HaemovigilanceReport 2012

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HaemovigilanceReport 2012

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 has 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 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
TAGvHD	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 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 mucocutaneous 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, characterized 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: • 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 Continued

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° C or equivalent or a change of > 2° C from pre-transfusion value with or without minor rigors and chills, but without haemolysis or features of an allergic reaction. The patient may have one or more of myalgia, nausea, changes in blood pressure or hypoxia. The most common cause is a reaction to passively transfused cytokines or a reaction to recipient antibodies and leukocytes in the donor's blood
Delayed Transfusion Reactions	Transfusion-related reactions that occur after 24 hours following a transfusion of blood or components.
Delayed Haemolytic Transfusion Reactions	The recipient develops antibodies to RBC antigens. Usually manifests between 24 hours and 28 days after a transfusion and clinical or biological signs of haemolysis are present. In practice, these are usually delayed haemolytic reactions due to the development of red cell antibodies. Simple serological reactions such as antibody development without a positive DAT or evidence of haemolysis are excluded (development of antibody without positive DAT or evidence of haemolysis).
Delayed Serologic Transfusion Reactions	Demonstration of new, clinically significant alloantibodies against red blood cells between 24 hours to 28 days after a transfusion despite an adequate haemoglobin response to transfusion that is maintained.
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 vs 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 TTVI'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 Continued

Category	Definition
Transfusion-transmitted Parasitic Infections	Detection of the same parasite in the recipient's blood and parasite or specific antibodies in the donor blood.
Incorrect Blood or Component Transfused	All reported episodes where a patient was transfused with a blood component or plasma product that did not meet the appropriate requirements or that was intended for another patient.
Near miss	An error or deviation from standard procedures or policies which, if undetected, could result in the determination of a wrong blood group or issue, collection or administration of an incorrect, inappropriate or unsuitable component, but which was recognized before the transfusion took place.
Misidentification – Hospital error	Near miss events related to the misidentification of specimens, units or patients, which occurs outside of the blood bank.
Misidentification – Blood Bank error	Near miss events related to the misidentification of specimens, units or patients, which occurs at the blood bank.
Misdirected Transfusion incidents	A misdirected transfusion **incident** is a case where the patient is transfused with a blood that was intended for another patient. It thus comprises transfusion errors and deviations from standard operating procedures or hospital policies that have led to mistransfusions. *It may or may not have led to an adverse reaction.*
Unclassifiable Complication of Transfusion (UCT)	Occurrence of an adverse event or reaction temporally related to transfusion, which cannot be classified according to an already defined ATE and with no risk factor other than transfusion.

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

Foreword

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1 Foreword

Message from the Medical Directors:

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

Haemovigilance has become a crucial part of the blood safety concept. Data is sourced from private and public hospitals in South Africa. Increasingly, healthcare professionals in the public and private sectors search for evidence-based utilization and improved patient outcomes for blood transfusions.

Since 2010, the annual Haemovigilance Report for the Blood Transfusion Services in South Africa started to include a section on donor vigilance, detailing the adverse reactions of blood donors over and above the adverse reactions of recipients of blood transfusion it has been covering over the years from 2000. The inclusion of donor reactions is an effort to improve on donor health care by tracking all adverse events associated with blood donation from the collection to the end delivery outcome.

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 2012 Haemovigilance Report.

The principal objectives of this report are:

To supply national data on the 2012 reported adverse events:

- Adverse reactions associated with transfusion;
- Data on serious adverse reactions associated with blood donation;
- To analyse the frequency of events (patient related and donor related) over the period from 2008 to 2012 (overall and per diagnosis); and
- To pinpoint the issues requiring further analysis.

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Executive Summary 2012

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2 Executive Summary 2012

This report is compiled from data gathered between January and December 2012, by the two services providing blood transfusion in South Africa, i.e. SANBS and the WPBTS.

Blood products and transfusions are not risk free. Despite significant improvements in product safety through careful donor selection and product screening, transfusion errors and reactions still occur in hospitals. Often, they result from human error and can lead to patients staying longer than anticipated in hospital and in some cases, death. Analyzing the haemovigilance reports provides a picture of current transfusion risks, and may provide information about the causes of preventable transfusion events and show where improvements are necessary and possible.

The information provided is as complete as possible and is relatively detailed.

2.1 Collections and issues 2012:

A total of **932 509** units of blood products were collected by the two services and; **1 069 407** blood products issued with, **922 402** products issued by SANBS and **147 005** by WPBTS for patients during this period.

2.2 Hospital participation:

In 2012, **196** of 729 healthcare facilities reported transfusion adverse events related blood and blood products to the Haemovigilance office. We are attributing this to an increased awareness of blood safety issues rather than an increase in events, which would be in keeping with international experience.

2.3 Summary of recipient adverse events 2012:

During 2012 a total of **879** transfusion-related adverse events from both SANBS and WPBTS were reported and analyzed. The bulk of the reactions 843, were due to acute transfusion reactions.

A total of **26** cases of incorrect blood component transfused (IBCT) were reported with errors having occurred at both the hospital and the blood banks.

3 cases of possible transfusion-related mortality were reported, however, in all the 3 cases, blood transfusion could not be completely identified as the definitive cause of death, since no post transfusion samples were obtained and no post mortem performed on the deceased patients.

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

2.4 Summary of look-back investigations 2012:

The Look-back Offices for SANBS and WPBTS received and investigated **629** cases of potential transfusion transmissible infections for 2012.

There were 607 (96,5%) donor-triggered cases and 22 (3,5%) recipient look-back cases.

There was an increase from 447 cases in 2009, 546 cases in 2010, 642 in 2011 to 629 cases in 2012.

No cases of transfusion-transmitted HIV and Hepatitis C infections were reported in 2012. There was, however, one case of Hepatitis B virus transmission confirmed by SANBS and 1 case of Malaria transmission confirmed by the WPBTS.

2.5 Summary of donor adverse events 2012:

A total of 4 249 donor adverse events from SANBS and WPBTS were reported and analysed with a decrease from 5 152 in 2011 noted. SANBS had 2 730 donor adverse events and WPBTS 1 519 events. Since the inclusion of donor adverse events in the Haemovigilance Report in 2010, we have noticed an improved rate of reporting and, less duplication of cases (refer to Chapter 11).

Introduction

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3 Introduction

This is the thirteenth annual haemovigilance report from South Africa, since 2000. The SANBS and WPBTS are working in collaboration towards a more integrated haemovigilance reporting system. The South African haemovigilance system collects data and reports on adverse events in blood donors. Reporting is done manually on forms obtainable from the blood banks. In order to ensure that the evaluations lead to significant conclusions, the transfusion form should be filled in by hospital personnel as completely as possible and should contain 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.

3.1 Previous reports regarding transfusion safety and quality in South Africa

Every year, SANBS together with WPBTS, put together 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 2012 report shows that adverse events related to blood transfusion have increased in most of South African hospitals. This is due to thorough collaboration between the South African Blood Services, blood banks, the clinicians and hospital personnel.

Since 2000 South African Blood Transfusion Services have continued to collect data and participated in haemovigilance reporting, publishing baseline data on an annual basis. Trend monitoring has only more recently been implemented, however. This data shows very important and positive trends in the patterns of reporting.

3.2 Haemovigilance Project Working Groups' progress and achievements to date – International Haemovigilance initiatives

South Africa is a participating member of the International Haemovigilance Networks (IHN) since 2009 and the data is available on the ISTARE data base by country. International peer review of our data takes place at the regular international meetings attended. Some of the other member states include countries like 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 educational activities between members.
  - Undertake educational activities in relation to haemovigilance.

Overview of Product Issues for 2012

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4 Overview of Product issues for 2012

A collective total of **1 069 407** blood and blood products were issued to patients in South Africa by the two supplying services (SANBS and WPBTS). SANBS issued a total of **922 402 (86,3%)** while WPBTS issued **147 005 (13,7%)** units of blood.

SANBS has 2 donation testing centres (Constantia Kloof and Pinetown), 7 processing centres, 79 blood banks and more than 400 emergency blood fridges (storing emergency Group O blood).

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

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

Both services provide blood and blood products to ± 729 hospitals and clinics country wide.

Table 4.1 Component/Product Issues 2012 (SANBS and WPBTS)

Products	SANBS	WPBTS	Total
Plasma products			
Cryo-poor Plasma	17 467	1 257	18 724
Fresh Frozen Plasma	106 806	24 134	130 940
Total	**124 273**	**25 391**	**149 664**
Platelet products			
Apheresis Platelet	27 271	3 361	30 632
Pooled Platelet	26 673	3 669	30 342
Total	**53 944**	**25 391**	**60 974**
Red Cell Products			
Paediatric	36 767	3 732	40 499
Red Cells	672 217	103 021	775 238
Reserved	369	3 732	7 889
Emergency Units and Ward Stock	32 399	0	32 399
Whole Blood	2 433	311	2 744
Total Red Cell Products	**744 185**	**114 584**	**858 769**
Grand Total	**922 402**	**145 005**	**1 069 407**

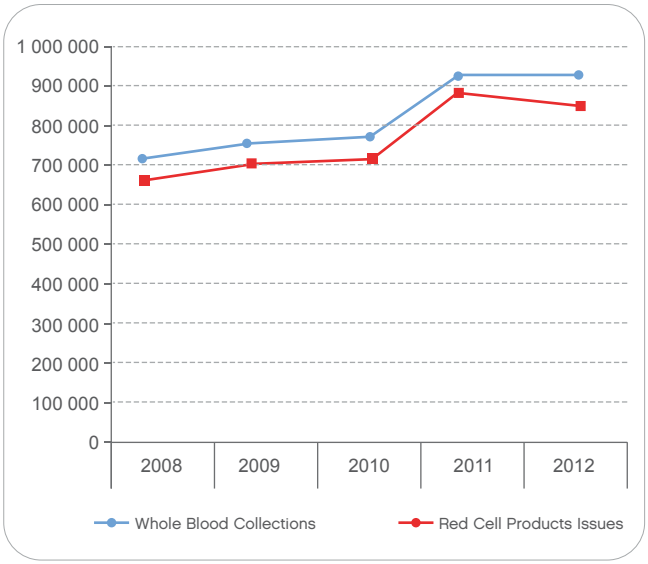
The percentage (%) difference between collections and usable units was 7% in 2012, an increase from 6% in 2011 as shown in the table 4.2 and figure 1 below.

Table 4.2: Collections and Issues (2008-2012)

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

Red cell product issues continued to closely follow units collected and maintaining a percentage difference of around 7%. The 7% difference between collections and usable units represents a loss in collections due to products not meeting various safety and quality requirements as well as products that expire before being used. With a buffer of less than 7%, there is a continuous risk of blood shortages, often exacerbated during school holidays and winter months.

Figure 1: Collections and Issues (2008-2012)



SANBS and WPBTS Transfusion Adverse Events 2012

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5 SANBS and WPBTS Transfusion Adverse Events 2012

5.1 Summary of transfusion adverse events 2012 (National data)

	Adverse Events	SANBS	WPBTS	South Africa
Acute Transfusion Reactions	Acute Haemolytic Transfusion Reaction (AHTR)	3	1	**4**
	Allergic Reaction	140	108	**248**
	Severe Allergic Reaction	26	0	**26**
	Anaphylactic Reaction	9	17	**26**
	Febrile Non-haemolytic Reactions (FNHTR)	288	72	**360**
	Circulatory Overload (TACO)	0	0	**0**
	Transfusion-related Acute Lung Injury (TRALI)	2	0	**2**
	Transfusion-associated Dyspnoea (TAD)	64	0	**64**
	Hypotensive Reaction	39	1	**40**
	Unclassifiable (Incomplete information)	55	3	**58**
	Unclassifiable complications of transfusion (UCT)	14	0	**14**
	Total (Acute Transfusion Reactions)			**842**
Delayed Transfusion Reactions	Delayed Haemolytic Transfusion Reaction (DHTR)	1	0	**1**
	Delayed Serological Reaction (DSTR)	0	0	**0**
	Total (Delayed transfusion reactions)			**1**
Incorrect Blood Component Transfused (IBCT)	ABO + Rh incompatible transfusions	0	0	**0**
	ABO incompatible transfusions	2	0	**2**
	Misdirected transfusions	12	7	**19**
	Patient misidentifications	1	4	**5**
	Total (IBCT)			**26**
Other Reactions	Near miss	7	0	**7**
	Transfusion-associated Graft versus Host Disease (TAGvHD)	0	0	**0**
	Transfusion-transmitted Infections	0	0	**0**
	Post Transfusion Purpura	0	0	**0**
	Mortality	3	0	**3**
	GRAND TOTAL	**666**	**213**	**879**

As shown in table 5.1, in 2012 a total of **879** cases were received and analyzed by the haemovigilance offices of both **SANBS (75,8%)** and **WPBTS (24,2%)**.

Of the 879, a total of 360 cases were febrile non-haemolytic transfusion reactions (FNHTR) and they remain the most frequently reported, contributing to about 41% of all reactions. Allergic reactions were the second most frequently reported reactions with 300 cases (including mild, severe and anaphylactic) accounting for 34% of all reactions.

A total of 64 cases (7,3%) of transfusion-associated dyspnoea (TAD), 40 cases (4,6%) of hypotensive reactions, 26 cases (3,2%) of incorrect blood components transfused (IBCT), 7 (0,8%) near miss events, 3 (0,34%) mortality cases, 2 (0,22%) cases of transfusion-related acute lung injury (TRALI) and 1 case (0,11%) of delayed haemolytic transfusion reaction were reported to the blood transfusion services.

72 cases (8,2%) were unclassifiable with **14 cases** excluded because the reaction forms were not sent through from the reporting clinicians and **58 cases** had incomplete information and they could not be classified into any definite category.

Table 5.2 Rates of transfusion adverse events per classification

Adverse Events	Rates per 100 000 units issued - South Africa
Acute haemolytic transfusion reactions (AHTR)	0,37
Delayed haemolytic transfusion reactions (DHTR)	0,09
Delayed serologic transfusion reactions (DSTR)	0,00
Allergic reacting	23,19
Severe allergic	2,43
Anaphylactic reaction	2,43
Febrile non-haemolytic transfusion reactions (FNHTR)	33,66
Circulatory overload (TACO)	0,00
Transfusion-related acute lung injury (TRALI)	0,19
Transfusion-associated dyspnoea (TAD)	5,98
Hypotensive reaction	3,74
Transfusion-associated Graft versus Host Disease (TAGvHD)	0,00
Unclassifiable (Incomplete information)	5,42
Unclassifiable (No forms)	1,31
SUBTOTAL	**78,83**
ABO + Rh Incompatible transfusion	0,0
ABO Incompatible transfusion	0,0
Misdirected transfusion	1,78
Patient misidentification	0,47
Near miss	0,65
SUBTOTAL IBCT	**3,09**
Mortality	0,28
GRAND TOTAL	**82,20**

Table 5.2 shows that the number of transfusion adverse events reported in South Africa is 82,20 per 100 000 units issued.

The classification with the highest rate of reporting per 100 000 is FNHTR at 33,66, followed by allergic reactions at 28,05, unclassifiable at 6,73, TAD at 5,98 and hypotensive at 3,74 per 100 000 units issued.

Table 5.3 and figure 2 below shows that the rates of adverse reactions reported per 100 000 units issued in the past 5 years (2008-2012) have increased from 61,3 to 82,20. This indicates that there is an improvement in the year-on-year reporting and this could be attributable to various factors including, amongst others, awareness of haemovigilance created through education of blood users and the establishing and maintaining of hospital transfusion committees.

Table 5.3 Adverse Reaction Rates 2008 to 2012:

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

Figure 2: Adverse Reactions Rates (2008-2012)

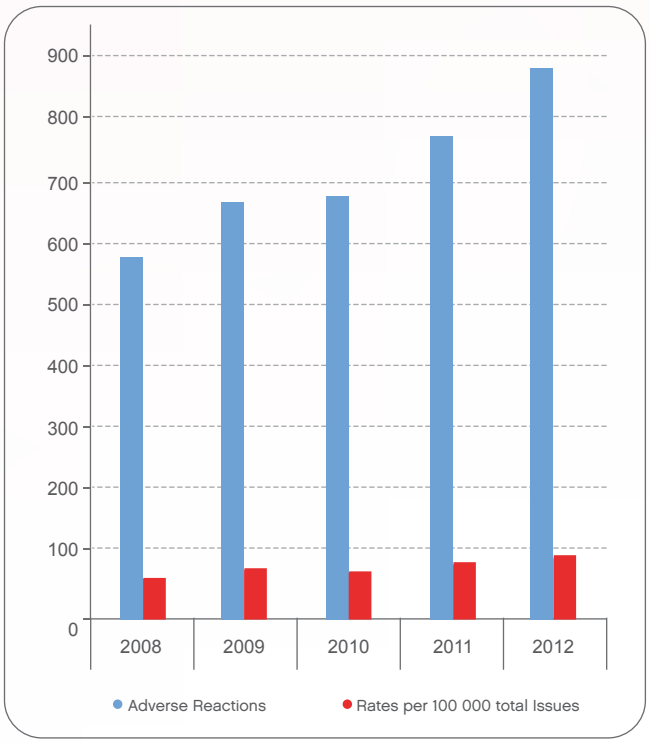

Table 5.4 Acute Transfusion Reactions 2008 to 2012 (National data)

Acute Reactions	2008	2009	2010	2011	2012	Totals
AHTR	13	15	15	1	4	**48**
ALLERGIC (INCLUDING SEVERE ALLERGIC)	177	222	231	221	274	**1 125**
ANAPHYLACTIC	11	5	6	16	26	**64**
TRALI	0	4	1	1	2	**8**
TACO	0	3	5	1	0	**9**
TAD	64	36	47	71	64	**282**
FNHTR	150	229	257	255	360	**1 254**
HYPOTENSIVE	25	12	51	54	40	**182**
UNCLASSIFIABLE	126	116	97	117	72	**514**
Totals	**566**	**642**	**710**	**737**	**842**	**3 500**

Acute Transfusion Reactions 2012: Case Discussions

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6 Acute Transfusion Reactions 2012: Case Discussions

Acute Transfusion Reactions: Case Discussions

Acute Haemolytic Transfusion Reactions
Allergic Transfusion Reactions
Anaphylactic Transfusion Reactions
Transfusion-related Acute Lung Injury
Transfusion-associated Circulatory Overload
Transfusion-associated Dyspnoea
Febrile Non-haemolytic Transfusion Reactions
Hypotensive Reactions
Unclassifiable Complication of Transfusion

6.1 Acute Haemolytic Transfusion Reactions (AHTR)

2008	2009	2010	2011	2012
13	14	15	1	4

4 cases of AHTR were reported in 2012. An example of a case is described below.

Case JTR 36

- A 68 year old female with pulmonary embolism.
- Diagnosed with anaemia, haemoglobin (Hb) of 5,5 g/dl.
- The patient's blood group was confirmed as AB, Rh positive and the pre-transfusion direct antiglobulin test was negative.
- Two Compatible units of Red cells were cross matched and issued.
- A reaction was reported to the blood service by the treating doctor.
- Within 1-2 hours the patient had back pain, a drop in Hb, elevated unconjugated bilirubin, raised LDH and haemoglobinuria.
- Post reaction samples were sent to the Red Cell Serology Lab for further testing:
  - Anti-C and -P1 antibodies were detected in the patient's pre and post transfusion samples.
  - Red cell phenotyping was performed on the 2 transfused units.
  - Both the units were C and P1 antigen positive and were found to be incompatible at cross match.
- There was mixed field agglutination demonstrable with the strength of 1 to 2+ and a weakly positive DAT noted causing a serological incompatibility.

6.2 Allergic Transfusion Reactions

2008	2009	2010	2011	2012
177	221	231	201	274

274 cases of allergic reactions were reported in 2012. An example of a case is described below.

Case (TR 112)

- A 61 year old female patient.
- Was admitted for a fractured left humerus, was also anaemic, with haemoglobin of 6,0 g/dl.
- Two units of red cell concentrate were ordered by the treating doctor.
- Two AB positive units were cross matched, found compatible and issued to the patient.
- Less than an hour into the transfusion the patient developed, a skin reaction, urticarial, flushing of the skin and tachycardia.
- Post transfusion specimens were sent to the laboratory for post testing.
- The Direct antiglobulin tests for both the pre and post transfusion specimens were negative.
- On repeat cross match a weak serological incompatibility was demonstrable, when the patient's pre and post transfusion were tested against the donor's red blood cells by the saline room temperature technique.
- The unit was compatible by the indirect antiglobulin technique.
- On patient sample antibody screening, it was detected that, Anti-Le^a antibodies were reacting by saline room temperature technique and Anti-Le^a reacting by the indirect antiglobulin technique.
- One of the units issued was typed Le (a-b+) causing a serological incompatibility when cross matched with the patient's serum sample.
- The patient then suffered an allergic reaction.
- Conclusion: Missed weak serologically positive antibodies.

6.3 Anaphylactic Transfusion Reactions

2008	2009	2010	2011	2012
15	5	6	16	26

26 cases of anaphylactic reactions were reported in 2012. An example of a case is described below.

Case TR 223

- A 35 day old female baby with anaemia.
- Transfused with a unit of red cells.
- Immediately after about 1-2 mls transfused, baby had dyspnoea, bronchospasms, cyanosis, a decrease in oxygen and collapsed.
- The transfusion was immediately stopped, adrenaline given and the baby was resuscitated.
- The baby responded well to treatment and settled on oxygen support.

6.4 Transfusion-related Acute Lung Injury (TRALI)

2008	2009	2010	2011	2012
0	1	1	1	2

2 cases of TRALI were reported in 2012. An example of a case is described below.

Case TR 123

- A 24 year old female, diagnosed with HELLP Syndrome and renal failure.
- Units of Cryo-poor FFP were ordered by the treating doctor and 5 units were issued.
  6 hours later the patient reacted to one of the units issued.
- Patient had tachycardia, dyspnoea, bronchospasm, and a decrease in oxygen saturation.
- The unit was stopped; patient was put on an oxygen face mask, and Lasix 120 mg.
- On post transfusion investigation, the patient's post transfusion specimen was found to be Group A (weak A), Rh positive.
- The direct antiglobulin test was negative.
- The transfused frozen plasma units were both confirmed Group A, Rh positive.
- No incompatibility was demonstrable when the patient's red cell sample was tested against the plasma donations.
- No irregular antibodies on the patient's sample, that would be capable of causing a haemolytic reaction, were detected.
- On White cell Antibody screening: HLA Class 1 anti-B8 antibodies were detected in the donor's plasma.
- On HLA typing: The presence of B*44 and B*58 antigens were detected in the patient's post transfusion sample
- In conclusion, the patient did not possess the corresponding antigen to the donor's HLA anti–B8 antibody and no apparent cause of the TRALI could be detected by the laboratory.

Case 2 (JTR 408)

- A female patient with retained placenta.
- Two units of blood ordered for anaemia due to acute haemorrhage.
- In less than 6 hours, the patient had flushing, sweating, tachycardia, dyspnoea, decrease in oxygen, a drop in blood pressure, and haemoglobinuria.
- The doctor also reported acute pulmonary oedema.
- Blood transfusion was stopped immediately, patient was ventilated, Lasix 40 mg administered.
- On repeat cross-matching, no incompatibility was demonstrable when patient's sample was tested against the donor's red blood cells.
- HLA antibody screen: Donor Sample: multiple antibodies to Class 1 Human Leucocyte Antigens (HLA) including anti-B13 and anti-B71 antibodies were detected in one of the donor units.
- Conclusion: The patient was found to have corresponding HLA Class 1 antigens and thus most likely had a transfusion-related acute lung injury.

6.5 Transfusion-associated Circulatory Overload (TACO)

2008	2009	2010	2011	2012
7	3	5	1	0

There were no cases of Transfusion-associated circulatory overload for the year 2012.

6.6 Transfusion-associated Dyspnoea (TAD)

2008	2009	2010	2011	2012
64	36	47	71	64

There were 64 cases of TAD reported in 2012. An example of a case is described below.

Case JTR 156

- A request for blood was received by a blood bank, for a 1 month old, premature baby.
- The sample was typed Group O, Rh positive.
- A unit of Group O, Rh positive Paediatric, Leucodepleted red cell concentrate was issued.
- The blood bank was later informed that the patient had a transfusion reaction.
- The patient reportedly had tachycardia, decrease in oxygen and dyspnoea.
- Post transfusion specimens were received and preliminary transfusion reaction investigation tests were performed in the blood bank.
- Later in the day the patient was reported to have demised.
- Red cell serology laboratory could not perform repeat cross match tests on the patient's pre and post transfusion samples due to insufficient serum in samples.
- Post mortem results were also not obtained to determine the cause of death.

6.7 Febrile Non-haemolytic transfusion reactions (FNHTR)

2008	2009	2010	2011	2012
150	229	257	255	360

There were 360 cases of FNHTR reported for 2012. An example of a case is described below.

Case JTR 0165

- A 10 year old pediatric male patient.
- Diagnosed with Spina bifida, sacral bedsores and anaemia.
- Was transfused with a leucodepleted unit of red cells.
- An hour into the transfusion, the patient had tachycardia, a temperature rise from 37,6°C to 39,3°C and a drop in blood pressure.
- The transfusion was stopped and an anti-pyretic administered.
- The patient reportedly cooled down after the management.

6.8 Hypotensive Reactions

2008	2009	2010	2011	2012
12	17	257	54	40

There were 40 cases of Hypotensive reactions reported in 2012. An example of a case is described below.

Case JTR 146

- A 31 year old female.
- Had anaemia post caesarian section, an Hb 6,8 g/dl and was transfused with a unit of red cells.
- Immediately after commencement the patient had a drop in blood pressure, flushing and sweating.
- The transfusion was stopped immediately.
  50 mg Phenergan, 500 mls of Voluven and ringers lactate administered.
- The patient's condition and blood pressure improved after management.

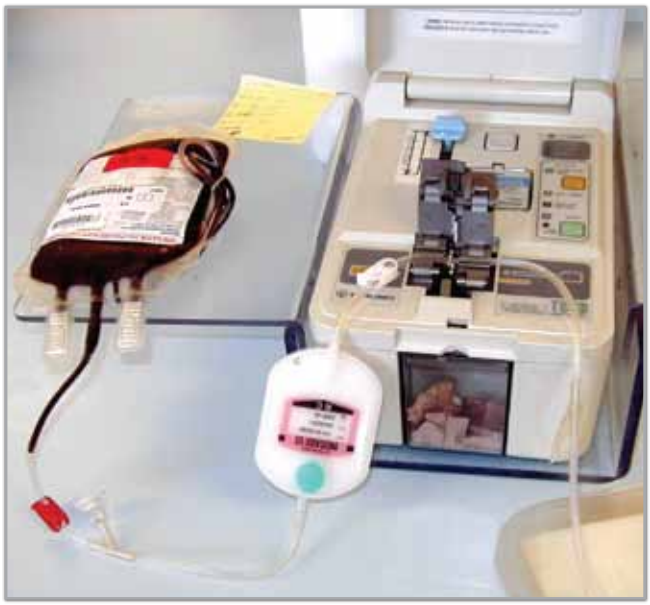
6.9 Unclassifiable Complication Of Transfusion (UCT)

2008	2009	2010	2011	2012
44	43	48	117	72

There were 72 cases of unclassifiable reactions in 2012.

Learning points:

- Patients with a serious Acute transfusion reaction 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 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 classification.



Delayed Haemolytic Transfusion Reactions (DHTR): Case Discussions

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7 Delayed Haemolytic Transfusion Reactions (DHTR): Case Discussions

7.1 Delayed Haemolytic Transfusion Reactions (DHTR)

2008	2009	2010	2011	2012
0	0	0	0	1

There was 1 case of DHTR reported in 2012. An example of a case is described below.

Case JTR 173

- A cross match request was received for a 43 year old female patient with anaemia.
- The sample typed **Group A, Rh Positive**.
- The presence of red cell antibodies were noted in the patient's serum at cross match, however, two units of Group A, Rh Positive red cell concentrate were cross matched and deemed to be compatible by the indirect antiglobulin technique. The units were issued.
- A blood sample from the patient was also sent to the Red Cell Serology Laboratory for further identification of the antibodies present in her serum.
- The presence of red cell antibodies, specificity anti-E, was confirmed by the Red Cell Serology Laboratory.
- These antibodies were demonstrable by the automated gel indirect anti-globulin technique (IAT) and in the manual IAT screen.
- 8 days later the Blood Bank was informed that the patient had reacted to the blood received.
- The patient reported passing dark urine, body pains and deep jaundice, after being discharged.
- The doctor confirmed that the patient had reacted to the blood received, and that no post transfusion blood samples or blood packs had been forwarded to the Blood Bank for investigation.
- The donors of the transfused units were contacted and requested to provide blood samples for investigation of the case.
- Samples from the patient were also drawn and forwarded to the Red Cell Serology Lab
- The presence of red cell antibodies was confirmed in the patient's post transfusion sample;
  - **Anti-C antibodies were demonstrable by the manual indirect anti-globulin technique.**
  - **Anti-C, -E and additional antibodies of unknown specificity were demonstrable by the automated gel indirect anti-globulin technique.**

- A specimen from the first donor recalled was received and tested in the Red Cell Serology Laboratory and the results were as follows:
  - **Blood Group: A Positive**
  - **Rh Phenotype: R1R1 (CCDee)**
- A specimen from the second donor was also received in the Red Cell Serology Laboratory and tested on the results were as follows:
  - **Blood Group: A Positive**
  - **Rh Phenotype: R1R1 (CCDee)**
- Compatibility test
  - Serological incompatibility was evident when serum from the patient's post transfusion sample was cross matched against the red blood cells from the 2 donors.
  - A repeat cross match using the patient's pre transfusion specimen could not be performed as this specimen was discarded prior to the case being reported to the Blood Bank.

Conclusion

The donors are both homozygous for the C antigen, to which the patient has the corresponding antibody. Although the anti-C antibody was not demonstrable at the time of initial cross match and antibody identification, the infusion of 2 homozygous C antigen units has stimulated the patient to develop the anti-C antibodies now demonstrable in her serum, resulting in serological incompatibility with the donor units. The patient had suffered a delayed haemolytic transfusion reaction due to serological incompatibility.

Incorrect Blood Components Transfused (IBCT): Case Discussions

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8 Incorrect Blood Components Transfused (IBCT): Case Discussions

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

8.1 Misdirected transfusions

8.2 Misidentification

8.3 Near miss events

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

8.1 Misdirected transfusions

2008	2009	2010	2011	2012
10	31	10	22	26

There were 26 cases of IBCT transfusions in 2012.
An example of a misdirected case is described below.

Case JTR 109

- A cross match request was received at the Blood Bank for a 67 year old male;
- The sample typed **Group B**, **Rh Positive**.
- Six units of Group B, Rh Negative blood were cross matched and deemed to be compatible.
- **On the same day, about 2 hours later, another cross match request** was received at the same Blood Bank for a different female patient.
- Admitted for an Aortic aneurysm repair with pre-operative Hb of 8,0.
- The sample typed **Group O**, **Rh Positive**.
- Two units of Group O, Rh Positive blood were cross matched and deemed to be compatible.
- **The Blood Bank was later notified that 2 units, which had been cross matched and issued for the male patient, had been transfused to the female patient who had a severe reaction.**

- A transfusion reaction investigation was then carried out and the outcome was as follows:
- **Pre transfusion specimen – Female patient**
  - **Blood type: Group O, Rh Positive**
  - **Direct Anti-globulin Test: Negative**
  - **Irregular antibody screen: Negative**
- **Post transfusion specimen – Female patient**
  - **Blood type: Group O, Rh Positive**
  - **Direct Anti-globulin Test: Negative**
  - **Irregular antibody screen: Negative**
- **Misdirected Unit 1:**
  - **Blood Type: Group B, Rh Negative**
  - **Direct Anti-globulin Test: Negative**
- **Misdirected Unit 2:**
  - **Blood Type: Group B, Rh Negative**
  - **Direct Anti-globulin Test: Negative**
- Compatibility test
  - Strong serological incompatibility was demonstrable when the serum from the Female patient pre- and post-transfusion samples were cross matched against the red blood cells from the donor.

Group B (misdirected units) by the immediate spin and indirect anti-globulin techniques.

- The misdirected units transfused to the female patient were incompatible with the ABO blood group.

8.2 Misidentification

Case TR 115

- A cross match request was received by the blood bank for a 3 month old male patient.
- On checking the patient's transfusion history on the blood bank's system the technician discovered a discrepancy with the blood grouping results.
- The patient's sample typed Group B, Rh Positive and the patient had a previous history of Group A, Rh Positive.
- Due to the ABO discrepancy another sample was requested from the blood bank.
- The doctor acknowledged the misidentification of the patient during sample collection and another specimen was sent by the doctor.

8.3 Near miss events

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

2008	2009	2010	2011	2012
0	2	2	0	7

Of the 7 reported near miss events, 5 were related to deviation from standard operating procedures on blood sample collection by the ward staff.

One case was of a sample taken from a wrong patient and the blood bank technician missed the error. The last case, the treating doctor did not forward a second specimen when a discrepancy in blood group results was noted on the previous transfusion records of that patient.

Blood samples were collected from patients other than those intended for transfusions. This is a result of not properly identifying patients before procedures by the hospitals' personnel. In the 5 sample collection errors reported the errors were picked up at the blood banks when cross-matching of samples was done.

An example of a case is described below.

Case TR 145, 181, 196, 70, 118

- Blood samples were sent for cross-matching for a female patient.
- The initial sample was grouped as a B Positive, 1 unit of red cell leucodepleted and 2 units normal red cells were transfused to that patient.
- 4 days later the blood bank received a request for more blood, for the same patient, from a different doctor.
- This 2nd specimen was grouped as A Positive.
- Due to the previous records of this patient, the blood bank technician did not issue more units, but requested a second specimen from the doctor.
- The doctor didn't honor the request.
- Later on, on the same day, a different doctor sent a blood sample for the same patient.
  The sample was grouped B Positive, a follow-up sample was requested, again from this particular doctor.
  The sample was received, re-grouped as a B Positive sample.

Table 8.1 Hospital and lab errors reported in 2012 (SANBS ONLY)

Incidents in 2012	Event	Comments	Source of Error
1. Patient with anti-Jka transfused with Jka positive unit	Missed Antibodies noted post transfusion	Serological incompatibility only noted post transfusion. Pre-transfusion tests	Could not be confirmed as the sample was insufficient
2. Patient with anti-Jka transfused with Jka positive unit	Missed Antibodies noted post transfusion	The antibody was not demonstrable in the pre transfusion sample	Not blood bank/hospital error
3. Patient with anti-K transfused with K positive unit	Missed Antibodies noted post transfusion	The antibody was not demonstrable in the pre transfusion sample	Not blood bank/hospital error
4. Misdirected transfusion	Patient "D" was wrongfully transfused with an ABO incompatible unit of RBC that was supposed to be transfused to Patient "N" - no reaction noted	ABO incompatibility	Hospital error
5. Misdirected transfusion	Patient "X" pre and post transfusion samples were confirmed to be different – pre sample tested **A Positive** and post sample tested **O Positive**	ABO incompatibility – wrong samples sent for the same patient	Hospital error
6. Misdirected transfusion	Obstetric Patient wrongfully transfused with an A Positive RBC unit belonging to another patient	Error of misidentification	Hospital error
7. Patient Misidentification	Paediatric patient, (3 months old) wrong sample collected. On cross match testing laboratory records were discrepant to the sample received	Sample collection error	Hospital error
8. Antibodies identified	Least incompatible units issued – patient with antibodies identified as warm auto antibodies by Red Cell Serology (RCS) Laboratory	Further investigation confirmed the presence of reduced expression of Kell blood group antigens, associated with the presence of auto antibodies mimicking alloantibodies in cases of autoimmune haemolytic anaemia and microbial infection	This is normal practice in WAIHA cases.

Table 8.1 Hospital and lab errors reported in 2012 (SANBS ONLY) (Continued)

Incidents in 2012	Event	Comments	Source of Error
9. Rh incompatibility – Rh Positive patient with anti-D antibodies issued with Rh Positive blood –	A female of child-bearing age, was transfused with 3 units of Rh incompatible blood. Blood bank phoned the ward to notify of the incompatibility, but all the 3 units had already been transfused	Laboratory error	Laboratory error
10. ABO Incompatible transfusion	Group O female patient, transfused with Group B units that were meant to be transfused to a male patient	Reaction reported, classified as an allergic transfusion reaction by haemovigilance	Hospital error
11. Expired unit transfused	Hospital personnel transfused an expired, emergency O Positive unit	No reaction reported	Hospital error
12. Misdirected transfusion	A unit of O Positive blood was cross matched for Patient "M" wrongfully transfused to patient "Z"	No reaction reported	Hospital error
13. ABO incompatibility	O Positive patient transfused with A Positive unit – No reaction noted	Error of misidentification	Hospital error
14. Misdirected transfusion	Patient "K" received over 1 unit of O Positive blood, no adverse reaction noted. The RBC unit was intended for another patient	No serological incompatibility	Hospital error
15. Serological incompatibility	Missed antibodies	Patient with anti-Cw trans-fused with Cw positive unit. Not blood bank error – screening cells were Cw negative, antibody therefore not detected at cross match Cw is a low frequency antigen and not a require-ment in screening cells	Not blood bank/hospital error

11 cases from WPBTS are not included in table 8.1 above. The number of errors is a concern and extensive education and training of the hospitals' and blood bank staff needs to be conducted on an on-going basis.

Post Transfusion Purpura (PTP)

Transfusion-associated Graft versus Host Disease (TAGvHD)

Look-back Programme (National Data)

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9 Post Transfusion Purpura (PTP)

2008	2009	2010	2011	2012
0	0	0	0	0

There were no cases of Post Transfusion Purpura (PTP) for the year 2012.

10 Transfusion-associated Graft versus Host Disease (TAGvHD)

2008	2009	2010	2011	2012
0	0	0	0	0

There were no cases of Transfusion-associated Graft versus Host Disease (TAGvHD) for the year 2012.

11 Look-back Programme (National Data)

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 initial (index) donation 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, counselled and tested for the relevant viral marker and the result reported to the Blood Service.

Table 11.1: Total Donor-triggered look-back cases 2012

Total number of look backs	SANBS	WPBTS	TOTAL
HIV	371	24	**395**
HBV	186	11	**197**
HCV	3	2	**5**
HIV/HBV Co-infection	3	4	**7**
Other	3	0	**3**
Total	**566**	**41**	**607**

A total of 607 cases were reported and investigated through the donor-triggered look-back. There was a 100% follow up of all cases. Of the 607 cases, 65,1% of look-backs were due to HIV and 32,5% HBV.

Table 11.2: Investigations outcomes

Donor-triggered Investigation outcome	SANBS	WPBTS	TOTAL
Retest negative	61	11	**72**
Recipient positive before transfusion	34	1	**35**
HIV positive recipient/s – phylogenetic analysis	2	0	**2**
Recipient died between transfusion and initiation of look-back	92	5	**97**
Unresolved	321	7	**328**
Untraceable patient	43	11	**54**
Other	6	5	**11**
Refused/Declined testing	4	0	**4**
HBV Immune	1	1	**2**
HBV positive recipient-phylogenetic analysis	1	0	**1**
On dual therapy (HBV lb)	1	0	**1**
Total	**566**	**41**	**607**

At the time of the report, 279 **(46%) of the 607 cases were closed**. Of the 279 cases, 72 recipients were traced and tested negative while 35 cases were confirmed positive before transfusion (confirmed on requisition form or by treating doctor). Two HIV positive recipients had phylogenetic analysis performed and determined in one case that there was no genetic linkage and transfusion transmission was excluded. The outcome in the second case is still pending.

Ninety seven recipients were confirmed to have died between the transfusion episode and the look-back investigation initiation period, 54 cases were untraceable because the patients were unreachable by the hospital or due to missing hospital files and; in the other 4 cases recipients either refused to come or were too ill to present for testing and others, the hospital clinical manager refused to investigate look-backs that were more than 6 months old.

The hepatitis B phylogeny was confirmed by SANBS to be positive in one recipient and that resulted in a transfusion-transmitted Hepatitis B infection (case discussed below). The WPBTS has one unresolved case of HBV because they are still tracing the donors involved.

Transfusion-transmitted hepatitis B virus (HBV) case discussion

One case of HBV transmission was identified in a patient who had received a red cell transfusion from an ID-NAT non-reactive donor who upon further testing had an occult HBV low level viraemia. The donor was a **36 year old male** who has donated 5 times. Sequence analysis confirmed transmission of HBV genotype D with 100% nucleotide homology between donor and recipient HBV strains. The viral burden in the infectious red cell concentrate was estimated at 1,6 copies/ml or 32 HBV DNA copies/20 ml of plasma. It was estimated that this donation had a 5,1% probability of causing transmission to a recipient if the minimum infectious dose is 316 virions for an occult infection. Although it has been documented that occult infection can be transfusion transmitted this is the first donation screened with ID-NAT to transmit, giving an observed Occult transmission rate of 0,25 per million. **Donation 5 was the positive (index) donation.**

One case of malaria transmission was confirmed by the WPBTS and the case discussion is outlined below.

Transfusion-transmitted malaria case discussion

An 81 year old female patient received 2 red cell concentrates during insertion of arterial shunts on 15 October 2012. She developed fever of unknown origin in December 2012 and on 5 December 2012 tested positive for Plasmodium Malariae on PCR testing. The donors of the red cell concentrates were re-called and tested for malaria. A 23 year old male donor tested positive for Plasmodium Malariae on PCR testing. He was negative on malaria antigen, malaria antibody and thick and thin smears. The donor's country of origin was Nigeria, which he had left in 2007. He had not visited any malaria endemic areas since 2007. The donor experienced an episode of shivering and headaches about 4 months prior to donation. He fulfilled all malaria deferral criteria and had no symptoms at the time of index donation.

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.

The other **328 (54%) 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 SANBS.

Recipient-triggered look-backs 2012

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 11.3 Recipient-triggered look-backs 2012

Donor-triggered	Resolved	Unresolved	TOTAL
HIV	7	2	**9**
HBV	1	3	**4**
HCV	0	0	**0**
Other	7	2	**9**
Total	**15**	**7**	**22**

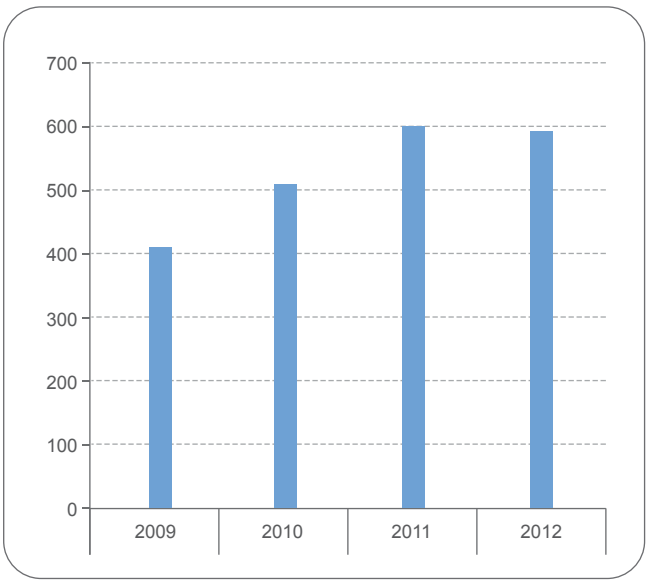
A total of 22 recipient-triggered look-back cases were reported and 15 (68%) of cases had been resolved/closed at the time of the report. In the 15 cases that were resolved, 13 donors re-tested negative and the other 2 cases were information requests from treating doctors that subsequently informed the office to close the cases. Of the total 22 reported recipient-triggered look-back cases, 7 (32%) cases remain unresolved because no records were found due to time lapsed or the donors being untraceable.

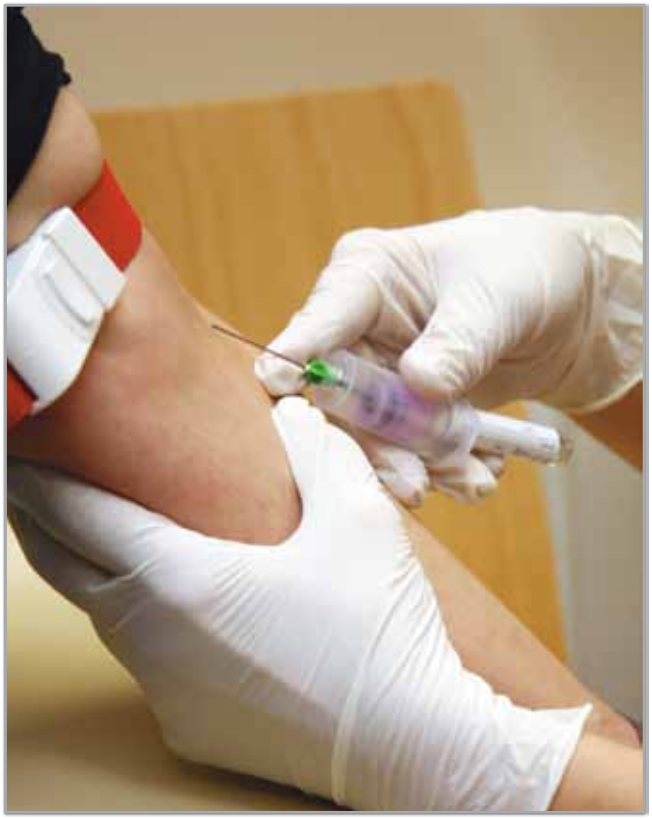
There has been an increase in the total number of all look-back cases (donor and recipient triggered) from 447 (2009), 546 (2010), 642 (2011) and slightly decreased to 629 in 2012 as shown in table 11.4 and figure 3 below.

Table 11.4: Overview of look-back investigations (2009-2012)

	2009	2010	2011	2012	TOTAL
Total number of look-back cases	447	546	642	629	**2 264**

Figure 3. Look-back cases 2009-2012





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 practice.
- 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 were also mentioned by several doctors and hospital managers.

Donor Vigilance 2012 (National Data)

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12 Donor Vigilance 2012 (National Data)

12.1 Background

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 decades[1], the provision of a constant and sufficient blood supply remains a challenge.

Research has shown that donors who suffer adverse events not only have lower return rates, but also take longer to return to donate.[2-4] It has also been noted that collections at the blood drives where these events occur decreased 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 interrogation of the DAE database is used internally to identify problem areas, perform a root cause analysis and implement corrective action. Trends are identified and this information is used to adapt and amend operations to ensure safe practices and continuous improvement. It is hoped that this information will be used to benchmark 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 categorized according to whether the symptoms are localized to the donation/needle site or whether they are generalized in nature. Generalized symptoms are those associated with vasovagal reactions either experienced at the time of donation or after leaving the blood collection centre. There is a separate category for adverse events associated with apheresis procedures.

Categories of complications related to blood donation:

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

Complications mainly with local symptoms

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

Complications mainly characterized by the occurrence of blood outside the vessels

Adverse Event	Definition
Haematoma	An accumulation of blood in the tissues outside the vessels. Symptoms: Include bruising, discolouration, swelling and local pain.
Arterial Puncture	A puncture of the brachial artery or of one of its branches by the needle used for bleeding of the donor. Symptoms: There may be weak pain localized to the elbow region. Objectively a lighter red colour than usual of the collected blood can be seen and perhaps some movements of the needle caused by arterial pulsation; the bag fills very quickly. In uncomplicated cases there may be no haematoma. Complications: The risk of a large haematoma is increased and thereby risks such as Compartment Syndrome in the forearm, Brachial Artery Pseudo Aneurysm and arterio-venous fistula.
Delayed bleeding	Spontaneous recommencement of bleeding from the venipuncture site, which occurs after the donor has left the donation site.

Complications mainly characterized by pain

Adverse Event	Definition
Nerve irritation	Irritation of a nerve by pressure from a haematoma. Symptoms are nerve type as radiating pain and/or paraesthesia in association with a haematoma. The haematoma may not always be apparent at the time. Symptoms do not occur immediately on insertion of the needle, but start when the haematoma has reached a sufficient size, sometime after insertion of the needle.
Nerve injury	Injury of a nerve by the needle at insertion or withdrawal. Symptoms are pain often associated with paraesthesia. The pain is severe and radiating. It arises immediately when the needle is inserted or withdrawn.
Tendon injury	Injury of a tendon by the needle. Symptoms are severe local non-radiating pain initiating immediately when the needle is inserted.
Painful arm	Cases characterized mainly by severe local and radiating pain in the arm used for the donation and arising during or within hours following donation, but without further details to permit classification in one of the already more specific categories mentioned above.

Other kinds of categories with local symptoms

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

Complications mainly with generalized symptoms

Vasovagal reaction

Adverse Event	Definition
Vasovagal Reaction (Faint)	A vasovagal reaction is a general feeling of discomfort and weakness with anxiety, dizziness and nausea, which may progress to loss of consciousness (faint). Most give only minor symptoms, but a few have a more severe course with symptoms like loss of consciousness and convulsions or incontinence. Symptoms are discomfort, weakness, anxiety, dizziness, nausea, sweating, vomiting, pallor, hyperventilation, convulsions and loss of consciousness. The reaction is generated by the autonomic nervous system and further stimulated by psychological factors, and the volume of blood removed relative to the donor's total blood volume.
Immediate Vasovagal Reaction	Symptoms occur before donor leaves the donation site.
Immediate Vasovagal Reaction with injury	Injury caused by falls or accidents in donors with a vasovagal reaction and unconsciousness before the donors have left the donation site.
Delayed Vasovagal Reaction	Symptoms occur after donor has left the donation site.
Delayed Vasovagal Reaction with injury	Injury caused by a fall or accident in a donor with a vasovagal reaction and unconsciousness after the donor has left the donation site.

Complications related to apheresis

Complications mainly characterized by pain

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

Table12.1 Collections 2012 (National data)

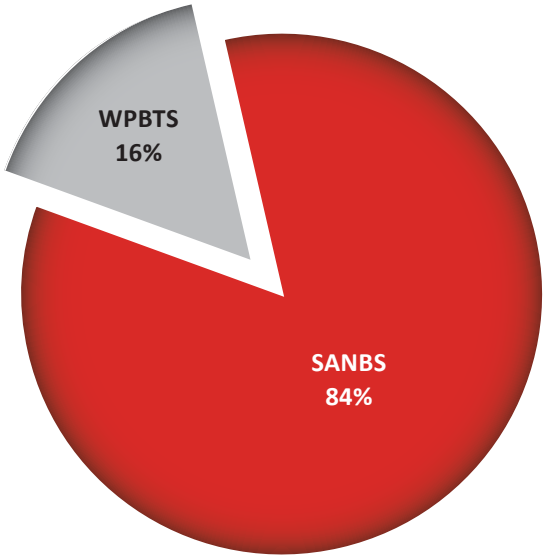
Collections 2012	SANBS	WPBTS	TOTAL
Whole Blood	763 204	143 444	**906 648**
Apheresis Red cells	1 996	0	**1 996**
Apheresis Platelets	15 561	2 936	**18 497**
Plasma	2 724	2 644	**5 368**
Total	**783 485**	**149 024**	**932 509**

In 2012, a total of **932 509** blood products were collected by SANBS and WPBTS combined as shown in table 12.1 above and figure 4 below with SANBS having contributed 84% and WPBTS 16%.

SANBS collections were undertaken at **84 permanent** collection centres as well as 90 mobile donor units. Apheresis platelet donations are collected at **7 fixed-site** collection centres.

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

Figure 4: Product collections 2012 (SANBS and WPBTS)



Summary of Donor Adverse Events 2012

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13 Summary of Donor Adverse Events 2012

13.1 By donation type

		Whole Blood	Apheresis	Unallocated	**Total**
Local Adverse Events	Haematoma	320	245	35	**600**
	Arterial puncture	1	0	0	**1**
	Delayed bleeding	22	0	0	**22**
	Nerve irritation	9	2	1	**12**
	Tendon injury	1	0	0	**1**
	Nerve injury	1	0	0	**1**
	Painful arm	101	22	9	**132**
	Total local symptoms	**455**	**269**	**45**	**769**
Vasovagal	Faint immediate type	2 486	27	47	2 560
	Faint immediate, accident	64	3	3	70
	Faint delayed type	668	10	28	706
	Faint delayed, accident	44	1	1	46
	Total no. Vasovagal Reactions	**3 262**	**41**	**79**	**3 382**
Others	Citrate reaction	3	88	2	93
	Haemolysis	0	0	0	0
	Generalized allergic reaction	3	2	0	2
	Embolism	0	0	0	0
	Others	0	0	0	0
	Total	**6**	**90**	**2**	**92**
	Grand Total	**3 723**	**400**	**126**	**4 249**

In 2012, all donor adverse events reported contributed 0,46% (4 249 out of 932 509) of total collections. The adverse events have been categorized into whole blood, apheresis and unallocated. The main concern is with the unallocated category i.e. those that do not fall into either whole blood or apheresis. 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.

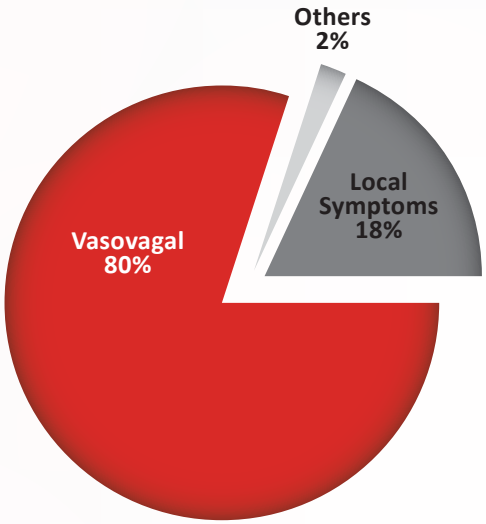
The capturing with the WPBTS is accurately classified as whole blood and apheresis and as such the unallocated group is only with SANBS.

Most DAE were with whole blood donations at 87,6 %, apheresis 9,4% and unallocated 3%.

Table 13.1.1 Donor adverse events according to broad categories

	Local Symptoms	Vasovagal	Others	TOTAL
SANBS	662	1 973	95	**2 730**
WPBTS	107	1 409	3	**1 519**
Total	**769**	**3 382**	**98**	**4 249**

Figure 5: Percentage Donor Adverse Events 2012



The majority of donor adverse reactions were vasovagal (80%), local symptoms (18%) and others (2%) as shown in table 13.1.1 and figure 5.

Of the vasovagal reactions, 75,6% were attributable to immediate faints without accident, 2,1% immediate faints with accidents; 20,9% delayed faints without accident and 1,4% delayed faints with accident. The majority of vasovagal events are without accidents, but all events must be managed immediately and effectively with all staff involved.

In the local symptoms category, 78% were due to haematomas followed by 17% of painful arm cases. Studies have shown that retention in donors who have had DAE is a challenge, efforts to reduce the occurrences are investigated and controls must be in place to minimize all events.

13.2 Analysis of Adverse Events by Severity

	Severity	Mild	Moderate	Severe	Subtotal
Local Adverse Events	Haematoma	469	106	25	**600**
	Arterial puncture	1	0	0	**1**
	Delayed bleeding	20	2	0	**22**
	Nerve irritation	6	2	4	**12**
	Tendon injury	0	0	1	**1**
	Nerve injury	0	0	1	**1**
	Painful arm	59	55	18	**132**
	Total local symptoms	**555**	**165**	**49**	**769**
Vasovagal	Faint immediate type	1 726	763	71	2 560
	Faint immediate, accident	40	23	7	70
	Faint delayed type	463	190	53	706
	Faint delayed, accident	17	23	6	46
	Total no. Vasovagal Reactions	**2 246**	**999**	**137**	**3 382**
Others	Citrate reaction	83	8	2	93
	Haemolysis	0	0	0	0
	Generalized allergic reaction	3	2	0	5
	Embolism	0	0	0	0
	Others	0	0	0	0
	Total	**86**	**10**	**2**	**92**
	Grand Total	**2 887**	**1 174**	**188**	**4 249**

As shown in table 13.2 above, 67,94% of donor adverse reactions were mild, 27,63 % moderate and 4,43% severe.

13.3 Analysis of Adverse Events by Age Group (National data)

As shown in table 13.3.1, donors below 21 years had the most donor adverse events at 36,22% and the elderly group above 50 years contributed about 9,32% of events. The result is similar to 2010, 2011 and 2012.

Table 13.1.1 Donor adverse events according to broad categories

Age group	WP	SANBS	Total	%
< 21	542	997	1 539	36,22
21-30	477	684	1 161	27,32
31-50	421	732	1 153	27,14
> 50	79	317	396	9,32
546	**1 519**	**2 730**	**4 249**	**100**

Conclusion

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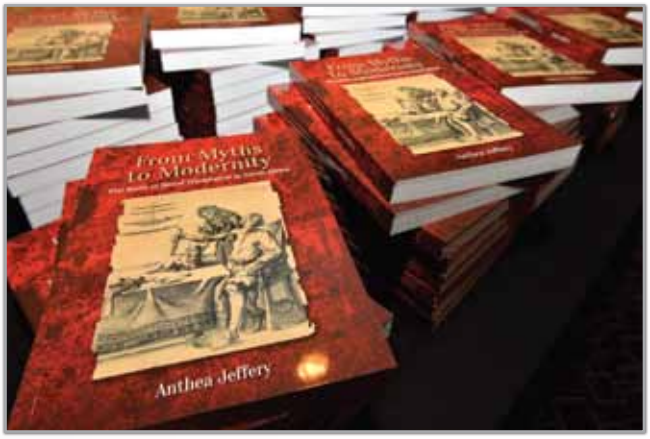
14 Conclusion

Blood transfusion is an important component of modern day medicine. For doctors the first consideration must always be the interest and safety of patients. Haemovigilance programmes collect and analyze 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 continue to deliver the goods without unintended negative consequences.



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 needs all parties involved to address and manage patients that experience adverse events. The haemovigilance data collected in South Africa over the years has shown a significant improvement on blood safety.

The WPBTS and 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 minimize risks related to blood donation and implement corrective systems.

References

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15 References

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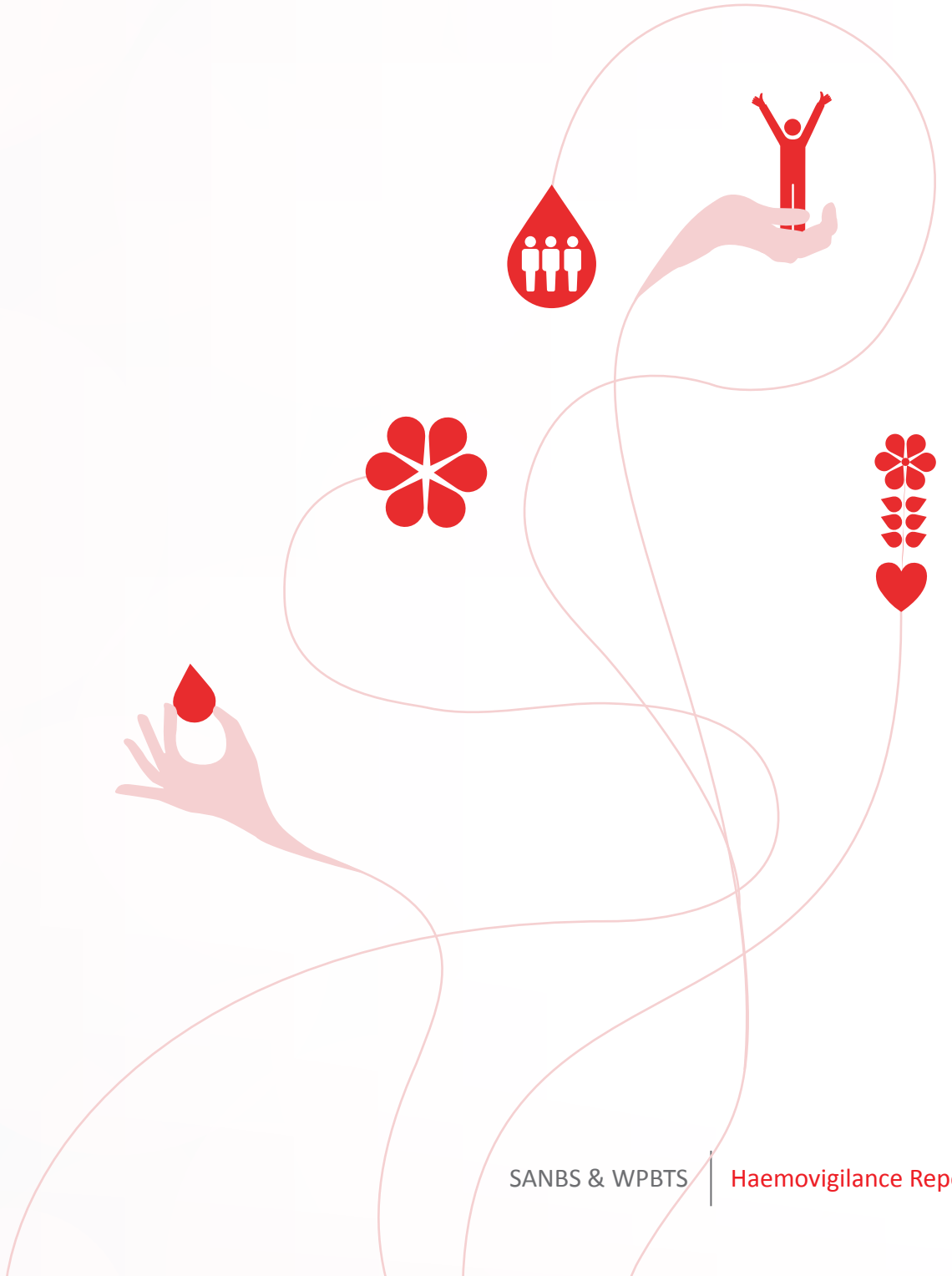

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