookback investigation due to possible microbial contamination.

Eight hundred and forty nine of 1 133 204 (0.075%) transfused products resulted in a lookback investigation due to possible contaminated transfusions

Figure 3. Lookback cases investigated 2009-2014



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 missing.
- 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 clearly indicate that this is the duty of the attending doctor who prescribed the transfusion or the hospital manager of the Provincial 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)



WP Blood Transfusion Service
Do something remarkable



SANBS
South African National Blood Service

14. Platelet Bacterial Testing (SANBS ONLY)

As part of the SANBS quality assurance programme and policy, 1% or a minimum of 16 platelets units, 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 2014 showed an annual contamination rate of 1.4% as demonstrated in Table 14.1 below. Table 14.2 provides a summary of the organisms cultured.

Table 14.1 Platelet Bacterial Testing 2014

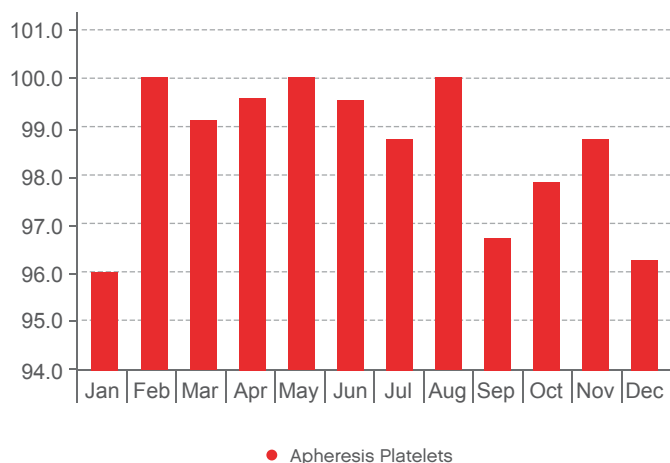
Product Tested	Number Tested	Number Positive (%)
Apheresis Platelets	2 756	41 (1.49%)
Expired Platelets	93	0 (0.00%)
Total	2 849	41 (1.49%)

Table 14.2 Summary of Micro-Organisms Isolated

	Cocci n = 18	Bacilli n = 11
Gram Positive Bacteria n = 25	<i>Peptostreptococcus</i> sp X1 <i>Streptococcus mitis</i> X3 <i>Streptococcus parasanguinis</i> X1 <i>Streptococcus salivarius</i> X1 <i>Staphylococcus epidermidis</i> X8 <i>Staphylococcus hominis</i> X1 <i>Coagulase negative staphylococcus</i> X2	<i>Leuconostoc</i> sp X3 <i>Bacillus</i> sp X1 <i>Corynebacterium</i> sp X1 <i>Corynebacterium accolens</i> X2 <i>Brevibacterium</i> sp X1
Gram Negative Bacteria N = 4	<i>Propionibacterium acnes</i> X1	<i>Acinobacter</i> sp X1 <i>Ochrobactrum anthropi</i> X1 <i>Chryseobacterium indolegenes</i> X1
Fungi n = 1	<i>Acremonium</i> sp X1	
No Bacterial Growth n = 11		

14. Platelet Bacterial Testing (SANBS ONLY)

Average Monthly Platelet Compliance Rates



The average monthly compliance rate as demonstrated in the histogram above was 98.5% for 2014.

The commonest bacteria cultured were Gram positive cocci, followed by Gram positive bacilli, indicating mostly skin commensals and environmental contaminants.

Since platelets are usually transfused to severely ill and /or immunocompromised patients, potentially 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 Officers (MO). Once a positive culture and Gram stain are available the MOs are contacted immediately so that they can discuss the findings with the patients' treating doctors.

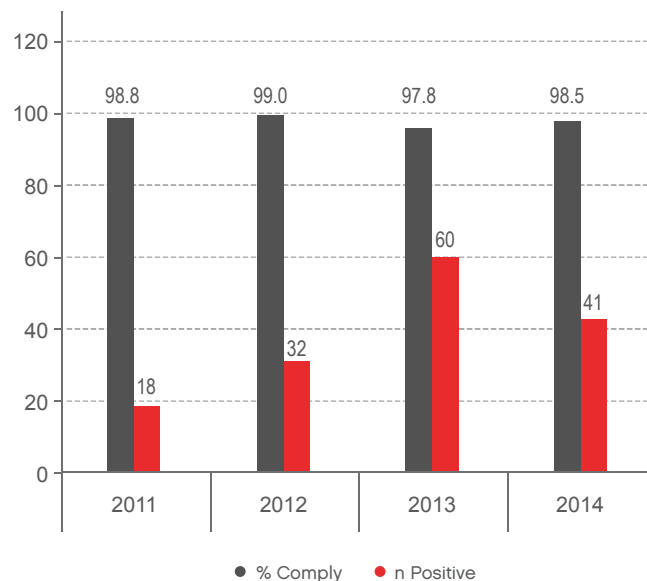
As the demand for platelets is high, recall of product is usually not possible.

In 2014 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.

Table 14.3 Annual Trends of platelet sterilities (2011-2014)

	2011	2012	2013	2014
Product Total	14 928	15 605	15 030	24 457
Number Tested	1 486	2 680	2 762	2 726
Product Passed	98.8%	99.0%	97.8%	98.5%
Number Positive	18 (1.2%)	32 (1.2%)	60 (2.2%)	41 (1.4%)

Annual Trends 2011-2014



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

The aim is to ensure:

- that the products are collected and processed to the highest possible aseptic standards
- that micro-organism contamination does not present an unacceptable risk to the product quality and safety
- the efficacy of disinfectants used for work areas, bench tops, utensils and hand washing

Table 14.4 Environmental Testing 2014

Number of tests (contact plates sampled)	Number compliant	Number not complying (>2+ Growth)	Most detected organisms
2 061	2 055	6	<i>Micrococcus sp</i> Coagulase negative Staphylococcus (CNS) <i>Bacillus sp</i> Fungi

Further improvements to the sterility programme will be the introduction of an aseptic course for the SANBS employees involved with product collection and processing.

Donor Vigilance



WP Blood Transfusion Service
Do something remarkable



SANBS
South African National Blood Service

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. <u>Symptoms</u> : 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. <u>Symptoms</u> : 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. <u>Complications</u> : 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. <u>Symptoms</u> 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, some time after insertion of the needle.
Nerve Injury	Injury of a nerve by the needle at insertion or withdrawal. <u>Symptom</u> 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. <u>Symptom</u> 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. <u>Symptoms</u> 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. <u>Symptoms</u> are rash, swelling and itching at venipuncture site.

15. Donor Vigilance continued

15.2 Classifications continued

Complications mainly with generalised symptoms.	
Vasovagal reaction	
Adverse Event	Definition
Vasovagal Reaction (Faint)	<p>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.</p> <p><u>Symptoms</u> are discomfort, weakness, anxiety, dizziness, nausea, sweating, vomiting, pallor, hyperventilation, convulsions, and loss of consciousness.</p> <p>The reaction is generated by the autonomic nervous system and further stimulated by psychological factors, and the volume of blood removed relative to the donor's total blood volume.</p>
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	<u>Symptoms</u> and signs associated with the transient hypocalcaemia caused by citrate. Donors usually present with mild tingling around the mouth and on the lips, metallic taste in the mouth and peripheral paraesthesia. Severe cases are characterised by respiratory difficulty with nausea and vomiting.
Haemolysis	Destruction of the donor's red blood cells.
Generalised Allergic Reaction	<p>The result of an interaction of an allergen with preformed antibodies.</p> <p>Minor allergic reaction: Reaction limited to the skin, with or without a rash.</p> <p>Severe allergic reaction: Reaction with risk to life, characterised by bronchospasm causing hypoxia, or angioedema causing respiratory distress.</p>
Air Embolism	An air-lock that obstructs the outflow of blood from the right ventricle of the heart or air that lodges in the pulmonary or cerebral vasculature. Air may gain access to the circulation as a result of surgery, injury or intra-venous infusion.

15. Donor Vigilance continued

In 2014, a total of **967 272** blood products were collected by the SANBS and the WPBTS combined as shown in table 15.1 and figure 4 below with the SANBS having contributed 83% and the WPBTS 17% which remained the same as in 2013.

Table 15.1 Collections 2014

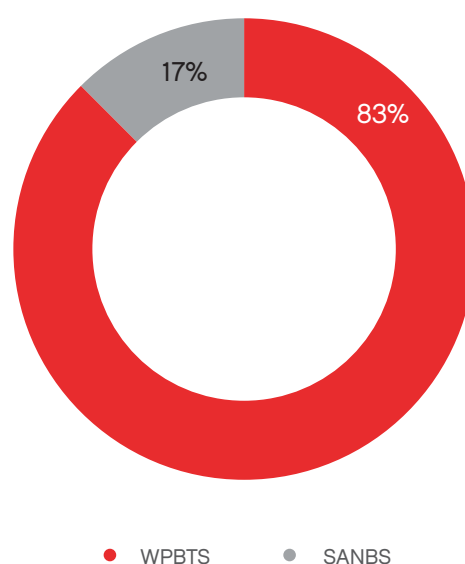
Collections 2014	SANBS	WPBTS	Total
Whole Blood	784 010	160 048	944 058
Apheresis Red Cells	3 929	0	3 929
Apheresis Platelets	14 402	2 681	17 083
Plasma	2 202	0	2 202
Totals	804 543	162 729	967 272



The SANBS collections were undertaken at **87 permanent** collection centres, approximately **90 mobile blood collection teams** and **13** 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 centers, **7** mobile units and an apheresis and autologous/designated donation unit at the Head Quarters in Pinelands.

Figure 4: Product Collections 2014 (SANBS and WPBTS)



15. Donor Vigilance continued

15.3 Summary of Donor Adverse Events 2013

15.3.1 By Donation Type

Acute Reactions	Whole Blood	Apheresis	Unallocated	Totals
Haematoma	309	229	16	554
Arterial Puncture	2	0	0	2
Delayed Bleeding	14	1	0	15
Nerve Irritation	25	0	0	2
Tendon Injury	0	0	0	0
Nerve Injury	0	0	0	0
Painful Arm	69	12	4	85
Total Local Symptoms	396	242	20	658
Faint Immediate Type	2 066	39	14	2 119
Faint Immediate, Accident	98	3	6	107
Faint Delayed Type	550	10	11	571
Faint Delayed, Accident	42	3	1	46
Total no. Vasovagal Reactions	2 756	55	32	2 843
Citrate Reaction	0	17	1	18
Haemolysis	0	0	0	0
Generalised Allergic Reaction	1	0	0	1
Embolism	0	0	0	0
Others	0	0	0	0
Total	1	17	1	19
Grand Total	3 153	314	53	3 520

In 2014, all donor adverse events reported contributed 0.36% (3 520 out of 967 272) of total collections same as in 2013. 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 do not accurately classify donor adverse events (DAE) according to donation type and more training needs to take place for staff to understand the importance of correct capturing.

Most DAE were experienced with whole blood donations at 89.6 %, apheresis 8.9% and unallocated donations 1.5%. The rate of unallocated DAE has however improved from 3% in 2012 to 1.5% in 2014 which could indicate that there is a positive impact with training.

15. Donor Vigilance continued



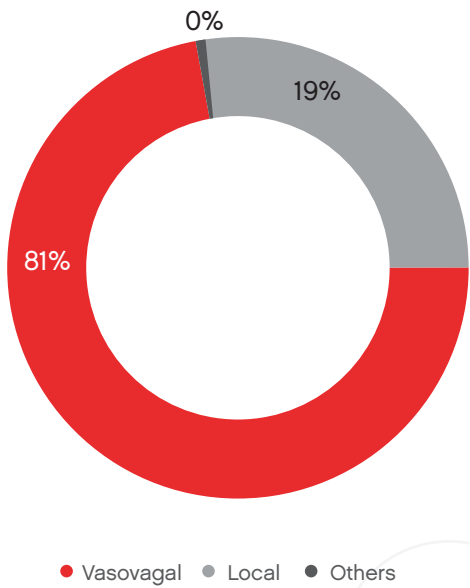
Table 15.3.2 Donor adverse events according to broad categories

	Local Symptoms	Vasovagal	Others	Total
SANBS	450	1 367	16	1 833
WPBTS	208	1 476	3	1 687
Total	658	2 843	19	3 520

The majority of donor adverse reactions were vasovagal (81%), local symptoms (18.5%) and others (0.5%) as shown in table 15.1.1 and figure 5. Of the vasovagal reactions, ± 95% were attributable to faints without accidents and ± 5% 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, ± 84% events were due to haematomas followed by ± 13% 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 2013



15. Donor Vigilance continued

15.3.4 Analysis of Adverse Events by Severity

	Severity	Mild	Moderate	Severe	Subtotal
Local Adverse Events	Haematoma	493	55	6	554
	Arterial Puncture	1	1	0	2
	Delayed Bleeding	15	0	0	15
	Nerve Irritation	0	1	1	2
	Tendon Injury	0	0	0	0
	Nerve Injury	0	0	0	0
	Painful Arm	65	15	5	84
	Total Local Symptoms	574	72	12	658
Vasovagal	Faint Immediate Type	1 928	80	111	2 119
	Faint Immediate, Accident	90	14	3	107
	Faint Delayed Type	413	118	40	571
	Faint Delayed, Accident	30	11	5	46
	Total no. Vasovagal Reactions	2 461	223	159	2 843
Others	Citrate Reaction	15	2	1	18
	Haemolysis	0	0	0	0
	Generalised Allergic Reaction	1	0	0	1
	Embolism	0	0	0	0
	Others	0	0	0	0
	Total	16	2	1	19
Grand Total		3 051	297	172	3 520

As shown in table 15.3.4 above, 86.7% of donor adverse reactions were mild, 8.4% moderate and 4.9% severe.



15. Donor Vigilance continued

15.3.5 Analysis of Adverse Events by Age Group

As shown in table 15.3.1 and figure 6 below, donors 20-30 years had the most donor adverse events at 32.0% followed by donors 16-19 years at 31.5%, 31-40 years at 14.2% and the elderly group above 71+ years had the least events at 0.3%. The results are similar to 2010, 2011, 2012 and 2013.

Age Groups	WPBTS	SANBS	Total
16-19	613	495	1 108
20-30	552	574	1 126
31-40	263	237	500
41-50	119	228	347
51-60	53	196	249
61-70	17	93	110
71+	1	10	11
Unallocated	69	0	69
Total	1 687	1 833	3 520

Figure 6

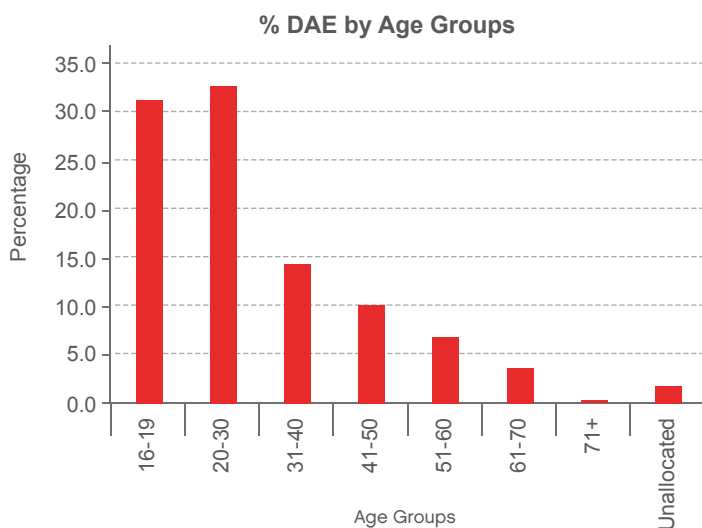
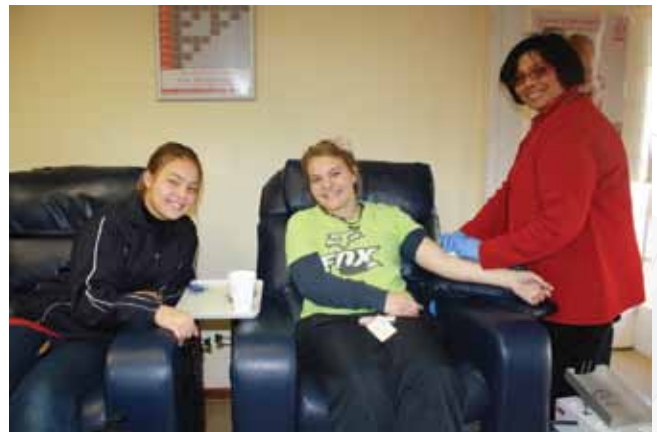
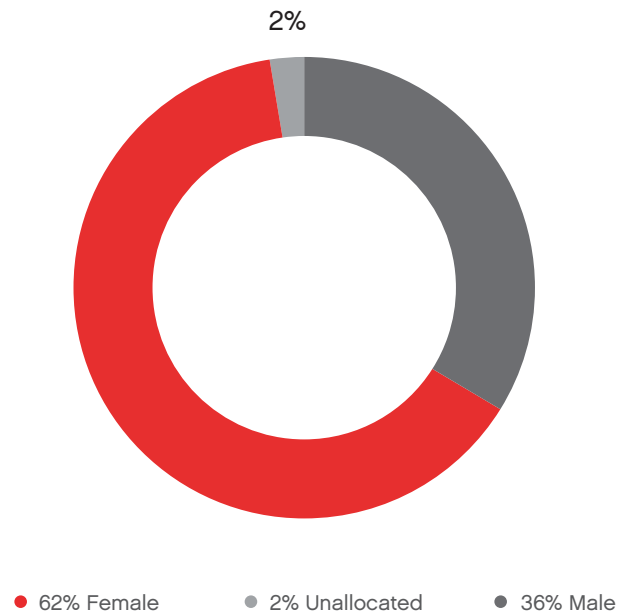


Figure 7 below illustrates that 62% of females had donor adverse events as compared to 36% of males. The finding is in keeping with literature that females are more prone to reactions than males.

Figure 7



15. Donor Vigilance continued

15.4 Donor care and health

Iron Study conducted in 2014

During this period, the SANBS also finalised the planning as well as the data collection for a national research project aimed at evaluating the iron status of South African blood donors. The Western Province Blood Transfusion Service (WPBTS) collaborated with the SANBS enabling the evaluation of blood donors in all nine provinces of South Africa. Iron deficiency is the most common nutritional disorder world-wide and blood donation can increasingly contribute to such iron deficiency.

During a blood donation, donors donate between 450 and 500 ml of blood resulting in the loss of around 213 to 236 mg of iron or 4 to 10% of total body iron. Repeated blood donations may, over time result in the depletion of iron stores and even cause iron deficiency anaemia. Such resulting anaemia affects donor return rates, but most importantly negatively affects donor health.

Various studies on this topic have been conducted in both Europe and the USA, but none in Africa or in South Africa. For these reasons the SANBS conducted a study to determine the iron status of South African blood donors.

The project included two pilot studies, one to assess the stability of ferritin samples kept for varying time periods prior to analysis and another to assess the extensive and complicated logistics plan for the main study. Specimen collection involved the participation of more than 750 of the SANBS's donor, transport, medical, laboratory and IT staff and included all 7 operational zones as well as WPBTS. Specimen collection was conducted over 8 weeks between August and October 2014. About 80% of all eligible donors were included; \pm 15% of donors were planned exclusions due to time delays in getting their specimens to the appropriate testing centres. The other 5% were excluded due to logistical and other issues on the day of collection. In total, 4 465 donors were tested of which 2.4% of the results were not traceable back to the appropriate donor and therefore excluded from the study data set.

Table 1. Demographic profile on Iron Study participants.

	Number	%
Gender		
Female	2 116	47%
Male	2 349	53%
Race		
Asian	279	6%
Black	1 088	24%
Coloured	377	8%
White	2 658	60%
Unknown	63	1%
Zone		
Eastern Cape	433	10%
Egoli	842	19%
Free State/Northern Cape	469	11%
KwaZulu-Natal	557	12%
Mpumalanga	358	8%
Northern	799	18%
Vaal	589	13%
Western Cape	418	9%
Total	4 465	100%

The SANBS is currently busy with the data analysis for this study which will likely inform future policy regarding donation intervals, iron replacement therapy as well as possible iron surveillance programmes for at-risk donors.

International Corner



WP Blood Transfusion Service
Do something remarkable



SANBS
South African National Blood Service

16. International Corner

16.1 WHO Guidelines Drafting

The SANBS team, in conjunction with the core writing group, has completed the WHO haemovigilance guidelines. The guidelines are currently being edited by the WHO and are targeted to be published in 2016. The guidelines are aimed to assist countries (mostly in Africa) without haemovigilance systems or those wanting to improve their current systems mainly.

16.2 International Haemovigilance participation

SANBS continues to be an active member of the International Haemovigilance Network (IHN) and SANBS staff attended a Haemovigilance Research Strategy meeting held in Washington on the 27th February 2015. Guidelines will be drafted to guide how support can be offered for research within the haemovigilance space for the Blood Transfusion Services (BTS).



Conclusion



WP Blood Transfusion Service
Do something remarkable



SANBS
South African National Blood Service

17. Conclusion

In this 15th issue it is evident that more questions will still remain unanswered for the blood services. Why are we getting increasing Allergic and Febrile reactions? We should monitor gaps and trends closely.

With more cooperation from the hospitals, there will be an even better and accurate reporting of transfusion adverse events. Collaborations and enforcement by the Department of Health towards hospitals in performing post mortems 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. The haemovigilance data collected in South Africa over the years has shown a significant improvement in blood safety.

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.

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



WP Blood Transfusion Service
Do something remarkable



SANBS
South African National Blood Service

18. References

1. Bolton-Maggs P et al. Annual SHOT report 2013.
2. Bolton-Maggs P et al. Serious Hazards of Transfusion (SHOT) haemovigilance and progress is improving transfusion safety. *British Journal of Haematology* 2013; 163: 303-314.
3. US Food and Drug Administration. Fatalities Reported to FDA Following Blood Collection and Transfusion: Annual Summary for Fiscal Year 2013.
4. <http://www.ihn-org.com/haemovigilance-databases/istare-2/>
5. Olatunji BO, Etzel EN, Ciesielski BG. Vasovagal syncope and blood donor return: examination of the role of experience and affective expectancies. *Behaviour Modification* 2010; 34:164.
6. Glynn SA. Blood supply safety: an NHLBI perspective. *Transfusion* 2008; 48: 1541-4.
7. Newman BH, Newman DT, Ahmad R, Roth AJ. The effects of whole blood donor adverse events on blood donor return rates. *Transfusion* 2006; 46:1374-9.
8. Eder AF, Dy BA, Kennedy JM, et al. The American Red Cross donor haemovigilance program: complications of blood donation reported in 2006. *Transfusion* 2008; 48:1809-19.
9. <http://www.sanbs.org.za>
10. <http://www.wpblood.org.za>

Notes

[illegible]

Notes

[illegible]

