Haemovigilance Annual Report

Blood Transfusion South Africa

2003

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Table of Contents

1. Executive Summary

Blood Transfusion is universally recognised as a medical intervention that safes millions of lives each year. Blood safety is concerned with the overall process of delivering blood products to the patient and is currently probably safer than it has ever been. This has been achieved by collaborative worldwide efforts to improve the safety of the blood supply in the developing and industrialised countries. It must, however, be recognised that blood products are living human tissue and as in the case of other biological products, are therefore not without risk. During the last three decades the quality of blood components resulted in impressive improvements in blood safety. However, the bedside transfusion process received far less attention with the result that serious problems still exist in the hospital transfusion process.

Haemovigilance is the process whereby transfusion reactions are monitored and centrally reported. The programme aims to improve blood systems and thus contributes to making the blood supply safer. Haemovigilance is thus a system to detect, gather and analyse information on the untoward and unexpected effects of the transfusion of blood and blood products. The Haemovigilance programme is integrated in blood transfusion practice to maximise the safety of not only the blood supply, but all other aspects of laboratory and clinical blood transfusion.

The South African data accumulated in this report is based on the collation of the available historical information. The information was gathered by a questionnaire and encompasses the period January to December 2003. The reporting of the cases to the programme is anonymous: once the case report is finalised it is unlinked. In this year a total of 880 880 blood products (prepared from whole blood and aphaeresis donations) were issued. These were constituted of 708 801 red cell products, 117 518 fresh frozen plasma units, and 54 561 platelet concentrates.

In the year 2003 there was a 10% decrease in reported transfusion reactions. The reactions recorded since 2000 were as follow: 50 in 2000, 71 in 2001, 93 in 2002 and 84 in 2003. This decrease might be due to the fact that in some regions the responsibility of reporting to the programme was delegated to non-medical staff. This might also contribute to the considerable increase in the reporting of incorrect blood products transfused (IBPT). In 2003 IBPT increased by 93% and the reporting for acute haemolytic reactions (AHR) decreased by 53%. The IBPT accounted for 56 (67%) of the reported cases. These are mainly caused by human error.

Acute haemolytic reactions, 20 (24%) of the total reported reactions, were the second most common incidents. These reactions included haemolytic reactions not caused by IBPT and reactions due to IgA antibodies, manifesting as hypotensive and anaphylactic reactions. Delayed haemolytic reactions (DHR) accounted for four (5%) of the reported cases and transfusion transmitted diseases for three (4%) of the reactions. One of these was a possible bacterial infection and two were possible viral window period transmissions. Only one (1%) unclassified reaction was reported in 2003 as opposed to 9 (10%) in 2002. There were no reports of transfusion-related acute lung injury (TRALI), post-transfusion purpura (PTP) or transfusion-associated graft-versus-host disease (TA-GvHD). This may be due to a lack of knowledge in recognising these conditions on the part of the medical practitioners.

The sequelae ascribed to transfusion reactions were classified as asymptomatic, minor reactions, major reactions and death. This report makes no allowance for causality. Eight (10%) of the reported cases were asymptomatic, 41 (49%) had minor reactions and six (7%) had major reactions. No deaths were reported and for 29 (35%) cases the outcome was unknown.

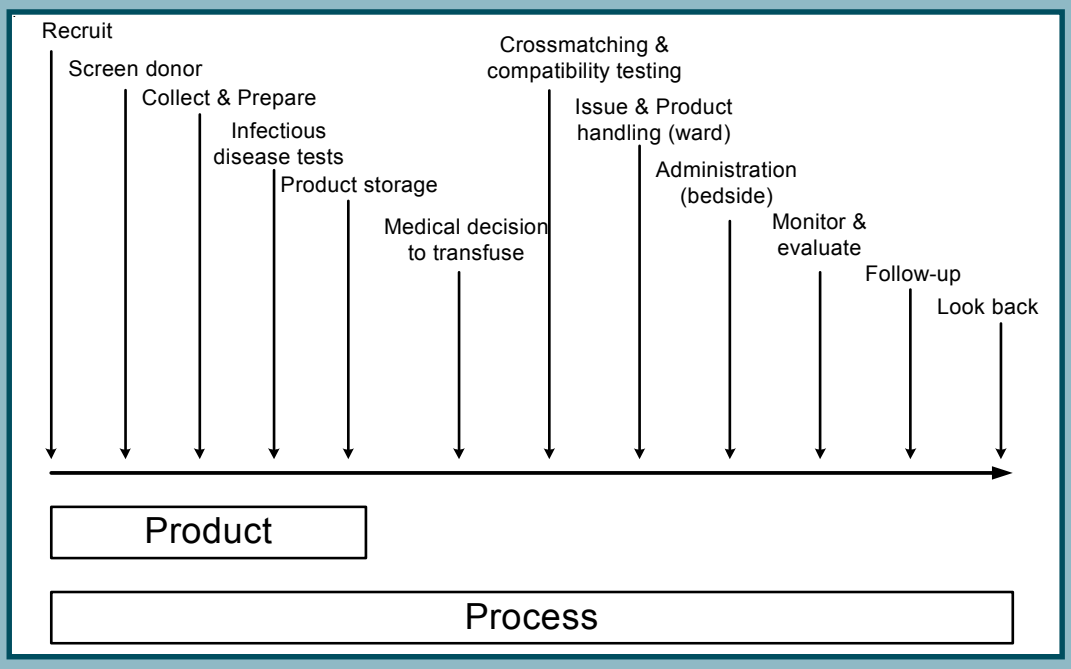
This is the fourth national report on transfusion-related adverse events in South Africa. All health care workers involved in transfusion practice, whether as employees of a blood transfusion service, doctors or employees of private or public hospitals, must be made aware of the importance of reporting transfusion-related problems. This will only be achieved by implementing structured and appropriate educational programmes. The fear of possible litigation must be allayed in those who report the incidents. This report provides valuable information to enable physicians to obtain informed consent from patients for the transfusion of blood products and also assist in the risk:benefit ratio estimation of a blood transfusion.

2. Introduction

The transfusion of blood products safe millions of lives each year across the world and is an extremely cost-effective measure in developed countries such as the USA, where the two percent of the health care budget that is spend on Blood Transfusion Services, benefits 50% of the health care services[1]. Blood safety is concerned with the overall process of delivering blood products to the patient and is currently safer than it has ever been. This can be ascribed to the efforts that have been made to ensure the safety and quality of the blood supply. Blood products are, however, living human tissue used in the treatment of patients and, as other biological products, are not without risk.

In South Africa all blood products are procured from voluntary, non-remunerated blood donors. All products are processed, and screened for the presence of transmissible diseases and red cell antibodies before being released for eventual administration to patients. In this chain of events (*Figure 1*) there are numerous activities, which may contribute to transfusion reactions. In the last three decades enormous resources - financially, intellectual, technological and governmental - have been invested in improving the purity, potency and safety of the blood that is collected, tested, packaged, and labelled as suitable for tranfusion[2].

Figure 1: *Blood transfusion chain of events[2]*



In transfusion medicine literature a distinction is now being made between blood safety and transfusion safety[2]. Blood safety encompasses all those areas directly relating to the product, while transfusion safety pertains to the hospital process. In *Figure 1* it is demonstrated that this includes the process from the medical decision to transfuse, the administration at the bedside, the handling of product in the ward,the monitoring of the patient throughout the transfusion process and follow-up. Resources need to be invested in transfusion safety as we can make the biggest impact in this area in the next decade. Haemovigilance programmes can play a vital role in increasing the general awareness of transfusion safety among hospital staff[3].

Possible transfusion reactions that can occur are listed in *Table 1*[4]. (See Annexure 1 for a more comprehensive description on transfusion reactions.)

2. Introduction

Table 1: *Transfusion Reactions*

A	**Immediate Immunologic Complications**	
	1	Acute haemolytic reactions
	2	Immune-mediated platelet destruction
	3	Febrile non-haemolytic reactions
	4	Allergic reactions
	5	Anaphylactoid reactions
	6	Transfusion-related acute lung injury
	7	Pseudo-haemolytic transfusion reactions
B	**Delayed Immunologic Complications**	
	1	Delayed haemolytic reactions
	2	Allo-immunisation
	3	Post-transfusion purpura
	4	Transfusion-associated graft-versus-host disease
C	**Non-immunologic Complications**	
	1	Transfusion transmissible disease
	2	Circulatory overload
	3	Hypothermia
	4	Metabolic complications

The majority of the nearly 900 000 products that are transfused in South Africa annually are not associated with any adverse reaction. Nevertheless, the treating physician must obtain informed consent from his or her patient for the procedure. This will be stipulated as a requirement in the new National Health Act[5]. The Haemovigilance Report is an important tool that can be used by physicians as an information source in order to facilitate the process of obtaining informed consent from patients.

Haemovigilance should be seen as the process whereby transfusion reactions are monitored and reported with the aim to improve systems associated with transfusion medicine. It contributes to improving the safety of the blood supply by[6]:

- Providing the medical community with a reliable source of information about untoward effects of blood transfusion;
- Indicating corrective measures required to prevent the recurrence of some accidents or dysfunctions in the transfusion process;
- Warning health care workers and hospitals, as well as the blood transfusion services, about adverse events that could involve more individuals than just the index case;
- Informing blood users and stakeholders about policy; and
- Improving standards.

Haemovigilance incorporates the surveillance of procedures carried out at the time of blood collection, the entire blood component processing chain, the transfusion episode, the outcome of the transfusion, as well as an appropriate look-back process. Haemovigilance thus identifies factors throughout the process that may be related to risk. Haemovigilance plays a critical role in ensuring that laboratory and clinical blood transfusion practice is optimal.

According to the provisions of the Human Tissue Act 1983 (No 65 of 1983) and the Regulations Regarding Blood and Blood Products (No R. 1935 of 17 August 1990) there is a legal obligation to report any adverse blood transfusion event to the Director-General of the Department of Health[7]. Although the transfusion services keep records of the reactions brought to their attention, these prior to 2000 have not been consolidated into a structured official report and linked to a programme where such incidents are addressed, corrected and utilised in a continuous improvement programme.

2. Introduction

This is the fourth Haemovigilance Report. Similar to the reports of the years 2000 to 2002, this programme was initiated by collating historical information gathered by means of a questionnaire[8, 9, 10].

The programme focused on a range of selected potentially serious reactions, namely:

1 Incorrect blood product transfused (IBPT)(misdirected transfusion);
2 Acute haemolytic reactions (AHR) (including anaphylaxis);
3 Delayed haemolytic reactions (DHR);
4 Transfusion transmissible diseases (TTD) (including viruses, bacteria and malaria);
5 Transfusion-associated graft-versus-host disease (TA-GvHD);
6 Transfusion-related acute lung injury (TRALI);
7 Post-transfusion purpura (PTP); and
8 Other reactions (e.g. incorrectly warmed and transfusion of expired red cells).

Minor reactions such as febrile and minor allergic reactions have not been included in the report.

3. Results

The results are based on the information obtained from a questionnaire sent to the Blood Transfusion Services of South Africa. It is thus a retrospective analysis of the reactions reported to the transfusion services in the year 2003.

3.1 Overview of the results

In the year 2003 a total of 880 880 blood products [constituted of 708 801 red cell products, 117 518 fresh frozen plasma units, and 54 561 platelet concentrates (random and aphaeresis)] were issued to patients in South Africa[11].

During 2003 a total of 84 adverse events were reported to the blood transfusion services (Table 2). Of these 42 (42/84; 50%) events occurred in the six-month period between January 2003 and June 2003 and the other 42 (42/84; 50%) in the last six months of the year. The incident reporting rate is 9.5 per 100 000 blood products transfused for 2003. In comparison, in 2000, 50 reports were received with an incidence rate of 5.7 per 100 000; in 2001, 71 reports were received with an incidence of 8.1 per 100 000 and in 2002, 93 reports were received with an incidence of 10.4 per 100 000 [8, 9, 10].

The French Haemovigilance System in 1999 reported a rate of 216 per 100 000 blood products transfused[12]. There are several possible explanations for the large discrepancy between South Africa and France. Firstly, the South African report only includes serious transfusion reactions. The far more common reactions such as fever and minor allergic reactions are excluded. Secondly, in France there is a sophisticated and dedicated network of professionals, including full-time regional coordinators, who collect haemovigilance data. The third reason is that of under reporting of adverse events in South Africa.

Johannesburg (Inland Region) recorded the greatest number of transfusion-related reactions, viz 33. This region is the biggest service provider covering the largest geographical area in the country and it is therefore expected that the greatest number of reactions would come from this region.

Table 2: *Transfusion reactions reported in 2003*

	Durban	East London	Port Elizabeth	Johannesburg	WPBTS	Total
Transfusion Transmissible Diseases	2	0	0	1	0	3
Incorrect Blood Product Transfused	20	4	0	30	2	56
Acute Haemolytic Reactions	0	7	1	0	12	20
Delayed Haemolytic Reactions	1	0	0	1	2	4
TA-Graft-versus-Host Disease	0	0	0	0	0	0
TR-Acute Lung Injury	0	0	0	0	0	0
Post-Transfusion Purpura	0	0	0	0	0	0
Unclassified	0	0	0	1	0	1
Total	**23**	**11**	**1**	**33**	**16**	**84**

The incorrect blood product transfused (IBPT), 56 (56/84; 67%) were the most common of the 84 reported incidents. Acute haemolytic reactions (AHR), 20 (20/84; 24%), were the second most common reported incidents. AHR includes haemolytic reactions, reactions to IgA, hypotensive and anaphylactic reactions. For all the data available from 2000 to 2003, more AHR (119/298; 40%) relative to IBPT (115/298; 39%) were reported. The percentage of total reactions recorded for AHR is higher than that reported in the United Kingdom's (UK) Serious Hazards of Transfusion (SHOT) report for the period 1996-2002[13]. In the UK report 64% (1093/1711) of all reactions were ascribed to IBPT and 12% (209/1711) were due to AHR (*Figure 7*)[13].

In the year 2003 the reported reactions decreased by 10% from 93 in 2002 to 84 in the year 2003. This decrease might be due to the fact that in some regions the responsibility of reporting to the programme was delegated to non-medical staff. This change in procedure might also contribute to the considerable increase in the reporting of IBPT. In 2003 IBPT increased by 93% and the reporting for AHR decreased by 53%. The IBPT accounted for 56 (67%) of the reported cases. These are mainly caused by human error. In 2000 15 reactions due to IBPT were recorded, in 2001 again 15 of these reactions were recorded and in 2002, 29 of the reactions recorded for the year were because of the IBPT [8, 9, 10].

3. Results

The causes of the unclassified reactions for 2000 to 2003 are listed in Table 3. It is evident that the majority of these are due to human error. It would also be appropriate to add these reactions to the incorrect blood product transfused. If this is done, IBPT will contribute to 48% (143/298) of all reactions.

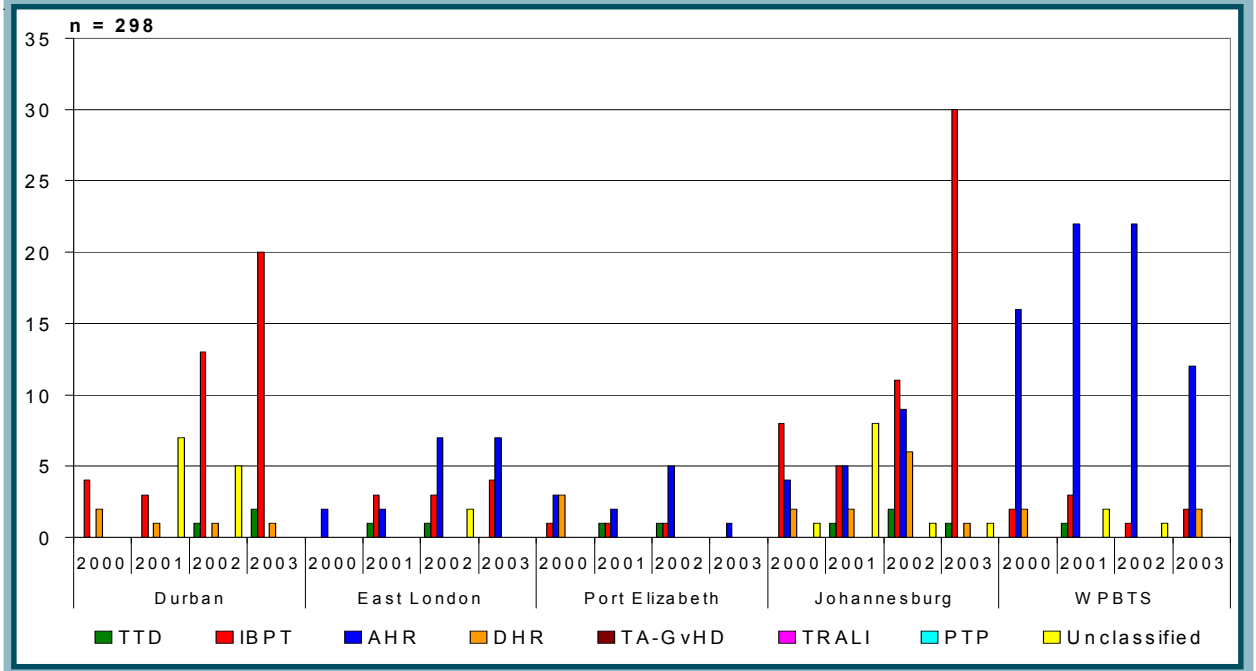
Table 3: *Transfusion reactions recorded as unclassified from 2000 to 2003*

	2000	2001	2002	2003	Total
Expired blood transfused	0	1	0	0	1
Blood inappropriately warmed	1	10	2	0	13
Emergency blood incompatible	0	4	4	0	8
Reason for haemolysis unknown	0	2	1	1	4
Other	0	0	2	0	2
Total	**1**	**17**	**9**	**1**	**28**

The major contributing factor for the problems that have been experienced with inappropriate warming of blood can be related to the lack of procedures and equipment. As a matter of urgency health care providers must address this issue, as it is a preventable complication.

Figure 2 compares the reported reactions for 2000 to 2003.

Figure 2: *Transfusion reactions recorded from 2000 to 2003 by the various blood services*



3. Results

Figure 3: *Serious reactions associated with the transfusion of blood products in 2003*

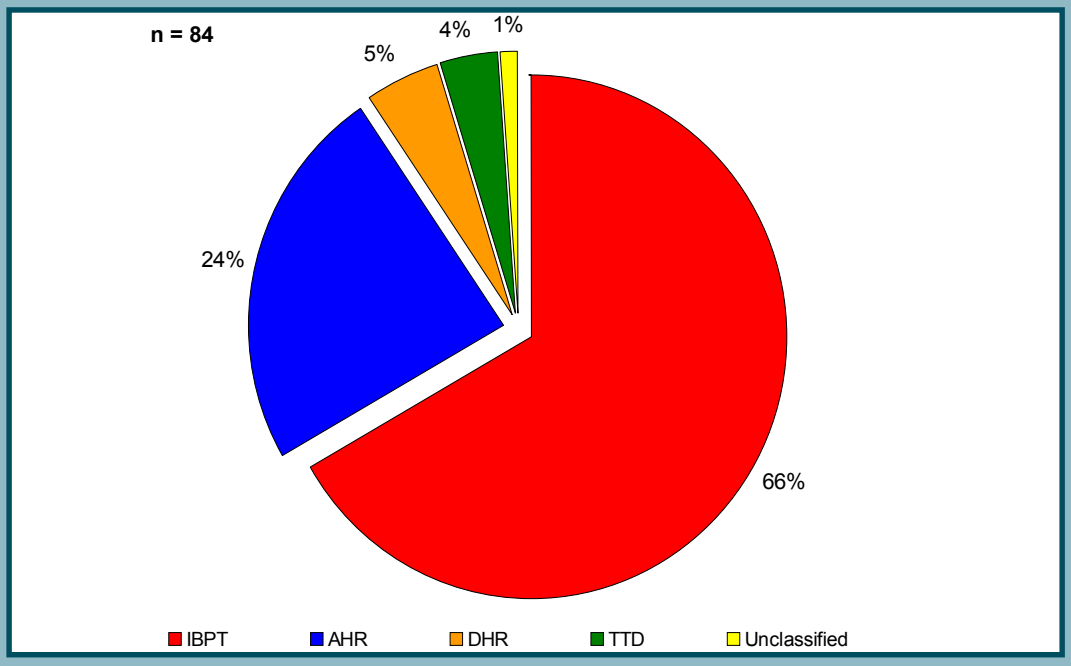
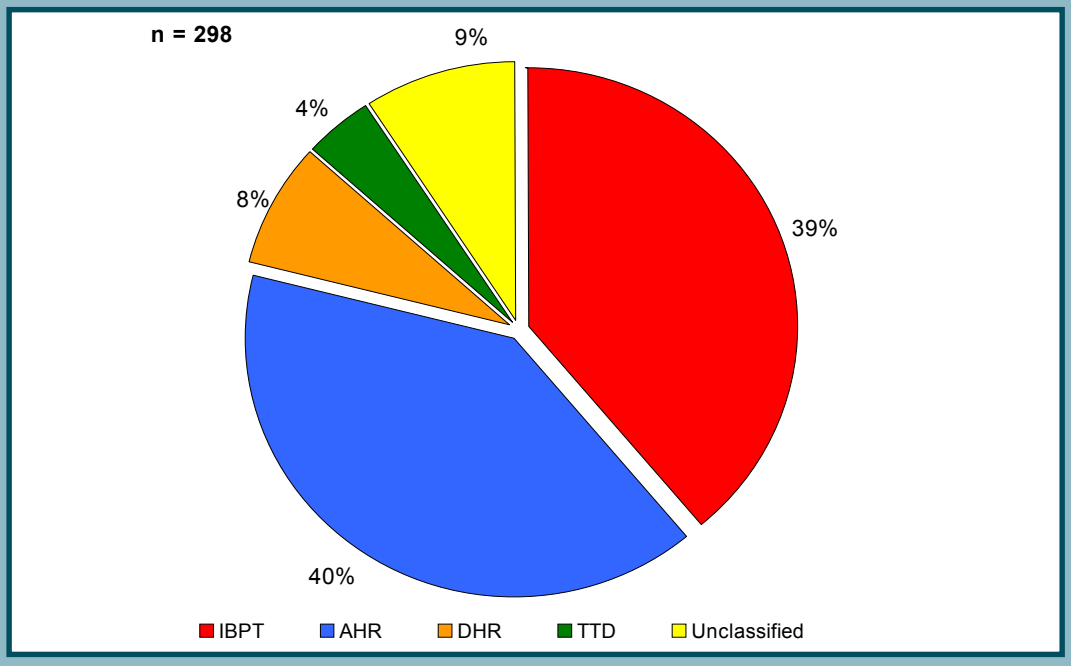


Figure 4: *Serious reactions associated with the transfusion of blood products from 2000 to 2003*



In 2003 as the previous years there were no reports of transfusion-associated graft-versus-host disease (TA-GvHD), post-transfusion purpura (PTP) or transfusion-related acute lung injury (TRALI). The outcomes of the transfusion reactions are given in *Tables 4 and 5*.

3. Results

***Table 4**: Sequelae of transfusion reactions* for 2003

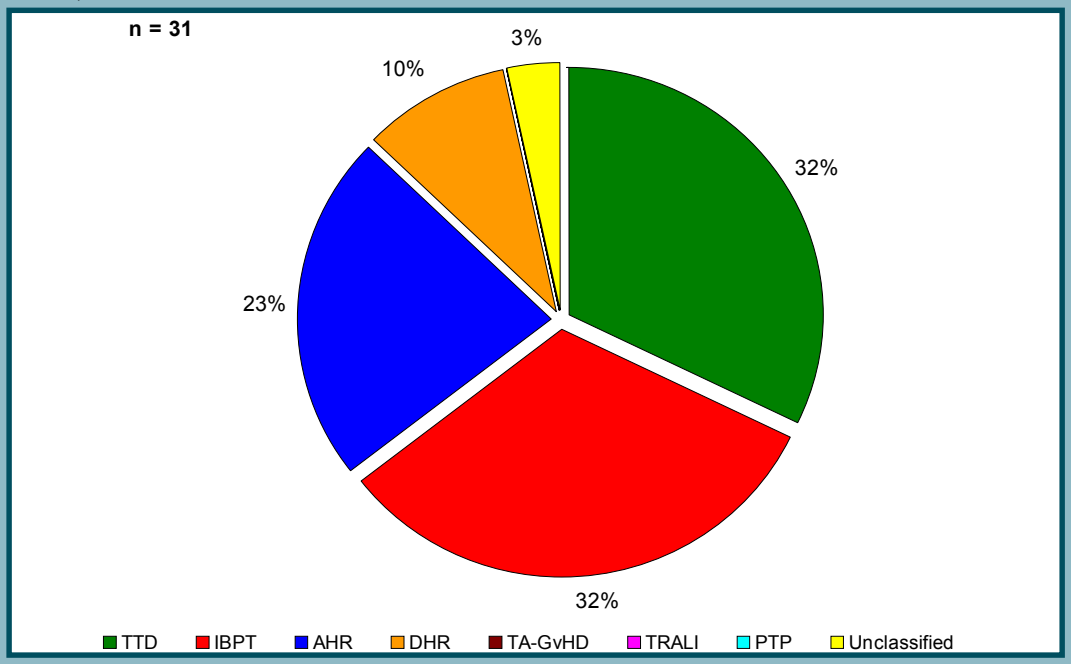
	Asymptomatic	Minor reaction	Major reaction	Death	Unknown	Total
Transfusion Transmissible Diseases	0	0	2	0	1	3
Incorrect Blood Product Transfused	8	21	0	0	27	56
Acute Haemolytic Reactions	0	18	2	0	0	20
Delayed Haemolytic Reactions	0	2	2	0	0	4
TA-Graft-versus-Host Disease	0	0	0	0	0	0
TR-Acute Lung Injury	0	0	0	0	0	0
Post-Transfusion Purpura	0	0	0	0	0	0
Unclassified	0	0	0	0	1	1
Total	**8**	**41**	**6**	**0**	**29**	**84**

***Table 5**: Summary of the sequelae for the transfusion reactions reported from 2000 to 2003*

	Asymptomatic	Minor reaction	Major reaction	Death	Unknown	Total
Transfusion Transmissible Diseases	0	0	8	2	3	13
Incorrect Blood Product Transfused	28	41	7	3	36	115
Acute Haemolytic Reactions	5	80	6	1	27	119
Delayed Haemolytic Reactions	2	17	3	0	1	23
TA-Graft-versus-Host Disease	0	0	0	0	0	0
TR-Acute Lung Injury	0	0	0	0	0	0
Post-Transfusion Purpura	0	0	0	0	0	0
Unclassified	0	0	1	0	27	28
Total	**35**	**138**	**25**	**6**	**94**	**298**

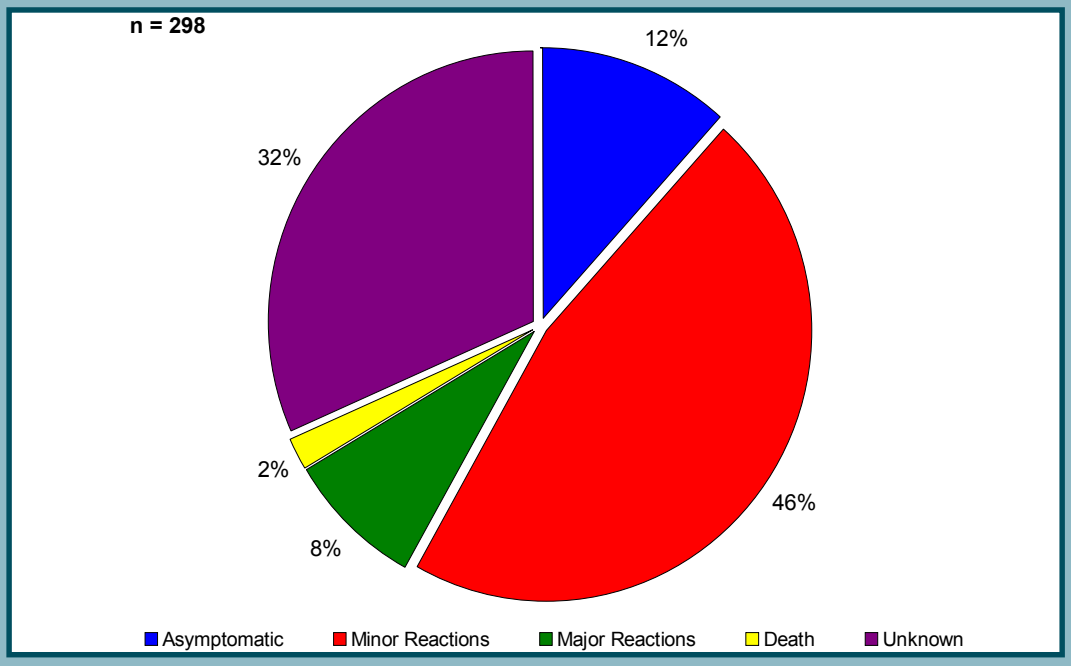
See Annexure 3 for the definitions of the various types of reactions.

***Figure 5**: The main reasons for major reactions and deaths in patients from 2000 to 2003*



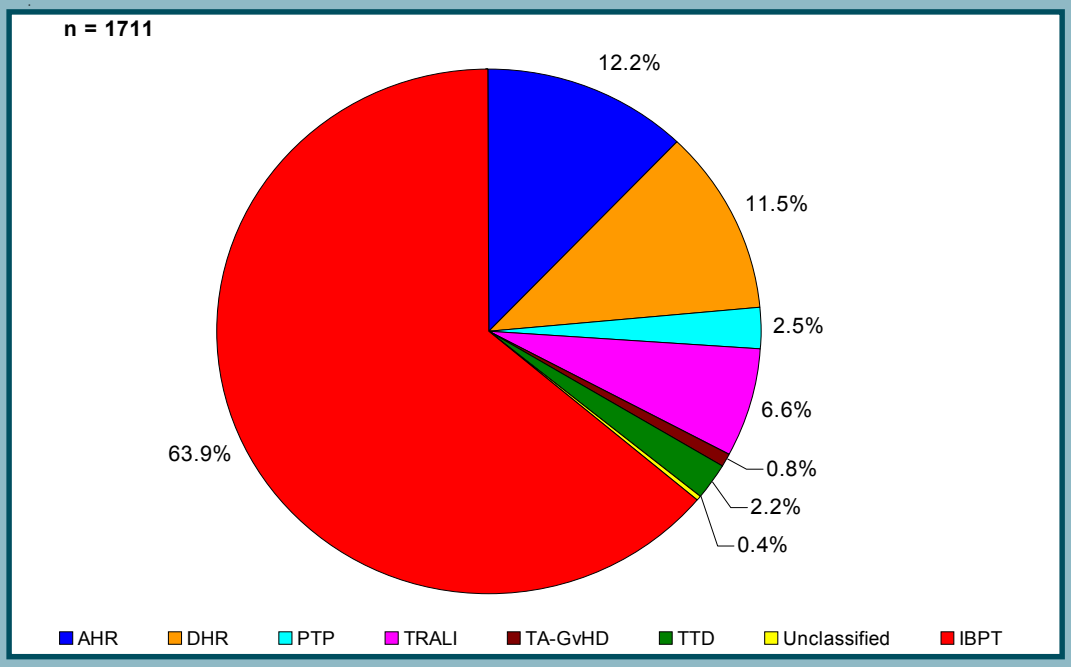
3. Results

Figure 6: *Total number of sequelae* for 2000 to 2003



The South African haemovigilance programme is broadly based on the SHOT programme of the UK. The total number of reactions reported to the SHOT programme is substantially more than that of the South African programme. The trends demonstrated in the two programmes, however, are similar except for the greater number of acute haemolytic reactions reported in the South African haemovigilance programme. The programme in the UK has been expanded to also record near-miss events. This information is not currently captured in South Africa. The reactions recorded for the SHOT programme are illustrated in *Figure 7*[13].

Figure 7: *Cumulative initial reports by incidence for the SHOT programme from 1996-2002*



3. Results

3.2 Incorrect Blood Product Transfused

A reaction due to the transfusion of an incorrect blood product is a well-known adverse event. These incidents can be ascribed to human error and is therefore preventable.

Medical errors, especially those related to medication, have been studied extensively for several reasons:

- It is one of the most common types of errors;
- Substantial numbers of individuals are affected;
- It accounts for a sizable increase in health care costs[14].

A medical error is defined as the failure of a planned action to be completed as intended (i.e. error of execution) or the use of a wrong plan to achieve an aim (i.e. error in planning)[12]. An adverse event is an injury caused by medical management rather than the underlying condition of the patient. An adverse event attributable to error is a "preventable adverse event"[14]. Negligent adverse events represent a subset of preventable adverse events that satisfy legal criteria used in determining negligence (i.e. whether the care provided failed to meet the standard of care that is reasonable to be expected from the average physician)[14].

In extensive studies done on adverse events by the Harvard Medical Practice, the proportion of adverse events attributable to errors was 58%. The proportion of adverse events due to negligence was 28%. These studies investigated medication and technical complications[15, 16]. In addition to the unfortunate health consequences suffered by many as a result of medical error, there are direct and indirect costs carried by society as a whole as a result of medical errors. There is loss of productivity, costs of disability and personal cost of care[14].

Error rates pertaining to transfusion medicine are also high. It is reported for instance, that between 1982 and 1992 error rates in the Mayo Clinic Division of Transfusion Medicine fluctuated between 20 and 30 errors per 10,000 procedures[17]. The estimate of the overall error rate per 10,000 procedures for the three-year period from 1990 through to 1992 was averaged at 28.3 (95%CI; 27.1 and 29.0%)[17]. Transfusion errors are the final outcome of one or more procedural errors or technical failures in the blood transfusion process, starting with the decision to transfuse a patient and ending with the actual administration of the blood product[18].

It is notable that in South Africa the risk of receiving an incorrect blood product (1:30 700) far outweighs the risk of being infected with the human immune deficiency virus (1:390 000) as was reported in the 2000 to 2003 haemovigilance reports[8, 9, 10]. Huge strides have been made in the technical aspects of blood transfusion. In contrast, the risk of transfusing incorrect blood products has not decreased and the rate of preventable errors have remained virtually constant over the last several decades[19].

The observed incidence of the IBPT is lower (115/298; 39%) in South Africa than reported in the UK programme (1093/1711; 64%)[13]. Linden et al. estimate that the risk of an incorrect unit of blood being transfused is 1:12 000 in New York[20]. Using this information, one would expect about 74 misdirected transfusions per year in South Africa. It is likely that the number of cases reported in South Africa reflects underreporting, possibly because of fear of litigation or disciplinary action. In support of this observation is the report by Kaplan et al. where it was stated that the best indicator of the acceptance of the no-fault/no-fear form of reporting by people, is an increase in the number of incidents that are reported[21].

The provision of safe blood products involves thus two broad elements. The first is the *production process*, i.e. putting safe blood into stock at the point of distribution and the second is the *clinical supply process.* This process may be summarised as providing the RIGHT blood product, in the RIGHT quantity, for the RIGHT patient, in the RIGHT place, at the RIGHT time[22].

Table 6 demonstrate the sequelae that were reported due to the IBPT. While no major reactions or deaths were reported for 2003 this type of reaction resulted in 32% (10/31; 32%) of all major reactions and deaths from 2000 when this programme was started.

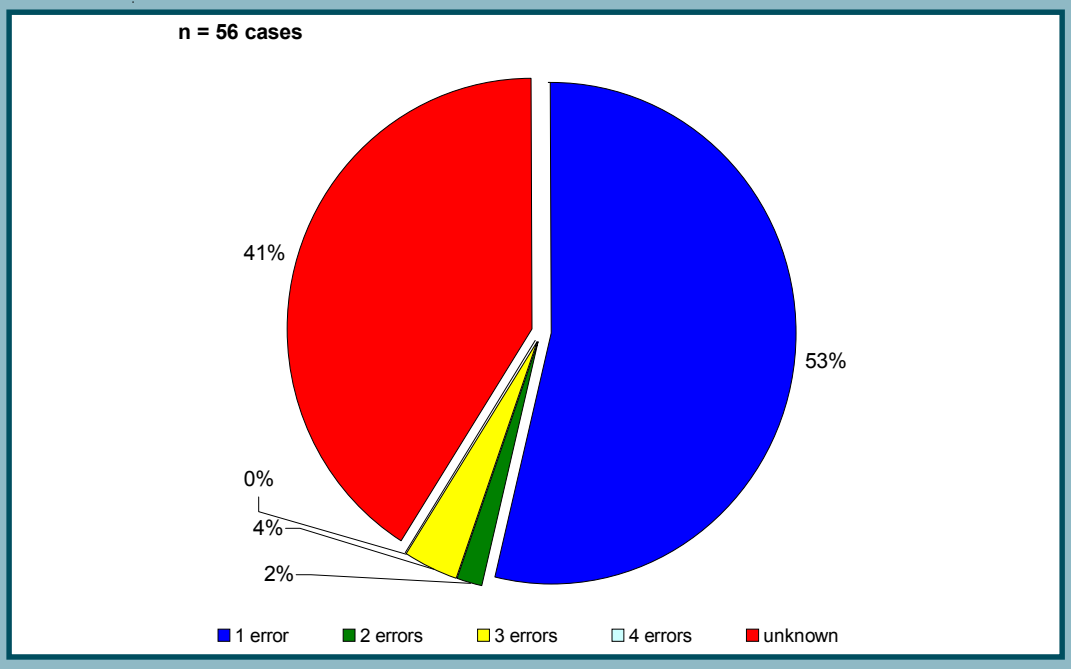
3. Results

Table 6: *Sequelae due to Incorrect Blood Product Transfused in 2003*

	Durban	East London	Port Elizabeth	Johannesburg	WPBTS	Total
Asymptomatic	4	3	0	2	1	8
Minor reactions	0	1	0	19	1	21
Major reactions	0	0	0	0	0	0
Death	0	0	0	0	0	0
Unknown	16	0	0	11	0	27
Total	**20**	**4**	**0**	**30**	**2**	**56**

Data on the total number of errors made is available for 33 of the 56 cases (*Figure 8*) where an incorrect blood product was transfused. In 30 of the cases for which data is available (30/33; 91%) a single mistake was noted in the chain of events. In one of the cases (1/33; 3%) two causal errors per case were identified and in the remaining two cases (2/33; 6%) three causal errors per case were identified. The relatively high incidence of only one mistake per case might be ascribed to the retrospective collection of the data for this report. In the SHOT report of 2001–2002, multiple errors were reported in 40% of the cases[12]. Whitsett and Robichaux reported that in 202 directly observed transfusion episodes there was a rate of 1.65 standard operating procedure (SOP) deviations per transfusion[23]. They further reported that in 45% of cases more than one mistake was noted[23].

Figure 8: *Number of errors recorded per case for 2003*

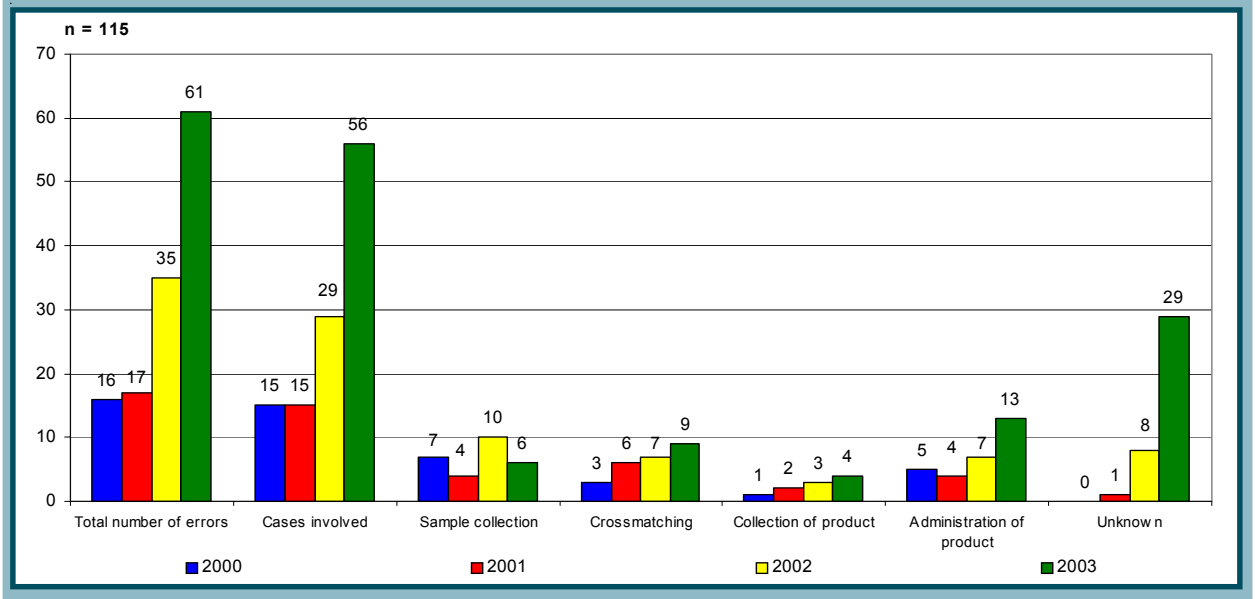


In 59% (19/32; 59%) of the errors for which information was available these occurred at the bedside of the patient (figure 9). The finding that the majority of errors happen at the bedside is in accord with those of Linden et al. (61/104; 58%), Sazama (37/54; 68%), the SHOT 1996-2002 reports and the South African Haemovigilance Reports of 2000-2002 (34/51; 67%)[8, 9, 10, 13, 20, 24].

Nine of the errors (9/32; 28%) were due to technical errors in the blood bank and in four (4/32; 13%) of the cases the wrong product was taken at the time of collecting the blood product from the Blood Bank.

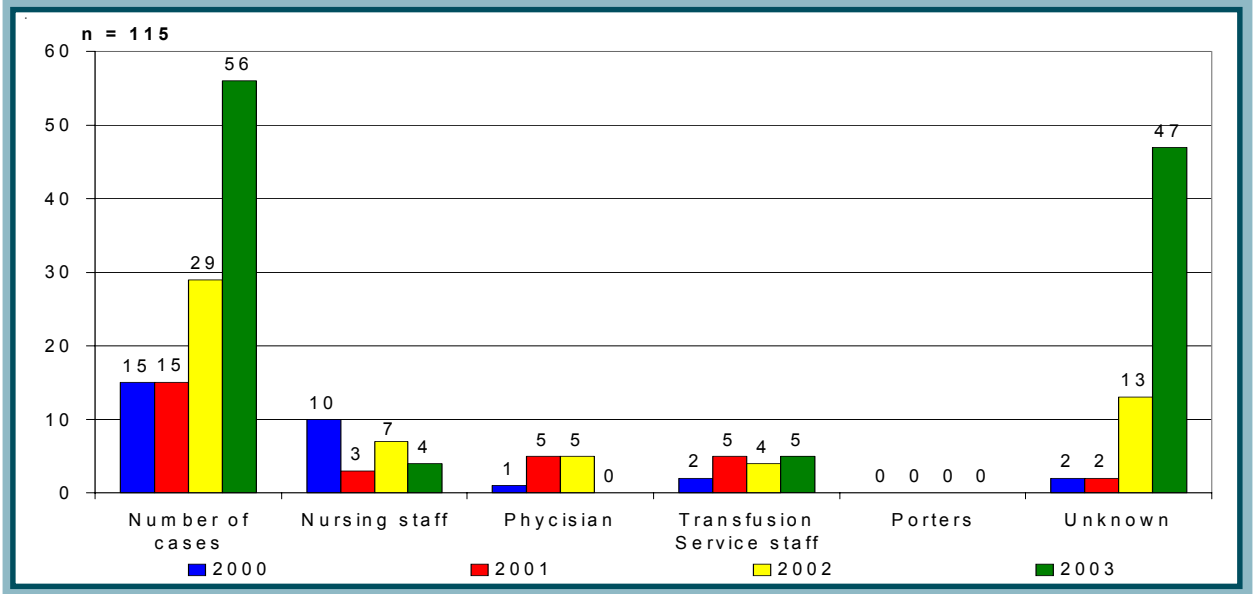
3. Results

Figure 9: *Distribution of errors due to Incorrect Blood Product Transfused form 2000 to 2003*



In 44% (4/9; 44%) of the cases for which information are available a qualified professional nurse was involved in the error that resulted in the IBPT (*Figure 10*). This is the same as was reported for 2002 (7/16; 44%)[10]. The results are not surprising, because it probably reflects that nursing staff handles almost all the bedside work. Hospital systems must ensure that processes and systems are in place to assist nursing staff with the responsibility they carry in terms of transfusion medicine. In 2003 a much greater number of cases were reported where the qualification of the person responsible for the error is not known (47/56; 84%).

Figure 10: *Qualification of the person involved in the error as recorded for 2000 to 2003*



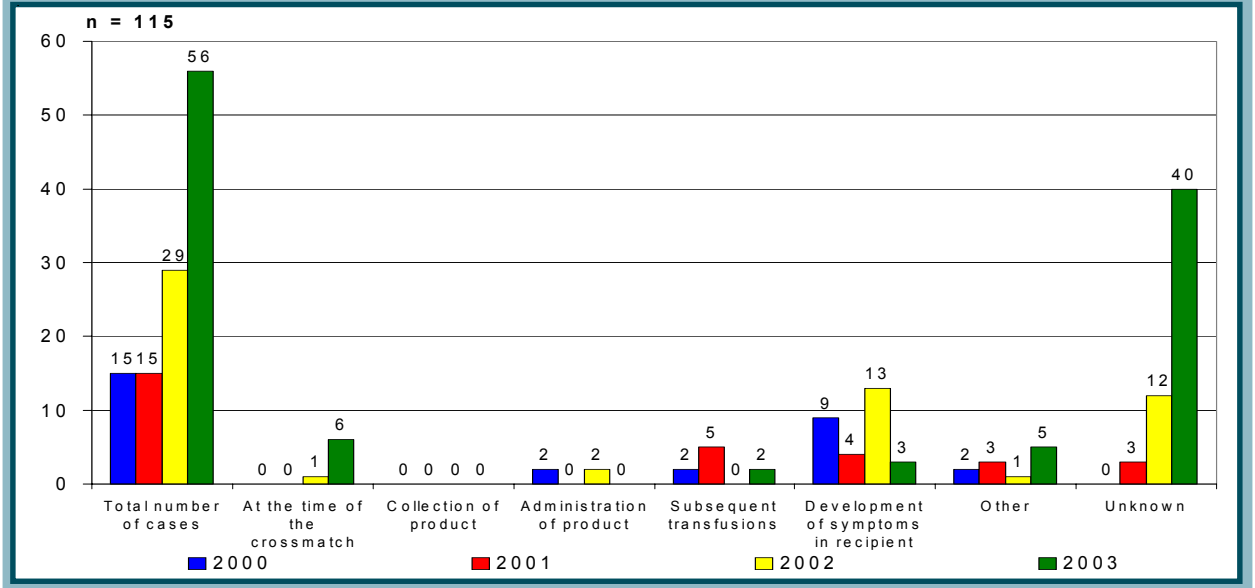
In this South African report no physicians (0/9; 0%) were reported to be involved in errors. Transfusion service staff (5/9; 56%) contributed to the rest of the errors that were recorded. Despite the fact that there are reports from 2000 to 2003 of errors at the time of collection of the product no porters have ever been implicated in being responsible for an error.

3. Results

The time of discovery of the error was as follows (*Figure 11*):

- in two (2/16; 13%) recipients the error was discovered during the preparation for a subsequent transfusion;
- in three (3/16; 19%) recipients the error was discovered due to the fact that the patients developed symptoms of an acute haemolytic reaction;
- in six (6/16; 38%) recipients it was discovered at the time of a subsequent crossmatch procedure;
- in five (5/16; 31%) cases the error was discovered at the time of a disciplinary enquiry; and
- in 40 (40/56; 71%) recipients the time of discovery of the errors were not recorded.

Figure 11: *Time of discovery of the error as recorded for 2000 to 2003*



Five (5/16; 31%) of the events were discovered at the bedside. This is a decrease from previous years where the nursing staff played a critical role in the discovery of errors. One would expect this figure to be higher due to the critical role that the nursing staff plays in monitoring patients and checking whether the correct products are transfused. The nursing staff is also responsible for recognising the development of symptoms related to the transfusion.

Table 7: *Qualification of the person responsible for detecting the error for 2000 to 2003*

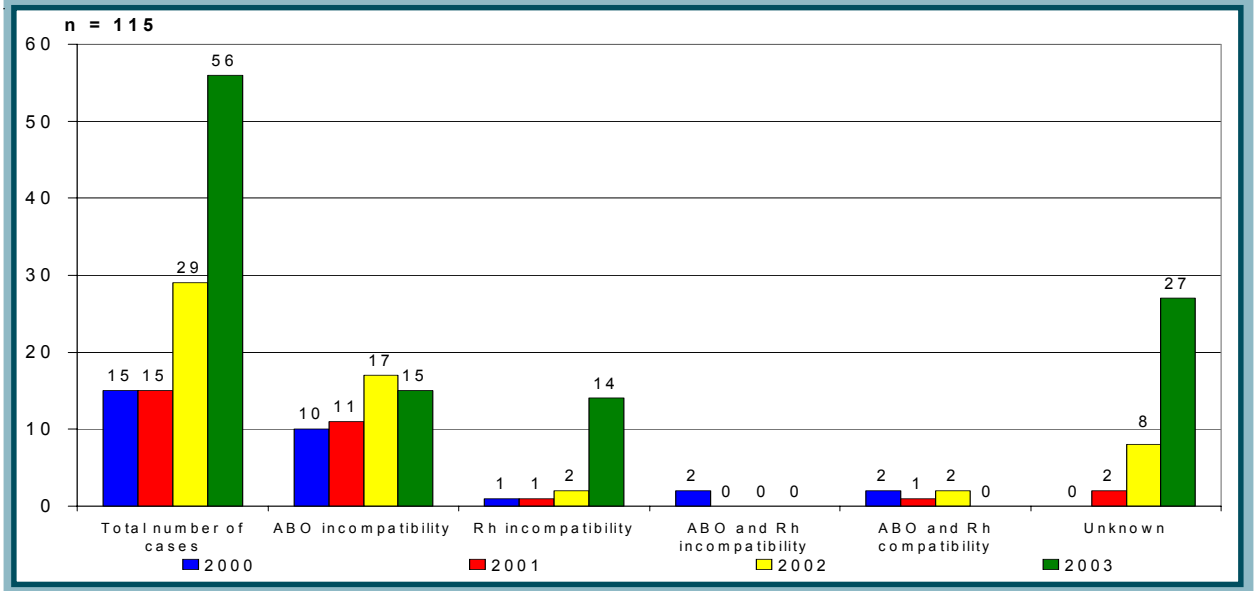
	2000	2001	2002	2003	Total
Nursing staff	4	1	8	5	18
Physicians	2	3	5	0	10
Transfusion Service staff	4	10	3	13	30
Patient	1	0	0	0	1
Unknown	4	1	13	38	56
Total	**15**	**15**	**29**	**56**	**115**

The professional qualifications of the people responsible for the discovery of the error were: five (5/18; 28%) by nursing staff, none by physicians and 13 (13/18; 72%) by the transfusion service personnel (*Table 7*). Over the time period for which reports are available the majority of mistakes were discovered by the blood transfusion staff (30/59; 51%). This is due to the laboratory procedures and might highlight the fact that patients might not necessarily experience any symptoms due to an incorrect blood product received. This fact, however, does not remove the responsibility of the health care service to ensure that patients are not exposed to this risk.

3. Results

The only product involved in all the errors for which this was recorded (43/56; 77%) was red cell concentrate (43/43; 100%). The most likely cause of a major reaction in recipients is red cell products. Reactions due to the incorrect transfusion of a platelet or plasma product is less likely to be the cause of a major transfusion reaction and is therefore less likely to be reported. The type of incompatibility is summarised in *Figure 12*.

Figure 12: *Type of incompatibility of the product that transfused was for 2000 to 2003*



In none of the reported cases for 2003 the IBPT was both ABO and Rh compatible with the recipient's blood groups. Fifteen (15/29; 52%) of the cases were ABO incompatible and 14 (14/29; 48%) were Rh incompatible. None of the cases reported for 2003 were both ABO and Rh incompatible. The blood group was not reported for 27 (27/56; 48%) of the cases.

3. Results

Table 8: *Summary of results for the Incorrect Blood Product Transfused for 2000 to 2003*

	2000	2001	2002	2003	Total
Number of patients involved	15	15	29	56	115
Number of errors involved	16	17	35	61	129
Error at the time of:	**16**	**17**	**35**	**61**	**129**
Sample collection	7	4	10	6	27
Crossmatching	3	6	7	9	25
Collection of product	1	2	3	4	10
Administration of product	5	4	7	13	29
Unknown	0	1	8	29	38
Error discovered at the time of:	**15**	**15**	**29**	**56**	**115**
Receiving the crossmatch at the blood bank	0	0	0	0	0
Checking historical blood groups	0	0	0	1	1
Blood grouping and crossmatching	0	0	1	5	6
Collection of product	0	0	0	0	0
Preparation for administration of products	2	0	2	0	4
Subsequent transfusions	2	5	0	2	9
Development of symptoms in the patient	9	4	13	3	29
Other: (e.g. quality control, disciplinary investigation)	2	3	1	24	30
Unknown	0	3	12	21	36
Qualification of the person involved in the error:	**15**	**15**	**29**	**56**	**115**
Professional nurse	10	3	7	4	24
Student nurse	0	0	0	0	0
Nursing assistant	0	0	0	0	0
Medical student	0	0	0	0	0
House officer	0	2	0	0	2
Medical officer	0	3	5	0	8
Registrar	1	0	0	0	1
Specialist	0	0	0	0	0
Technician	1	4	4	0	9
Technologist	1	1	0	3	5
Student technologist	0	0	0	0	0
Student technician	0	0	0	2	2
Porter	0	0	0	0	0
Unknown	2	2	13	47	64
Qualification of person responsible for detecting the error:	**15**	**15**	**29**	**56**	**115**
Nursing staff	4	1	8	5	18
Physician	2	3	5	0	10
Transfusion Service staff	4	10	3	13	30
Patient	1	0	0	0	1
Unknown	4	1	13	38	56
The product involved:	**15**	**15**	**29**	**56**	**115**
Whole Blood	1	1	2	0	4
Red Cell Concentrate	12	13	19	43	87
Fresh Frozen Plasma	0	0	0	0	0
Platelets	0	0	0	0	0
Cryoprecipitate	0	0	0	0	0
Unknown	2	1	8	13	24
Type of incompatibility detected:	**15**	**15**	**29**	**56**	**115**
ABO incompatible	10	11	17	15	53
Rh incompatible	1	1	2	14	18
ABO and Rh incompatible	2	0	0	0	2
ABO and Rh compatible	2	1	2	0	5
Unknown	0	2	8	27	37
Sequelae:	**15**	**15**	**29**	**56**	**115**
Asymptomatic	5	7	8	8	28
Minor reaction	3	6	11	21	41
Major reaction	4	1	2	0	7
Death	3	0	0	0	3
Unknown	0	1	8	27	36

3. Results

3.3 Acute Haemolytic Reactions

Acute haemolytic reactions are defined as those reactions that occur within 24 hours of the transfusion and are not the result of an IBPT. Febrile and minor allergic reactions were excluded because it had been decided to focus only on severe reactions for the initial implementation of the haemovigilance programme.

In 2003 a total of 20 (20/84; 24%) acute haemolytic reactions were reported. One (1/20; 5%) of these presented as a haemolytic transfusion episode, seven (7/20; 35%) presented with severe hypotension, 12 (12/20; 60%) resulted in anaphylactic shock (*Table 9*).

Table 9: *Type of Acute Haemolytic Reactions reported for 2000 to 2003 and SHOT*

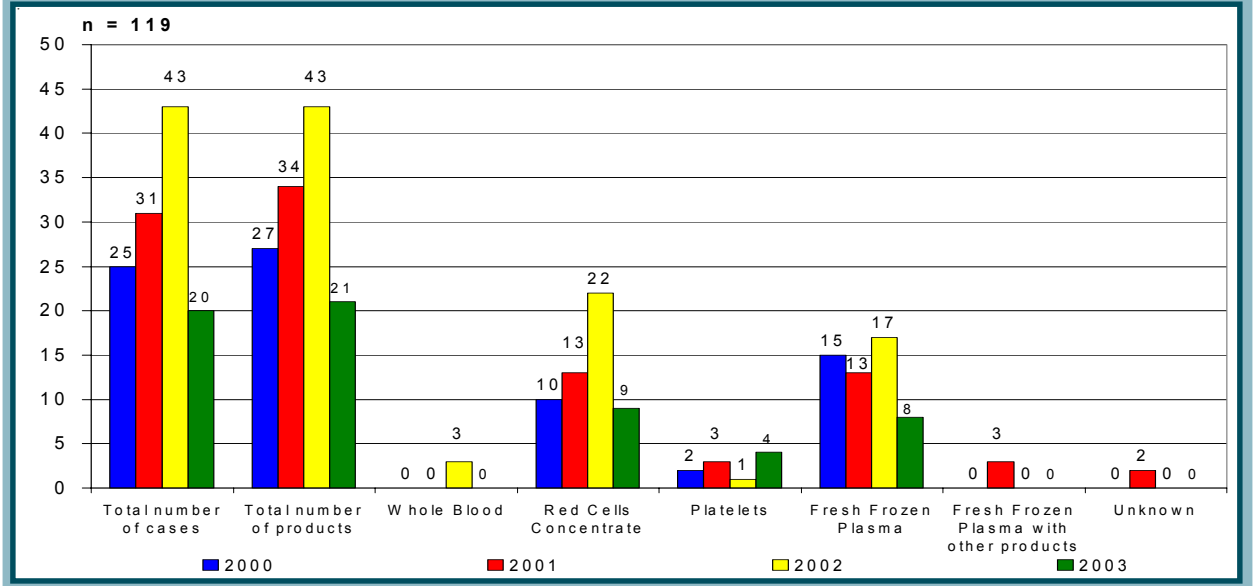
	2000	2001	2002	2003	Total	SHOT (1996 - 2002)
Haemolytic reactions	4	5	11	1	21	32
Hypotensive reactions	0	6	7	7	20	13
Reactions due to IgA antibodies	0	0	0	0	0	2
Anaphylactic reactions	21	20	24	12	77	54
Non-haemolytic reactions	0	0	0	0	0	25
Unclassified	0	0	1	0	1	68
Total	**25**	**31**	**43**	**20**	**119**	**194**

ABO blood group antibodies caused all the haemolytic reactions reported in South Africa.

Plasma was the product responsible for 40% (8/20) of the reported reactions. The number of reactions to plasma is much higher than that reported in the SHOT report, where these types of reactions contributed only 28% (54/194; 28%) to the total number[11]. The reactions to plasma products may indeed even be higher in South Africa: reactions to the freeze-dried product, BIOPLASMA FDP (classified as a pharmaceutical product and manufactured by the Natal Bioproducts Institute (NBI)), are not included in this report. Those reactions are reported in the Pharmacovigilance programme to the Medicines Control Council of South Africa.

Red cell products were implicated in nine (9/20; 45%) of the cases, platelets in four (4/20; 20%). See *Figure 13* and *Table 10* for more information.

Figure 13: *Products implicated in the Acute Haemolytic Reactions recorded for 2000 to 2003*



3. Results

In 18 (18/20; 90%) cases minor reactions were recorded and in two (2/20; 10%) major reactions were noted (*Table 10*). If all the information available is evaluated it is noted that in most of the cases (77/119; 65%) the patients presented with anaphylaxis. In the time period from 2000 till 2003 no reports due to IgA antibodies were recorded. This might be because it is not part of the investigation protocol for patients reacting to blood products.

Table 10: *Summary of results for Acute Transfusion Reactions reported for 2000 to 2003*

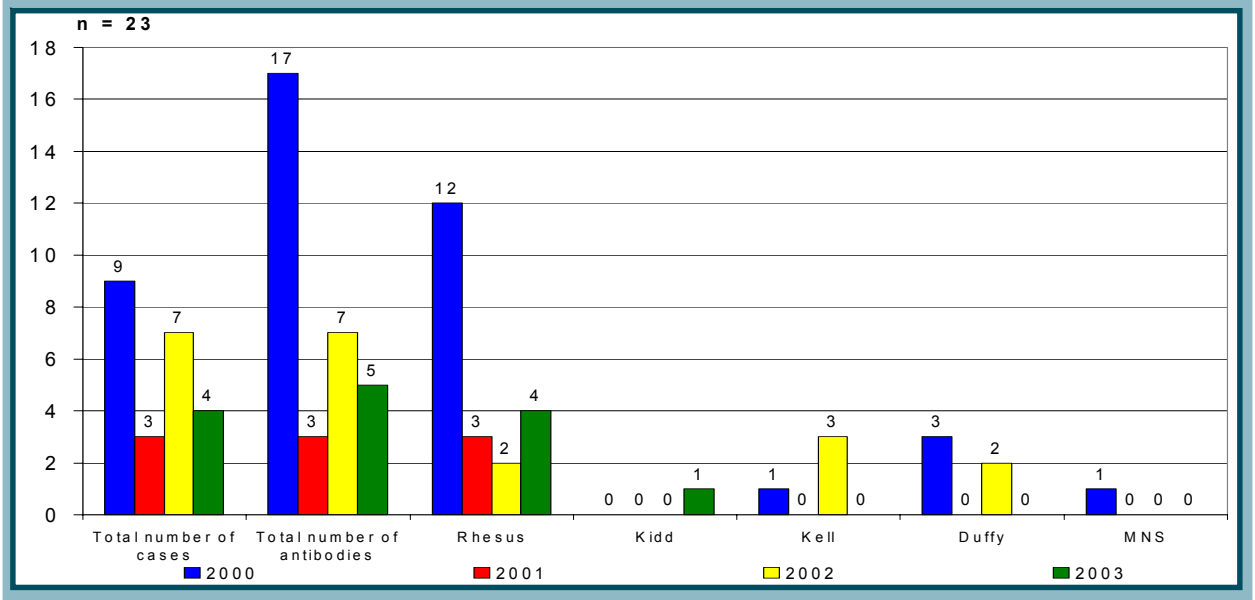
	2000	2001	2002	2003	Total
Type of reaction that occurred	**25**	**31**	**43**	**20**	**119**
Haemolytic	4	5	11	1	21
Hypotension	0	6	7	7	20
Due to IgA antibodies	0	0	0	0	0
Anaphylaxis	21	20	24	12	77
Non-Haemolytic febrile	0	0	0	0	0
Unclassified	0	0	1	0	1
Product involved	**27**	**34**	**43**	**21**	**125**
Whole Blood	0	0	3	0	3
Red Cell Concentrate	10	13	22	9	54
Fresh Frozen Plasma	15	13	17	8	53
Platelets	2	3	1	4	10
Fresh Frozen Plasma with other products	0	3	0	0	3
Cryoprecipitate	0	0	0	0	0
Unknown	0	2	0	0	2
Sequelae	**25**	**31**	**43**	**20**	**119**
Asymptomatic	1	0	2	0	3
Minor reaction	22	26	16	18	82
Major reaction	2	0	3	2	7
Death	0	0	0	0	0
Unknown	0	5	22	0	27

3. Results

3.4 Delayed Haemolytic Reactions

Delayed haemolytic reactions accounted for five percent (4/84; 5%) of the transfusion reactions reported for 2003. The incidence in South Africa for all the data available is eight percent (23/298; 8%) and this is less than the number reported in the SHOT report (196/1711; 11%) for the period from 1996-2002[13]. For 2003, antibodies against the Rhesus blood group caused all the DHR. See *Figure 14* and *Table 11*.

Figure 14: *Antibodies implicated in the Delayed Haemolytic Reactions recorded in 2000 to 2003*



The delayed haemolytic reactions followed the administration of red cell concentrate in all four of the reported cases. In two (2/4; 50%) of these cases minor reaction were recorded and in the remaining two (2/4; 50%) cases major reactions were documented. Sazama reported that in 355 transfusion-associated deaths, seven percent (26/355) were due to delayed haemolytic reactions[24]. No transfusion-associated deaths due to DHRs were recorded in the South African data.

Table 11: *Summary of results for Delayed Haemolytic Reactions reported for 2000 to 2003*

	2000	2001	2002	2003	Total
Antibodies Identified	**17**	**3**	**7**	**4**	**31**
Rhesus	12	3	2	4	31
Kidd	0	0	0	0	0
Kell	1	0	3	0	4
Duffy	3	0	2	0	5
MNS	1	0	0	0	1
Product implicated	**9**	**3**	**7**	**4**	**23**
Whole Blood	0	0	0	0	0
Red Cell Concentrate	9	3	7	4	23
Fresh Frozen Plasma	0	0	0	0	0
Platelets	0	0	0	0	0
Cryoprecipitate	0	0	0	0	0
Sequelae	**9**	**3**	**7**	**4**	**23**
Asymptomatic	1	0	1	0	2
Minor reaction	7	2	6	2	17
Major Reaction	1	0	0	2	3
Death	0	0	0	0	0
Unknown	0	1	0	0	1

3. Results

3.5 Transfusion Transmissible Diseases

In the year 2003, three (3/84; 4%) possible cases of transfusion transmissible diseases were reported to the haemovigilance programme. One (1/3; 30%) case was ascribed to a possible bacterial contamination of the product. The product responsible was not recorded for the case. The type of organism was not confirmed and appropriate specimens were not collected to enable correlation of organism identity in the product and in the patient.

Two cases (2/3; 60%) of possible transmission of HIV were reported to the haemovigilance programme. Both transmissions occurred in the window period of infectivity. In one of the cases genotyping of the HIV was done and was the same for the donor and recipient of the product. Both implicated donors (as was the case in the previous reports) were repeat donors who at the time of the interview and selection process had denied participation in high-risk behaviour[10]. The incidence of HIV window period transmissions in South Africa concurs with the historical reported cases correlating with a risk of approximately 1:390 000 products transfused[8, 9, 10]. In the SHOT report 40 possible post-transfusion infective reactions were recorded for the period from 1995 to 2002[13].

Table 12: *Summary of results for Transfusion Transmissible Diseases for 2000 to 2003*

	2000	2001	2002	2003	Total	SHOT(1996-2002)
Bacterial infection	0(0)*	1(1)	3(3)	1(1)	5(5)	26(26)
Malaria	0(0)	2(2)	0(0)	0(0)	2(2)	1(1)
Human Immune Deficiency Virus	2(3)	2(2)	2(2)	2(2)	8(9)	1(3)
Hepatitis A Virus	0(0)	0(0)	0(0)	0(0)	0(0)	1(1)
Hepatitis C Virus	1(1)	0(0)	0(0)	0(0)	1(1)	2(2)
Hepatitis B Virus	0(0)	0(0)	0(0)	0(0)	0(0)	8(9)
HTLV-1	0(0)	0(0)	0(0)	0(0)	0(0)	1(1)
Total	**3(4)**	**5(5)**	**5(5)**	**3(3)**	**16(17)**	**40(43)**

*The numbers in brackets pertains to the recipients infected and the numbers before the brackets to the number of implicated donors.

It is important to note that all the cases noted in *Table 12* are considered possible transmissions and not confirmed transmissions as no confirmatory testing was done at the time of the reaction. The viral transmissions are recorded at the time of notification to the transfusion service and not when it actually happened. Therefore the transmissions could actually have happened in any of the preceding years.

4. Recommendations

According to the Fourth Annual Report less incidents have been reported than was the case the previous year. The fourth report is still based on retrospective reporting and analysis. The format will change in 2004 due to additional resources becoming available. The awareness of the programme has hopefully increased due to communication at lectures, congresses and at the Blood User Committee meetings. The haemovigilance programme needs to be actively promoted by including it in formal education programmes and by publishing data in South African medical journals. This will increase the scope of health care workers that may be reached.

Hospitals in both the private and public sectors must take cognisance of the preventable errors. It is essential that policies, procedures and systems are put in place for the appropriate sampling of blood for cross-matching, checking of blood products at the time of administering of products and for the appropriate warming of products when indicated.

The blood transfusion services must extend their quality management to ensure that the appropriate procedures and systems are in place and monitored at all levels of their operations. This will reduce the number of errors that occur in the transfusion services.

The aim of this programme is to instil a culture of quality management and to ensure that the system is optimised. This will minimise preventable errors. This approach is more appropriate than an attempt to address the problem at the level of the person who was involved in the error. A focus on people will not eliminate errors because the processes involve cognitive aspects. System changes to reduce errors have been shown to be the most effective approach[25].

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Annexure 1: Transfusion Reactions

A Immediate Immunological Complications

1. **Acute haemolytic reactions**
   This is the immunologic destruction of transfused red cells, nearly always due to incompatibility of antigen on the transfused red cells with antibody in the recipient's circulation. The most common cause of severe, acute haemolytic transfusion reactions is the transfusion of ABO-incompatible blood, resulting from identification errors occurring at some point(s) in the transfusion process.

2. **Immune-mediated platelet destruction**
   One of the causes of refractoriness to platelet transfusion is the result of alloantibodies in the recipient to HLA or platelet-specific antigens on transfused platelets. Platelets bear a variety of antigens, including HLA and platelet-specific antigens. Patients transfused with platelets often develop HLA antibodies. When platelets are transfused to a patient with an antibody specific for an expressed antigen, the survival time of the transfused platelets may be markedly shortened.

3. **Febrile non-haemolytic reactions**
   This typically manifistate as an increase in temperature of more than 1 ^{o}C occurring during or shortly after a transfusion and in the absence of any other pyrexic situation. This may reflect the action of antibodies against white cells or the action of cytokines, either present in the transfused component or generated by the recipients in response to the transfused product. Febrile reactions may accompany 1% of transfusions. They also occur more frequently in patients previously immunised by transfusions or pregnancy.

4. **Allergic reactions**
   These reactions usually occur as urticaria, but may also include wheezing or angio-oedematous reactions. These might occur with any type of blood component but are associated with the amount of plasma that is transfused. Possible mechanisms of allergic transfusion reactions include antibodies to leucocyte antigens and infusion of vasoactive substances such as C3a and C5a, histamine or mast cell activators such as leucotrines.

5. **Anaphylactoid reactions**
   This is a rare but dangerous complication and is characterised by autonomic disregulation, severe dyspnoea, pulmonary and/or laryngeal oedema, and bronchospasm and/or laryngospasm. The majority of these type of reactions has been documented in IgA deficient patients who have IgA antibodies of the IgE class. These patients may not have had previously transfusions and may develop symptoms after infusion of a very small amount of IgA containing plasma in any blood component.

6. **Transfusion-related acute lung injury (TRALI)**
   This reaction is caused when acutely increased permeability of the pulmonary microcirculation causes massive leakage of fluids and protein into the alveolar spaces and interstitium, usually within 6 hours of transfusion. In many patients the occurrence of TRALI is associated with the presence of granulocyte antibodies in the donor or recipient. The specific mechanism of action is not clear.

7. **Pseudo-haemolytic reactions**
   Haemolysis during or after a transfusion may not be related to the transfusion. Other causes might be the transfusion of aged cells, thermal haemolysis (overheating or freezing), osmotic haemolysis (administration of hypotonic solutions or medication in conjunction with the transfusion), mechanical haemolysis (improper infusion devices, catheters or needles) and haemolysis due to congenital defects (G6PD deficiency, sickle trait, etc.).

Annexure 1: Transfusion Reactions

B Delayed Immunologic Complications

1. Delayed haemolytic transfusion reaction

These reactions occur in previously red-cell-alloimmunised patients in whom antigens on transfused red cells provoke anamnestic production of antibody that reaches a significant circulating level while the transfused cells are still present in the circulation. Usually 2 to 14 days after the transfusion a drop in the haemoglobin level is noted. Typically haemolysis is extravascular, but intravascular haemolysis might also occur.

2. Alloimmunisation

Alloimmunisation of antigens of red cells, white cells, platelets or plasma proteins may occur unpredictably after transfusion. Primary immunisation does not become apparent until days or weeks after the immunising event and does not usually cause symptoms or physiologic changes. If components that express the relevant antigen are subsequently transfused there may be an accelerated removal of cellular elements from the circulation and/or systemic symptoms. Clinically significant antibodies to red cell antigens will ordinarily be detected by pre-transfusion testing. Alloimmunisation to antigens of white cells, platelets or plasma proteins can only be detected by specialised testing.

3. Post-transfusion purpura (PTP)

This is a rare syndrome characterised by the development of dramatic, sudden and self-limiting thrombocytopenia, typically 5-10 days after a blood transfusion, in a patient with a history of sensitisation by either pregnancy or transfusion. While the immune specificity may be to a platelet-specific antigen the patient lacks, the autologous and allogeneic platelets are destroyed. The mechanism of platelet destruction is not 100% clear but appears to be immune mediated. The implicated transfusion may be of any blood product.

4. Transfusion-associated graft-versus-host disease (TA-GvHD)

This rare but extremely dangerous condition occurs when viable T lymphocytes in the transfused component engraft in the recipient and react against the tissue antigens in the recipient. GvHD can occur if the host does not recognise as foreign and reject the transfused cells, and can follow transfusion of any blood product that contains even very small numbers of viable T lymphocytes. Severely immunocompromised patients are at greatest risk, but GvHD has been reported in immunologically normal recipients heterozygous for a tissue antigen haplotype for which the donor is homozygous. This is most likely to occur when the transfused component is from a blood relative or has been selected for HLA compatibility. GvHD remains a risk with leucocyte-reduced components because these still contain sufficient residual T lymphocytes. Irradiation of the component renders T lymphocytes incapable of proliferating and is presently the only approved means to prevent GvHD.

Annexure 1: Transfusion Reactions

C Non-immunologic Complications

1. Transfusion transmissible diseases

a. Viruses

Transmission of infections occur because blood products are made from human blood. The transmissions can occur despite the careful selection of donors and the routine testing of all blood units. This is due to the window period, which differs between the various blood transmissible viruses. Donor selection criteria are designed to screen out potential donors with increased risk of infection for HIV, hepatitis B and C and syphilis. For each transfusion episode it is critical that the risk-benefit of the transfusion is determined as well as getting informed consent from the recipient or guardian. All blood donations are subjected to routine stringent testing procedures intended to reduce to a minimum the risk that they will transmit HIV, hepatitis B and C and syphilis.

Cytomegalovirus (CMV) may, unpredictably, be present in white-cell-containing products from donors previously infected with this virus, which can persist lifelong despite the presence of serum antibodies. Transfusion of CMV by transfusion may be of concern in low-birthweight premature infants born to seronegative mothers and in certain other categories of immunocompromised individuals, if they are sero-negative. For at-risk recipients, the risk of CMV transmission by cellular products can be reduced by transfusing blood products that have been leucocyte-reduced in laboratory conditions.

b. Bacterial contamination

Bacterial contamination occurs rarely but can cause severe, acute, sometimes life-threatening effects. Onset of high fever (>2 ^{o}C rise in temperature), severe chills, hypotention, or circulatory collapse during or immediately after transfusion should suggest the possibility of bacterial contamination and/or endotoxin reaction. Both gram-positive and gram-negative organisms have been identified as causing septic reactions. Organisms capable of multiplying at low temperatures and those using citrate as a nutrient are most often associated with red cell contamination. A variety of pathogens, as well as skin contaminants, have been found in platelet concentrates.

c. Other organisms

Organisms such as plasmodia, rikettsia, etc. can also be transmitted through blood products. All potential blood donors are subjected to stringent screening procedures intended to reduce to a minimum the risk that they will transmit these infectious agents.

2. Circulatory overload

This can occur after transfusion of excessive volumes or at excessively rapid rates. This is a particular risk in the elderly and patients with chronic severe anaemia in whom low red cell mass is associated with high plasma volume. Small transfusion volumes can precipitate symptoms in at-risk patients who already have a positive fluid balance.

3. Hypothermia

Rapid infusion of large volumes of cold blood can depress body temperature, and the danger is compounded in patients experiencing shock or surgical or anaesthetic manipulations that disrupt temperature regulation. Hypothermia carries a risk of cardiac arrhythmia or cardiac arrest.

4. Metabolic complications

Citrate “toxicity” reflects a depression of ionised calcium due to the presence in the circulation of large quantities of citrate anticoagulant. This complication is rare due to the fact that citrate is promptly metabolised by the liver. Other metabolic derangements can accompany rapid or large-volume transfusions, especially in patients with pre-existing circulatory or metabolic problems. These include acidosis or alkalosis and hyper- or hypokalaemia.

Annexure 2: Abbreviations

AHR	Acute Haemolytic Reactions
DHR	Delayed Haemolytic Reactions
HIV	Human Immune Deficiency Virus
HTLV-1	Human T-Lymphotrophic Virus-1
IBPT	Incorrect Blood Product Transfused
PTP	Post-Transfusion Purpura
RBC	Red Blood Cells
SANBS	South African National Blood Service
SHOT	Serious Hazards of Transfusion
TA-GvDH	Transfusion-Associated Graft-versus-Host Disease
TRALI	Transfusion-Related Acute Lung Injury
TTD	Transfusion Transmissible Diseases
WPBTS	Western Province Blood Transfusion Service

Annexure 3: Definition of Reaction Severity

1. Asymptomatic Reactions

No symptoms were directly attributed to the transfusion.
Death due to any transfusion unrelated cause must be included in this category.

2. Minor Reactions

The patient suffers from symptoms and/or complications attributed to the transfusion.
This excludes death and major reactions.
The patient recovers rapidly.

3. Major Reactions

Admission to an Intensive Care Unit and/or requirement for ventilation.
Need for dialysis and/or presence of renal dysfunction.
Presence of major haemorrhage.
Presence of jaundice with or without intravascular haemolysis.
Risk for Rhesus sensitisation in a female of child bearing age.