



Haemovigilance Report 2013



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SANBS
South African National Blood Service

Haemovigilance Report 2013



Privacy Statement

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

Disclaimer

This document is a general report only. The data, analysis and conclusions contained herein are intended to provide healthcare professionals and the public with general information only on transfusion-related adverse events in South African hospitals.

This report is a snapshot of currently available data, which have been obtained from limited resources.

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Abbreviations

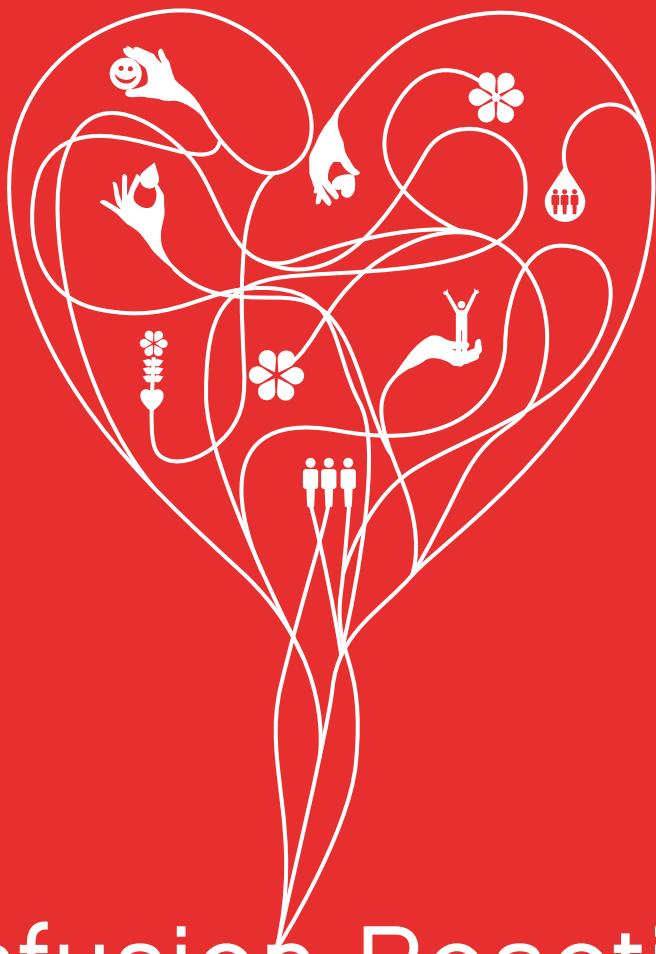


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Abbreviations

AHTR	Acute Haemolytic Transfusion Reactions
ATR	Acute Transfusion Reactions
DAE	Donor Adverse Events
DAT	Direct Antiglobulin Test
DHTR	Delayed Haemolytic Transfusion Reactions
DSTR	Delayed Serological Transfusion Reactions
FFP	Fresh Frozen Plasma
FNHTR	Febrile Non-Haemolytic Transfusion Reactions
HBV	Hepatitis B Virus
HCV	Hepatitis C Virus
HIV	Human Immunodeficiency Virus
IBCT	Incorrect Blood Component Transfused
ID-NAT	Individual Donation Nucleic Acid Amplification Test
IHN	International Haemovigilance Network
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
TA-GvHD	Transfusion Associated Graft versus Host Disease
TTI	Transfusion Transmissible Infections
TRALI	Transfusion Related Acute Lung Injury
TACO	Transfusion Associated Circulatory Overload
SHOT	Serious Hazards of Transfusion
WPBTS	Western Province Blood Transfusion Service



Transfusion Reaction Classifications and Definitions



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Transfusion Reaction Classifications and Definitions

Category	Definition
Acute Transfusion Reactions	Transfusion related reactions that occur at any time during or up to 24 hours following a transfusion of blood or components. The most frequent reactions are fever, chills, 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 (e.g. haemoglobinuria) 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 >30 mm 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 Classifications and Definitions

Category	Definition
Anaphylactic Transfusion Reactions	Hypotension with one or more of: Urticaria, rash, dyspnoea, angioedema, stridor, wheeze, 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 TTIV's are HIV, Hepatitis B and Hepatitis C.
Transfusion Transmitted Bacterial Infection	Detection of the same bacterial strain in the recipient's blood and in the transfused blood product by approved techniques. Probable cases of TTBI include cases where the recipient has evidence of infection post-transfusion, and there was no evidence of infection prior to transfusion and no evidence of an alternative source of infection.

Transfusion Reaction Classifications and 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



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1. Foreword - Message from the Medical Directors



Dr Charlotte Ingram
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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) look-back and haemovigilance officers as well as the healthcare professionals in the hospitals for their contribution in providing information for the production of this 2013 Haemovigilance Report.

The principal objectives of this report are:

To supply national data on the adverse events reported during 2013:

- Adverse reactions associated with transfusion,
- Data on serious adverse reactions associated with blood donation,
- To analyse the frequency of events (patient and donor related) over the period 2008 to 2013 (overall and per diagnosis); and
- To pinpoint the issues requiring further analysis and intervention.



Executive Summary 2013



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2. Executive Summary 2013

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 rare cases, death. Analysing the Haemovigilance Reports provides a picture of current transfusion risks, and may provide information on the causes of preventable transfusion events and show where improvements are necessary and possible.

This is the fourteenth 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 2013 by the two services providing blood and blood products in South Africa i.e. the SANBS and the WPBTS.

2.1 Blood product issues and usage data:

There were 1 133 204 blood component products issued in South Africa in 2013. Red blood cells (RBC) products accounted for about 79% of all issues. The demand for blood products has been increasing over the last few years, the issue of blood products increased from 1 069 407 in 2012 to 1 113 204 in 2013 (4% increase)

2.2 Collections and issues:

A total of 967 125 units of blood were collected by the two services and separated into various blood products. Collectively the two services issued 1 133 204 blood products with 962 857 products issued by SANBS and 170 347 by WPBTS. There was an increase of 3.7% in total collections and 4.0% in products issued compared to 2012 by both services.

2.3 Hospital participation:

In 2013, 192 of the 749 (25.6%) healthcare facilities in South Africa reported transfusion adverse events to the Haemovigilance Office. The participation remains at ± 26% from 2012 to 2013, which indicates that the same hospitals are reporting and much more education needs to be conducted for the rationale and aim of haemovigilance to be understood by all healthcare workers and accurate hospital participation to occur.

2.4 Summary of recipient adverse events:

There were 1 036 adverse events reported to the National Haemovigilance Programme for 2013. The number of reports received increased by 18% from 879 in 2012 likely due to the improved adverse event reporting. The most frequently reported adverse events are febrile non-haemolytic transfusion reactions (FNHTR) and allergic reactions (including minor, severe and anaphylactic), representing 38% and 35% of all reports respectively. Other significant adverse reactions reported include 76 transfusion associated dyspnoea cases and 52 hypotensive reaction cases representing 7.3% and 5.0% of all reports respectively.

A total of 35 cases of incorrect blood component transfused (IBCT) were reported with errors originating from both the hospitals and the blood banks.

Seven cases of possible transfusion related mortality were reported, translating to an estimated risk of death from transfusion of 1 in 167 000 components issued. However, in all the 7 cases, blood transfusion remains a possible contributing factor and not confirmed 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.

One hundred and twelve cases remained unclassified due to lack of sufficient transfusion reaction data.

No cases of confirmed transfusion transmitted HIV, Hepatitis B, Hepatitis C or malaria were reported in 2013. There is however one potential case of HTLV transmission being investigated by SANBS.

2. Executive Summary 2013 continued

2.5 Summary of Platelet Bacterial Testing

Of the 15 030 apheresis platelet units collected in 2013, a total of 2 762 (18.4%) were tested for microbial growth and from 60 (2.2%) 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% of all platelets tested met the required specifications which exceeded the 80% set standard. There was no case of transfusion related bacteraemia reported.



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 for blood donors.

During 2013 there was a total of 967 125 of collections, including 942 601 whole blood collections, 3 719 apheresis red cells; 2 418 plasma collections and 18 387 apheresis platelet donations.

There were 3 550 donor adverse events reported in 2013, a significant decrease from those reported in 2012. The overall reported ratio of donation-related adverse events was 1: 272 in 2013, a decrease from 1:212 reported in 2012 and is attributable to the change in the reporting and recording which may have resulted in under-reporting for the SANBS.

Vasovagal events as a category accounted for more than 79% of all adverse events and translate to a vasovagal rate of 0.3% of all donations. Eighty percent of all vasovagal events were of the immediate type without associated injuries. Haematomas were the second most common adverse event reported, accounting for 17% of all adverse events reported. The overall donor adverse event rate of 0.37% is also significantly lower than reported internationally. The frequency of adverse events was found to be higher in younger blood donors, especially those under the age of 21 years.



Introduction



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3. Introduction

This is the fourteenth annual haemovigilance report for South Africa since 2000 when the first report was published. The SANBS and WPBTS are working in collaboration towards a more integrated and electronic haemovigilance reporting system. The South African Haemovigilance system 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 completed by hospital personnel as accurately 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 immediately verbally inform the Director-General or a person specifically designated by him or her of any report received in terms of subregulation (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, compiles a summary report regarding all the events that occurred over the year in retrospect. This document also contains an analysis of the trends regarding the evolution (since 2000) of the principal indicators featured in the report.

This makes it possible, if required, to review the data from previous reports in order to take into account information obtained after they were written. This 2013 report shows an increased number of reported adverse events related to blood transfusion in most of South African hospitals. This is in part due to an improved good 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 International Haemovigilance initiatives

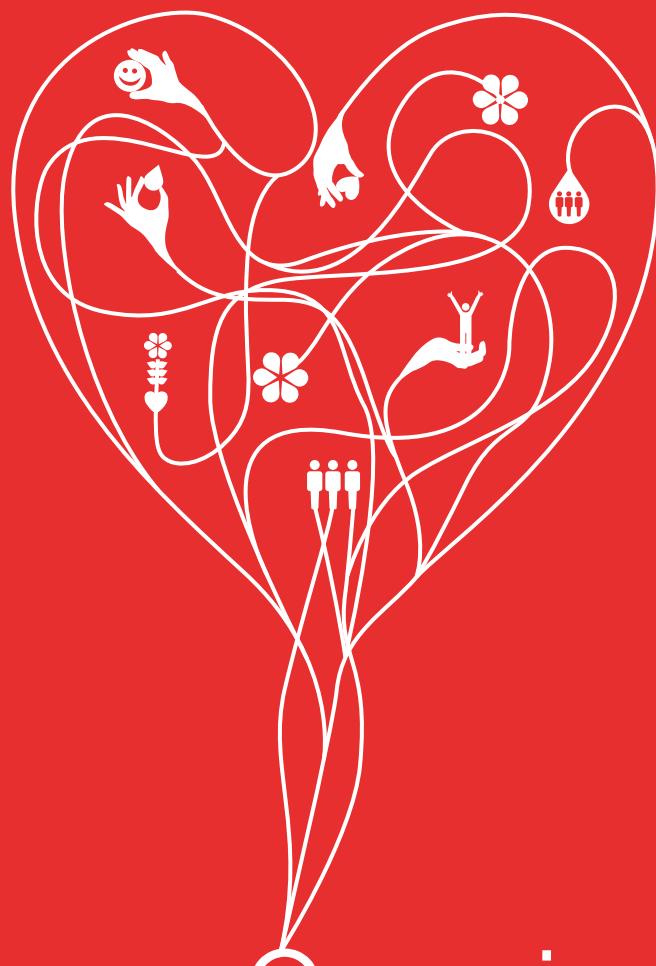
South Africa is a participating member of the International Haemovigilance Network (IHN) since 2009 and the South African data is available on the ISTARE data base.

International peer review of our data takes place at the regular international meetings. Some of the other participating member countries include the United Kingdom, Netherlands, Australia, Greece, Canada, Japan and Germany.

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 on establishing a national haemovigilance system, as per set timelines. The guidelines are aimed to assist countries without haemovigilance systems, mainly in low and development index countries.





Overview of Product Issues for 2013



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4. Overview of Product Issues for 2013

Collectively **1 133 204** blood and blood products were issued to patients in South Africa by the two supplying services (SANBS and WPBTS). The SANBS issued **962 857 (85%)** while the WPBTS issued **170 347 (15%)**.

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 its Head Office in Pinelands. 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.

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

The services provide blood and blood products to ± 749 hospitals and clinics country wide.

**Table 4.1 Component/ Product Issues 2013
(SANBS and WPBTS)**

Products	SANBS	WPBTS	Total
Plasma products			
Cryo-Poor Plasma	22 426	1 1 475	23 901
Fresh Frozen Plasma	117 097	26 236	143 333
Totals	139 523	27 711	167 234
Platelet Products			
Apheresis Platelet	26 784	3 594	30 378
Pooled Platelet	28 943	4 586	33 529
Total	55 727	8 180	63 907
Red Cell Products			
Paediatric	36 895	4 238	41 133
Red Cells	694 625	121 370	815 995
Reserved	333	1 108	1 441
Emergency Units and Ward Stock	32 816	7 286	40 102
Whole Blood	2 938	454	3 392
Total Red Cell Products	767 607	134 456	902 063
Grand Total	962 857	170 347	1 133 204

The 7 percent (%) difference between collections and usable red cell products units was the same in 2013 as in 2012 (Table 4.2 and Figure 1).

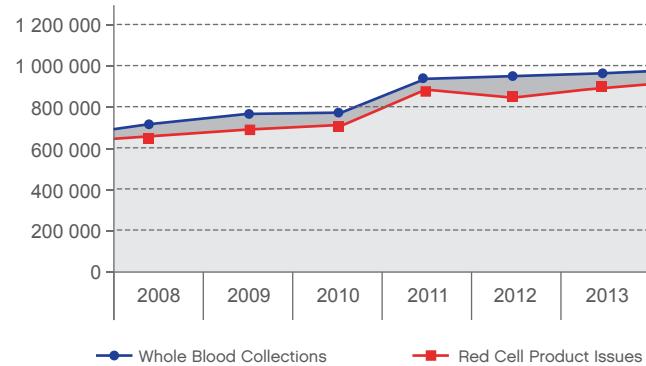
Table 4.2: Collections and Issues (2008-2013)

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



Red cell product issues continued to closely follow whole blood units collected and maintaining a percentage difference of around 7%. This difference represents the loss of blood products to various reasons, including products not confirming to Quality Standards, voluntary recall of donations by donors and units testing positive for TTI's.

Figure 1: Collections and Issues (2008-2013)



5. Transfusion Adverse Events (National Data) 2013

5.1 Summary of transfusion adverse events 2013

	Adverse Events	SANBS	WPBTS	South Africa
Acute Transfusion Reactions	Acute Haemolytic Transfusion Reactions (AHTR)	2	2	4
	Allergic Reactions	136	117	253
	Severe Allergic Reactions	38	6	44
	Anaphylactic Reactions	48	16	64
	Febrile Non-haemolytic Reactions (FNHTR)	287	101	388
	Transfusion Associated Circulatory Overload	0	0	0
	Transfusion-related Acute Lung Injury (TRALI)	1	0	1
	Transfusion-associated Dyspnoea (TAD)	76	0	76
	Hypotensive Reactions	44	8	52
	Unclassifiable (Incomplete information)	79	27	106
	Unclassifiable (No Forms)	6	0	6
	Total ATR (Acute Transfusion Reactions)	717	277	994
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	8	0	8
	ABO Incompatible Transfusions	7	0	7
	Misdirected Transfusions	8	2	10
	Patient Misidentifications	2	8	10
	Total (IBCT)	25	10	35
Other Reactions	Near Miss	0	0	0
	Transfusion-associated Graft versus Host Disease (TAGvHD)	0	0	0
	Transfusion Transmitted Infections	0	0	0
	Post Transfusion Purpura	0	0	0
	Mortality	7	0	7
GRAND TOTAL		749	287	1 036

5. Transfusion Adverse Events (National Data) 2013 continued

Table 5.2 Rates of transfusion adverse events per classification

Adverse Events		South Africa	Rates per 100 000 units issued
Acute Transfusion Reactions	Acute haemolytic transfusion reactions (AHTR)	4	0.4
	Allergic reactions	253	22.3
	Severe allergic reactions	44	3.9
	Anaphylactic reactions	64	5.6
	Febrile non-haemolytic transfusion reactions (FNHTR)	388	34.2
	Transfusion associated circulatory overload (TACO)	0	0.0
	Transfusion related acute lung injury (TRALI)	1	0.1
	Transfusion associated dyspnoea (TAD)	76	6.7
	Hypotensive reactions	52	4.6
	Unclassifiable (Incomplete information)	106	9.4
	Unclassifiable (No forms)	6	0.5
Total ATR		994	87.7
Delayed Reactions	ABO + Rh Incompatible transfusion	0	0.0
	ABO Incompatible transfusion	0	0.0
Incorrect Blood Component Transfused (IBCT)	ABO + Rh incompatible transfusions	8	0.7
	ABO incompatible transfusions	7	0.6
	Misdirected transfusions	10	0.9
	Patient misidentifications	10	0.9
Total IBCT		35	3.1
Other Reactions	Near Miss	0	0.0
	Transfusion Associated Graft versus Host Disease (TA-GvHD)	0	0.0
	Transfusion Transmitted infections	0	0.0
	Post Transfusion Purpura	0	0.0
	Mortality	7	0.6
GRAND TOTAL		1 036	91.4



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

Table 5.2 shows that in South Africa the rate of all transfusion adverse events reported was 91.4 per 100 000 units issued in 2013, an increase from 82.20 in 2012. Of all adverse events, ATRs were the most frequently reported at 87.7 per 100 000 units issued and IBCT at 3.1 per 100 000 units issued.

5. Transfusion Adverse Events (National Data) 2013 continued

Within the ATR category, the most commonly reported adverse events were FNHTR at a rate of 34.2 per 100 000 units issued then followed by allergic (including mild, severe and anaphylactic) at 31.8 per 100 000 units issued.

Table 5.3 and figure 2 below shows that the rates of adverse reactions reported in the past 6 years (2008-2013) 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 (2008-2013)

	2008	2009	2010	2011	2012	2013
Issued	950 460	984 381	1 032 580	1 081 690	1 069 402	1 133 204
Adverse Reactions	583	682	688	763	879	1 036
Rates per 100 000 Total Issues	61,3	69,3	66,6	70,5	82,2	91,4

Figure 2: Adverse Reactions Rates (2008-2013)

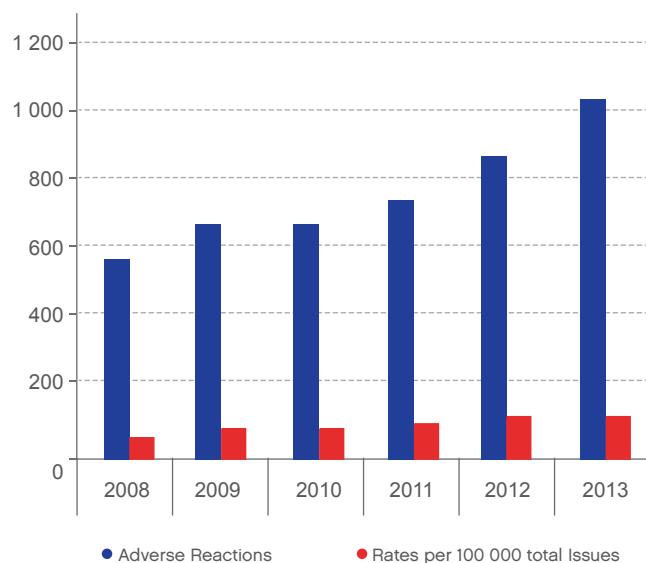


Table 5.4 below shows that over a period of 6 years there has been an increase in the number of reported adverse events. There has been an upward trend in the reporting of ATRs from 566 in 2008 to 994 in 2013. The increase was two-fold for both allergic reactions (188 in 2008 to 361 in 2013) and FNHTR (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	Totals
AHTR	13	15	15	4	4	52	52
ALLERGIC (INCLUDING SEVERE ALLERGIC)	177	222	231	221	274	297	1 422
ANAPHYLACTIC	11	5	6	16	26	64	128
TRALI	0	4	1	1	2	1	9
TACO	0	3	5	1	0	0	9
TAD	64	36	47	71	64	76	358
FNHTR	150	229	257	255	360	388	1 639
HYPOTENSIVE	25	12	51	54	40	52	234
UNCLASSIFIABLE	126	116	97	117	72	112	640
Totals	566	642	710	737	842	994	4 491



Acute Transfusion Reactions 2013: Case Discussions



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6. Acute Transfusion Reactions 2013: Case Discussions

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 Reactions (FNHTR)
Hypotensive Reactions
Unclassifiable Reactions

6.1 Acute Haemolytic Transfusion Reactions (AHTR)

2008	2009	2010	2011	2012	2013
13	14	15	1	4	4

4 cases of Acute Haemolytic Transfusion Reactions (AHTR) were reported in 2013.

An example of a case is described below.

Case JTR 327

- ◆ A 62 year old female.
- ◆ Diagnosed with upper gastrointestinal bleeding and anaemia, haemoglobin (Hb) of 7.2 g/dl.
- ◆ She was transfused with two units of Group O Rh Positive red cells.
- ◆ In less than 6 hours the patient had flushing, sweating, rigors and an increase in temperature, tachycardia and haemoglobinuria.
- ◆ Blood was stopped immediately and the patient managed accordingly.
- ◆ Although post transfusion reaction investigations performed in the laboratory did not confirm any haemolysis, this case was classified as a possible haemolytic reaction.

6.2 Allergic Transfusion Reactions

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

297 cases of allergic reactions were reported in 2013.

An example of a case is described below.

Case TR 0019

- ◆ An 8 day old baby.
- ◆ Diagnosed with congenital sepsis and anaemia, haemoglobin of 6.2 g/dl.
- ◆ Was transfused with 1 unit of leucodepleted paediatric red cells.
- ◆ In less than an hour, the patient had a skin reaction and tachycardia only.
- ◆ The transfusion was stopped immediately.
- ◆ The baby's condition improved after appropriate management by the paediatrician.
- ◆ This reaction was classified as an allergic reaction.

6.3 Anaphylactic Transfusion Reactions

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

64 cases of anaphylactic reactions were reported in 2013.

An example of a case is described below.

Case JTR 326

- ◆ A 44 year old female patient.
- ◆ Diagnosed with cancer of the breast.
- ◆ Was transfused with 1 unit of leucodepleted red cells.
- ◆ 16 minutes into transfusion the patient had a skin reaction, tachycardia, dyspnoea, and bronchospasm.
- ◆ Blood transfusion was stopped immediately; Solu-cortef® 100mg, Phenergan® 25mg and oxygen was administered.
- ◆ The patient's symptoms resolved after the management.
- ◆ This reaction was classified as a possible anaphylactic transfusion reaction.

6. Acute Transfusion Reactions 2013: Case Discussions continued

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 anti-bodies I and II.

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

Only **1 case** of possible TRALI was reported in 2013.

The case description is outlined below.

Case 1 JTR 0370/13

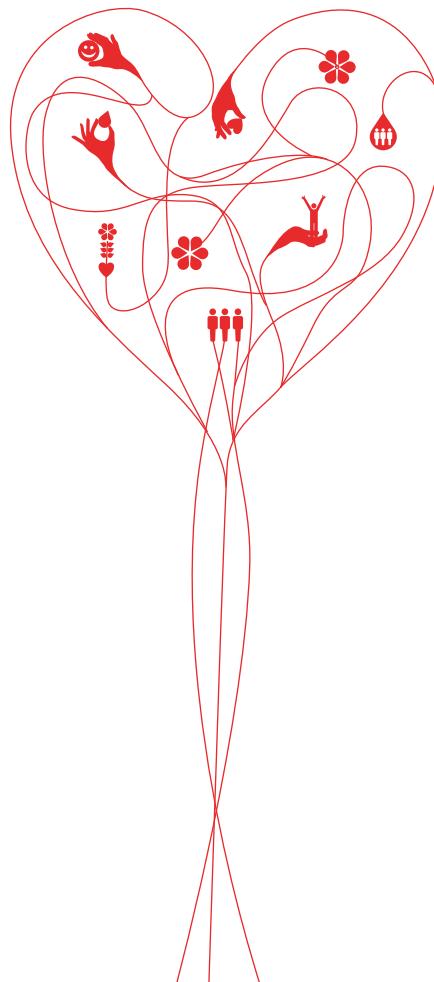
- ◆ A 17 year old female patient.
- ◆ Admitted for ruptured ovarian cysts.
- ◆ Two emergency **Group O Rh Positive** red cell units (ward stock) and one unit of fresh frozen plasma were transfused to the patient.
- ◆ No pre-transfusion cross matching and antibody testing was performed by the blood bank as it was an emergency case and the patient was transfused with emergency units available in the ward.
- ◆ Twelve hours after the transfusion the patient experienced dyspnoea with decreased oxygen saturation and collapsed.
- ◆ The patient was intubated, transferred to a tertiary hospital and admitted into ICU.
- ◆ A chest x-ray and blood investigations were performed by the treating physician to determine the cause of the reaction.
- ◆ Post transfusion reaction investigations from the blood bank and Red Cell Serology Laboratory were carried out.
- ◆ The patient's blood group was **Group O Rh Positive**.
- ◆ The direct antiglobulin test was negative.
- ◆ No irregular antibodies capable of causing a haemolytic reaction were detected in the patient's post-transfusion sample.

- ◆ No irregular antibodies capable of causing an Acute Haemolytic Transfusion Reaction (AHTR) were detected in the patient's post-transfusion sample.
- ◆ The two transfused units were not returned to the Blood Bank for investigation.
- ◆ As such, no post-transfusion crossmatch testing could be performed, as pre-samples were not sent due to the units being issued prior as Emergency ward stock.
- ◆ **On telephonic follow up with the treating doctor, she confirmed that the patient did suffer a transfusion reaction, which was a definite TRALI case, demonstrable on chest X-ray.**
- ◆ There was clear bilateral lung infiltrates demonstrable.
- ◆ This reaction was classified as TRALI.

6.5 Transfusion Associated Circulatory Overload (TACO)

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

- ◆ There were no cases of Transfusion Associated Circulatory Overload for the year 2013.



6. Acute Transfusion Reactions 2013: Case Discussions continued

6.6 Transfusion Associated Dyspnoea (TAD)

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

There were **76 cases** of TAD reported in 2013.

An example of a case is described below.

Case TR 008

- ◆ A 17 month old male baby.
- ◆ Diagnosed with anaemia.
- ◆ Was transfused with 1 unit of leucodepleted red cells.
- ◆ After 1 - 2 hours the patient experienced dyspnoea, a decrease in oxygen saturation and a drop in blood pressure.
- ◆ Blood transfusion was stopped immediately, the baby was given oxygen and chest x-rays were performed.
- ◆ The baby stabilised after resuscitation.
- ◆ The reaction was classified as transfusion associated dyspnoea.



6.8 Hypotensive Reactions

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

There were **52 cases** of Hypotensive Reactions reported in 2013.

An example of a case is described below.

Case JTR 486

- ◆ A 31 year old female.
- ◆ Diagnosed with 45% burns, inhalation injuries and anaemia due to blood loss in theatre.
- ◆ Transfused with 2 units of red cells.
- ◆ Less than an hour into the transfusion the patient presented with tachycardia, a decrease in oxygen saturations and a drop in blood pressure.
- ◆ The transfusion was stopped immediately.
- ◆ The patient was managed with Phenergan® and Solucortef®.
- ◆ The patient recovered after about an hour and the blood pressure gradually increased to 100 over 60 mm/Hg.
- ◆ The reaction was classified as a hypotensive transfusion reaction.

6.7 Febrile Non-Haemolytic Transfusion Reactions (FNHTR)

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

There were **388 cases** of Febrile Non-Haemolytic Transfusion Reactions (FNHTR) reported in 2013.

An example of a case is described below.

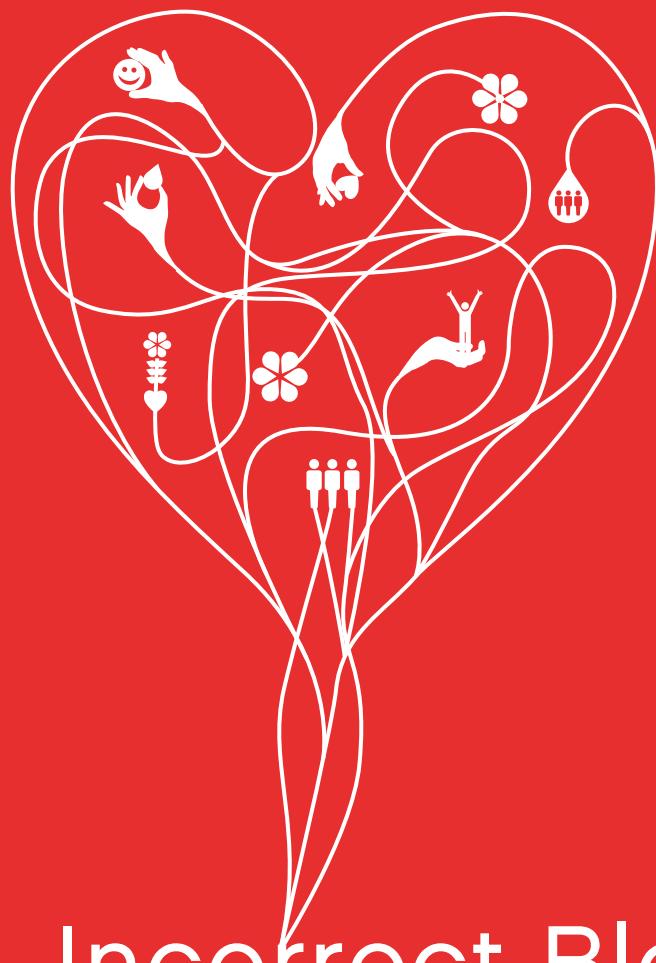
Case JTR 265

- ◆ A 28 year old male with 60% burns and anaemia post-sloughectomy.
- ◆ Was transfused with 1 unit of Red cells.
- ◆ Less than 1 hour into the transfusion, patient had flushing, sweating, tachycardia, dyspnoea, an increase in blood pressure, rigors and an increase in temperature from 38°C to 40°C.
- ◆ The transfusion was stopped immediately.
- ◆ The patient was managed appropriately.
- ◆ The patient stabilised after management.
- ◆ The reaction was classified as a FNHTR.

6.9 Unclassifiable Reactions

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

There were **112 cases** of Unclassifiable Reactions in 2013 due to lack of sufficient transfusion reaction data submitted.



Incorrect Blood Components Transfused (IBCT)



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

Incorrect Blood Components Transfused (IBCT): Case Discussions

Incorrect blood component transfused (Incompatible units)

Misdirected transfusions

Misidentification

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

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

There were **35 cases** of IBCT errors in 2013.

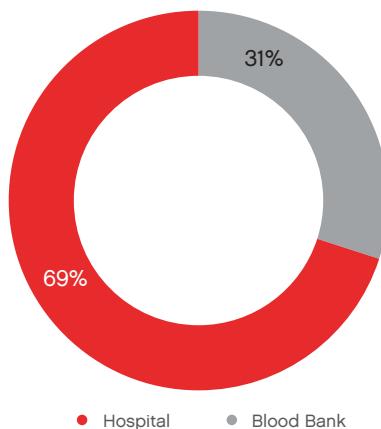
The personnel involved in these errors were:

Type of Error	Personnel Involved	Number of Cases	Percentage (%)
Wrong blood issued/incompatibilities	Blood Bank Technicians	11	31
Patient Misidentification at Transfusion (Bedside/Theatre)	Clinical Staff (Doctors and Nurses)	24	69
Total ATR		35	100

Of the 11 errors committed in the blood bank, 5 cases were due to serological incompatibilities, 3 cases due to Rh incompatibilities, 3 cases were due to ABO incompatibilities of which 1 was a misdirected/sample mix in the blood bank.

Of the 24 hospital errors that occurred, 14 cases were due to sample collection errors and the other 10 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.

Figure 3
Blood Bank and Hospital Errors 2013



An example of an ABO incompatibility case is outlined below. The basis of this case was a clerical error in the blood bank where swapping of blood requisition forms led to the mixing of samples. As a result the patients ended up being transfused with wrong ABO group units.

Case JTR 0240/13

- On the **16/07/13** a request was received at the blood bank for a **39 year old male patient (Patient 1)**.
- The sample was typed as Group O Rh Positive.
- One Group O Rh Positive red cell unit was cross matched, deemed compatible and issued to the ward.
- During the same time period as patient 1's case, a second request was received in the blood bank for another male patient (Patient 2) with a surname almost similar to that of Patient 1.
- **Patient 2 samples were typed as Group B Rh Positive.**
- Two Group B Rh Positive red cell units were issued to the ward.

On the following day, during a routine administrative check of the blood bank case documentation, the Blood Bank Supervisor noted that the names on pages 1 and 2 of the *Request for Blood or Blood Components* (FRM-ISS-006) for both of the above-mentioned patients did not correspond:

- On page 2 of Patient 1's request form, Patient 2's name had been written.
- On page 2 of Patient 2's request form, Patient 1's name had been written.
- On noticing this clerical error, repeat blood typing tests were performed on both patient samples in the blood bank.

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

Case JTR 0240/13 continued

The results were as follows:

- ◆ Patient 1: was typed as a Group B Rh Positive.
 - ◆ Patient 2: was typed as a Group O Rh Positive.
 - ◆ The hospital was notified, and post-transfusion samples as well as all of the empty packs of the transfused units were requested from both patients. The Blood Bank Supervisor also requested that a *Transfusion Reaction Form* (FRM-ISS-006) be completed for each patient, and forwarded to the Blood Bank.

 - ◆ The post-transfusion samples from both patients were received and blood typing tests were performed in the blood bank on them.
- The results were as follows:**
- ◆ Patient 1: was confirmed as **Group B Rh Positive** (initially typed as **Group O Rh Positive**).
 - ◆ Patient 2: was confirmed as **Group O Rh Positive** (initially typed as **Group B Rh Positive**).

 - ◆ The case was forwarded to the Red Cell Serology Laboratory for further investigation.

The results were as follows:

Patient 1:

- ◆ Pre-transfusion specimen: **Group B Rh Positive**. The direct antiglobulin test was negative.
- ◆ Post-transfusion specimen: **Group B Rh Positive**. The direct antiglobulin test was negative.
- ◆ There were no irregular red cell antibodies detected.

Patient 2

- ◆ Pre-transfusion specimen: **Group O Rh Positive**. The direct antiglobulin test was negative.
- ◆ Post-transfusion specimen: **Group O Rh Positive**. The direct antiglobulin test was negative.
- ◆ Mixed field agglutination was noted.
- ◆ Irregular red cell antibody screen: No irregular red cell antibodies were detected in the patient's post-transfusion sample.
- ◆ Allo-agglutinin titration: The patient's post-transfusion plasma demonstrated an anti-A titre of 64 and an anti-B titre of 4 by the immediate spin technique.

Case JTR 0240/13 continued

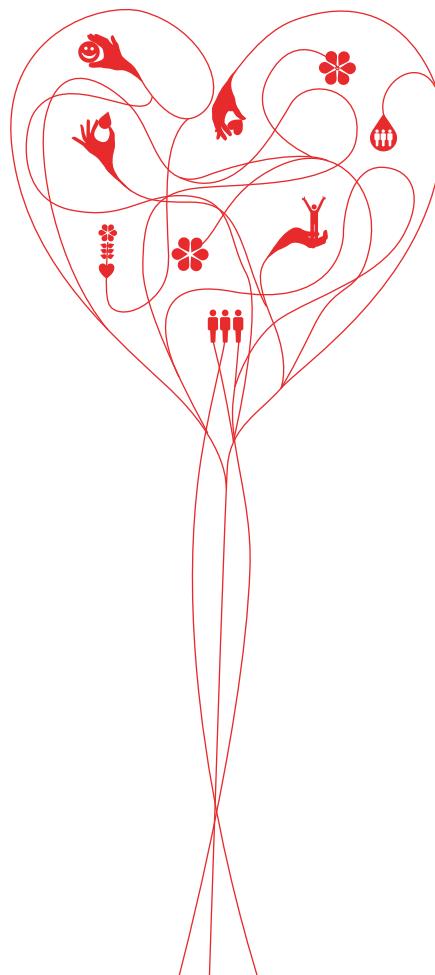
Comments

- ◆ It was identifiable that the swapping of patient samples in the blood bank lead to incorrect case processing:
- ◆ Patient 1's sample was processed with patient 2's request form.
- ◆ Patient 2's sample was processed with patient 1's request form.

Conclusion:

- ◆ Patient 1: Confirmed Group B Rh Positive and received blood Group O Rh Positive unit. No serological incompatibility between his plasma and the donor's red blood cells were demonstrable.

- ◆ Patient 2: Confirmed Group O Rh Positive patient and received 2 blood Group B Rh Positive units. As this patient is Group O Rh Positive, these units were incompatible within the ABO Blood Group System. This incompatibility may have lead to a severe haemolytic transfusion reaction.



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

7.2 Misdirected transfusions

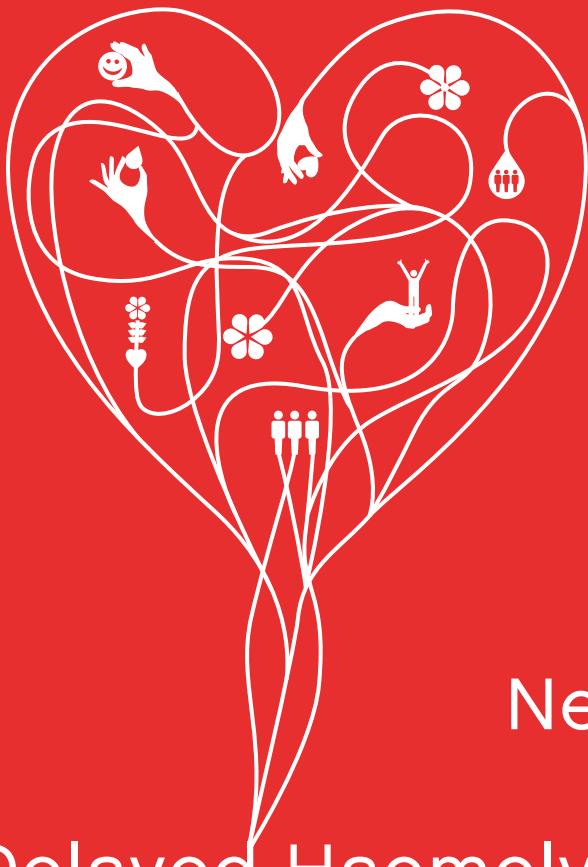
An example of a misdirected transfusion case is outlined below

Case 1 JTR 0366/13

- ◆ On the 03/10/13 at 12:05, two units of red cells were ordered for Patient 1 in ICU.
- ◆ The request was received in the blood bank and the sample was typed Group O Rh Positive.
- ◆ One Group O Rh Positive unit was cross matched, deemed to be compatible and issued at 17:07.
- ◆ Later on the same day, the blood bank also received an order for two units of red cells for Patient 2 in the surgical ward.
- ◆ The sample was typed as Group O Rh Positive.
- ◆ One Group O Rh Positive unit was cross matched, deemed to be compatible and issued at 21:40.
- ◆ **The blood bank was notified 4 days later that the units of blood cross matched for Patient 1 were transfused to Patient 2 in the surgical ward, no transfusion reaction was reported.**
- ◆ A post transfusion sample of Patient 2 (who was transfused with a wrong unit) was forwarded to the blood bank.

Case 1 JTR 0366/13 continued

- ◆ **Pre transfusion specimen**
 - Blood type: Group O Rh Positive
 - Direct Antiglobulin Test: Negative
 - Irregular antibody screen: Negative
- ◆ **Post transfusion specimen**
 - Blood type: Group O Rh Positive
 - Direct Antiglobulin Test: Negative
 - Irregular antibody screen: Negative
- ◆ **Compatibility Test**
 - The transfused pack was not returned to the blood bank from the ward, and as such, no further investigations could be performed.
- ◆ **Comments**
 - Positive verification of patient identity must be carried out prior to the transfusion of blood products.
 - The patient did not suffer an adverse reaction to the transfusion as the blood Groups of the two implicated patients were both Group O Rh Positive.



Near Miss Events

Delayed Haemolytic Transfusion
Reactions (DHTR): Case Discussions

Post Transfusion Purpura (PTP)

Transfusion Associated Graft versus
Host Disease (TA-GvHD)



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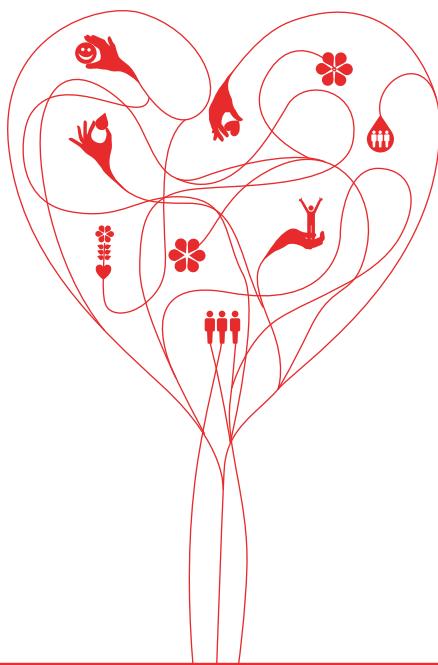


8. Near Miss Events

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

2008	2009	2010	2011	2012	2013
0	2	2	0	2	0

- There were no cases of Near Miss Events reported in 2013.



9. Delayed Haemolytic Transfusion Reactions (DHTR): Case Discussions

9.1 Delayed Haemolytic Transfusion Reactions (DHTR)

2008	2009	2010	2011	2012	2013
0	0	0	0	1	0

- There were no cases of Delayed Haemolytic Transfusion Reactions (DHTR) reported in 2013.

10. Post Transfusion Purpura (PTP)

2008	2009	2010	2011	2012	2013
0	0	0	0	1	0

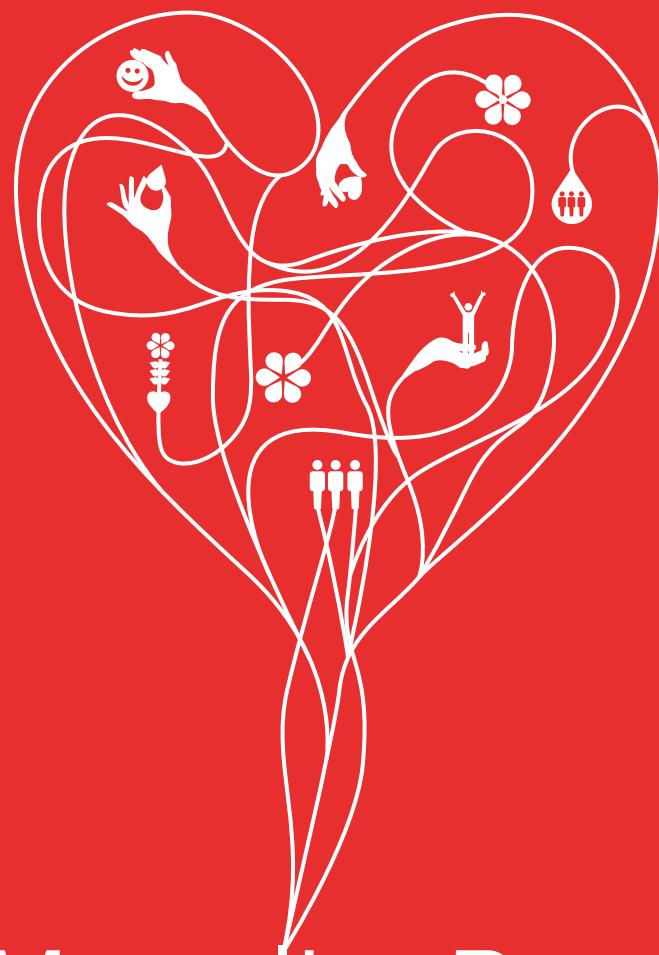
- There were no cases of Post Transfusion Purpura (PTP) reported in 2013.

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

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

- There were no cases of Transfusion Associated Graft versus Host Disease (TA-GvHD) reported in 2013.





Mortality Reports 2013



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12. Mortality Reports 2013

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

Case JTR 147, JTR 148, JTR 421, JTR 468, JTR 354, TR 116.

There were 7 reports of patient mortality following transfusions in 2013. It is important to note that blood transfusion remains a possible contributing factor and not confirmed as a definitive cause of death, since no post transfusion samples were obtained and no post mortem performed on the deceased patients to have clinical evidence that transfusion was the cause of the demise.

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

A brief description of the 7 reports follows:

Case 1: Paediatric: (JTR 147/13)

On the 7th of May 2013, the Haemovigilance office was notified of this mortality case:

- ◆ A 17 month old female baby diagnosed with sepsis.
 - ◆ A paediatric red cell leucodepleted unit was ordered by treating doctor.
 - ◆ A compatible unit was issued by the blood bank
 - ◆ The patient reportedly demised after receiving about 4 - 5 ml of the issued unit.
 - ◆ A post transfusion reaction form was NOT COMPLETED by the reporting personnel.
 - ◆ No post-mortem performed and no post transfusion samples were obtained from the hospital.
- ◆ Conclusion: On telephonic follow up the doctor confirmed that the baby demised as a result of the underlying medical condition and not as a result of the unit transfused.

Case 2: Geriatric, Oncology: (JTR 148/13)

On the 10th of May 2013, the Haemovigilance office was notified of this case:

- ◆ A 68 year old female patient diagnosed with carcinoma of the breast.
 - ◆ A filtered and irradiated red cell unit was ordered.
 - ◆ A compatible unit of filtered, irradiated red cells was issued for the patient.
 - ◆ The blood bank at that hospital, subsequently received a notification of this patient's death following the transfusion.
 - ◆ No reaction form was completed by the reporting personnel.
 - ◆ The suspected unit was discarded.
 - ◆ No post transfusion samples were received and no post mortem conducted.
- ◆ Conclusion: Transfusion remains a possible cause, but it could not be confirmed as a definitive cause of the patient's demise.

Case 3: Geriatric (TR 116 /13)

On the 24th of May 2013, the Haemovigilance office was notified of this case:

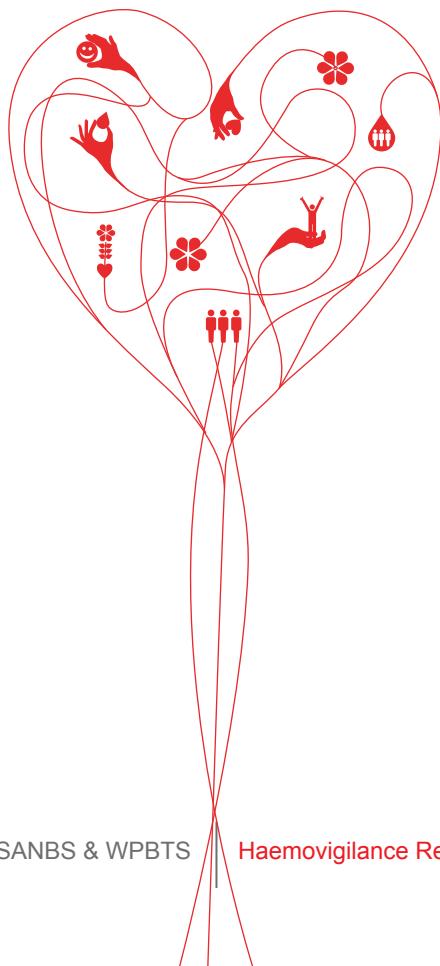
- ◆ A 75 year old male patient.
 - ◆ Diagnosed with congestive cardiac failure and anaemia, haemoglobin of 5.5 g/dl
 - ◆ One unit of compatible blood was issued to the ward by the blood bank, as per the clinician's request;
 - ◆ The ward nurse called and informed the blood bank that:
 - About 45 minutes into the transfusion, the patient developed tachycardia, a decrease in oxygen saturation, cyanosis, bronchospasm, a drop in blood pressure and collapsed.
 - The blood transfusion was stopped immediately, the patient was given Combivent nebulisation and adrenalin.
 - The patient demised.
 - ◆ The suspected unit was discarded.
- No post transfusion samples were obtained by the blood bank and neither were the post mortem results.
- ◆ Conclusion: Transfusion remains a possible cause, but it could not be confirmed as a definitive cause of the patient's demise.

12. Mortality Reports 2013 continued

Case 4: Paediatric (JTR 354/13)

On the 8th of October 2013, the Haemovigilance office was notified of this case:

- ◆ A 7 day old female baby diagnosed with **neonatal sepsis and anaemia – Haemoglobin of 7.8 g/dl.**
 - ◆ A paediatric leucodepleted red cell unit was ordered for the baby.
 - ◆ A compatible paediatric leucodepleted red cell unit was issued by the blood bank.
 - ◆ In less than an hour, the baby was reported to have reacted to the issued unit.
 - ◆ The baby presented with: a drop in blood pressure and cyanosis.
 - ◆ The blood transfusion was stopped, and CPR was commenced.
 - ◆ The baby demised.
 - ◆ A transfusion reaction form was completed by the treating doctor.
 - ◆ No post transfusion samples were obtained by the blood bank and no post mortem conducted.
- ◆ **Conclusion: Transfusion remains a possible cause, but it could not be confirmed as a definitive cause of the patient's demise.**



Case 5: (JTR 395/13)

On the 23rd of October 2013, the Haemovigilance office was notified of this case:

- ◆ **A 30 year old male patient diagnosed with Crohn's disease and Hb of 2.7 g/dl.**
- ◆ A cross match request was received at the blood bank and the sample was typed **Group AB Rh Positive.**
- ◆ **Four units of Group AB Rh Positive red cell concentrates were cross matched, deemed to be compatible and issued to the patient.**
- ◆ Two units of Fresh Frozen Plasma (FFP), Group A Rh Positive were also issued to this patient.
- ◆ The blood bank was later informed that the patient had experienced a transfusion reaction after receiving an undisclosed volume of the blood issued, and had subsequently demised.
- ◆ Two units of RBC and one of FFP were returned to the blood bank for investigation, together with the patient's post transfusion sample.
- ◆ A preliminary transfusion reaction investigation was performed by the blood bank.
- ◆ **The results were as follows:**
 - The blood type on the pre transfusion sample was confirmed Group AB Rh Positive.
 - The post transfusion sample was however typed as Group O Rh Positive.
 - **Strong serological incompatibility was demonstrable by the immediate spin and direct antiglobulin techniques when the post transfusion plasma was cross matched against the red blood cells of the returned packs, which both typed Group AB Rh Positive.**
- ◆ The case was received in the Red Cell Serology Laboratory.
- ◆ **The results were as follows:**
 - **Pre transfusion specimen:**
 - Blood type: **Group AB Rh Positive.**
 - Direct Antiglobulin screen: Not performed due to insufficient plasma.
 - **Post transfusion specimen:**
 - Blood type: **Group O Rh Positive.**
 - Direct Antiglobulin Test: **Negative.**
 - Irregular antibody screen: **Negative.**
- ◆ **Conclusion:**

The pre- and post-samples were both labelled with hospital stickers. It was clear that the pre transfusion blood sample was not obtained from the same patient intended to be transfused and, the error resulted in the patient's demise. This type of incompatibility may cause a severe haemolytic transfusion reaction.

12. Mortality Reports 2013 continued

Case 6: Oncology (JTR 421/13)

On the 6th of November 2013, the Haemovigilance office was notified of this case:

- ◆ A female patient diagnosed with leukaemia and thrombocytopenia.
- ◆ A request for compatible unit of red cells was received by the blood bank.
- ◆ The pre-transfusion was typed Group A Rh Negative.
- ◆ Two units of Group A Rh Negative Red Cell Concentrate were cross matched and deemed compatible and issued.
- ◆ The following day, only one unit was returned to the blood bank. Upon enquiry, the blood bank supervisor was informed that the patient had demised, prior to being transfused with the second unit.
- ◆ The first unit was not returned for post-transfusion testing and was reported incinerated by the ward staff.
- ◆ A transfusion reaction form was not completed by the treating doctor.
- ◆ The case was received in the Red Cell Serology Laboratory and testing was performed.

◆ The Results were as follows:

Pre transfusion specimen:

- Blood type: **Group A Rh Negative**.
 - Direct Antiglobulin Test: **Negative**.
 - Irregular antibody screen: **Negative**.
- ◆ Post transfusion samples were also not obtained by the blood bank and no post mortem conducted.

◆ Conclusion:

- ◆ No further testing could be performed as neither a post transfusion sample nor the other unit forwarded to the blood bank for investigation.
- ◆ No irregular red cell antibodies capable of causing a haemolytic transfusion reaction were detected in the patient's pre transfusion sample.
- ◆ No serological cause for the patient's demise could be determined.
- ◆ Transfusion remains a possible cause, but it could not be confirmed as a definitive cause of the patient's demise.

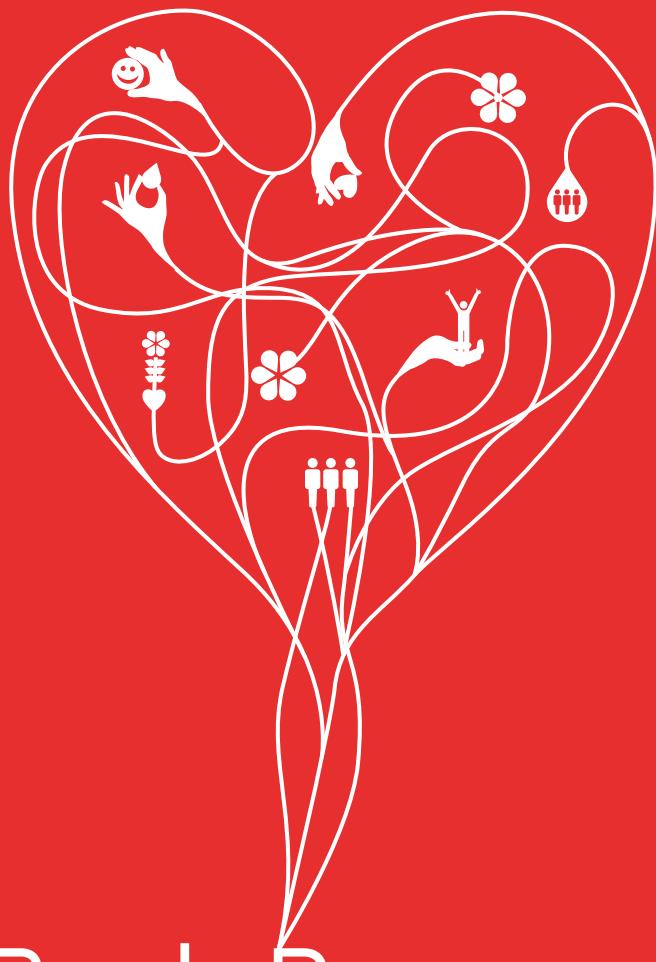
Case 7: (JTR 468/13)

On the 3rd of December 2013, the Haemovigilance office was notified of this case :

- ◆ A request was received at the blood bank for a female patient with retroviral disease stage 4.
 - ◆ Two units of Group O Rh Positive Red Cell Concentrate were cross matched and deemed compatible.
 - ◆ The blood bank was later informed that the patient had experienced a transfusion reaction after receiving approximately 150 ml of the blood issued and subsequently demised.
 - ◆ One unit was received in the blood bank and preliminary transfusion reaction tests using the patient's sample were conducted.
 - ◆ A reaction report form was not completed by the treating doctor.
 - ◆ No post transfusion samples were obtained by the blood bank and no post mortem conducted.
- ◆ Conclusion: Transfusion remains a possible cause, but it could not be confirmed as a definitive cause of the patient's demise.

Learning points:

- ◆ Patients with serious acute transfusion reactions need further investigation and proper planning for transfusion management in the future.
- ◆ Appropriate assessment of all patients prior to transfusion, to ensure that all transfusions are appropriate and that the transfusions are completed with appropriate monitoring as recommended by the guidelines in the Standards of Practice for Blood Transfusion in South Africa 2013.
- ◆ All cases of transfusion adverse reactions need to be reported and transfusion reaction forms completed as accurately as possible to ensure proper classifications.



Look Back Programme



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13. Look Back Programme

The Transfusion Transmissible Infection (TTI) Look Back 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 Look Back 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 look back investigation** the recipient/s of the previous negative units are identified and their treating doctor notified. As far as possible, the patient is recalled, counseled 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 (2013)

Total number of look backs	SANBS	WPBTS	Total
HIV	422	31	453
HBV	195	13	208
HCV	5	3	8
HIV/HBV Co-Infections	5	1	6
Other	3	0	3
Total	630	48	678

For 2013, a total of 678 donors sero-converted and were investigated through the donor triggered look back process, an increase compared to 566 cases in 2012. There was a 100% follow up of all cases. Of the 678 cases, 66.8% of look backs were due to HIV, 30.7% HBV and 1.2% cases were due to HCV. Six cases had HIV/HBV co-infection and the 3 other cases were investigated for malaria.



Table 13.2: Investigation outcomes

Donor-triggered investigation outcome	SANBS	WPBTS	Total
Retest negative	69	9	78
Recipient positive before transfusion	36	2	38
HIV positive recipient/s – phylogenetic analysis	2	0	2
Recipient died - between transfusion and initiation of look back	115	11	126
Unresolved	513	24	537
Untraceable patient	28	4	32
Other	3	12	15
Refused/Declined testing	2	0	2
HBV Immune	1	0	1
HBV positive recipient - phylogenetic analysis	0	0	0
On dual therapy (HBV lb)	0	0	0
Total	769	62	831

At the time of the report, 831 donor-triggered investigations were conducted from the 678 donors with previous donations. Two hundred and ninety four (**35.4%**) of the **831 cases were resolved/closed**. Of the 294 cases, 78 recipients were traced and tested negative while 38 cases were confirmed positive before transfusion (confirmed on requisition form or by treating doctor). Two (2) HIV positive recipients had phylogenetic analysis performed and determined in both cases that there was no genetic linkage and transfusion transmission was excluded.

One hundred and twenty six recipients were confirmed to have died between the transfusion episode and the look back investigation initiation period, 32 cases were untraceable because the patients were unreachable by the hospital or due to missing hospital files and; in the other 17 cases recipients either refused to come or were too ill to present for testing and for some cases, the hospital clinical manager refused to investigate look backs that were more than 6 months old.

The other **537 of the 831 (64.6%) 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. Look Back Programme continued

Recipient-triggered look backs 2013

A **recipient-triggered look back 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: Recipient-triggered look backs 2013

	Resolved	Unresolved	Total
HIV	11	3	14
HBV	2	0	2
HCV	0	0	0
Other	0	2	2
Total	13	5	18

A total of 18 recipient-triggered look back cases were reported and 13 (72.2%) of cases had been resolved/closed at the time of the report. Of the 13 cases that were resolved, 11 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 18 reported recipient-triggered look back cases, 5 (27.8%) cases remain unresolved because no records were found due to time lapsed or the donors being untraceable.

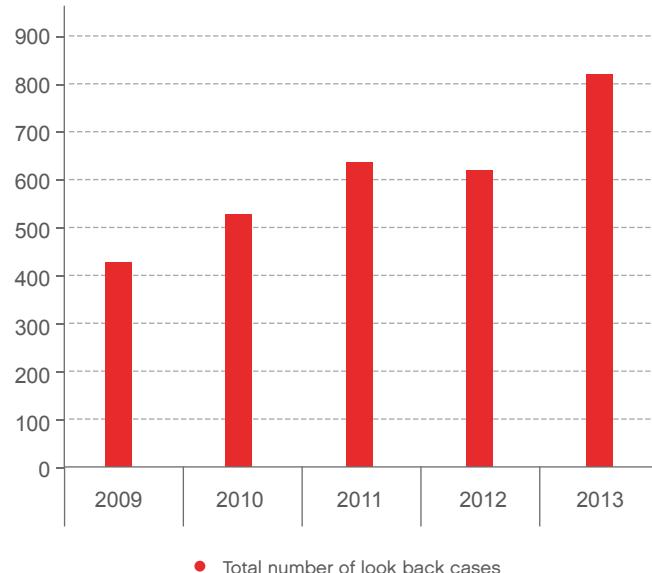
There has been an increase in the total number of all look back cases (donor and recipient triggered) from 447 (2009), 546 (2010), 642 (2011) 629 (2012) and 849 in 2013 which showed a huge increase as shown in Table 13.4 and Figure 3 below.

Table 13.4: Overview of look back investigations (2009-2013)

	2009	2010	2011	2012	2013	Total
Total number of look back cases	447	546	642	629	849	3 113

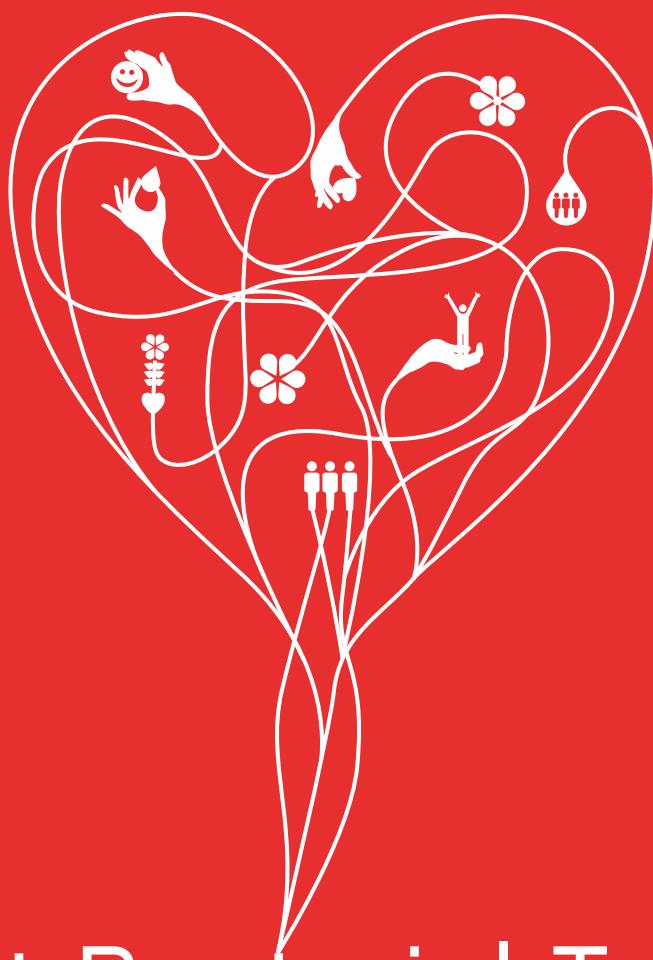
Eight hundred and forty nine of 1 133 204 (0.075%) transfused products resulted in a look back investigation due to possible contaminated transfusions

Figure3. Look back cases (2009-2013)



Challenges to the look back 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 look back is not always relayed timeously to the look back officer.
- Retest results are not sent to the look back officer as requested in the look back notification.
- Numerous follow-up calls have to be made before a result is obtained from several major provincial hospitals and many doctors in private sector.
- Several hospitals and doctors consider it the duty of 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)



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14. Platelet Bacterial Testing (SANBS ONLY)

As part of the SANBS quality assurance programme and policy, 1% or a minimum of 16 units, whichever is greatest, of all products processed must be tested monthly. All platelet components tested were screened for bacterial contamination using an automated culture system and incubated in aerobic and anaerobic culture bottles for 14 days at 35-39°C. The results showed an incidence (2.2%) of bacterial contamination as demonstrated in Table 14.1 below.

Product Tested	Number Tested	Number Positive & %	Organism Identified
Apheresis Platelets	2 762	60 (2.2%)	<i>Corynebacterium spp</i> x13 <i>Staphylococcus epidermidis</i> x9 <i>Propriionibacterium</i> x3 <i>Strep viridans</i> x3 <i>Micrococcus spp</i> x3 <i>Staph hominis</i> x2 <i>Cellumonas spp</i> x2 Others x 25 (<i>Staph aureus</i> , <i>Staph hominis</i> , <i>staph capitis</i> , <i>strept mitis</i> , <i>MRSA</i> , <i>P. acnes</i> , <i>P. avidum</i> , <i>Gardnerella vaginalis</i> , <i>Brevibacterium</i> , <i>Arcanobacterium</i> , <i>Rhodococcus</i> , <i>Bacillus cereus</i> & <i>Anginosus</i>)
Pooled Platelets	N/A	N/A	Pooled platelets are only tested for bacterial contamination if available at expiry
Expired Platelets	75	1 (1.3%)	<i>Corynebacterium spp</i>
Total	2 837	61 (2.2%)	

The commonest organisms cultured were corynebacterium and staphylococcus epidermidis species. On follow up of the cases by the SANBS medical officers, 4 cases were reported by the treating doctors not to have been received by the patients and discarded. Only one organism, a corynebacterium spp was identified in expired platelets.

These products are tested since storage of platelets at room temperature creates an ideal environment for bacterial growth. All positive sterility samples are quarantined and sent to an external referral laboratory for further identification.

Ten Colony Forming Units (10 CFU) of bacteria can cause infection in immuno-compromised patients therefore based on that risk, the SANBS medical officers are contacted immediately with the first screening results to discuss the findings with the patients' treating doctors as due to the short shelf-life and high demand for these products, apheresis platelets are on average transfused within 72 hours of collection while the bacterial screening results on the majority of products are only available after transfusion has already taken place.



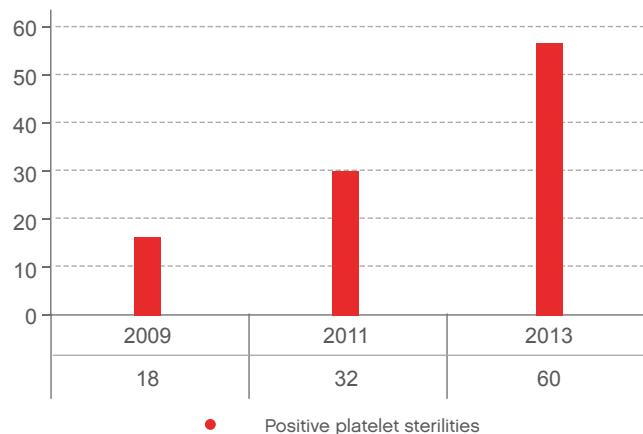
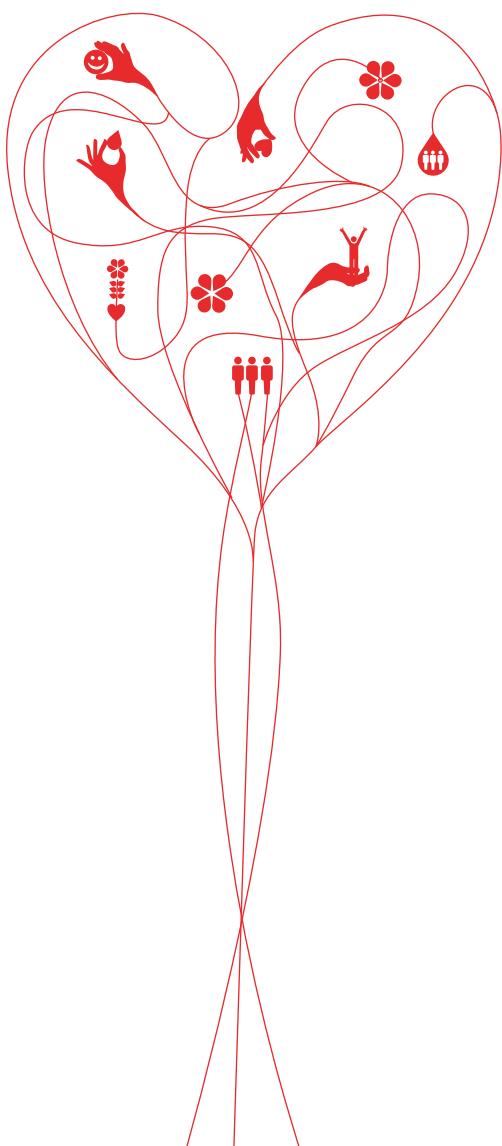
14. Platelet Bacterial Testing (SANBS ONLY) continued

Table 14.2 Overview of platelet sterilities (2011-2013)

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

More organisms were identified in Apheresis platelets in 2013 (60) by comparison to 2012 (32) and 2011 (18) as demonstrated in Table 14.2 above and the graph below.

The increase in 2013 was investigated but we were unable to determine the source of contamination. Additional measures were put in place to mitigate the increase in the number of contaminated units. These measures included the environmental monitoring within the Microbiology laboratory and communication of proper hand-washing techniques.



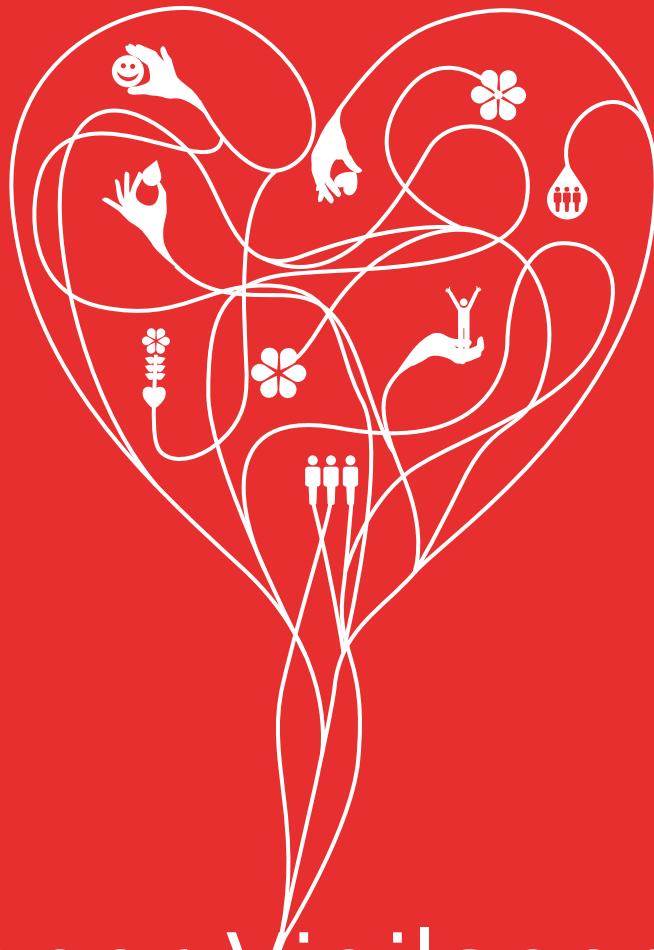
Environmental monitoring is performed monthly in apheresis collection areas and bi-annually in processing centres.

The aim is to ensure:

- that the products are collected and processed to the highest possible 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

As part of the improvement, the WHO hand washing techniques was incorporated into the SANBS procedures within 2013.





Donor Vigilance 2013 (National Data)



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15. Donor Vigilance 2013 (National Data)

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 sustainable 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.^{2,4} 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, 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 review and analysis 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	Nerve irritation	
		Nerve injury	
		Tendon injury	
		Painful arm	
	Others	Thrombophlebitis	
		Allergy (local)	
Generalised symptoms	Vasovagal reaction	Immediate	
		Immediate with injury	
		Delayed	
		Delayed with injury	
Related to apheresis		Citrate reaction	
		Haemolysis	
		Generalised allergic reaction	
		Air embolism	

An example of an ABO incompatibility case is outlined below. The basis of this case was a clerical error in the blood bank where swapping of blood requisition forms led to the mixing of samples. As a result the patients ended up being transfused with wrong **ABO** group units.

15. Donor Vigilance 2013 (National Data) 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, sometime after insertion of the needle. Injury of a nerve by the needle at insertion or withdrawal. <u>Symptoms</u> are pain often associated with paraesthesia. The pain is severe and radiating. It arises immediately when the needle is inserted or withdrawn.	
Nerve Injury	Injury of a tendon by the needle. <u>Symptoms</u> are severe local non-radiating pain initiating immediately when the needle is inserted.	
Tendon Injury	Injury of a tendon by the needle. <u>Symptoms</u> are 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 2013 (National Data) 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	<p><u>Symptoms</u> and signs associated with the transient hypocalcaemia caused by citrate. Donors usually present with mild tingling around the mouth and on the lips, metallic taste in the mouth and peripheral paraesthesia. Severe cases are characterised by respiratory difficulty with nausea and vomiting.</p>
Haemolysis	Destruction of the donor's red blood cells.
Generalised Allergic Reaction	<p>The result of an interaction of an allergen with preformed antibodies.</p> <p>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 or blood donation process.

15. Donor Vigilance 2013 (National Data)

In 2013, a total of **967 125** 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 WPBTS 17%. A slight change has been noted in the total collection contributions in 2012 of 84% by the SANBS and 16% by the WPBTS.

Table 15.1 Collections 2013 (National Data)

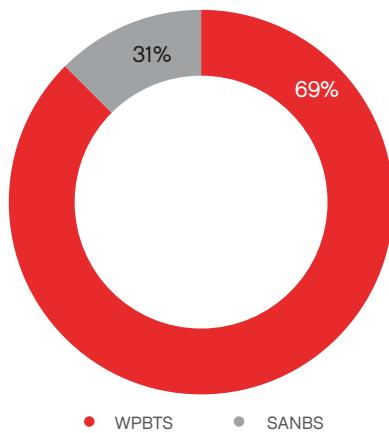
Collections 2013	SANBS	WPBTS	Total
Whole Blood	779 496	163 105	942 601
Apheresis Red Cells	3 719	0	3 719
Apheresis Platelets	14 793	3 594	18 387
Plasma	2 418	0	2 418
Totals	800 426	166 699	967 125



The SANBS collections were undertaken at **87 fixed** 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 (Paarl, Worcester and George), **3 fixed site** blood donor centres, **7 mobile units** and an apheresis and autologous/designated donation unit at the Head Quarters in Pinelands.

Figure 4: Product Collections 2013 (SANBS and WPBTS)



15. Donor Vigilance 2013 (National Data) continued

15.3 Summary of Donor Adverse Events 2013

15.3.1 By Donation Type

Acute Reactions	Whole Blood	Apheresis	Unallocated	Totals
Haematoma	360	225	12	597
Arterial Puncture	0	2	2	4
Delayed Bleeding	16	0	0	16
Nerve Irritation	5	0	0	5
Tendon Injury	0	0	0	0
Nerve Injury	1	0	0	1
Painful Arm	69	18	5	92
Total Local Symptoms	451	245	19	715
Faint Immediate Type	2 210	29	16	2 255
Faint Immediate, Accident	53	4	5	62
Faint Delayed Type	410	11	7	428
Faint delayed, Accident	46	0	1	47
Total no. Vasovagal Reactions	2 719	44	29	2 792
Citrate Reaction	5	32	2	39
Haemolysis	1	1	0	2
Generalised Allergic Reaction	1	0	0	1
Embolism	1	0	0	1
Others	0	0	0	0
Total	8	33	2	43
Grand Total	3 178	322	50	3 550

In 2013, all donor adverse events reported contributed 0.37% (3 550 out of 967 125) of the total collections. The adverse events have been categorised into whole blood, apheresis and unallocated donations. The main concern is with the unallocated category i.e. those that do not fall into either whole blood or apheresis donations. This indicates that the staff does not accurately 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.

The data capturing with the WPBTS is accurately classifying donations as whole blood and apheresis donations, as the unallocated group is only included with SANBS data. Most DAE were experienced with whole blood donations at 89.5%, apheresis donations at 9.1% and unallocated donations at 1.4%. The rate of unallocated DAE has however improved from 3% in 2012 to 1.4% in 2013, which could indicate that there is a positive impact with training.

15. Donor Vigilance 2013 (National Data) continued

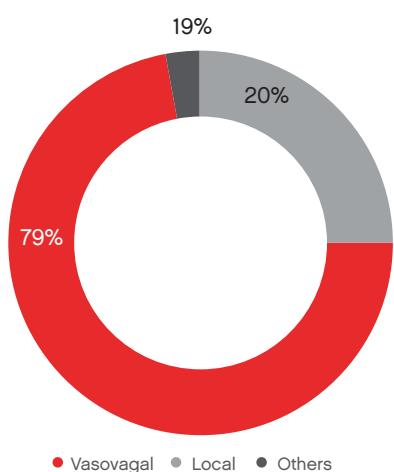
Table 15.3.2 Donor adverse events according to broad categories

	Local Symptoms	Vasovagal	Others	Total
SANBS	429	1 146	42	1 617
WPBTS	286	1 646	1	1 933
Total	715	2 792	43	3 550

The majority of donor adverse reactions were vasovagal (79%), local symptoms (20%) and others (1%) as shown in Table 15.1.1 and Figure 5. Of the vasovagal reactions, 81.1% were attributable to immediate faints without accident, 2.1% immediate faints with accidents; 15.5% delayed faints without accident and 1.3% delayed faints with accident. The majority of vasovagal events are without accidents, but all events must be managed immediately and effectively by all staff involved.

In the local symptoms category, 84.5% were due to haematomas followed by 12% 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 2013 (National Data) continued

15.3.4 Analysis of Adverse Events by Severity

	Severity	Mild	Moderate	Severe	Subtotal
Local Adverse Events	Haematoma	570	32	2	597
	Arterial Puncture	4	0	0	4
	Delayed Bleeding	13	1	0	14
	Nerve Irritation	0	3	0	3
	Tendon Injury	0	0	0	0
	Nerve Injury	1	3	0	4
	Painful Arm	61	19	6	86
	Total Local Symptoms	649	58	8	715
Vasovagal	Faint Immediate Type	1 934	79	250	2 263
	Faint Immediate, Accident	36	19	3	58
	Faint Delayed Type	325	76	33	434
	Faint Delayed, Accident	15	13	9	37
	Total no. Vasovagal Reactions	2 310	187	295	2 792
Others	Citrate Reaction	38	1	0	39
	Haemolysis	2	0	0	2
	Generalised Allergic Reaction	0	0	1	1
	Embolism	1	0	0	1
	Others	0	0	0	0
	Total	41	1	1	43
Grand Total		3 001	246	304	3 550

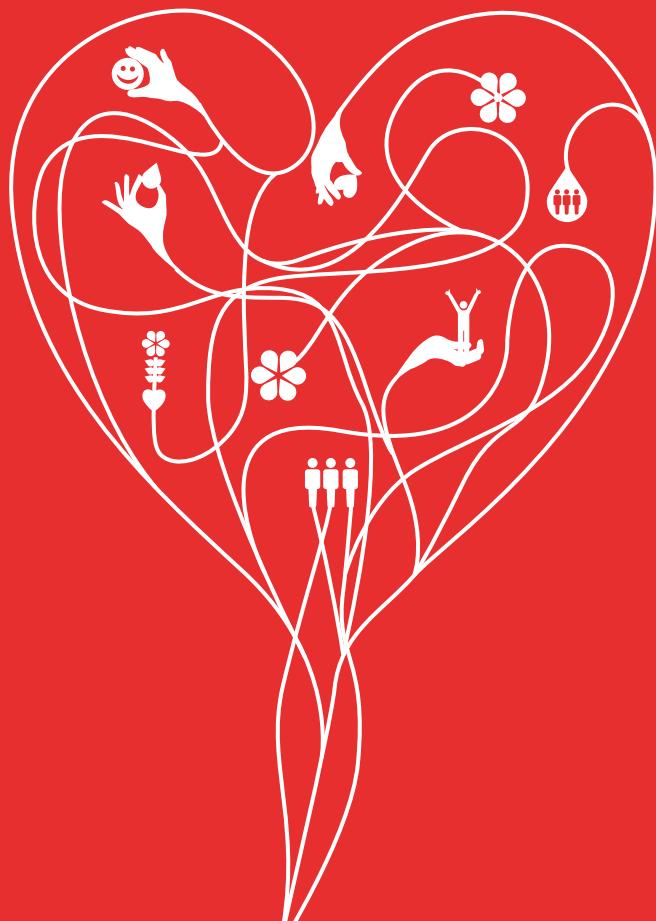
As shown in Table 15.2 above, 84.5% of donor adverse reactions were mild, 6.9 % moderate and 8.6% severe.

15.3.5 Analysis of Adverse Events by Age group (National Data)

As shown in Table 13.3.1 below, donors below 21 years had the most donor adverse events at 33.6% followed by donors 31-50 age group at 29.5% and the donor group above 50 years had the least events at 9.6%.The results are similar to 2010, 2011, 2012 and 2013.

Age Group	WPBTS	SANBS	Total	%
<21	741	452	1 193	36.6
21-30	512	457	969	27.3
31-50	600	447	1 047	29.5
>50	80	261	341	9.6
Total	1 933	1 617	3 550	100





International Corner



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16. International Corner

16.1 African Society of Blood Transfusion Congress 2014

The 7th Annual AfSBT was held in Victoria Falls in Zimbabwe from July 30th to August 2nd 2014. The congress was held at the Elephant Hills Hotel. A haemovigilance workshop hosted by the SANBS was held on the 1st of August, as a parallel session.

The aim/purpose of the workshop was:

- ◆ To sensitise and support African countries without haemovigilance systems to establish and implement these back in their countries as part of collaboration between the South African National Blood Service (SANBS) and the World Health Organization (WHO).
- ◆ To share information related to transfusion and importantly the South African haemovigilance experience.
- ◆ To share the risks/challenges which have been detected through haemovigilance programmes in the SANBS and the WPBTS.



The workshop was well attended by approximately 56 delegates from among others; countries like Ghana, Zambia, Malawi, Zimbabwe and Botswana. Even though most of our African colleagues do not have fully functional haemovigilance systems, the need to formally establish this has been escalated to World Health Organization level. Participation of African countries will allow better assessment of trends within the African continent.

Parallel Session 3.3 HAEMOVIGILANCE WORKSHOP: (SANBS) 10:30 - 12:05 hrs

Session Chair: Dr. K. van den Berg, **Co-Chair:** Dr. B. Lorke

Time	Speaker	Title
10:30 - 10:50	Dr. Charlotte Ingram (SANBS/RSA)	WHO Haemovigilance Working Party Feedback: A quick review of the work done to date by the WHO Haemovigilance Working Party, focusing on progress made and planned implementation.
10:50 - 11:05	Dr. Neo Moleli (SANBS/RSA)	Haemovigilance in Africa: An overview of the current situation /A short review of haemovigilance as it is currently being practiced across Africa, with particular focus on barriers to implementation.
11:05 - 11:20	Sr. Francis Ledwaba (SANBS/RSA)	Administrative Errors /A short summary of the risks passed by administrative errors in blood banking; how these occur and what systems can be implemented to minimise risk.
11:20 - 11:35	Ms. Debbie McLinden (SANBS/RSA)	Transfusion reactions /A review of the more common transfusion reactions focusing on the initial management and investigation thereof.
11:35 - 11:50	Dr. Petro-Lize Wessels (SANBS/RSA)	TTIs: Malaria /An assessment of the risks and potential mitigation strategies associated with TTIs in blood banking using Malaria as a point in case.
11:50 - 12:05	Dr. Charlotte Ingram (SANBS/RSA)	Look back Programmes: The South African experience /A review of the development, implementation and management of a look back programme in South Africa, with particular focus on ethics and legal liability.

16. International Corner continued

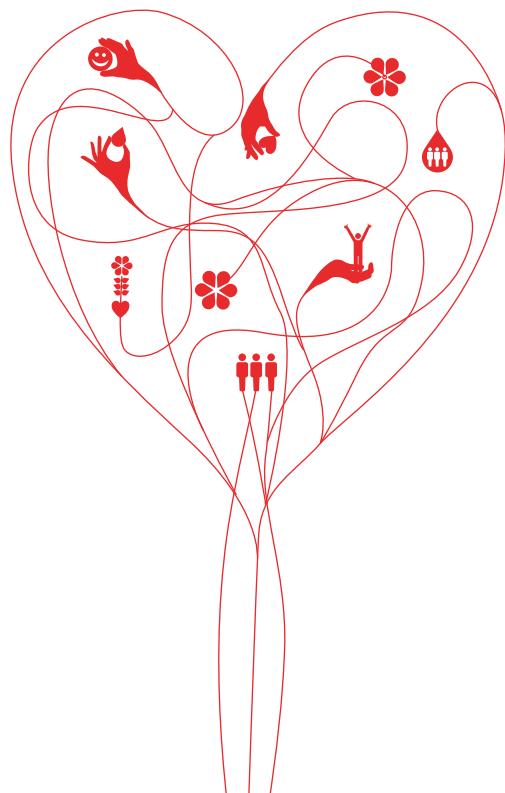
- ◆ Dr. Ingram gave a presentation on how far the WHO is with regard to assisting interested African countries to implement a form of a haemovigilance system. She highlighted the progress and plans of implementation relating to guidelines on how to establish a haemovigilance system which will be finalised and published in 2015. This is mainly a collaboration of SANBS and the WHO.
- ◆ Dr. Moleli gave an overview of the current situation on haemovigilance in Africa, how it is currently being practiced across Africa, with particular focus on barriers to implementation based on surveys conducted by the WHO.

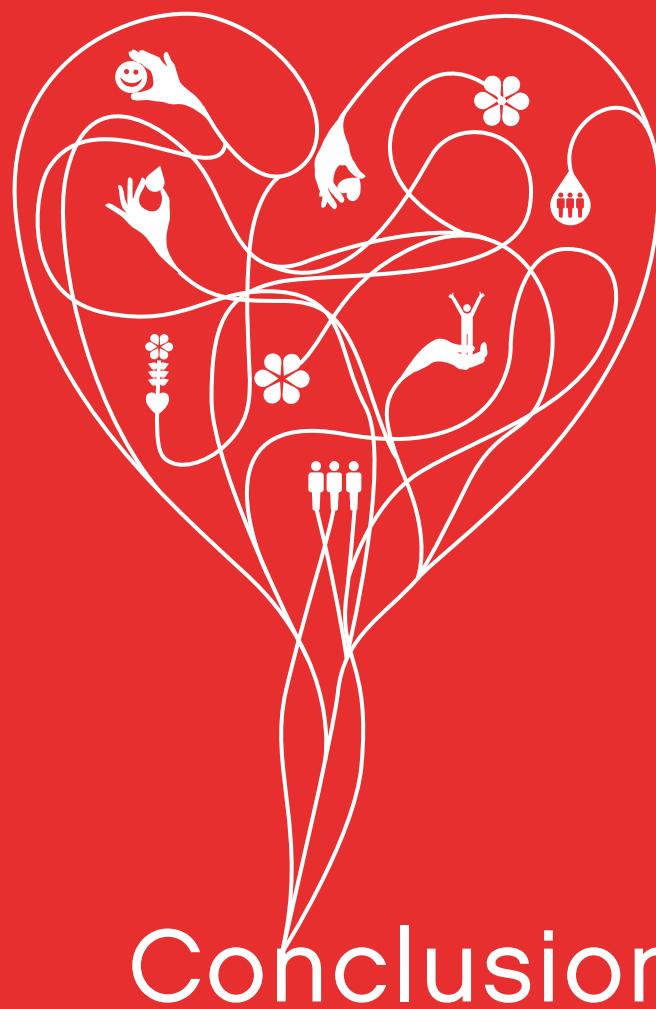


- ◆ Sr. Ledwaba gave a summary of the administrative errors and the risks passed by administrative errors in blood banking, how these occur and what systems can be implemented to minimise risk.
- ◆ The processes involved in the investigation of transfusion reactions, was given by Mrs. Debbie McLinden, and how SANBS is managing and investigating these transfusion reactions.
- ◆ Dr. Wessels gave a relevant presentation on the risk of transmission of malaria in blood donations based on the WPBTS transmission cases and the challenges Africa is facing with this risk.
- ◆ Dr. Ingram closed the session by giving an overview of the South African experience on TTI look back programme.

16.2 World Health Organization (WHO) Haemovigilance guidelines

SANBS is taking a leading role in the WHO haemovigilance core writing group in the drafting of WHO guidelines on establishing a national haemovigilance system, as per set timelines. The guidelines are aimed to assist countries without haemovigilance systems, mainly in Africa. The aim is to launch and publish the guidelines at the next haemovigilance annual meeting to be held in Rio de Janeiro in March 2015.





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17. Conclusion

Blood transfusion is an important component of modern day medicine. For doctors the first consideration must always be the best interests and safety of patients. Haemovigilance programmes collect and analyse data on untoward events associated with transfusion and must be supported. The information collated is then shared with health professionals who prescribe and administer blood products, so that they can continuously strive towards positive and beneficial interventions without unintended negative consequences, while minimising risks to recipients.



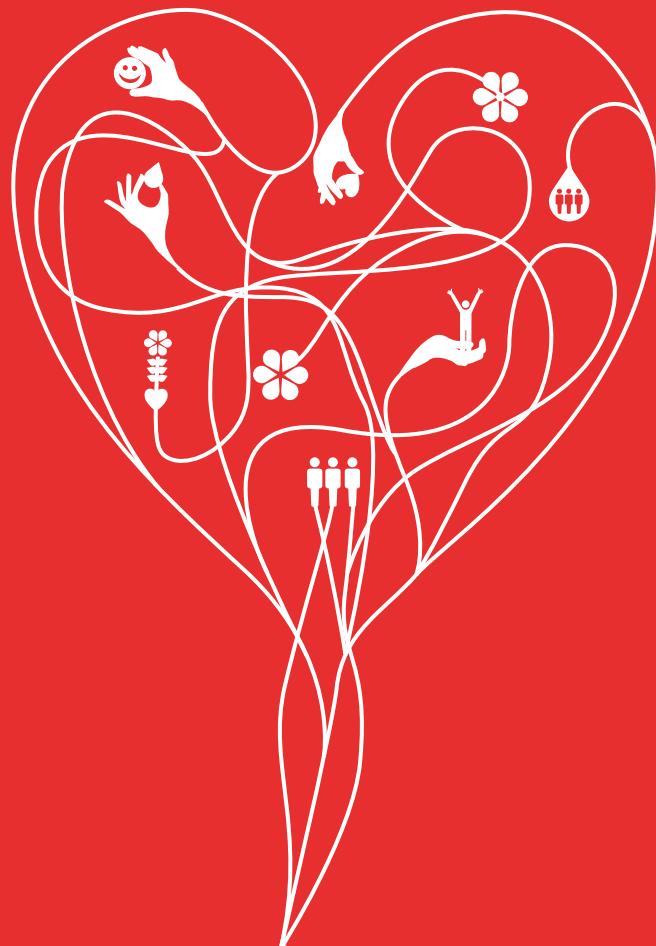
Haemovigilance will continuously highlight and educate the healthcare providers on the importance of monitoring, evaluating and reporting of transfusion adverse events. Human error rates remain a concern that all parties involved need to address along with the appropriate management of patients that 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 workshop was well attended by approximately 56 delegates from among others; countries like Ghana, Zambia, Malawi, Zimbabwe and Botswana. Even though most of our African colleagues do not have fully functional haemovigilance systems, the need to formally establish this has been escalated to World Health Organization level. Participation of African countries will allow better assessment of trends within the African continent.





References



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18. References

1. <http://www.ihn-org.com/haemovigilance-databases/istare-2/>
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. 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.
4. Glynn SA. Blood supply safety: an NHLBI perspective. *Transfusion* 2008; 48: 1541-4.
5. 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.
6. 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.
7. <http://www.sanbs.org.za>
8. <http://www.wpblood.org.za>

