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Haemovigilance Report 2011

SANBS
South African National Blood Service

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.

Acknowledgement

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

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

List of Authors

Compiled by the South African National Blood Service together with the Western Prvince Blood Transfusion Service.

Compiled by:

- Dr Neo Moleli
- Sr Francis Ledwaba
- Dr Tshilidzi Muthivhi

Contributors:

- Dr Charlotte Ingram (Medical Director SANBS)
- Dr Gregory Bellairs (Medical Director WPBTS)
- Dr Juanita Makan
- Sr Cindy Simms
- Dr Sibongile Nomganga
- Dr Nolwazi Putuka
- Vangie Walker

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What is haemovigilance?

Haemovigilance is the collection, analysis and sharing of information on unexpected or undesirable effects of blood transfusion. Haemovigilance is also increasingly associated with the best use of blood and improved patient care.

Why do we need haemovigilance?

Transfusion is a key part of modern healthcare but it's not without risks. Despite significant improvements in product safety through careful donor selection and infectious disease testing, errors and transfusion reactions still occur. These adverse events can lead to poor clinical outcomes for patients, longer hospital stays and in severe cases, death.

Who looks after haemovigilance?

Haemovigilance in South Africa is overseen by 2 Services: the South African National Blood transfusion Service (SANBS) and the Western Province Blood Transfusion Service (WPBTS). The 2 Blood Services monitor both donor and patient adverse events. SANBS then collates the data into a national report.

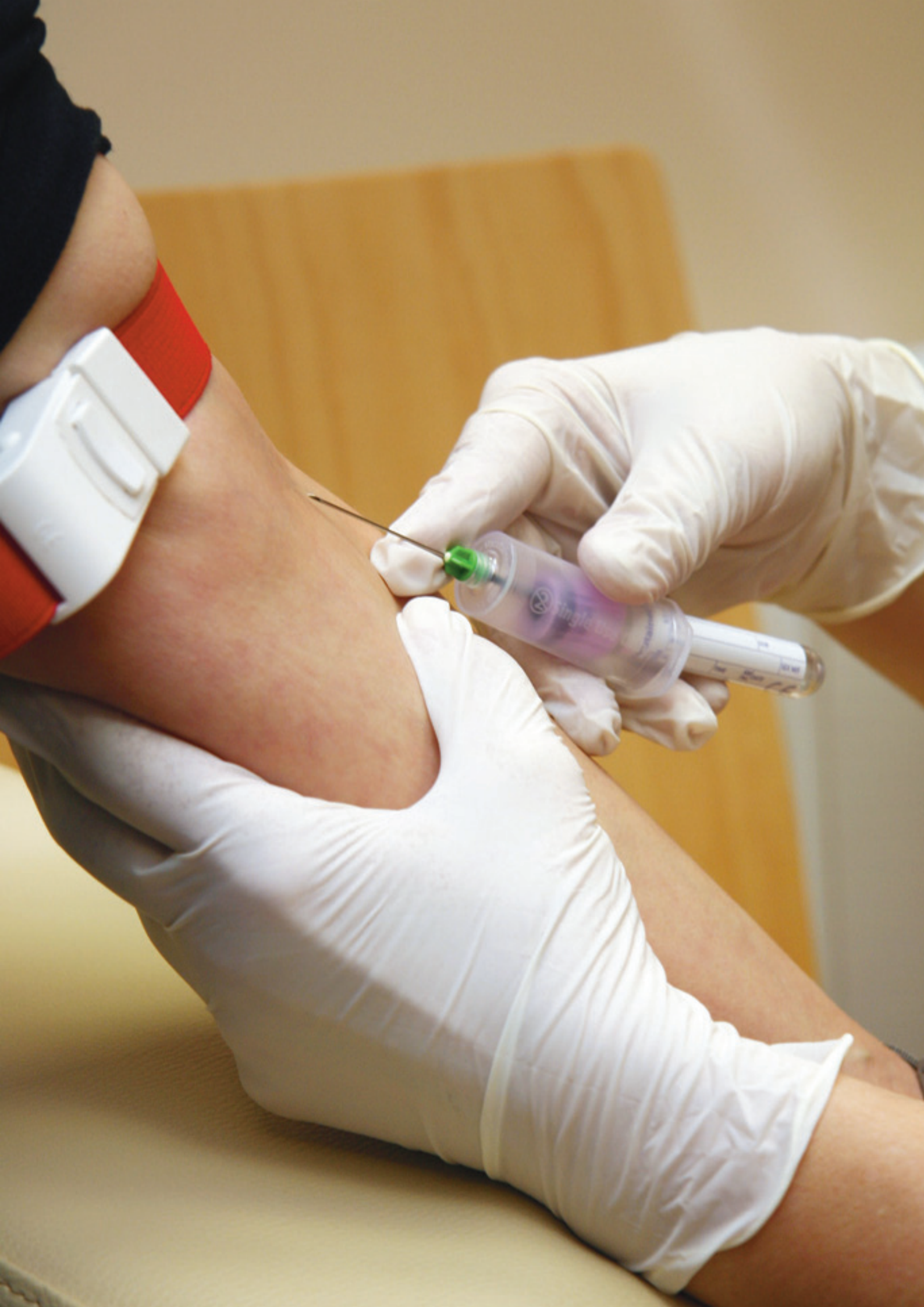
Does haemovigilance just focus on transfusion reactions?

Of particular interest are situations where something unplanned occurred but did not result in harm to the patient. Learning about these 'near misses' is extremely valuable. Understanding what went wrong teaches us how to improve practice and procedure.

Who is responsible for haemovigilance?

Haemovigilance should be an integral part of the organisation's quality system. All staff are encouraged to report adverse events and near misses that may affect blood product quality and other safety concerns related to transfusion. Ensuring the involvement of relevant stakeholders such as the Blood Service, hospital clinical staff and transfusion laboratory, hospital transfusion committee, regulator and The Department of Health is also important.

“ Transfusion is a key part of modern healthcare but it's not without risks



Adverse events: Classifications and definitions

CATEGORY	DEFINITION
Acute Transfusion Reactions	Transfusion related reactions that occur at any time during or up to 24hours 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 mucotaneous 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 24hours of transfusion that does not meet the criteria of TRALI, TACO or severe allergic reaction (SAR) and is not explained by the patient's underlying condition
Hypotensive Transfusion Reaction	A drop in systolic and/ or diastolic pressure of >30mm Hg occurring within one hour of completing the transfusion, provided all other adverse reactions together with underlying conditions that could explain hypotension have been excluded.
Transfusion Associated Circulatory Overload	Volume infusion that cannot be effectively processed by the recipient either due to high rates and volumes of infusion or underlying cardiac or pulmonary pathology and results in any 4 of the following occurring within 6 hours of transfusion: • Acute respiratory distress. • Tachycardia. • Increased blood pressure. • Acute or worsening pulmonary oedema. • Evidence of positive fluid balance.
Transfusion Related Acute Lung Injury	Acute hypoxemia with PaO2 fraction of inspired oxygen [FIO2] ratio of 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.
Anaphylactic TR	Hypotension with one or more of: urticaria, rash, dyspnoea, angioedema, stridor, wheeze, pruritus, within 24 hrs of transfusion.
Febrile Non Haemolytic Transfusion Reaction	Isolated fever > 39oC or equivalent or a change of >2oC 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

CATEGORY	DEFINITION
Delayed Transfusion Reactions	Transfusion related reactions that occur after 24hours 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 pos DAT or evidence of haemolysis).
Delayed Serologic Transfusion Reaction	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 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 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.
IBCT – No Reaction	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, but where the error did not result in any adverse outcome to the patient.
IBCT – With Reaction	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, and where the error resulted in an adverse reaction in the 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	Near miss events related to the misidentification of specimens, units or patients, which occurs outside of the blood bank
Misidentification – Blood Bank	Near miss events related to the misidentification of specimens, units or patients, which occurs at the blood bank
Near Miss – Other	Near miss events no related to misidentifications of specimens, units or patients
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

1. FOREWORD

The South African 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, health care professionals in the public and private sector 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 2007. The inclusion of donor reactions is an effort to improve on donor healthcare by tracking all adverse events associated with blood donation from the collection to the end delivery outcome.

The South African National and Western Province Blood Services would like to express sincere gratitude and appreciation to the staff in the hospital blood banks, specialised laboratory services, the transfusion transmissible infection (TTI) lookback & haemovigilance officers as well as the healthcare professionals in the hospitals for their contribution in providing information for the production of this 2011 haemovigilance report.

Dr Charlotte Ingram
National Medical Director (SANBS)

Dr Greg Bellairs
Director/CEO (WPBTS)

2. EXECUTIVE SUMMARY

2.1. Products collections and issues 2011

This National Haemovigilance report covers the period January 2011 to December 2011 and includes data collected via the South African National Blood Service (SANBS) and the Western Province Blood Service (WBTS). A total of **1 020 860** units of blood were collected by the two services and; **1 081 690** blood products were issued with **909 232** issued by SANBS and **172 458** by WPBTS for patients during this period.

South Africa is a member of the International Haemovigilance Network (IHN), the data for which is available on the ISTARE database by country. International peer review of our data takes place at the regular international meetings attended.

Since 2007 the South African blood transfusion services have continued to collect data, and participated in haemovigilance reporting and publishing baseline data on an annual basis. However trend monitoring has only more recently been implemented. These data shows very important and positive trends in the patterns of reporting.

2.2. Hospital participation

In 2011, 313 of 729 (43%) health care facilities reported adverse events related to blood & blood products to the Haemovigilance office. We would believe this to reflect an increased awareness of blood safety issues rather than an increase in events, which would be in keeping with international experience.

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.

2.3. Summary of transfusion adverse events

During 2011 a total of **763** transfusion-related adverse events from both SANBS and WPBTS were reported and analyzed. The bulk of the reactions, 621 (81.4%) were due to acute transfusion reactions. 117 (15.3%) cases remained unclassified due to lack of sufficient transfusion reaction data, 22 (2.9%) cases incorrect blood component transfused (IBCT). Three (0.4%) cases of possible transfusion related mortality were reported however, in all three cases, blood transfusion was excluded as definitive cause of death.

The National Look-back Officer investigated **589** cases of potential transfusion transmissible infections (TTI) for 2011, 96% donor-triggered and 4% recipient triggered look-backs. There was an increase from 394 cases in 2009, 507 cases in 2010 to 589 in 2011. No case of transfusion transmitted HIV, HBV, HCV or malaria was reported.

2.4. Summary of donor adverse events

A total of **5152** donor adverse events from both SANBS and WPBTS were reported and analysed showing an increase from 2221 in 2010. 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 captured on the business intelligence (BI) system.

> “ Participation in haemovigilance is a legal requirement for all organisations undertaking activity in any part of the transfusion chain within South Africa

3. INTRODUCTION

The South African National Blood Service has a national Haemovigilance program which focuses on the improvement of processes and procedures and on the prevention of recurrence of transfusion related reactions. This is done and achieved through continuously collecting and analyzing data on adverse reactions of infectious and non-infectious nature.

3.1. The South African Haemovigilance Program

Haemovigilance is a surveillance system aimed at improving the quality and safety of all processes or procedures related to blood transfusion as well as the prevention of transfusion-related reactions. It is seen as a 'vein-to-vein' process: monitoring all processes starting with the collection of blood from the donor and ending with the transfusion of the product to the patient.

The South African Haemovigilance Program was established in 2000 as a voluntary, non-punitive initiative by the South African National Blood Service (SANBS) and the Western Province Blood Transfusion Services (WPBTS). The WPBTS Haemovigilance system was initiated in September 1985. As the blood suppliers, SANBS and WPBTS are not responsible for the administration of blood products at the patient's bedside and depend heavily on clinicians and health care workers to monitor the administration process and report any untoward reactions.

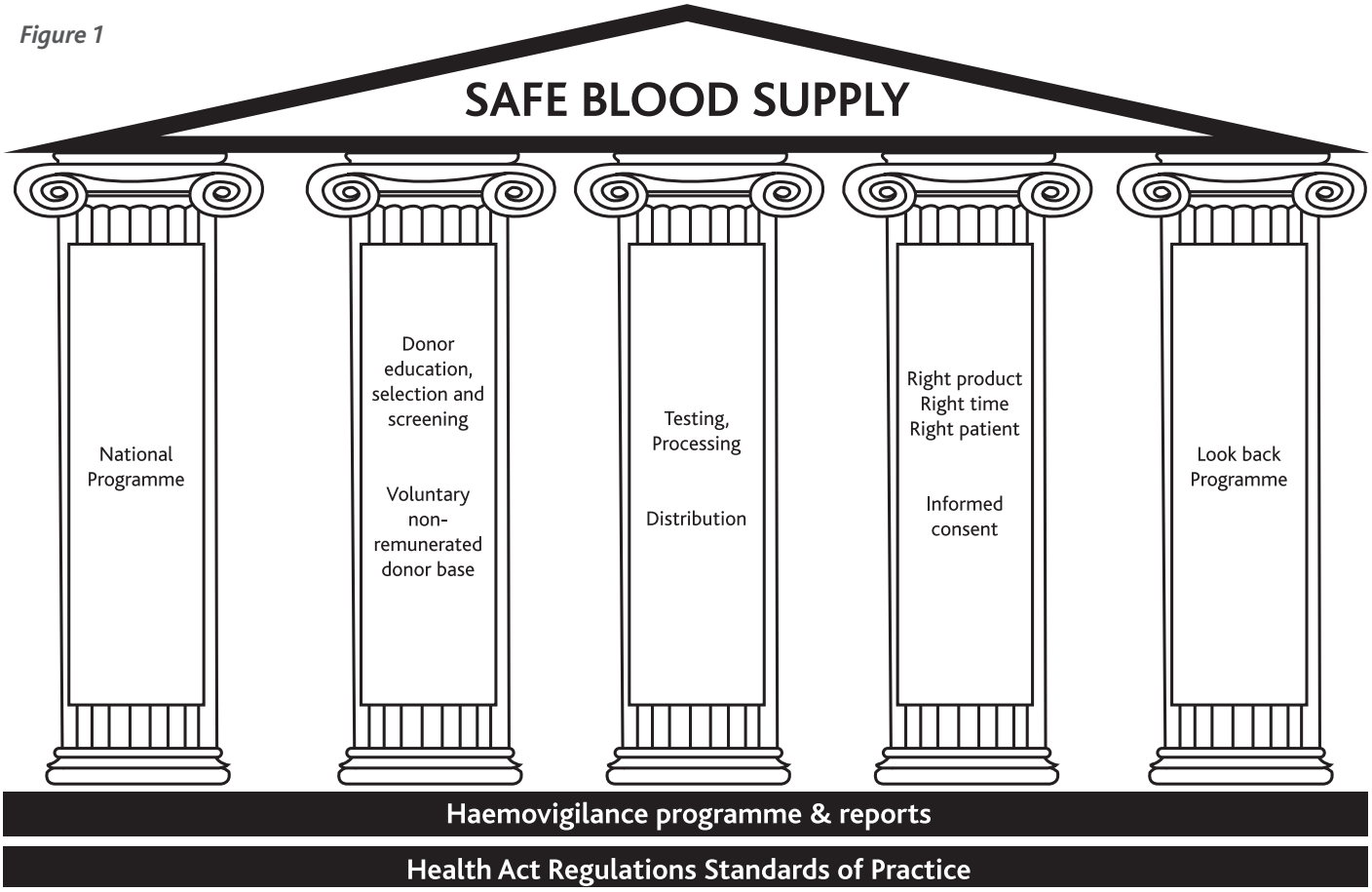
The South African Program is modeled on the United Kingdom's Serious Hazards of Transfusion (SHOT) system as well as the International Haemovigilance Network's system (IHN).All suspected adverse events must be reported as soon as possible to the local blood bank. The adverse transfusion reaction report form that is available from the blood banks, must be completed as fully and accurate as possible. Investigations of adverse transfusion reactions are currently performed by either the SANBS special serology testing centers in Constantia Kloof and Pine Town or by the WPBTS special serology laboratory in Cape Town. Reports are sent to the Haemovigilance team, (Haemovigilance Officer and Consultant) for retrospective analysis and classification. The Haemovigilance Program also incorporates information from the Look-back Program which traces all patients who may possibly have been exposed to an infection through a transfusion.

The data is used for compiling an annual Haemovigilance Report that is reported to the Director General of the Department of Health. This is in compliance with the **Section 68 of the National Health Act 61 of 2003 and with regulation R179 published in Government Gazette 35099 on 12 March 2012.**

This report is available on the SANBS and WPBTS websites. The information is used as a means of educating blood users on the incidence and management of adverse reactions as well as on the rational and appropriate use of blood.

> "The South African Haemovigilance Program was established in 2000 as a voluntary, non-punitive initiative by the South African National Blood Service

Figure 1



Objectives of the Haemovigilance Programme:

- The Haemovigilance Programme is responsible for the development of solutions to problems that threaten the safety of transfused patients.
- To identify all adverse reactions related to blood and blood products.
- To prevent the recurrence of these undesirable effects of blood transfusion in subsequent transfusions.
- To continuously collect and analyze data on adverse reactions, whether of an infectious or non-infectious nature. Where possible, this data should be correlated with the transfused component.
- To institute corrective measures required in the prevention of transfusion reactions, including measures related to skills development and training, both at hospital and transfusion service level.
- To help identify vulnerable groups of patients at risk of transfusion complications.
- To provide the medical community with a reliable source of information regarding the risks and benefits of blood transfusion

3.2.
Data collection

The authors of this report note that the data presented in the report should be treated with caution.

The collection and analysis of data on transfusion adverse events relies closely on collaboration between the blood banks, special serology team, haemovigilance team and the hospitals. This collaboration is essential, in order to ensure complete investigations of every unfavorable event.

“ This collaboration is essential, in order to ensure complete investigations of every unfavorable event

4. OVERVIEW OF PRODUCT ISSUES FOR 2011

As shown in Table 4.1 below, in 2011 a total of **1 081 690** blood products which constituted of **909 232** by SANBS and **172 458** by the WPBTS were issued to patients in South Africa.

SANBS has two donation testing centres (Constantia Kloof and Pine Town), seven processing centers, 79 compatibility testing laboratories (blood banks) and >400 emergency blood fridges (storing 'emergency group O blood).

WPBTS has one donation testing centre at the Head Office and; blood and blood components are distributed to seven blood banks and 92 emergency 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; TPHA for syphilis. Both services provide blood and blood products to ± 729 hospitals and clinics country wide.

Table 4.1 Component issues for 2011 (SANBS and WPBTS)

Plasma Products	SANBS	WPBTS	TOTAL
Cryo-Poor Plasma	15 917	1 758	17 675
Fresh Frozen Plasma	105 607	25 097	130 704
Totals	121 524	26 855	148 379
Platelet Products			
Apheresis Platelets	25 451	3 465	28 916
Pooled Platelets	26 572	4 470	31 042
Totals	52 023	7 935	59 958
Red Cell Products			
Paediatric	35 343	3 609	38 952
Red Cells	665 117	126 635	791 752
Reserved	508	0	508
Emergency Units	32 335	6 969	39 304
Whole Blood	2 382	455	2 837
Total Red cell products	735 685	137 668	873 353
GRAND TOTAL	**909 232**	**172 458**	**1 081 690**

Figure 2. SANBS products issued (2007-2011)

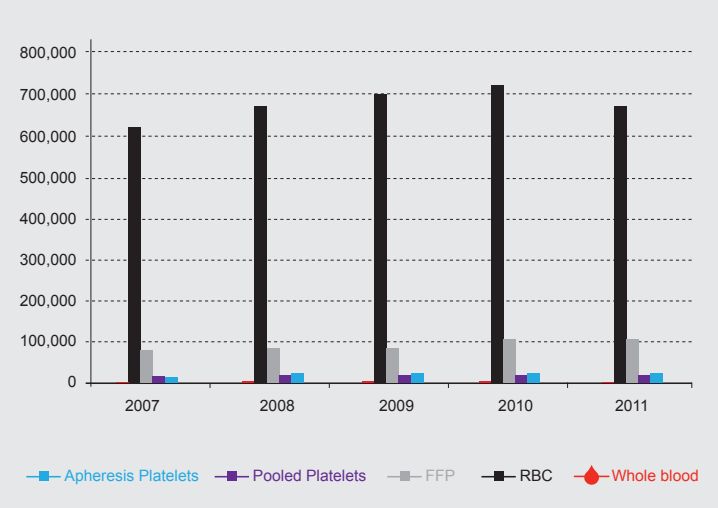
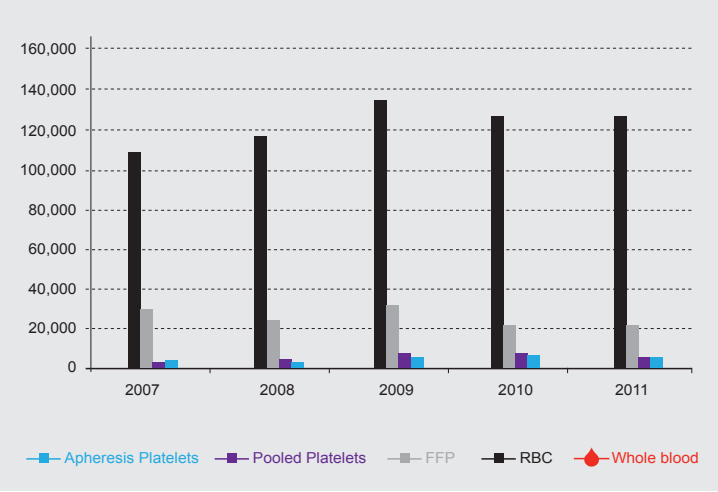


Figure 3. WPBTS products issued (2007-2011)



In both figure 2 and 3 above, it is evident that the highest issued blood component is red blood cells (RBC) at ± 80.8% across both services, plasma products 13.7% and platelet products the lowest issued at 5.5%. All components are issued at almost constant rates year-on-year since 2007.

	2010	2011
Whole Blood Collections	918 803	930 654
Red Cell Products Issues	841 193	873 353
% Difference	**8%**	**6%**

Percentage (%) difference between collections and usable units was 6% in 2011, a decrease from 8% in 2010. The decrease might indicate that the demand for blood has possibly increased between the 2 years.

5. SUMMARY OF TRANSFUSION ADVERSE EVENTS 2011 (SANBS AND WPBTS)

Table 5.1 Adverse transfusion events 2011

Adverse Events	SANBS	WPBTS	TOTALS
Acute haemolytic (AHTR)	1	0	1
Delayed haemolytic (DHTR)	0	1	1
Delayed serological reaction (DSTR)	0	0	0
Allergic reactions	113	88	201
Severe allergic	20	0	20
Anaphylactic reaction	1	15	16
Febrile non-haemolytic reactions (FNHTR)	210	45	255
Circulatory overload (TACO)	0	1	1
Transfusion related acute lung injury (TRALI)	0	1	1
Transfusion associated dyspnea (TAD)	71	0	71
Hypotensive reaction	53	1	54
Transfusion Associated Graft Versus Host Disease (TA-GVHD)	0	0	0
Subtotal ATR	**469**	**152**	**621**
Unclassifiable (UCT)	84	33	117
TTI	0	0	0
ABO + Rh Incompatable Transfusion	1	0	1
ABO Incompatable Transfusion	4	1	5
Misdirected Transfusion	9	0	9
Patient Misidentification	7	0	7
Near miss events	0	0	0
Subtotal IBCT	21	1	22
Mortality	3†	0	3
GRAND TOTAL	**577**	**186**	**763**

† Possible mortalities

During 2011 a total of **763** transfusion-related adverse events from both SANBS and WPBTS were reported and analyzed. The majority of cases at 33% were due to febrile non-haemolytic transfusion reactions, followed by allergic reactions at 30% (including severe), 15.3% cases remained unclassified due to lack of sufficient transfusion reaction data, 9.3% cases of transfusion associated dyspnoea, 7.1% cases of hypotensive reactions, 2.8% cases incorrect blood component transfused (IBCT).

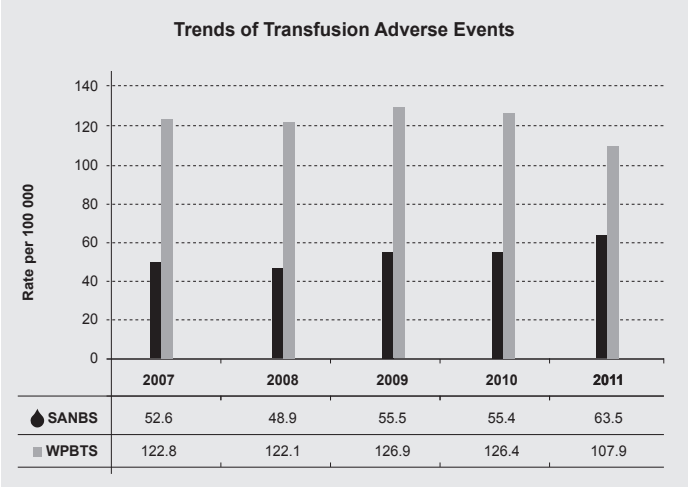
Possible transfusion related mortality cases were reported as 0.4%, however, in all three cases, blood transfusion was excluded as definitive cause of death. No cases of transfusion transmitted infections and no near miss events were reported. The high number of unclassifiable cases is concerning and; new transfusion reaction forms have been drafted and more education given to address and ensure improved capturing and reporting of transfusion adverse events. There has been an increase in the number of reported events from 688, in 2010 to 763, in 2011.

Table 5.2 Rates of adverse events per classification

Adverse Events	SANBS		WPBTS		TOTALS	
	Number	Rate per 100 000	Number	Rate per 100 000	Number	Rate per 100 000
Acute haemolytic (AHTR)	1	0.1	0	0	1	0.1
Delayed haemolytic (DHTR)	0	0.0	1	0.6	1	0.1
Delayed serological reaction (DSTR)	0	0.0	0	0	0	0.0
Allergic reactions	113	12.4	88	51.0	201	18.6
Severe allergic	20	2.2	0	0	20	1.8
Anaphylactic reaction	1	0.1	15	8.7	16	1.5
Febrile non-haemolytic reactions (FNHTR)	210	23.1	45	26.1	255	23.6
Circulatory overload (TACO)	0	1	0.6	1	1	0.1
Transfusion related acute lung injury (TRALI)	0	0.0	1	0.6	1	0.1
Transfusion associated dyspnea (TAD)	71	7.8	0	0.0	71	6.6
Hypotensive reaction	53	5.8	1	0.6	54	5.0
Transfusion Associated Graft Versus Host Disease (TA-GVHD)	0	0.0	0	0.0	0	0.0
Unclassifiable (UCT)	84	9.2	33	19.1	117	10.8
TTI	0	0.0	0	0.0	0	0.0
Subtotal ATR	**553**	**60.8**	**185**	**107.3**	**738**	**68.2**
ABO + Rh Incompatable Transfusion	1	0.1	0	0.0	1	0.1
ABO Incompatable Transfusion	4	0.4	1	0.6	5	0.5
Misdirected Transfusion	9	1.0	0	0.0	9	0.8
Patient Misidentification	7	0.8	0	0.0	7	0.6
Near miss events	0	0.0	0	0.0	0	0.0
Subtotal IBCT	21	2.3	1	0.6	22	2.0
Mortality	3	0.3	0	0.0	3	0.3
GRAND TOTAL	577	63.5	186	107.9	763	70.5

Table (5.2) above shows that in South Africa, the number of transfusion adverse events reported in relation to the number of blood components issued to be at 70.5 per 100 000. The classification with the highest rate of reporting per 100 000 is FNHTR at 23.6, followed by allergic reactions at 18.6, unclassifiable at 10.8, TAD at 6.6 and hypotensive at 5.0 per 100 000.

Figure 4. Trend analysis of reported events SANBS 2007 to 2011



The rate of reporting per 100 000 units issued at SANBS has increased from 52.6 to 63.5 per 100 000 over the 5 year period as shown in figure 4 .The increase in reporting may be attributable to various factors including amongst others awareness of haemovigilance created through education of blood users and; establishment and maintenance of hospital transfusion committees. A decrease in 2011 in the rate of reporting for WPBTS is noticed at 107.9 per 100 000 compared to 122.8 per 100 000 in 2007 and will need to be investigated. The reporting rates are however still better with WPBTS compared to SANBS as shown in the figure above.

Table 5.3 SANBS Transfusion Reactions 2007 to 2011

CLASSIFICATIONS	2007	2008	2009	2010	2011
Acute haemolytic (AHTR)	29	13	15	14	1
Delayed haemolytic (DHTR)	0	0	0	0	0
Delayed selogical reaction (DSTR)	0	0	0	0	0
Allergic reactions	83	91	114	121	113
Anaphylactic reaction	7	7	3	5	1
Febrile non-haemolytic reactions (FNHTR)	110	91	176	206	210
Circulatory overload (TACO)	0	0	3	5	0
Transfusion related acute lung injury (TRALI)	2	0	3	1	0
Transfusion associated dyspnea (TAD)	0	64	36	47	71
Hypotensive reaction	10	25	12	13	53
Transfusion Associated Graft Versus Host Disease (TA-GVHD)	0	0	0	0	0
Unclassifiable (UCT)	133	90	82	59	84
Subtotal ATR	**374**	**381**	**445**	**471**	**533**
TTI	0	0	1	0	0
ABO Incompatable Transfusion	21	9	22	9	21
Mortality	0	0	0	0	3
GRAND TOTAL	**395**	**390**	**467**	**480**	**577**

Table 5.4 WPBTS Transfusion Reactions 2007 to 2011

CLASSIFICATIONS	2007	2008	2009	2010	2011
Acute haemolytic (AHTR)	0	0	0	1	0
Delayed haemolytic (DHTR)	0	0	0	0	0
Delayed serological reaction (DSTR)	0	0	0	0	0
Allergic reactions	94	86	108	110	88
Anaphylactic reaction	12	8	2	1	15
Febrile non-haemolytic reactions (FNHTR)	62	59	53	51	45
Circulatory overload (TACO)	0	0	0	0	1
Transfusion related acute lung injury (TRALI)	0	0	1	0	1
Transfusion associated dyspnea (TAD)	0	0	0	0	0
Hypotensive reaction	0	0	0	4	1
Transfusion Associated Graft Versus Host Disease (TA-GVHD)	0	0	0	0	0
Unclassifiable (UCT)	9	36	34	38	33
Subtotal ATR	**177**	**189**	**198**	**206**	**184**
TTI	0	0	0	1	0
ABO Incompatable transfusion	3	4	7	1	1
Mortality	0	0	0	0	0
GRAND TOTAL	**180**	**193**	**205**	**207**	**186**

As shown in tables 5.2- 5.4, the trends over the 5 years show that FNHTR are the highest reported cases at ± 33% and allergic reactions at ± 26%.

6. REPORTED ADVERSE EVENT CASE PRESENTATIONS 2011

Any adverse reaction to the transfusion of blood or blood components should be reported to the blood bank personnel as soon as possible. The classification of these reported cases is the responsibility of the transfusion service's Haemovigilance team. Suspected post-transfusion infections should also be reported to the transfusion service, which will conduct a look- back to investigate the source of the infection.

A Blood transfusion medical officer should be consulted regarding the evaluation of patients with reactions, as well as selection of appropriate blood products for future transfusion. The following reported cases were classified by SANBS's Haemovigilance office for the calendar period of 2011.

6.1. Acute Transfusion Reactions (ATR's)

6.1.1 Acute Haemolytic Transfusion Reactions (AHTR)

2007	2008	2009	2010	2011
29	13	14	15	1

1 case of AHTR was reported in 2011 and, the case is discussed below.

CASE 1

A 63 year old female:

- Diagnosed with pancreatic cancer
- Typed O positive, DAT negative
- 2 units O positive RBC issued
- Reacted on the 1st unit after ±50mls infused, event reported to have occurred within 1-2 hours
- Presented with flushing sweating, tachycardia and rigors
- Transfusion stopped and patient managed accordingly
- Blood bank notified.
- Post transfusion samples sent for investigation
- Post transfusion cross match
  - > O positive, DAT negative
  - > Anti – Kell red cell antibodies detected
- Conclusion : anti – Kell antibodies were missed and lead to acute haemolytic transfusion reaction
- Patient recovered satisfactorily

6.1.2 Anaphylactic reactions

2007	2008	2009	2010	2011
19	15	5	6	16

There were 16 cases of anaphylactic reactions reported in 2011. An example of a case is described below.

CASE 2

A 47 year old male:

- Post thoracotomy left lung
- 2 units A negative RBC issued, reacted immediately to the 1st unit
- Presented with flushing, sweating, tachycardia, dyspnoea, drop in blood pressure and collapse
- Transfusion stopped and patient managed accordingly
- Blood bank notified and post transfusion investigation conducted
- No discrepancy detected
- Patient responded satisfactorily to management

6.1.3 Allergic Reactions

2007	2008	2009	2010	2011
177	177	221	231	201

There were 201 cases reported in 2011. An example of a case is described below.

CASE 3

A 31 year old female patient:

- Placenta Abruptio with anaemia
- Transfused with 3 units of FFP
- Reacted within an hour to the 1st unit
- Presented with Skin reactions, urticaria, flushing and sweating
- Transfusion stopped immediately, Solucortef 100mg given IVI and Phenergan 25mg IMI
- Patient improved condition after about 30 minutes of management

6.1.4 Febrile Non Haemolytic Transfusion Reactions (FNHTR)

2007	2008	2009	2010	2011
172	150	229	257	255

There were 255 cases of FNHTR reported in 2011. An example of a case is described below.

CASE 4

A 39 year old male:

- Pancreatic fistula post trauma with anaemia
- 2 units O positive RBC issued
- Reacted on the second unit in less than 6 hours
- Presented with increased temperature, flushing and sweating
- Transfusion stopped and patient managed accordingly
- Blood bank notified and no further investigations done
- Patient responded satisfactorily

6.1.5 Hypotensive Reactions

2007	2008	2009	2010	2011
†	12	17	257	54

† Possible mortalities

There were 54 Hypotensive reactions reported in 2011. An example of a case is described below.

CASE 5

A 70 years old male:

- Macroscopic haematuria with a low platelet count
- Transfused with a unit of pooled platelets
- 1-2 hours into the transfusion, experienced flushing, sweating, rigors and a drop blood pressure
- Transfusion stopped and patient managed accordingly
- Patient responded well to management

6.1.6 Transfusion Associated Dyspnea (TAD)

2007	2008	2009	2010	2011
†	64	36	47	71

71 cases of TAD were reported in 2011. An example of a case is described below.

CASE 6

A 72 year old female:

- Upper GIT bleed, Acute blood loss with Anaemia, Hb 8.7
- 1 unit of RBC issued
- Immediately, the patient reacted and had tachycardia, dyspnoea, bronchospasm, and rigors
- Blood transfusion was stopped
- No medication administered to patient or active management carried out
- Patient observed and condition improved

6.1.7 Transfusion Associated Circulatory Overload (TACO)

2007	2008	2009	2010	2011
7	7	3	5	1

There was only 1 case of TACO reported in 2011.

6.2.
Incorrect Blood Component Transfused (IBCT)

22 cases of incorrect blood components transfused to patients were reported. Six (6) of the cases were as a result of incompatable blood units being transfused to patients by the hospital personnel in the ward. Sixteen (16) of the cases were also as a result of unintended transfusions or misdirected transfusions due to hospital personnel error of not correctly identifying patients pre transfusion. These are some of the reported cases of human errors of transfusions which are preventable if procedures in place are adhered to.

2007	2008	2009	2010	2011
24	10	31	10	22

An example of a case is described below.

CASE 7 – Sample collection error (Testing)

A 50 year old female patient:

- anaemia, post total abdominal hysterectomy
- received 3 units RBC
- Reacted after infusion of ±30mls of the first unit
- presented with flushing, tachycardia, dyspnoea, decrease in oxygen saturation, rigors and elevated blood pressure
- Transfusion was immediately discontinued
- Patient subsequently developed transfusion associated dyspnea (TAD)
- Admitted in ICU for close monitoring
- Patient managed accordingly
- The reaction reported to the blood bank
- Post transfusion investigation
  - > Detected blood group discrepancy
  - > Pre sample typed B positive and; Post transfusion sample typed O positive
  - > The discrepancy was due to sample labeling error from the ward on pre testing sample collection
  - > The patient's name on the tube did not match the patient's details
- In conclusion: an O positive patient was transfused with B positive blood

Learning points:

- Transfusion medicine should be part of the core curriculum for doctors in training.
- Transfusion should only take place if there are sufficient competent staffs available to monitor the patient.

6.2.1 Misdirected Transfusions

There were 9 cases of reported misdirected transfusions in 2011.

CASE 8 – Misdirected transfusion

A 31 year old female:

- Diagnosed with ante partum haemorrhage (Abruptio placentae)
- 2 units FFP and 2 units B positive RBC were issued
- Transfusion stopped immediately after realizing a wrong unit was given to wrong patient
- Presented with no symptoms
- Blood bank was notified and an investigation conducted
  - > 1st unit transfused (suspected unit) was found to be O positive
  - > Intended for another patient
  - > The unit was serologically compatible therefore no transfusion reaction occurred
- Patient remained stable

Learning points:

- Positive verification of patient identity must be carried out prior to all transfusion.

6.2.2 Near Miss Events

2007	2008	2009	2010	2011
3	0	2	2	0

There were no near-miss cases reported in 2011.

6.3.
Transfusion Acute Lung Related Injury (TRALI)

2007	2008	2009	2010	2011
2†	0	1	1	1

† Possible TRALI cases

There was only one case of TRALI reported in 2011. The case is described below.

CASE 9

- A female patient experiencing post-partum haemorrhage following the birth of twins
- Transfused with 2 units of red cell concentrate.
- She experienced severe shortness of breath 2 hours later.
- Bilateral opacification was detected on CXR. She responded well to oxygen.

The presence of histocompatibility HLA class 2 DR12, & DRB1 04; 02 in both donor and recipient confirmed the diagnosis. Such reactions once recognized, are usually reversible with rapid respiratory support. Unfortunately donors involved in such cases, are permanently deferred.

6.4
Transfusion related mortalities

2007	2008	2009	2010	2011
5†	0	2†	3†	3†

† Possible mortality cases

There were no definite cases of transfusion associated mortalities in this year. There were however 3 cases of possible transfusion related mortality reported in 2011. In all three cases blood transfusion was clinically excluded as definitive cause of death since no blood samples were sent for post-transfusion investigation investigations and no postmortem done.

CASE 10

- A 9 months male baby in neonatal ICU for a Haemoglobin reading of 4.8
- Transfused with 1 unit of red cell concentrate
- Less than 6 hours into the transfusion, baby experienced Tachycardia, dyspnoea, decrease in oxygen, urticarial, sweating , rigors and a rise in temperature of 41°C
- The transfusion was stopped immediately as it was reported that the baby collapsed
- The baby wasoxygenated and given fluids
- A few hours the blood bank was notified of the transfusion reaction and ultimate baby"s demise
- No post transfusion sample was sent to the blood bank therefore transfusion as a contributory cause of death could not be excluded
- Post mortem results were not sent to the blood bank either.

Learning points:

- Post-transfusion samples need to be obtained for further investigations and postmortem conducted to determine if blood transfusion was the cause of death.

6.5.
Transfusion Transmitted Infections (TTI's)

2007	2008	2009	2010	2011
0	0	1†	0	0

There were no cases of TTIs reported in 2011.

6.6. Unclassifiable reactions

2007	2008	2009	2010	2011
16	44	43	48	117

There were 117 cases of unclassifiable reactions in 2011. In all of the cases, the patients were transfused and had a reaction which could not be classified under any of the adverse events classifications. The transfusion reaction reporting form has been reviewed, and changes made to ensure that more accurate information will be supplied by the doctors reporting the adverse events.

6.7. Post Transfusion Purpura (PTP)

2007	2008	2009	2010	2011
0	0	0	0	0

No cases of PTP were reported in 2011.

6.8. Transfusion Associated Graft Versus Host Disease (TA-GVHD)

2007	2008	2009	2010	2011
0	0	0	0	0

There were no cases of TA-GVHD reported in 2011


FERWAT TRANSFER PACK
CAPACITY - 500 ml VOLUME - 400 ml
REF R837
LOT 1102L51

7. ADVERSE REACTIONS BY PRODUCTS (SANBS PRODUCTS ONLY)

Table 7.1 Adverse reactions by products (SANBS)

Adverse Events	RBC	Platelets	FFP	Combined	Total
Acute haemolytic (AHTR)	1	0	0	0	1
Delayed haemolytic (DHTR)	1	0	0	0	1
Delayed selogical reaction (DSTR)	0	0	0	0	0
Severe Allergic and mild allergic reactions	81	8	42	2	132
Anaphylactic reaction	1	0	0	0	1
Febrile non-haemolytic reactions (FNHTR)	201	5	3	1	210
Circulatory overload (TACO)	0	0	0	0	0
Transfusion related acute lung injury (TRALI)	0	0	0	0	0
Transfusion associated dyspnea (TAD)	65	2	4	0	71
Hypotensive reaction	46	5	2	0	53
Incorrect blood components (IBCT)	21	0	0	0	21
Unclassifiable (UCT)	79	1	3	0	84
Mortality	3	0	0	0	3
TOTAL	**499**	**21**	**54**	**3**	**577**

Red cell concentrates accounted for 86.5% of transfusion adverse events, platelets 3.6%, FFP 9.4% and combined 0.5%. FNHTR contributed 40% (201/499) and allergic reactions 16% (81/499) of all RBC related reactions and this may be attributable to the fact that RBCs are not routinely leucodepleted but only on doctor's request.

8. THE LOOK BACK PROGRAM

The transfusion transmissible infection (TTI) Lookback Program was established in 1986. It has been incorporated into the Haemovigilance Program 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 (IDNAT). The Lookback Program 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 lookback investigation** the recipient/s of the previous negative units are identified and their treating doctor notified. As far as possible, the patient is recalled, counseled and tested for the relevant viral marker and the result reported to the Blood Service.

A **recipient-triggered lookback investigation** is initiated when the Blood Service is informed that a blood recipient has tested positive for a TTI and it is considered that the infection may have been transfusion transmitted. The implicated donors are identified and their donation history reviewed. Where subsequent donations do not prove that the donor was not in a window period for the infection, the implicated donors are recalled for further testing.

Transfusion transmitted hepatitis B virus (HBV)

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.

Donor-triggered Lookback 2011

Table 8.1 Donor-triggered reported Lookback totals for 2011

Infection	Number
HIV	419
HBV	145
HCV	2
TOTAL	**566**

A total of **566** cases were reported and investigated through the donor triggered lookback. There was a 100% follow up of cases.

Table 8.2 A breakdown of donor triggered lookbacks investigated

Investigation Outcome	Total
Recipient retest negative	46
Recipient positive before transfusion	58
Recipient test positive- phylogenetic analysis	1
Recipient negative/ unknown before transfusion	6
Recipient died- between transfusion and lookback	110
Unresolved	283
Untraceable	51
Other	11
TOTAL	**566**

At the time of the report, **283 (50%) of the 566 cases were closed.** Of the 283 cases, 46 recipients tested negative when re-tested, 58 were confirmed positive before transfusion (confirmed on requisition form or by treating doctor), 1 HIV positive recipient was eligible for phylogenetic analysis and determined not to be a transfusion transmitted infection (TTI), 6 cases were negative or status unknown before transfusion, 110 recipients were confirmed to have died between the transfusion episode and lookback investigation initiation period (presumed not related to transfusion), 51 cases were untraceable because the patient was unreachable by the hospital or due to missing hospital files and; other 11 cases recipients either refused to come or were too ill to present for testing and others; the hospital clinical manager refused to investigate lookbacks > 6months old.

The 6 cases that were negative before transfusion, information was given by the treating doctors that patients admitted to high risk lifestyle/behaviour. Of the 6 cases 5 (83.3%) recipients were HIV positive and 1 (16.7%) was Hepatitis B virus (HBV) positive. The HBV positive case had subsequently resolved the infection and investigation closed.

The other **283 (50%) cases remain unresolved/ open** at the time of the report but the investigation still continues. They remain unresolved because there was either no response from the doctor or hospital after 6 months of being contacted by SANBS.

Recipient-triggered Lookback 2011

Table 8.3 Recipient-triggered lookbacks for 2011

HIV	HBV	HCV	Other	TOTAL
14	2	3	4	23

A total of 23 recipient triggered lookback were reported. Of all these lookbacks only 5 (21.7%) cases remain unresolved because no records were found due to time lapsed or the donors were untraceable, in 9 (39.1%) cases donors retested negative, 4 (17.4%) cases unrelated to transfusion because they were never transfused and; 5 (21.7%) cases were information requests from treating doctors that subsequently informed the office to close the cases. A total of 78.3% of cases had been resolved/ closed at the time of the report.

There has been an increase in the total number of all lookbacks (donor and recipient triggered) from 394 (2009), 507 (2010) to 590 in 2011.

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

- Blood requisition forms are not completed correctly and patient information is missing
- Incorrect hospital number is entered and the patient cannot be traced in many provincial hospitals
- Information on deceased patients or patients who were HIV+ before transfusion in the case of an HIV lookback is not always relayed timeously to the lookback officer
- Retest results are not sent to the lookback officer as requested in the lookback notification
- Numerous follow-up calls have to be made before a result is obtained from several major provincial hospitals and many doctors in private practice
- Several hospitals and doctors consider it the duty of 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.

9. DONOR VIGILANCE

Introduction

The mission of the blood transfusion services in South Africa is to provide sufficient, safe blood for all the people of 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 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 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.

Classification

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 (Version 2008 draft) as compiled by the Working Group on Complications Related to Blood Donation, the International Society of Blood Transfusion Working Party on Haemovigilance, and the International Haemovigilance Network (IHN).

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

Categories of complications related to blood donation

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

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 Out-Side 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 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:** Nerve type as radiating pain and/or paraesthesia in association with a haematoma. The haematoma may not always be apparent at the time. Symptoms do not occur immediately on insertion of the needle but start when the haematoma has reached a sufficient size, some time after insertion of the needle.
Nerve Injury	Injury of a nerve by the needle at insertion or withdrawal. **Symptoms:** 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:** 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:** 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:** 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:** 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 parasthesia. Severe cases are characterized by respiratory difficulty with nausea and vomiting.
Haemolysis	Destruction of the donor's red blood cells
Generalised allergic reaction	The result of an interaction of an allergen with preformed antibodies. Minor allergic reaction: Reaction limited to the skin, with or without a rash **Severe allergic reaction:** Reaction with risk to life, 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.

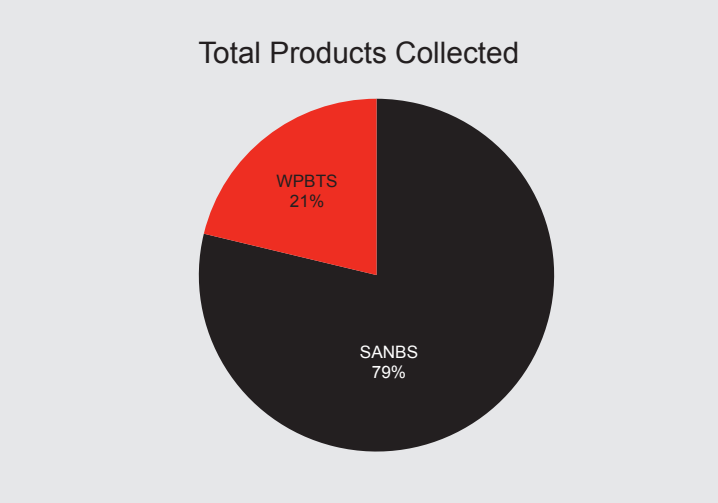
10. COLLECTIONS 2011 (SANBS AND WPBTS)

Collections 2011	SANBS	WPBTS	TOTAL
Whole Blood	786 335	144 319	930 654
Apheresis Platelets	15 046	4 486	19 532
Plasma	2 770	67 904	70 674
TOTALS	**804 151**	**216 709**	**1 020 860**

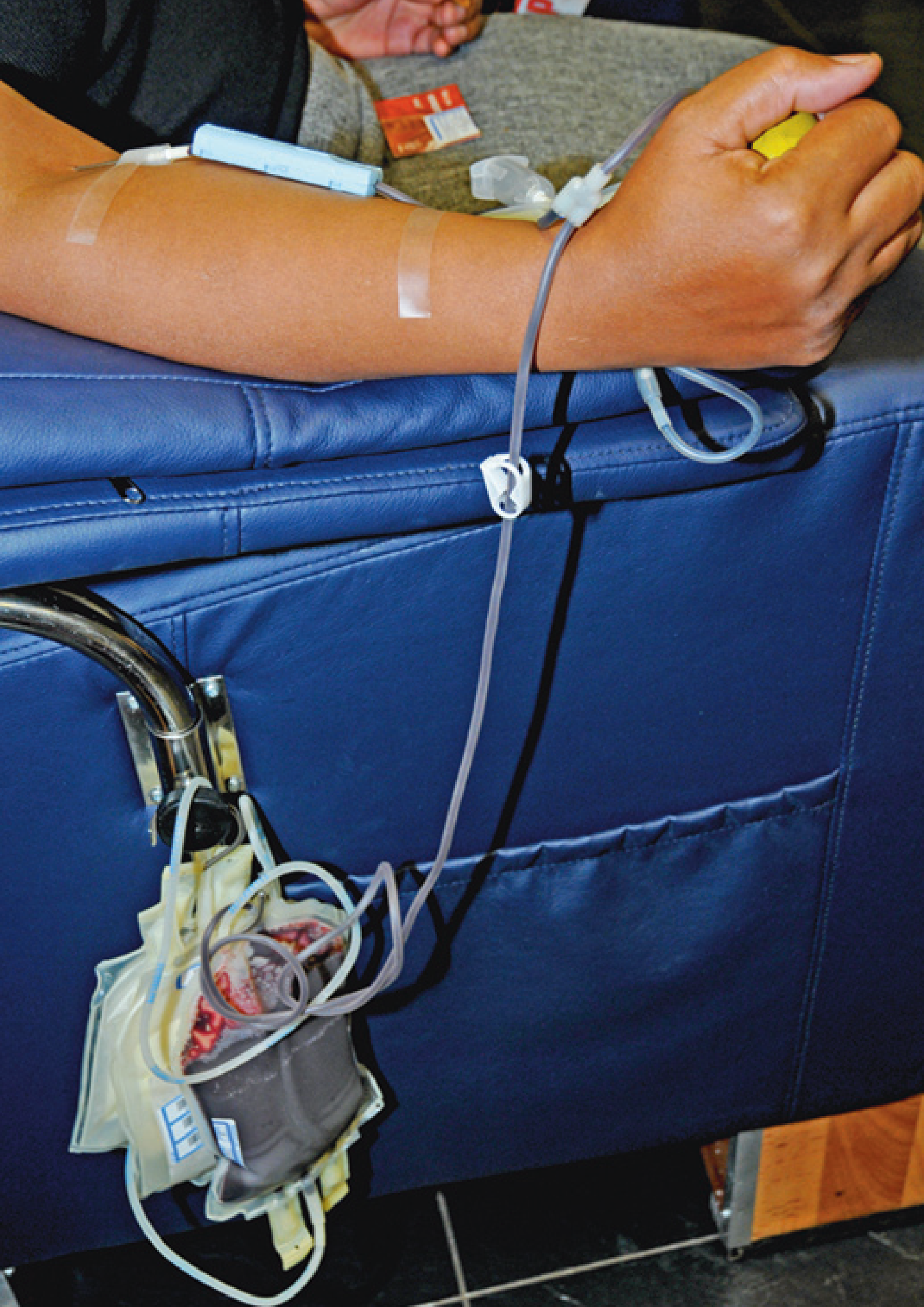
During 2011, a total of **1 020 860** blood products were collected by SANBS and WPBTS combined as shown in table and figure 5 below with SANBS having contributed 78.8% and WPBTS 21.2%. SANBS collections were undertaken at **84 permanent** collection centers as well as **90 mobile** donor units. Apheresis platelet donations are collected at seven fixed site collection centres.

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

Figure 5. Product collections 2011 (SANBS and WPBTS)



SANBS collected 79% of all blood products and WPBTS 21% as shown in figure 5 above.



11. SUMMARY OF DONOR ADVERSE EVENTS 2011 (BOTH SERVICES INCLUDED)

Table 11.1 Donor adverse events per categories

Category	Number of cases-whole blood	Number of cases-Apheresis	Unknown	TOTAL
	Subtotal	Subtotal	Subtotal	
Haematoma	431	156	26	613
Artrial Puncture	3	1	0	5
Delayed bleeding	32	0	0	32
Nerve irritation	1	0	0	1
Tendon injury	1	0	0	1
Nerve injury	1	0	0	1
Painful arm	101	14	3	118
Total local symptoms	572	171	29	772
Faint Immediate type	3 182	41	24	3 247
Faint Immediate, accident	113	1	4	119
Faint Delayed type	899	21	16	936
Faint delayed, accident	57	0	0	57
Total no. Vasovagal Reactions	4 251	63	44	4 358
Citrate reaction	3	11	0	14
Haemolysis	1	0	0	1
Generalised allergic reaction	7	0	0	7
Embolism	0	0	0	0
Total others	11	11	0	22
GRAND TOTAL	**4 834**	**245**	**73**	**5 152**

An overall/ grand total of donor adverse events reported was 10 085 with more than 1 venepuncture cases contributing 4933 of 10 085 (48.9 %). These events were recorded as it may affect return rates and have financial implications to the blood transfusion service but, have been excluded on the template in alignment with ISTARE data reporting.

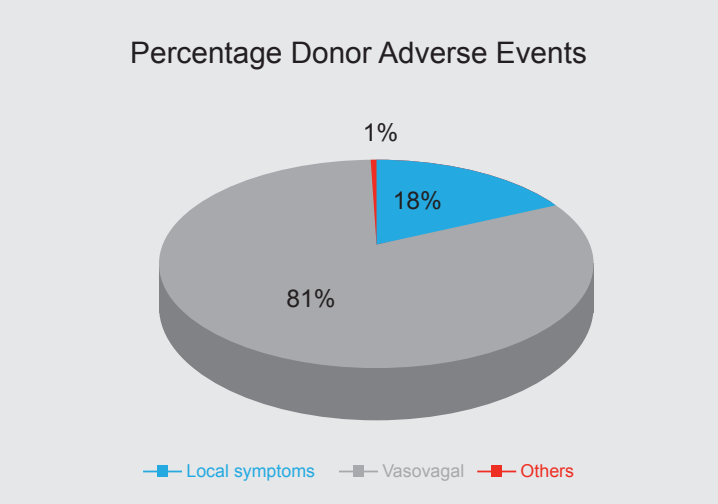
All donor adverse events reported (excluding more than 1 venepuncture cases) contributed 0.5% (5152 out of 1 020 860) of total collections. The adverse events have been categorized into whole blood, apheresis and unknown. The main concern is with the unknown category i.e. those that do not fall into either whole blood or apheresis. This indicates that the staff does not accurately classify DAE according to donation type.

Most DAE were with whole blood donations at 93.8 % (4834/5152), apheresis 4.8% and unknown 1.4%.

Table 11.2 Donor adverse events according to broad categories

	Local symptoms	Vasovagal	Others	TOTAL
SANBS	687	3 093	19	3 799
WPBTS	85	1 265	3	1 353
TOTALS	**772**	**4 358**	**22**	**5 152**

Figure 6



The majority of donor adverse reactions were vasovagal (81%), local symptoms (18%) and unknown (1%) as shown in table 11.2 and figure 6 above . Of the vaso-vagal reactions, 74.5 % were attributable to immediate faints without accident, 21.5% delayed faints without accident,2.7% immediate faints with accidents and; 1.3% delayed faints with accident.

In the local symptoms category, 79.3% of DAE is due to haematomas and because studies have shown that retention in donors who have had DAE is a challenge, efforts to reduce the occurrence are being investigated.

Reactions by severity

Table 11.2 Donor adverse events according to severity

Severity	Number	Percentage (%)
Mild	4335	84.1
Moderate	674	13.1
Severe	143	2.8
TOTAL	5152	100

As shown in table 11.2 above, 84.1% of donor adverse reactions were mild, 13.1 % moderate and 2.8 % severe.

Reactions by age groups (SANBS) only

Table 11.3 Vasovagal reactions according to age groups

Age	Number
<21	1 422
21-30	870
31-50	615
>50	233
TOTAL	**3 140**

As shown in table 11.2 above emphasis was placed on vasovagal reactions since they contributed 81% of all DAE. The total number of vasovagal donor adverse events at SANBS were **3093** and; according to age groups in table 11.3 the number of DAE were **3140.** The discrepancy indicates that there are data capturing errors resulting in duplication. There has been improvement however from duplications reported in 2010.

Vasovagal reactions by gender (SANBS only)

Figure 11.2 vasovagal reactions according to gender

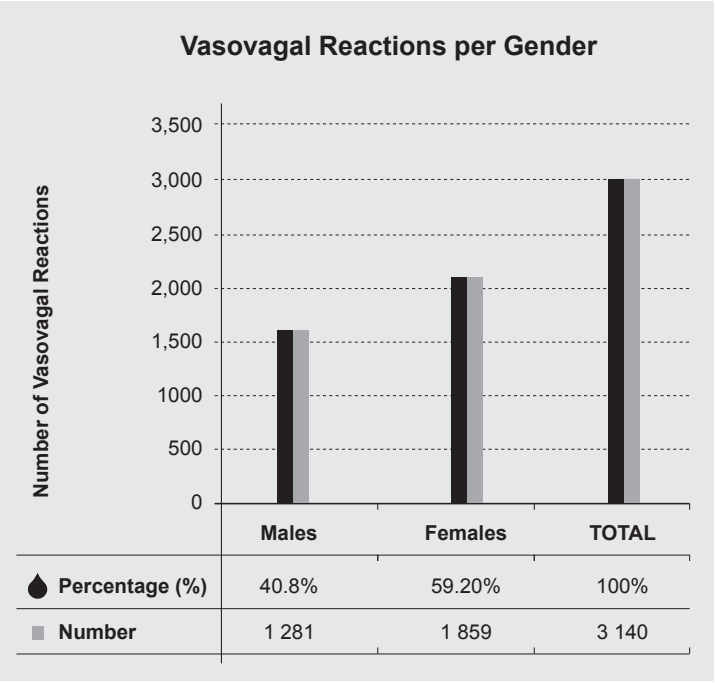


Figure 11.2 above illustrates that 59.2 % of females had vasovagal reactions as compared to 40.8% of males. The finding is in keeping with literature that females are more prone to vasovagal reactions than males.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12. CONCLUSION

Blood transfusion is an important component of modern day medicine. For doctors the first consideration must always be the interests and safety of patients. Haemovigilance programmes collect and analyse data on untoward events associated with transfusion. The information collated is then shared with health professionals who prescribe and administer blood products, so that they can continue to deliver the good without unintended negative consequences. Ongoing surveillance and review of untoward events associated with transfusion is vital so that we can continue to minimize risks related to blood products.

Haemovigilance has assisted in highlighting the importance of the role of continuous education and training of our hospital personnel. It has demonstrated significant improvements in the overall human error rates. The haemovigilance data collected in South Africa,over the years has had a significant improvement on blood safety. The management of patients that experience adverse events has also improved therefore reducing the risk of complications to patients.

“ Haemovigilance has assisted in highlighting the importance of the role of continuous education and training of our hospital personnel

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Glossary of Terms

ATR	Acute Transfusion Reaction
DAE	Donor adverse events
DAT	Direct Antiglobulin Test
DHTR	Delayed Haemolytic Transfusion reactions
FFP	Fresh frozen Plasma
IBCT	Incorrect Blood Component Transfused
PTP	Post Transfusion Purpura
SANBS	South African National Blood Service
TA-GvHD	Transfusion associated Graft Versus Host Disease
TTI	Transfusion Transmitted Infections
TRALI	Transfusion Related Acute Lung Injury (TRALI)
TACO	Transfusion Asssociated Circulatory Overload
SHOT	Serious Hazards of Transfusion