New Zealand Blood Service

National Haemovigilance Programme

Annual Report 2021

NZBLOOD
Te Ratonga Toto O Aotearoa

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ABBREVIATIONS	
AABB	Association for the Advancement of Blood & Biotherapies (formerly American Association of Blood Banks)
AHTR	Acute Haemolytic Transfusion Reaction
APH	Apheresis
ATR	Adverse transfusion reaction
Blood Component	A therapeutic constituent of human blood (red cells, fresh frozen plasma, platelets, cryoprecipitate) that can be collected by apheresis or separated from whole blood.
BNP	Brain (or B-type) Natriuretic Peptide
CAG	Clinical Advisory Group
CI	Confidence interval
DAT	Direct antiglobulin test
DHB	District Health Board
DHTR	Delayed haemolytic transfusion reaction
DSTR	Delayed serologic transfusion reaction
FNHTR	Febrile non-haemolytic transfusion reaction
Hb	Haemoglobin
HBsAg	Hepatitis B surface antigen
HBV	Hepatitis B virus
HCV	Hepatitis C virus
HIV	Human immunodeficiency virus
HTLV I/II	Human T-Cell Lymphotropic virus Types I and II
IAT	Indirect antiglobulin test
IBCT	Incorrect blood component transfused
IHN	International Haemovigilance Network
ISBT	International Society of Blood Transfusion
ITP	Idiopathic thrombocytopenic purpura
IV	Intravenous
LDH	Lactate dehydrogenase
NHI	National health index
NZBS	New Zealand Blood Service
PAS	Platelet additive solution
PTP	Post-transfusion purpura

RAADP	Routine antenatal anti-D prophylaxis
SHOT	Serious Hazards of Transfusion – the UK haemovigilance programme
TACO	Transfusion-associated circulatory overload
TAD	Transfusion-associated dyspnoea
TA-GVHD	Transfusion-associated graft-versus-host disease
TAH	Transfusion-associated hypotension
TMS	Transfusion Medicine Specialist
TNS	Transfusion Nurse Specialist
TRAE	Transfusion-related adverse event (includes reactions and errors)
TRALI	Transfusion-related acute lung injury
TTI	Transfusion-transmitted infection
UCT	Unclassifiable complication of transfusion
WB	Whole blood
WBIT	Wrong blood in tube

BLOOD COMPONENT AND BLOOD PRODUCT NAMES	
FFP	Fresh frozen plasma
Fresh Frozen Plasma Neo	Fresh frozen plasma for neonatal transfusion, volume 45 – 90 mL
Platelets APH	Platelets prepared by apheresis and suspended in plasma
Platelets APH PAS	Platelets prepared by apheresis and suspended in PAS, introduced 2012
Platelets Neo	Platelets for neonatal transfusion, volume 30 – 60 mL
Platelets Pooled PAS	Pool of platelets from buffy coats suspended in PAS, introduced 2011
RBC	Red blood cells
Red Cells Neo	Red cells for neonatal transfusion, volume 55 – 85 mL

Albumex® 20	20% human albumin solution for intravenous infusion
Albumex® 4	4% human albumin solution for intravenous infusion
Biostate®	Human coagulation factor VIII and von Willebrand factor complex
Evogam®	16% human normal immunoglobulin solution for subcutaneous use
Intragam® P	6% human normal immunoglobulin solution for intravenous infusion
Privigen®	10% human normal immunoglobulin solution for intravenous infusion
Prothrombinex®-VF	Human coagulation factors II, IX and X and low levels of Factor VII
Rh(D) Immunoglobulin-VF	Human anti-D immunoglobulin solution for intramuscular injection

CHAPTER 1

INTRODUCTION

Welcome to the 17th National Haemovigilance Programme Annual Report for New Zealand. During 2021, our health care services, blood banks and donor centres all came under significant pressure from the impact of the COVID-19 pandemic. Special thanks to those of you who submitted haemovigilance reports, despite those challenges. Thanks also to our amazing blood and plasma donors, who have continued to support our patients throughout the restrictions.

Our Clinical Surveillance team has been working hard throughout the year, increasing our focus on error reporting and near misses. Examining the underlying causes of errors will give us the best opportunity to improve the safety of transfusion, so please do keep reporting. Key areas of risk this year include errors of anti-D administration for pregnant women and Wrong Blood in Tube (WBIT) events.

2021 saw routine antenatal anti-D prophylaxis (RAADP) introduced in several DHBs, with more areas looking to offer this important safety initiative to their patients in future. Increased anti-D usage and change in practice has led to more errors this year, but understanding them will allow us to provide better safety guidelines to midwives, obstetricians and blood banks.

We have encouraged better reporting and screening for WBITs, which can potentially lead to life-threatening transfusion errors. Blood bank software systems can also help us identify WBITs that were previously unrecognised. Every WBIT reported is a learning opportunity and we hope that we will continue to see better reporting from all hospitals year on year. New Zealand Blood Service will be releasing new labelling guidance this year, that we hope will improve sample safety.

Donor Adverse Event (DAE) reporting is also an area where we have made a significant advance this year, although you will not see the results until next year's report. The Clinical Surveillance team developed a novel electronic reporting system which is being rolled out across all our donor sessions. The system makes reporting easier and captures data in a targeted way, that ensures accuracy. We are excited that the system has been well received by our donor teams, as we hope to use similar technology to improve our haemovigilance reporting in the next few years.

I hope that you enjoy the report and find it a useful tool to improve clinical practice. If you have questions about the report or ideas for improvement, please do make contact with the Clinical Surveillance team or your local Transfusion Medicine Specialist or Transfusion Nurse Specialist.

Dr Sarah Morley
Chief Medical Officer
New Zealand Blood Service

CHAPTER 2

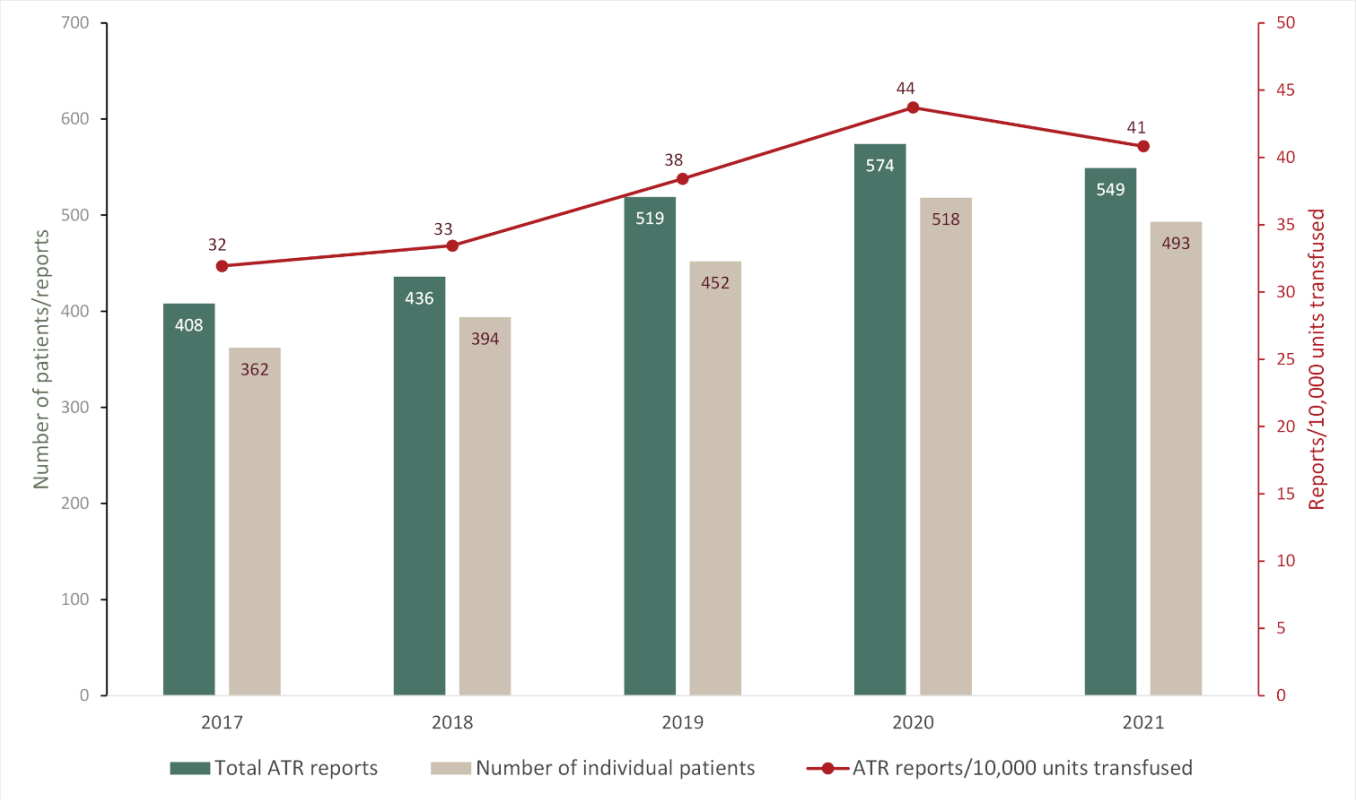
HAEMOVIGILANCE OVERVIEW

The Haemovigilance Programme receives reports for adverse transfusion reactions to blood components (ATR), fractionated product adverse events, error and near miss reports and adverse events associated with blood donation.

In 2021, the Haemovigilance Programme received 549 ATR reports, 49 fractionated product adverse event reports, 95 error and near miss reports and 8,275 donor adverse event reports. Figures 2-1 to 2-4 show overall reporting trends for the last five years. Further detail can be found in subsequent chapters of this report.

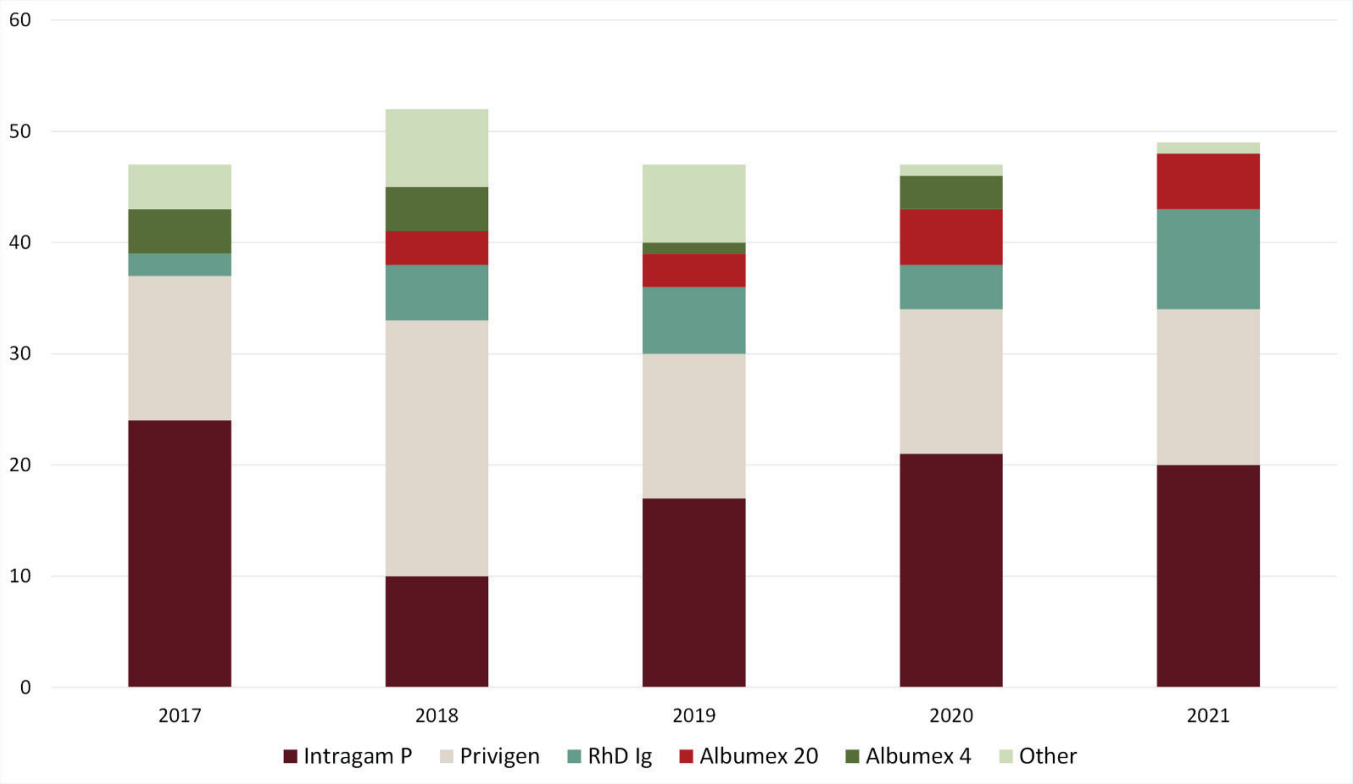
The number and frequency of ATR reports received in 2021 was slightly lower than that in 2020 (Figure 2-1). It is not clear if the Covid-19 pandemic was partly responsible for lower reporting rates, but this may become clearer in 2022 as Covid-19 hospital admissions increase.

Figure 2-1: Number and frequency of adverse transfusion reaction reports 2017 to 2021



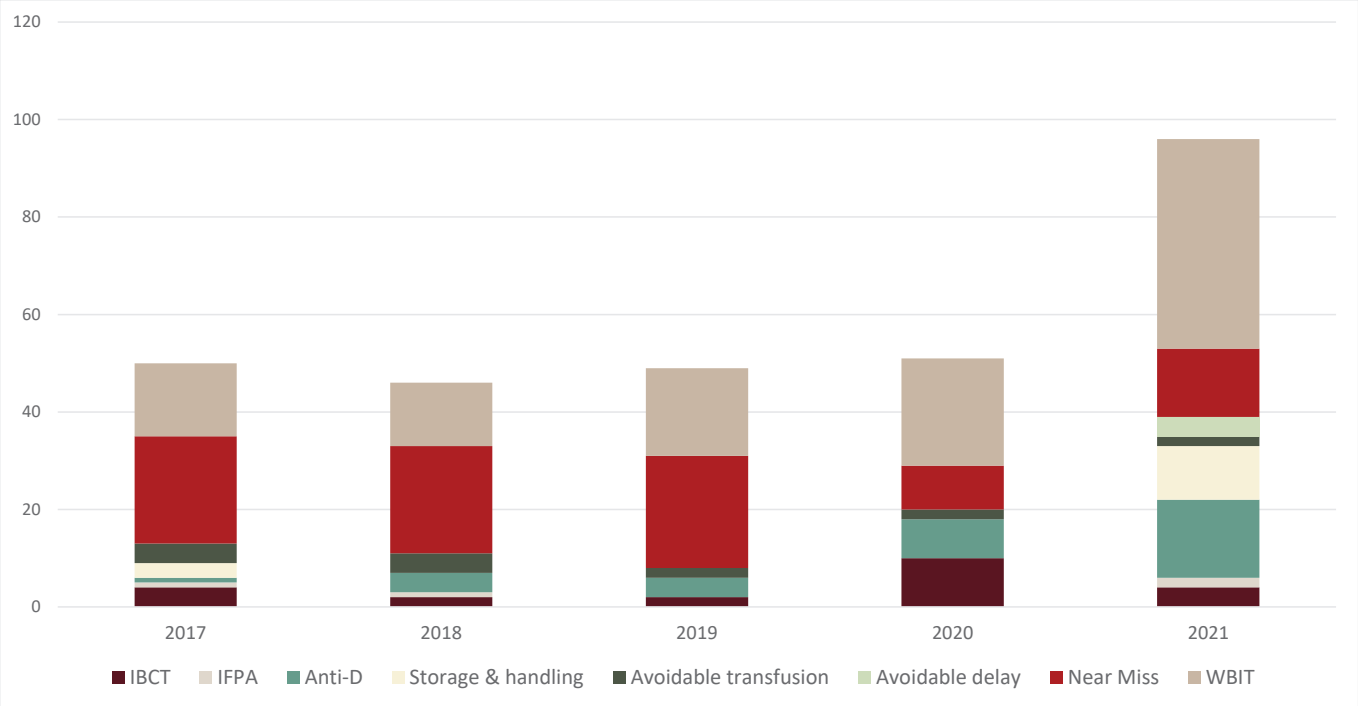
The total numbers of fractionated product adverse event reports have been relatively stable for the last five years (Figure 2-2).

Figure 2-2: Number of fractionated product adverse event reports 2017 to 2021



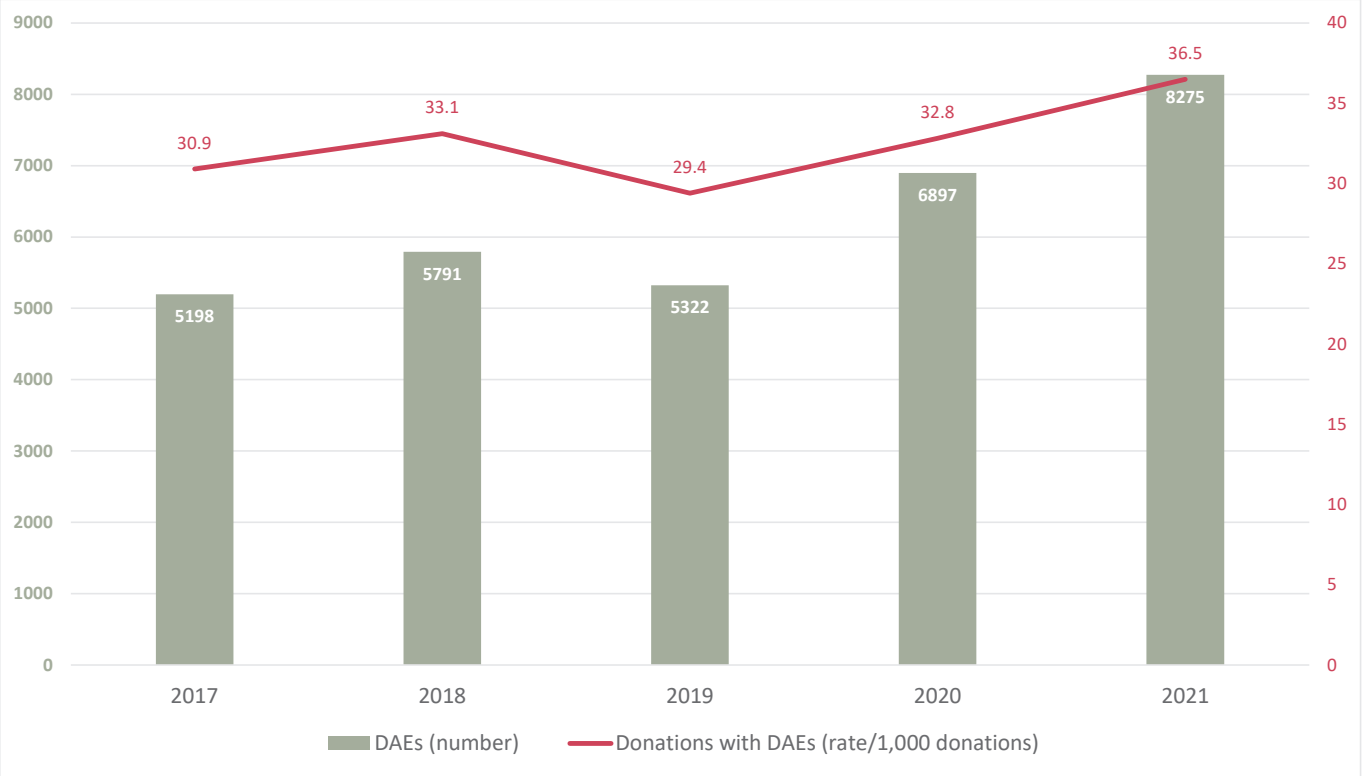
There has been a noticeable increase in error and near miss reporting in 2021, mostly due to better reporting of wrong blood in tube (WBIT) and anti-D errors (Figure 2-3).

Figure 2-3: Number of error and near miss reports 2017 to 2021



There was a 20% increase in the number of donor adverse events reported from 2020 to 2021. This was partly due to an increase in plasma collections but reporting frequency has also increased (Figure 2-4).

Figure 2-4: Frequency of donor adverse event reports 2017 to 2021



2.1 BLOOD COMPONENTS TRANSFUSED

The total number of blood components transfused in 2021 was 134,440. Figure 2.1-1. shows the numbers of each component type transfused annually from 2017 to 2021 has been relatively stable. Neonatal blood components transfused are shown in Figure 2.1-2.

Figure 2.1-1: Annual number of blood components transfused 2017 to 2021

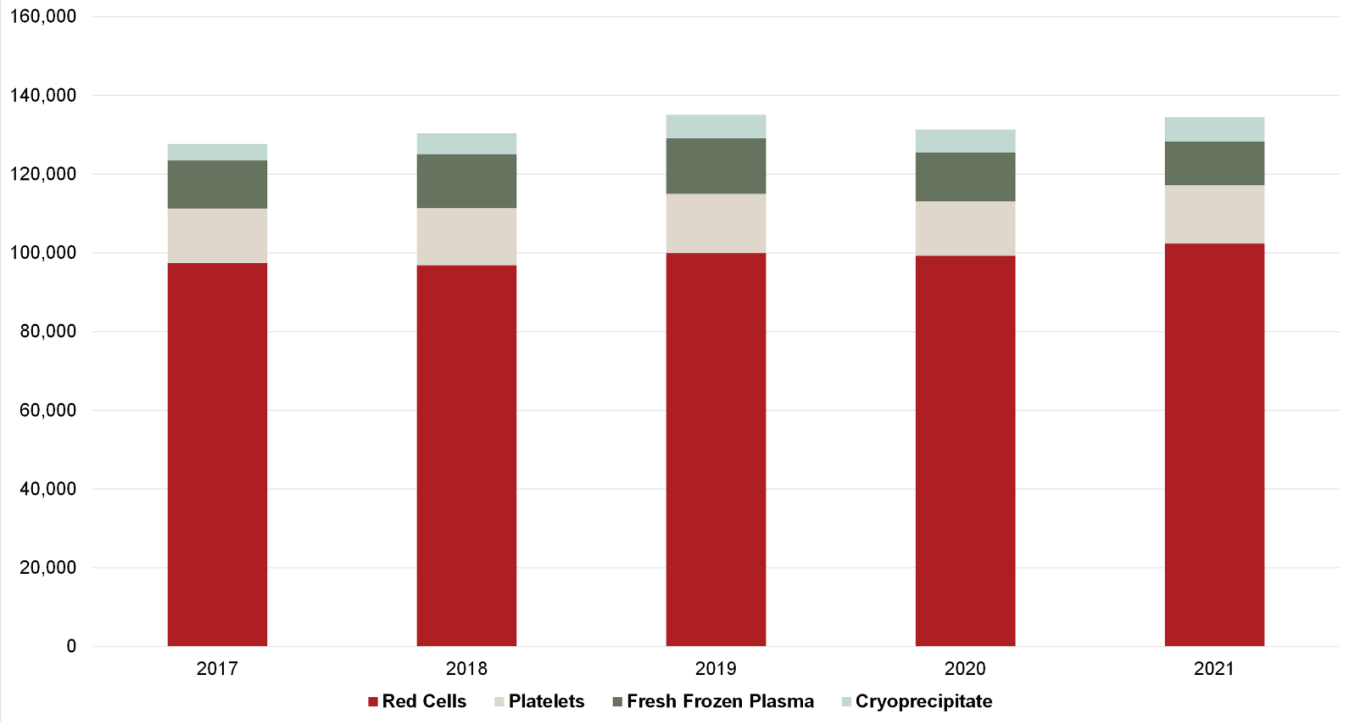
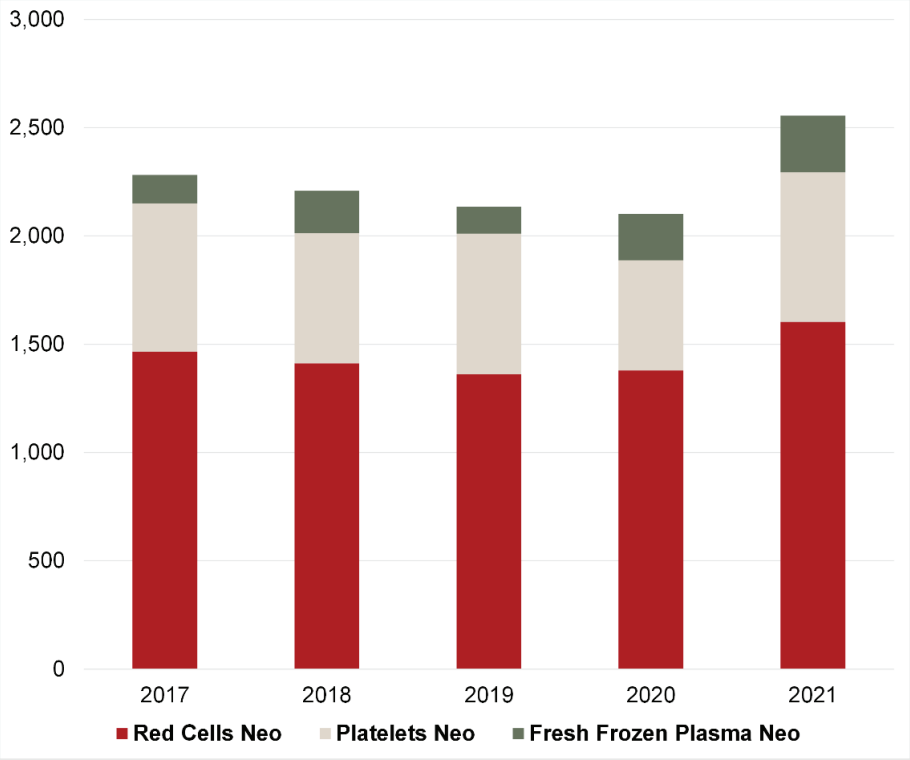


Figure 2.1-2: Annual number of neonatal blood components transfused 2017 to 2021



The total number of neonatal components transfused each year had been slowly declining since 2017 and had dropped by 7.9% up to 2020. However, in 2021 the usage of all neonatal components increased by 21.6% from 2020. The cause of this is not clear, but a number of factors, such as increased neonatal admissions, may have contributed to this increase.

Figures 2.1-3 and 2.1-4 illustrate the rate of transfusion per 1,000 population of the major components over the last five years.

Figure 2.1-3: Annual rate of red cells transfused per 1,000 population 2017 to 2021

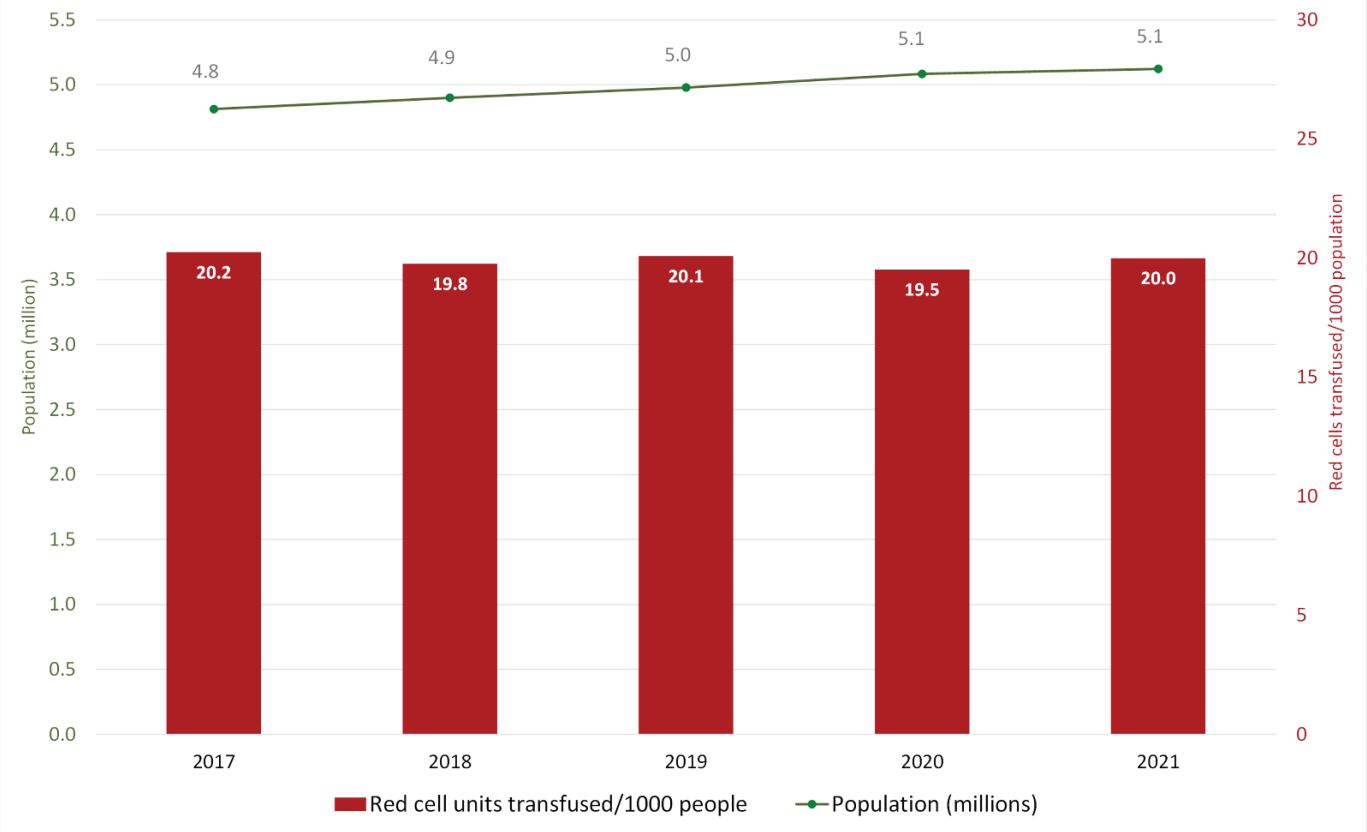
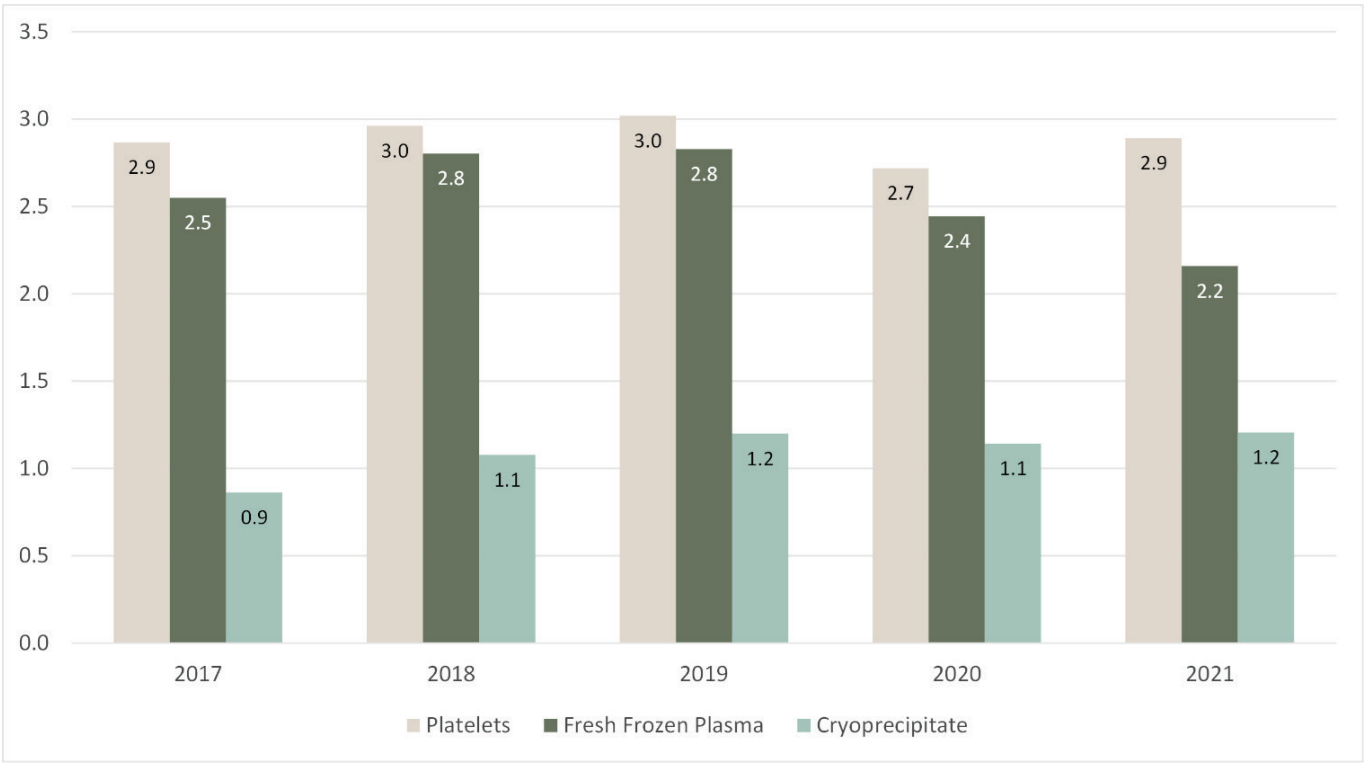


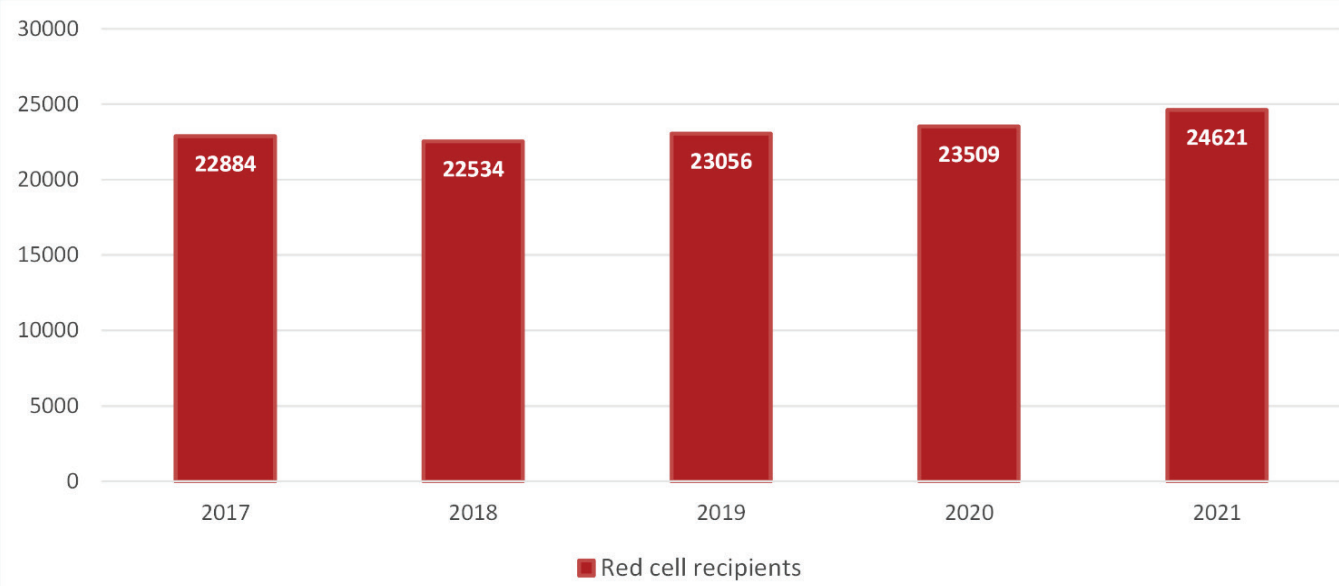
Figure 2.1-4: Annual rate of platelets, FFP and cryoprecipitate transfused/1,000 population 2017 to 2021

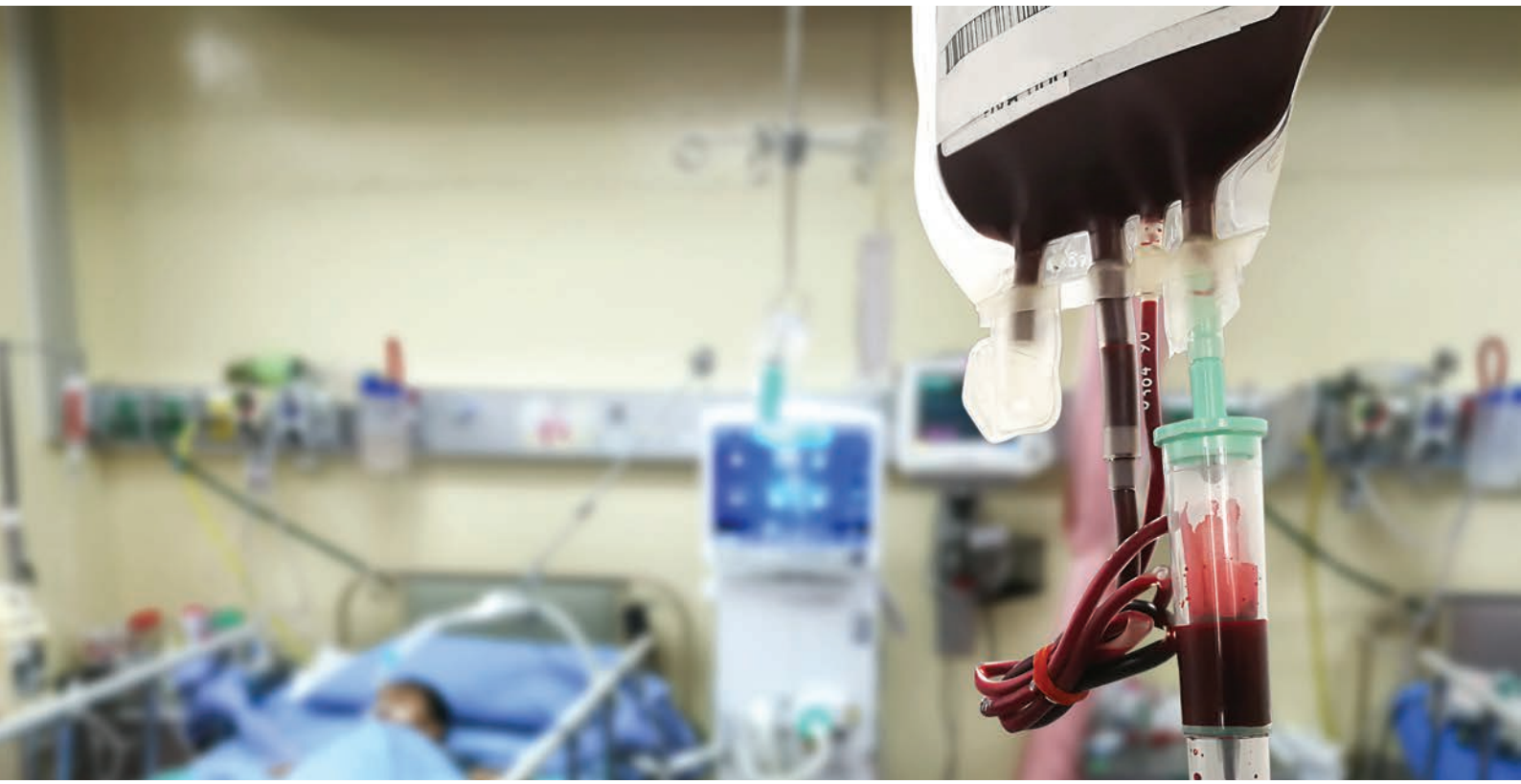


2.2 RECIPIENTS OF BLOOD COMPONENTS

Numbers of recipients of red cells have increased by 7.6% over the last five years (Figure 2.2-1). The New Zealand population has increased by an estimated 6.2% over the same period.

Figure 2.2-1: Annual number of red cell recipients 2017 to 2021





There have also been slight increases in the numbers of platelet and cryoprecipitate recipients, but a slight drop in FFP recipients over the last five years (Figure 2.2-2).

Figure 2.2-2: Annual number of platelets, FFP and cryoprecipitate recipients 2017 to 2021

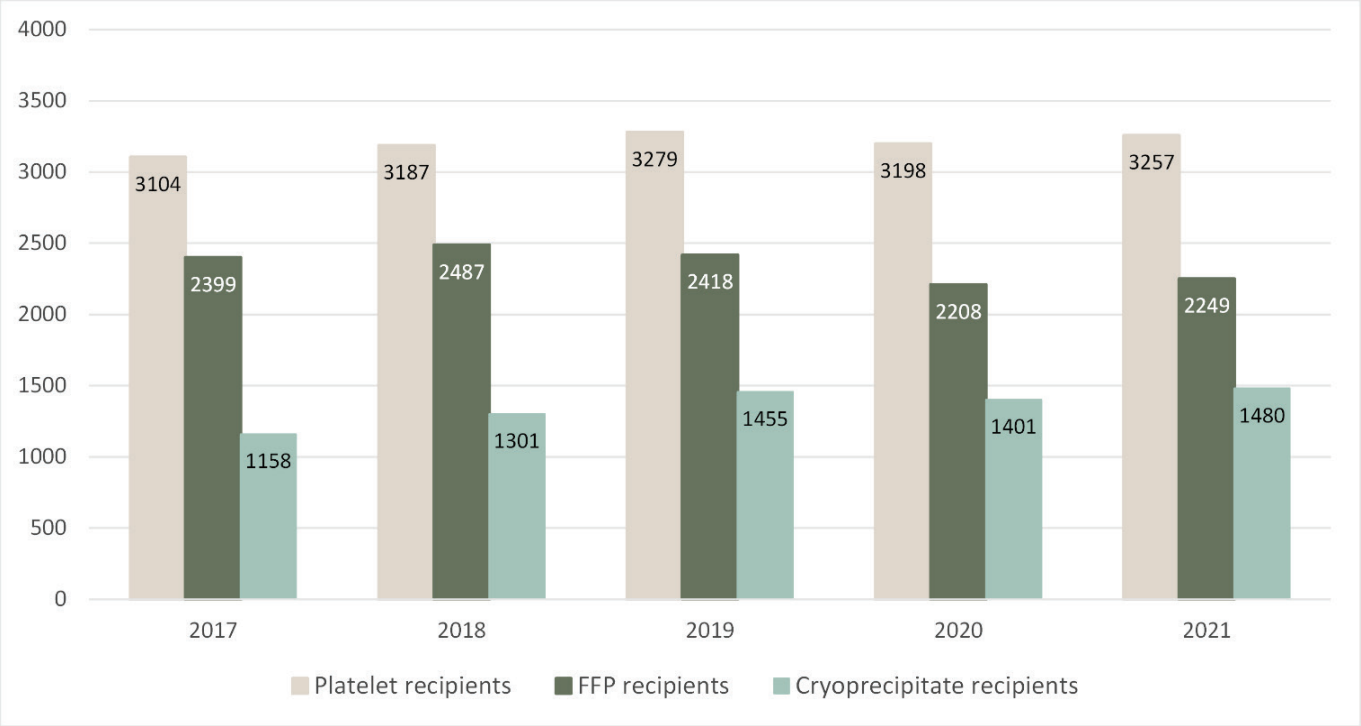
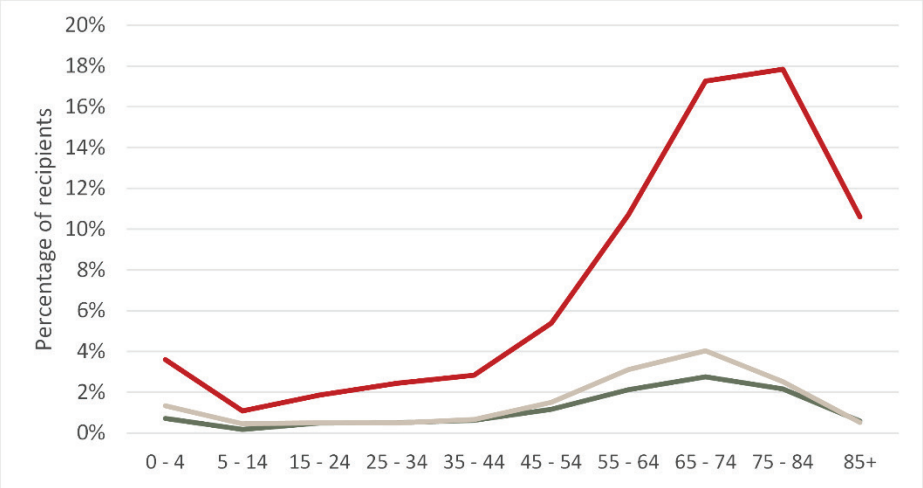


Table 2.2-1 shows recipients of components by gender. Females are significantly more likely to receive red cells, but significantly less likely to receive either platelets or fresh frozen plasma, than males ($p < 0.05$). This observation is consistent with the data from 2020.

Table 2.2-1: Recipients of blood components 2021

		Blood Component			
		Red Cells	Platelets	FFP	Cryoprecipitate
Recipient gender (number)	Female	13,785	1,204	889	586
	Male	10,814	2,052	1,356	892
	Unknown	24	1	4	2
	Total	**24,621**	**3,257**	**2,249**	**1,480**
Units Transfused per recipient over 1 year	Median	2	2	2	3
	Maximum	120	119	303	42

Figure 2.2-3: Males



Age group distribution of recipients 2017 to 2021

Figures 2.2-3 and 2.2-4 show the age distribution of male and female recipients of the three main components. There is an expected increase in use of components in the aging population but also a pronounced difference in red cell usage between males and females during the child-bearing years for women.

Figure 2.2-4: Females

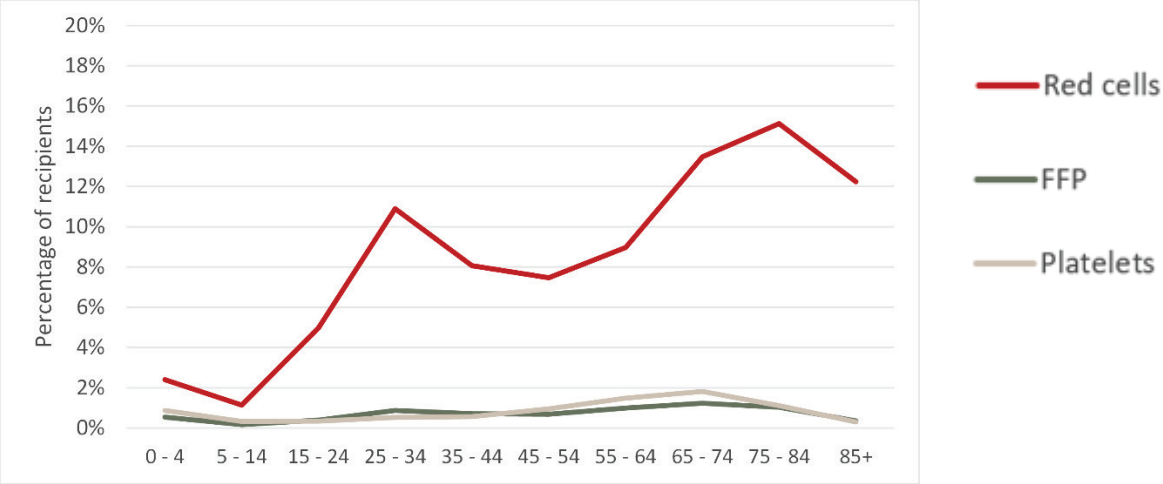
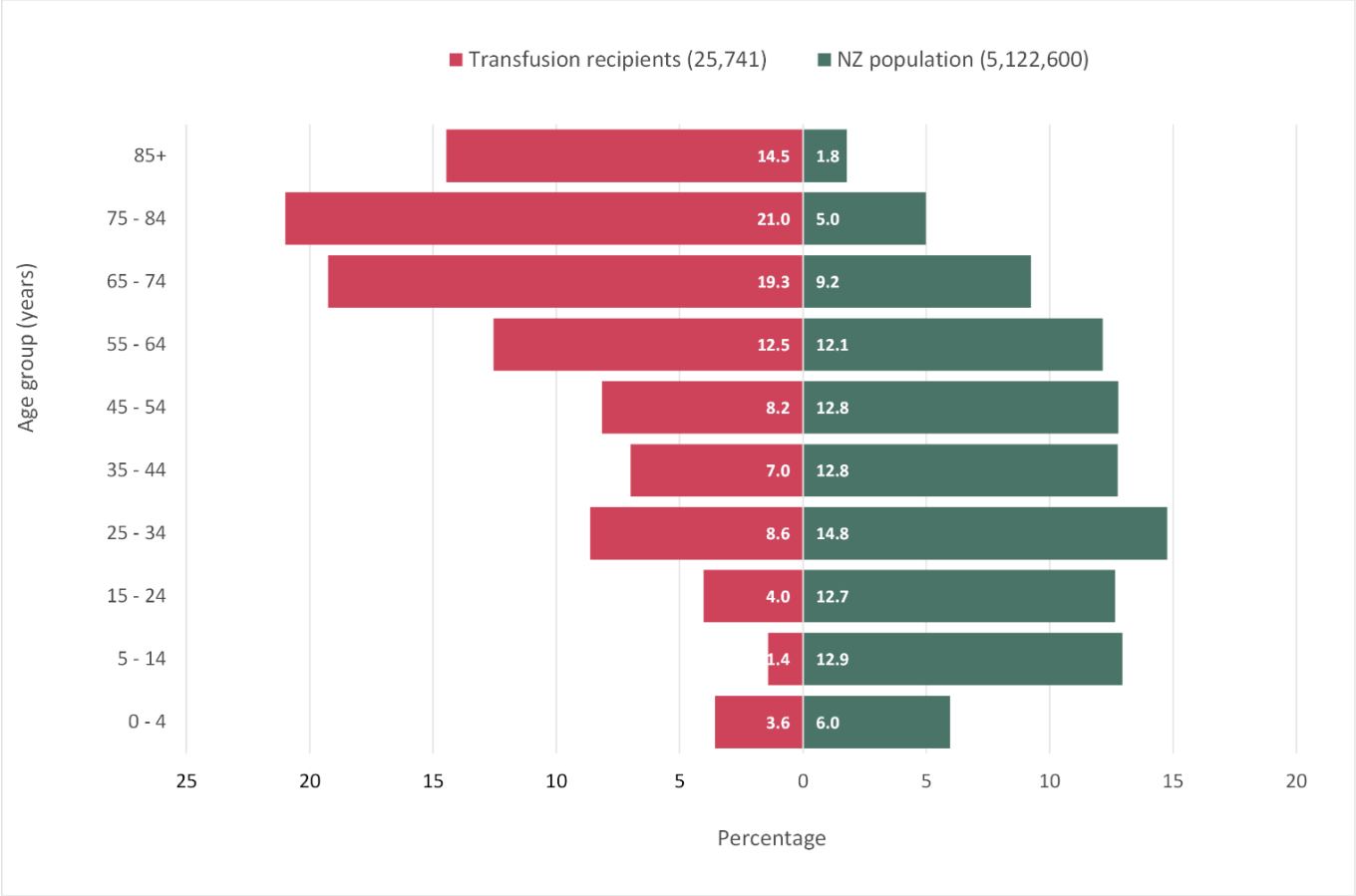


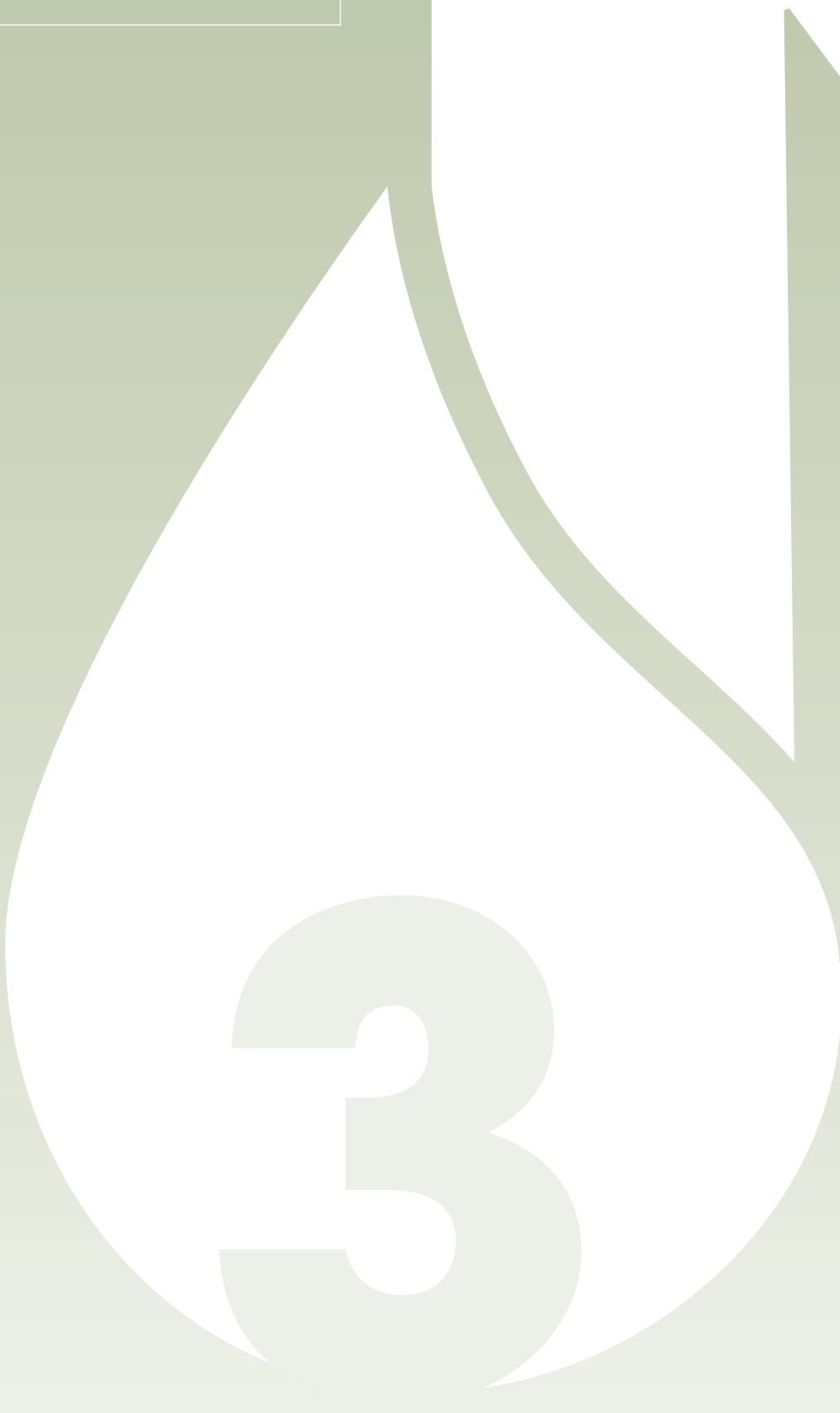
Figure 2.2-5 shows the age distribution of recipients of blood components compared with that of the New Zealand population in 2021. About 67% of the recipients of all blood component transfusions were ≥55 years old (65% in 2020). In contrast, 28% of the New Zealand population was ≥55 years old (28% in 2020).

Figure 2.2-5: Age group distribution of recipients compared with population 2021



CHAPTER 3

ADVERSE TRANSFUSION REACTION REPORTS



ADVERSE TRANSFUSION REACTION REPORTS

3.1 OVERVIEW

During 2021, 549 ATR reports were received. Section 3.1.1 discusses imputability of all 549 reports. Analysis in all remaining sections of Chapter 3 is limited to reports with an imputability of possible, probable or certain, i.e. cases with an imputability of unlikely or excluded have been removed from further analysis.

3.1.1 IMPUTABILITY

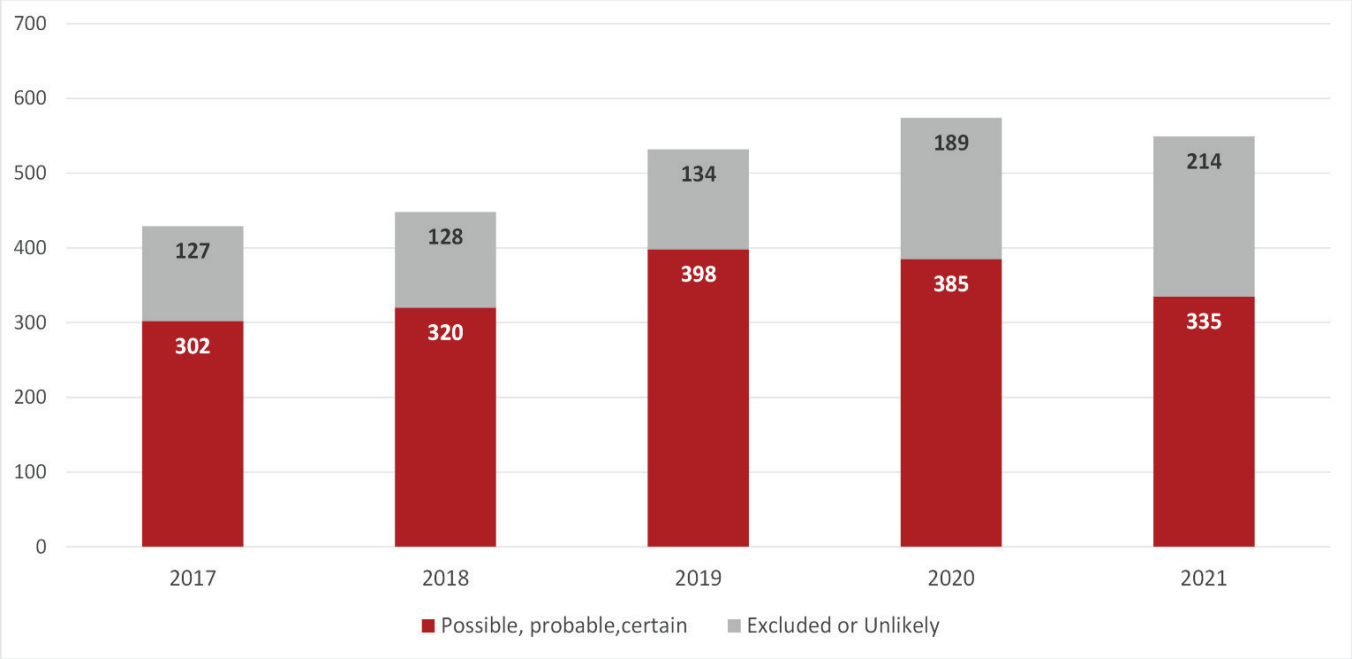
NZBS applies the following ISBT definitions[1] and scores for imputability when assessing reports:		
1	**Excluded**	When there is conclusive evidence beyond reasonable doubt for attributing the event to alternative causes.
2	**Unlikely**	When the evidence is clearly in favour of attributing the event to causes other than transfusion.
3	**Possible**	When the evidence is indeterminate for attributing the event either to the transfusion or alternative causes.
4	**Probable**	When the evidence is clearly in favour of attributing the event to the transfusion.
5	**Certain**	When there is conclusive evidence beyond reasonable doubt for attributing the event to the transfusion.

Out of 549 ATR reports received in 2021, 335 (61%) were assigned an imputability of possible, probable or certain and will be analysed in the rest of Chapter 3.

The remaining 214 (39%) reports were of low imputability (excluded or unlikely), a slightly higher proportion than previous years (Figure 3.1.1-1). These reports have been excluded from further analysis.

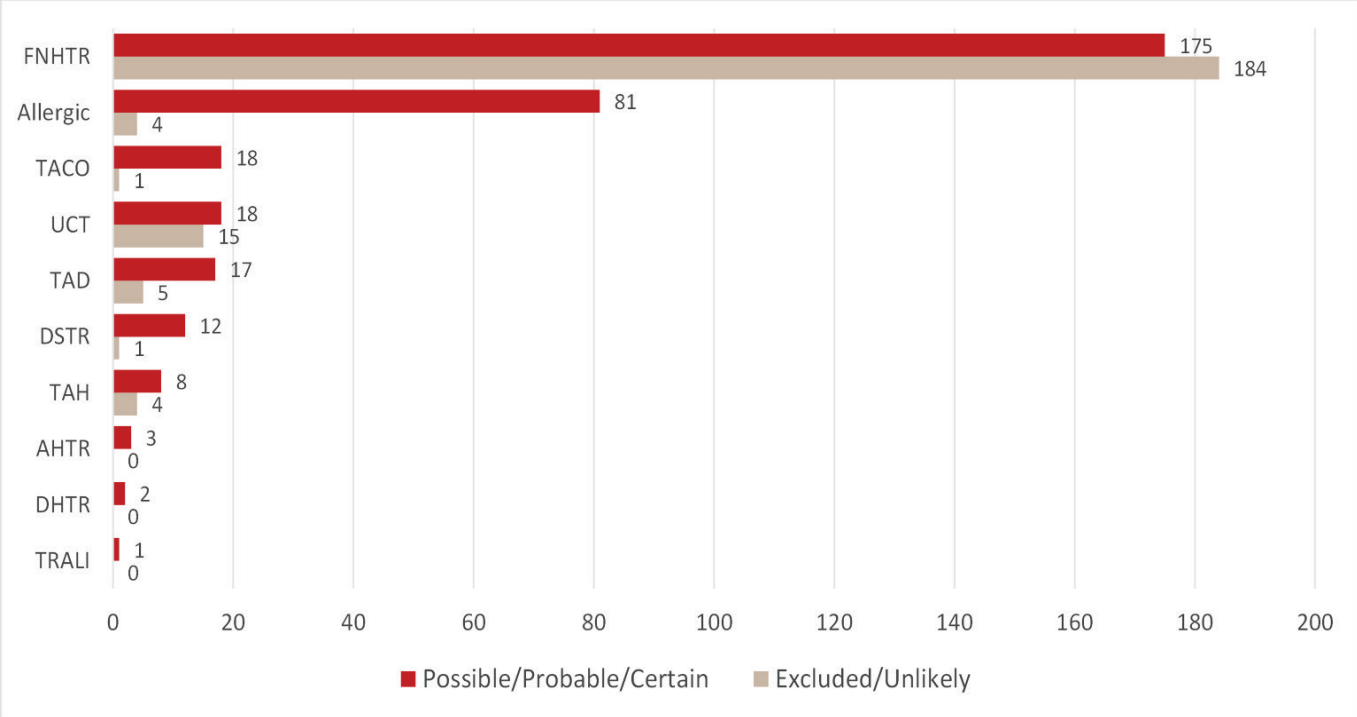
[1] *ISBT Working Party on Haemovigilance. Proposed standard definitions for surveillance of non-infectious adverse transfusion reactions (2011)*

Figure 3.1.1-1: Proportion of low imputability reports excluded from analysis 2017-2021



In 2021, the majority of low imputability reports (86%) had been classified as febrile non-haemolytic transfusion reactions (FNHTR). In addition, more than half (51%) of all FNHTR reports were assigned low imputability (Figure 3.1.1-2). The lower imputability score assignment is reflective of patients being neutropenic post-chemotherapy, being on antibiotics having concomitant infections or sepsis at the time of transfusion reactions. In contrast, only 5% of allergic reactions, the second most frequently reported reaction, were assigned low imputability.

Figure 3.1.1-2: Adverse reaction reports by type and imputability 2021



3.1.2 SEVERITY

NZBS applies the following ISBT definitions[2] and scores for severity when assessing reports:		
Grade 1	**Non-severe**	The recipient may have required treatment, but lack of such would not have resulted in permanent damage or impairment of a body function.
Grade 2	**Severe**	The recipient required hospitalisation or prolongation of hospitalisation directly attributable to the event; and/or the adverse event resulted in persistent or significant disability or incapacity; or the event necessitated medical or surgical intervention to preclude permanent damage or impairment of a body function.
Grade 3	**Life-threatening**	The recipient required major intervention following the transfusion (e.g., vasopressors, intubation, transfer to intensive care) to prevent death.
Grade 4	**Death**	The recipient died following an adverse transfusion reaction. Grade 4 should only be used if death is probably, or definitely, related to transfusion. If the patient died of another cause, the severity should be graded as 1, 2 or 3.

Table 3.1.2-1 shows transfusion reactions by type and severity. As observed in previous years, FNHTR and allergic reactions are the most common reaction types reported. 89.3% of reactions were of severity grade 1 and 57.5% of those were FNHTR. Of the 31 grade 2 reactions, most were allergic or TACO. All grade 3 reactions were TACO and no grade 4 reactions were reported.

Table 3.1.2-1: Adverse transfusion reactions by type and severity 2021

	Severity				
Reaction type	**Grade 1**	**Grade 2**	**Grade 3**	**Grade 4**	**Total**
FNHTR	172	3	-	-	175
Allergic	73	8	-	-	81
TACO	3	10	5	-	18
UCT	15	3	-	-	18
TAD	14	3	-	-	17
DSTR	12	-	-	-	12
TAH	7	1	-	-	8
AHTR	2	1	-	-	3
DHTR	1	1	-	-	2
TRALI	-	1	-	-	1
Total	**299**	**31**	**5**	**0**	**335**
% of total reactions	**89.3%**	**9.3%**	**1.5%**	**0%**	

[2] *ISBT Working Party on Haemovigilance. Proposed standard definitions for surveillance of non-infectious adverse transfusion reactions (2011)*

3.1.3 ADVERSE TRANSFUSION REACTION TYPES

Table 3.1.3-1 shows five reaction types and the trend in reporting over the last ten years. It indicates a downward trend in reporting of allergic reactions over that period. This corresponds with the gradual conversion of platelet components suspended in plasma to platelets suspended in PAS, which commenced in 2010. The last component type to be converted to PAS was neonatal platelets, which were introduced on 14 June 2021.

Table 3.1.3-1: Percentages and trending of selected reaction types 2012 to 2021

	Percent (%) of total reactions by year										
Reaction	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	Sparkline trend
FNHTR	32.9	38.5	40.6	41.3	37.1	31.7	39.1	38.5	38.5	31.9	
Allergic	24.4	23.1	17.9	22.0	21.8	17.9	16.7	17.3	15.0	14.8	
TAH	2.6	0.4	0.6	1.1	2.7	2.3	2.5	2.6	3.1	1.5	
TACO	5.1	3.2	2.6	3.5	2.7	2.1	2.7	3.0	3.1	3.3	
TRALI	0.4	0.2	0.2	0.2	0.2	0.0	0.0	0.6	0.2	0.2	

3.1.4 DEMOGRAPHICS

Table 3.1.4-1 shows adverse reactions by recipient gender for 2021 alongside historical data for the previous ten years. Compared with the previous ten years, 2021 shows a slightly higher proportion of reactions in female recipients.

Table 3.1.4-1: Distribution of adverse reactions by recipient gender 2021

	2021	2011 – 2020
Female	195 (58.2%)	1833 (50.8%)
Male	140 (41.8%)	1778 (49.2%)
Total	**335**	**3611**

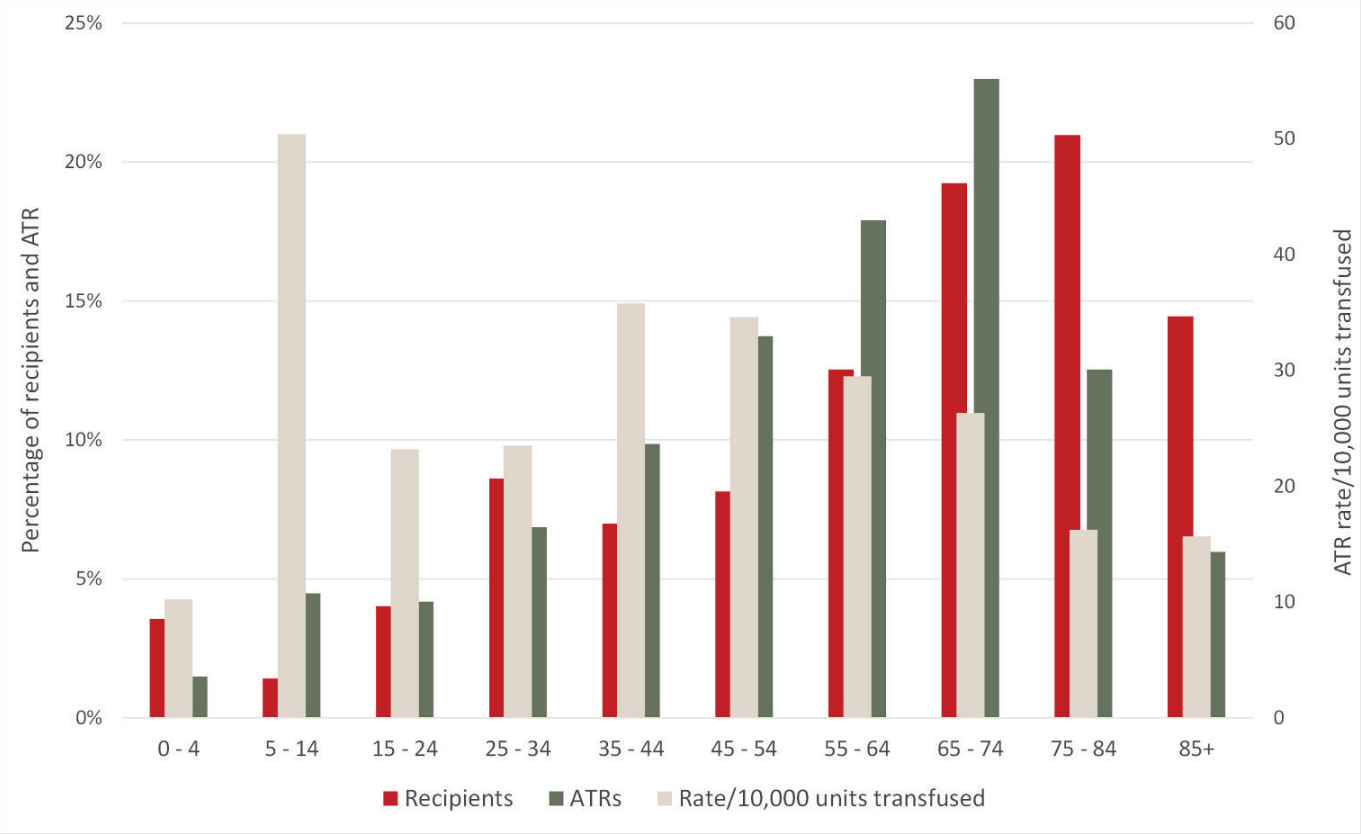
Multiple adverse reactions were reported in 28 recipients (Table 3.1.4-2). The event types in recipients who had 3 or more reactions were FNHTR, allergic and TAD.

Table 3.1.4-2: Distribution of recipients with multiple adverse reactions 2021

	Total	1 Reaction	2 Reactions	3 Reactions	4 Reactions
Recipient Numbers	307	284	19	3	1

Figure 3.1.4-1 shows that the age distribution of those patients having adverse reactions broadly follows the age distribution of recipients. However, similar to 2020 data, when the data for the ATR rate per 10,000 units transfused is overlaid there is a markedly higher rate of reactions in the 5 – 24 age group. NZBS is currently undertaking a retrospective study in the area of paediatric transfusion to understand this.

Figure 3.1.4-1: Percentage of all recipients and percentage of recipients with ATRs by age group 2021 (Rate of ATR/10,000 units transfused is overlaid).



3.1.5 IMPLICATED BLOOD COMPONENTS

Similar to previous years, the rates of reactions to platelet components are higher than reactions to other components (Table 3.1.5-1).

Table 3.1.5-1: Adverse transfusion reactions by blood component 2021

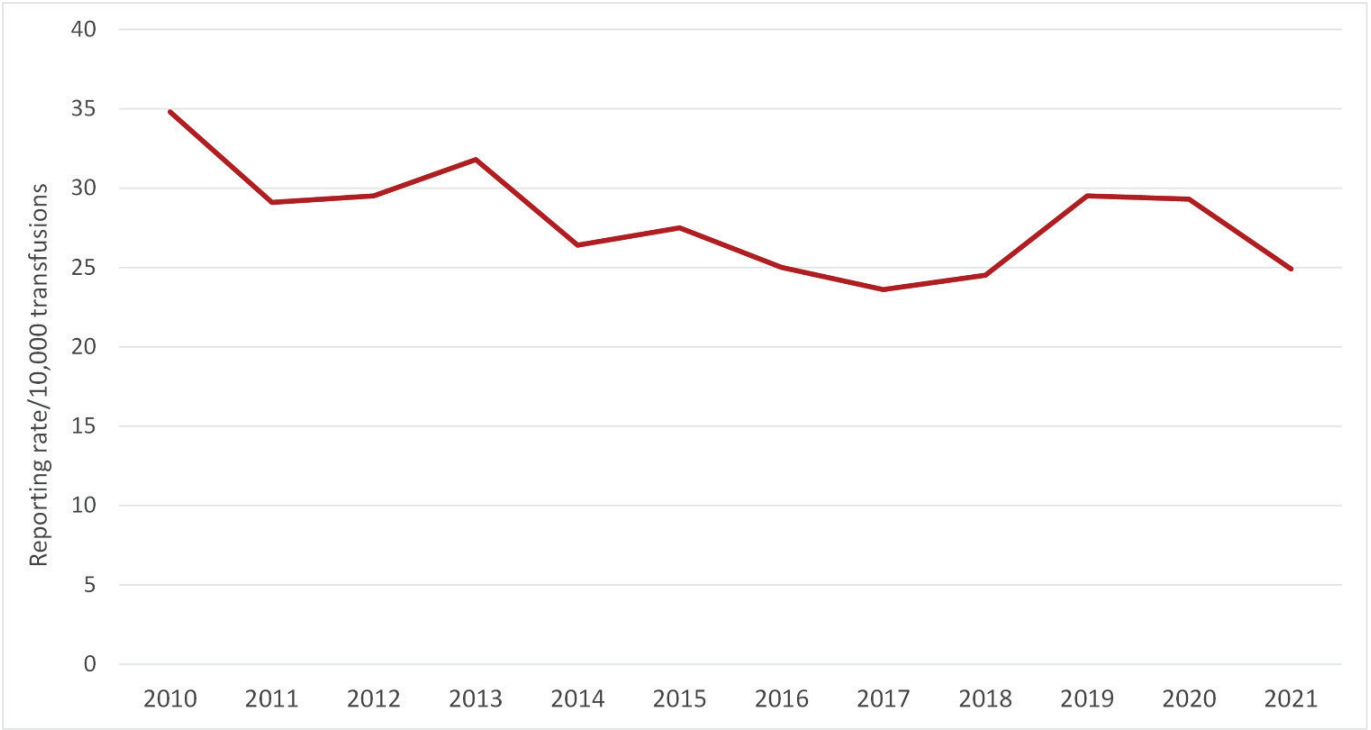
Component	Reactions*	Units Transfused	Frequency	Rate / 10,000 Units Transfused (95%CI)
Platelets	63	14,242	1:226	44.2 (34.5 to 56.6)
Red Cells	329	102,394	1:311	32.1 (28.8 to 35.8)
Fresh Frozen Plasma	39	11,059	1:284	35.3 (25.7 to 48.3)
Cryoprecipitate	9	6,197	1:689	14.5 (7.2 to 28.0)

** Some reactions are associated with the transfusion of more than one component type.*

3.1.6 REPORTING BY DISTRICT HEALTH BOARD

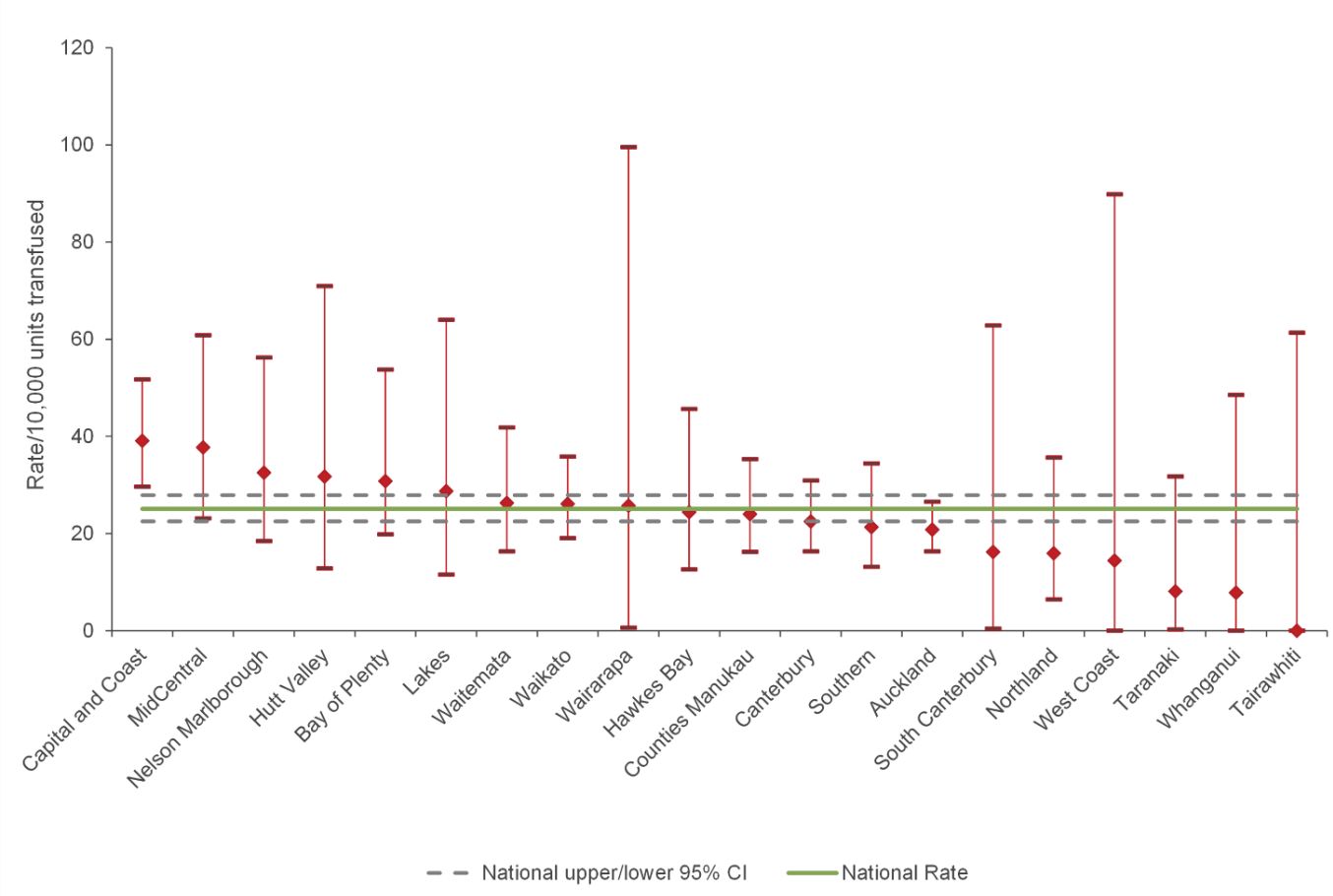
Since 2010, there has been a downward trend in the national ATR reporting rate (Figure 3.1.6-1).

Figure 3.1.6-1: National ATR reporting rate (imputability >2) 2010-2021



In 2021, adverse transfusion reactions were reported from all 20 District Health Boards (DHB). Reporting rates by DHB are shown in Figure 3.1.6-2. The largest DHB, Auckland, has consistently fallen below the national average reporting rate over the last eight years. Waikato, which has long had one of the highest reporting rates, fell to the average national rate in 2021.

Figure 3.1.6-2: Adverse transfusion reaction reporting rate (with 95% CI) by DHB 2021



The vignette on the following page illustrates how raising awareness of haemovigilance can increase reporting rates.

Focus on Bay of Plenty

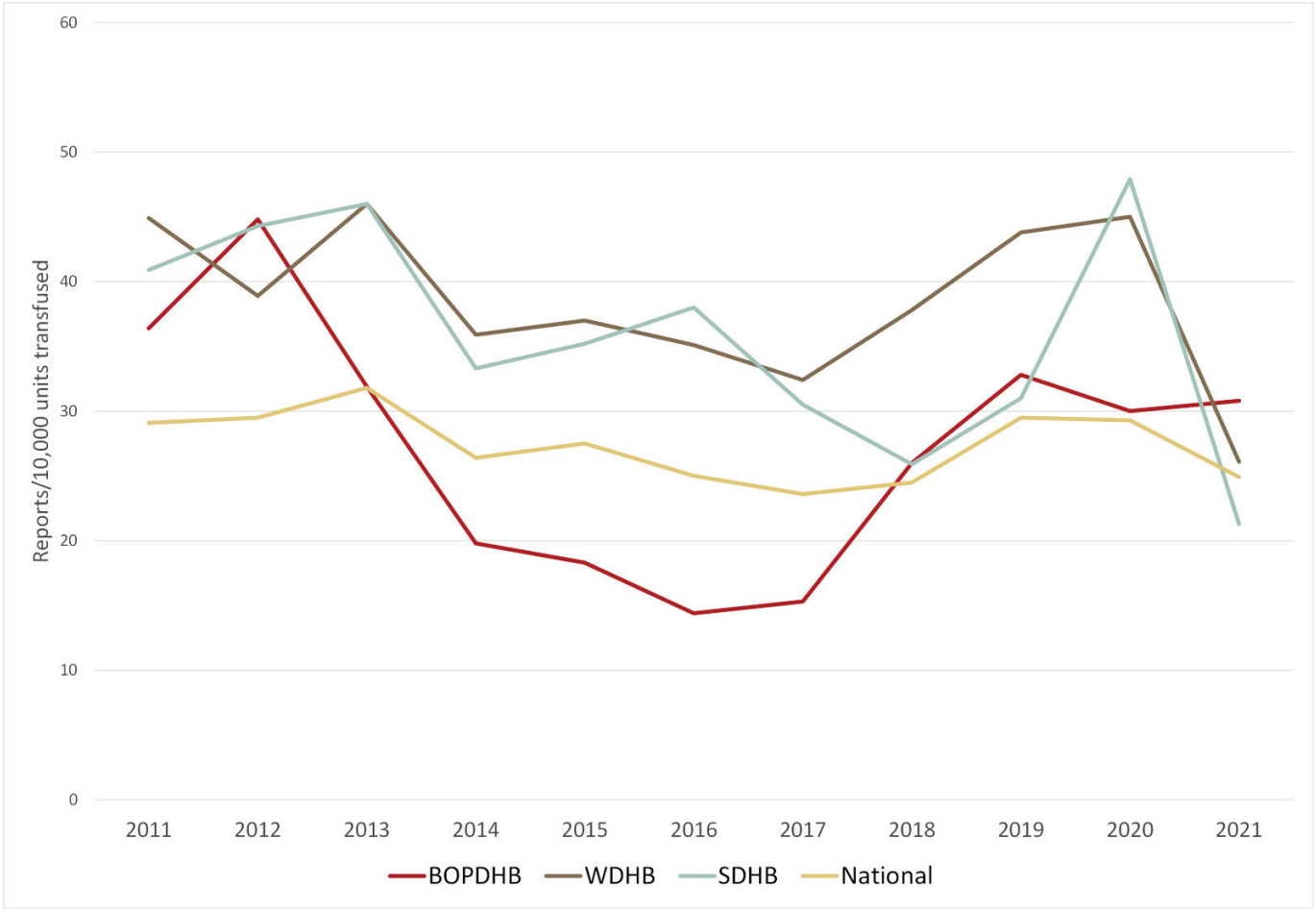
(From the NZBS Waikato Transfusion Nurse Specialist)

Successive haemovigilance reports have consistently shown wide variability in reporting rates amongst the DHBs. There appears to be no correlation between the number of transfusions and reporting rates as some of the larger hospitals have the lowest rates.

The Bay of Plenty DHB (BOPDHB) initially had above average reporting rates (Figure 3.1.6-3) but this declined from 2012 onwards. No clear cause was established for this decline. In comparison both Waikato DHB (WDHB) and Southern DHB (SDHB) have had above average reporting rates over the same period. Intervention (simple in-service sessions to nursing staff) was planned at BOPDHB with the aim of raising awareness of haemovigilance reporting and to identify any barriers to reporting. Adverse reporting rates before and after intervention were monitored. The intervention of simple in-service sessions, spread over a two-year period at Tauranga and Whakatane Hospitals, suggests that a raised awareness of haemovigilance has been achieved resulting in an increased reporting rate from nursing staff at the hospitals. During the intervention it was noted that some clinical staff were reporting adverse events to the hospital DATIX incident reporting system, but these were not forwarded to the Blood Banks involved. This has now been rectified. It may be useful to extend this intervention to other DHBs to identify barriers to reporting.

Interestingly, BOPDHB has maintained its above-average reporting rate into 2021, but WDHB and SDHB reporting rates have fallen since 2020 by 42% and 56% respectively.

Figure 3.1.6-3: ATR reporting rates for BOPDHB, WDHB and SDHB 2011-2021



3.2 FEBRILE NON-HAEMOLYTIC TRANSFUSION REACTIONS (FNHTR)

Fever (≥38°C and a change of ≥1°C from pre-transfusion value) and/or chills/rigors occurring during or within 4 hours of transfusion without any other cause such as haemolytic transfusion reaction, bacterial contamination or underlying condition.

There were 175 FNHTRs reported in 2021, 172 of severity grade 1 and three of severity grade 2. They continue to be the most frequently reported adverse transfusion reactions and continue to be most often associated with red cell transfusions (Table 3.2-1).

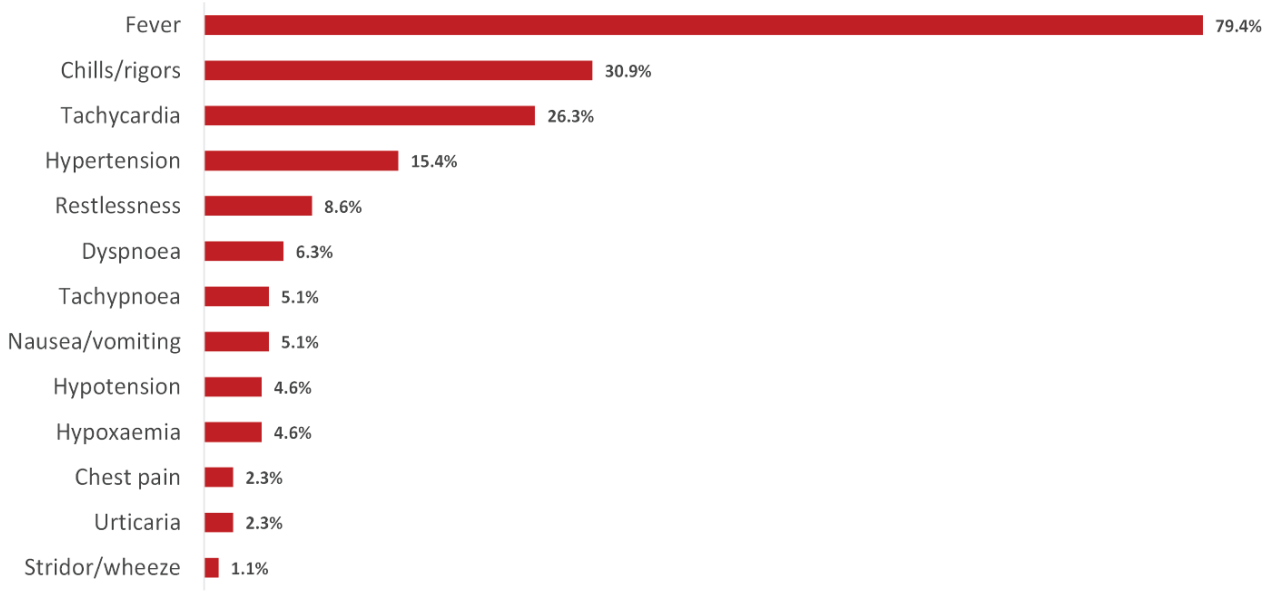
Table 3.2-1: FNHTR by blood component type 2021

Component	Reactions*	Units transfused	Rate/10,000 units transfused (95% CI)
Platelets	20	14,808	13.5 (8.6 to 21.0)
Red Cells	183	102,394	17.9 (15.5 to 20.7)
Fresh Frozen Plasma	5	11,059	4.5 (1.6 to 10.9)
Cryoprecipitate	2	6,179	3.2 (0.1 to 12.6)
Total	**210**	**134,440**	**15.6 (13.6 to 17.9)**

** Some reactions are associated with the transfusion of more than one component type.*

The signs and symptoms identified on the FNHTR reports received in 2021 are shown in Figure 3.2-1. Fever, chills and rigors are always the most frequently reported symptoms. These reactions, particularly when rigors are present, can be distressing for patients, sometimes leading to other signs such as raised heart rate and blood pressure.

Figure 3.2-1: FNHTR by associated signs and symptoms 2021



3.3 ALLERGIC TRANSFUSION REACTIONS

Mucocutaneous signs and symptoms during or within 4 hours of transfusion: morbilliform rash with pruritus, urticaria, localised angioedema, oedema of lips, tongue and uvula, periorbital pruritus, erythema and oedema, conjunctival oedema. Severe reactions may include laryngeal symptoms including throat tightness, dysphagia, dysphonia, hoarseness, stridor. Pulmonary symptoms include dyspnoea, cough, wheeze/bronchospasm, hypoxaemia. Cardiovascular symptoms include hypotension, syncope.

During 2021, 81 (24%) of the adverse reaction reports were classified as allergic reactions. Of these, 73 (90%) were non-severe and eight (10%) were severe. One of the severe cases is described in the case study below.

As seen in previous years, plasma and platelet components are associated with higher rates of allergic reactions than red cells (Table 3.3-1).

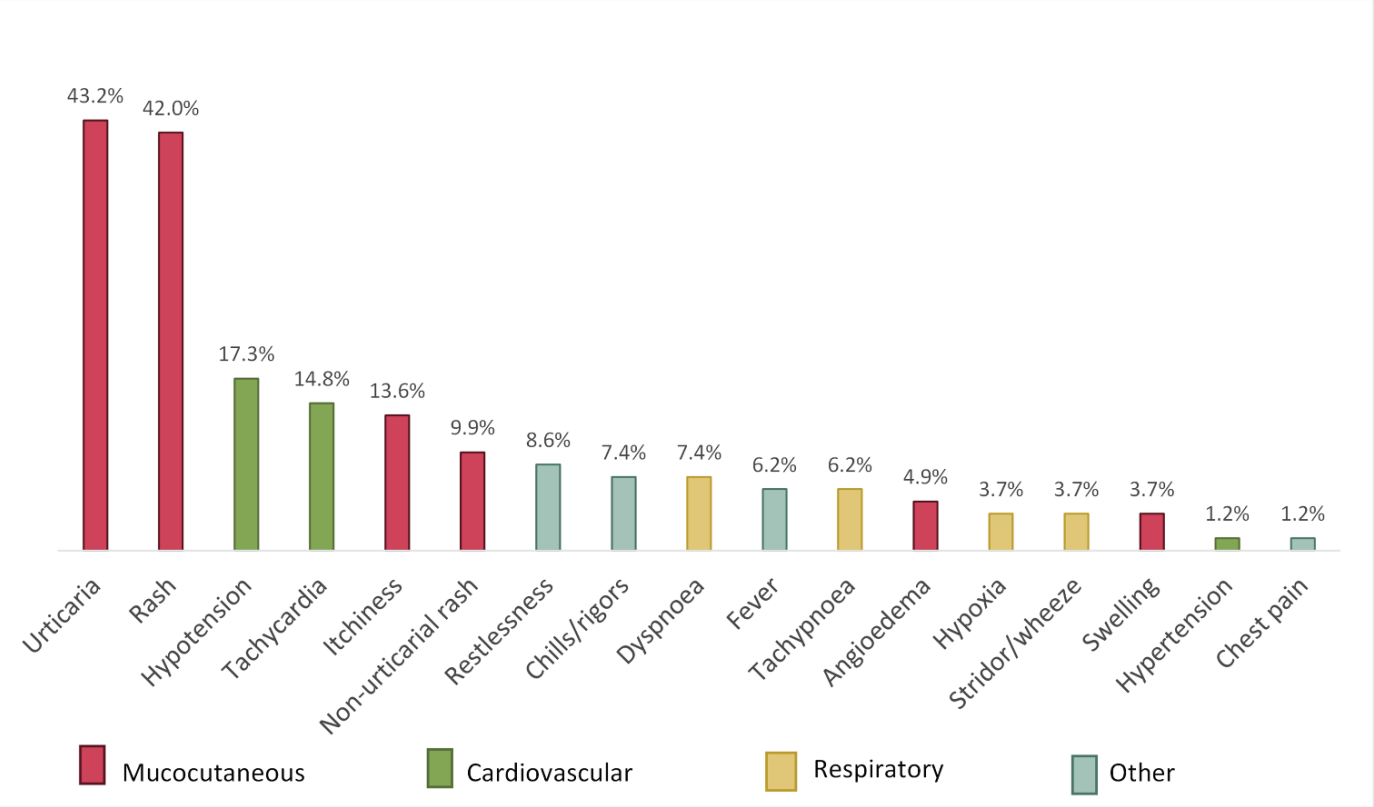
Table 3.3-1: Allergic transfusion reactions by component type 2021

Component	Reactions*	Units transfused	Frequency	Rate/10,000 units transfused (95% CI)
Fresh Frozen Plasma	33	11,059	1:335	29.8 (21.1 to 42.0)
Platelets	29	14,808	1:511	19.6 (13.5 to 28.2)
Cryoprecipitate	7	6,179	1:883	11.3 (5.0 to 23.9)
Red Cells	54	102,394	1:1,896	5.3 (4.0 to 6.9)
Total	**123**	**134,440**	**1:1,093**	**9.1 (7.7 to 10.9)**

** Some reactions are associated with the transfusion of more than one component type.*

Mucocutaneous reactions, primarily skin rashes and urticaria, constitute the highest proportion of signs and symptoms seen in allergic reactions in 2021 (Figure 3.3-1).

Figure 3.3-1: Allergic transfusion reactions by associated signs and symptoms 2021 (as % of cases – multiple symptoms per case)



CASE STUDY

Treatment of a severe allergic reaction

A 74-year-old, male patient had been diagnosed with myelodysplastic syndrome and acquired aplastic anaemia in June 2021. In December 2021 he was transfused with a unit of platelets for thrombocytopenia (platelet count 7 x 10^9/L). After receiving 330 mL of the platelet unit, he developed an extensive rash and urticaria with associated hypotension and dyspnoea.

The rash was described as widespread, accompanied with itchiness over arms and legs. He was treated with a dose of IV hydrocortisone and loratadine. This did not have the desired benefit and within five minutes of these, the patient's blood pressure dropped further to 67/40 mm Hg, he became drowsy and had difficulty breathing. At this stage, he was given intramuscular adrenaline, which promptly resolved the itchiness and drowsiness and restored the blood pressure back to normal. He required an overnight stay at the hospital and was discharged home the next day.

This case highlights a number of points:

1. Platelet transfusions are still associated with allergic reactions although the proportion of cases has dropped since the introduction of platelet additive solution (PAS). However, they still contain enough plasma to be able to elicit reactions in susceptible patients.

2. What started as an allergic reaction progressed rapidly to an anaphylactic reaction requiring intramuscular adrenaline to be administered. The patient's routine outpatient appointment turned rapidly into an inpatient admission requiring additional resources and adding to the cost of transfusion.

3. The decision to initially treat the patient with hydrocortisone and loratadine, highlights the inefficacy of these to prevent further progression of a severe allergic reaction. Only patients who are suspected to have mild reactions should be treated with oral antihistamines. In addition, the role of hydrocortisone is questionable as it will not be useful in an acute setting and its use should be strongly discouraged due to the immunosuppressive effects.

3.4 TRANSFUSION-ASSOCIATED HYPOTENSION (TAH)

Decrease in systolic and/or diastolic blood pressure of >30 mmHg occurring during or within one hour of completing transfusion. All other categories of adverse reactions presenting with hypotension must have been excluded together with underlying conditions that could explain hypotension.

During 2021, eight events were classified as transfusion-associated hypotension. Seven were non-severe and one was severe. Implicated components over the last ten years are shown in Table 3.4-1. Red cells are consistently the most commonly implicated component.

Table 3.4-1: Components implicated in TAH reactions 2012 - 2021

		Implicated Components						
Year	Total TAH Reactions	Red Cells	Pooled Platelets	Apheresis Platelets	Fresh Frozen Plasma	Cryo-precipitate	Multiple Components	Autologous Salvaged Red Cells
2012	14	10		2	1		1	
2013	2	1		1				
2014	3	2						1
2015	5	4			1			
2016	11	11						
2017	10	9			1			
2018	11	7	2	2				
2019	14	12	1			1		
2020	18	15	3					
2021	8	6	1				1	
Total	**96**	**77**	**7**	**5**	**3**	**1**	**2**	**1**
%		**80.2%**	**7.3%**	**5.2%**	**3.1%**	**1.0%**	**2.1%**	**1.0%**

3.5 PULMONARY COMPLICATIONS

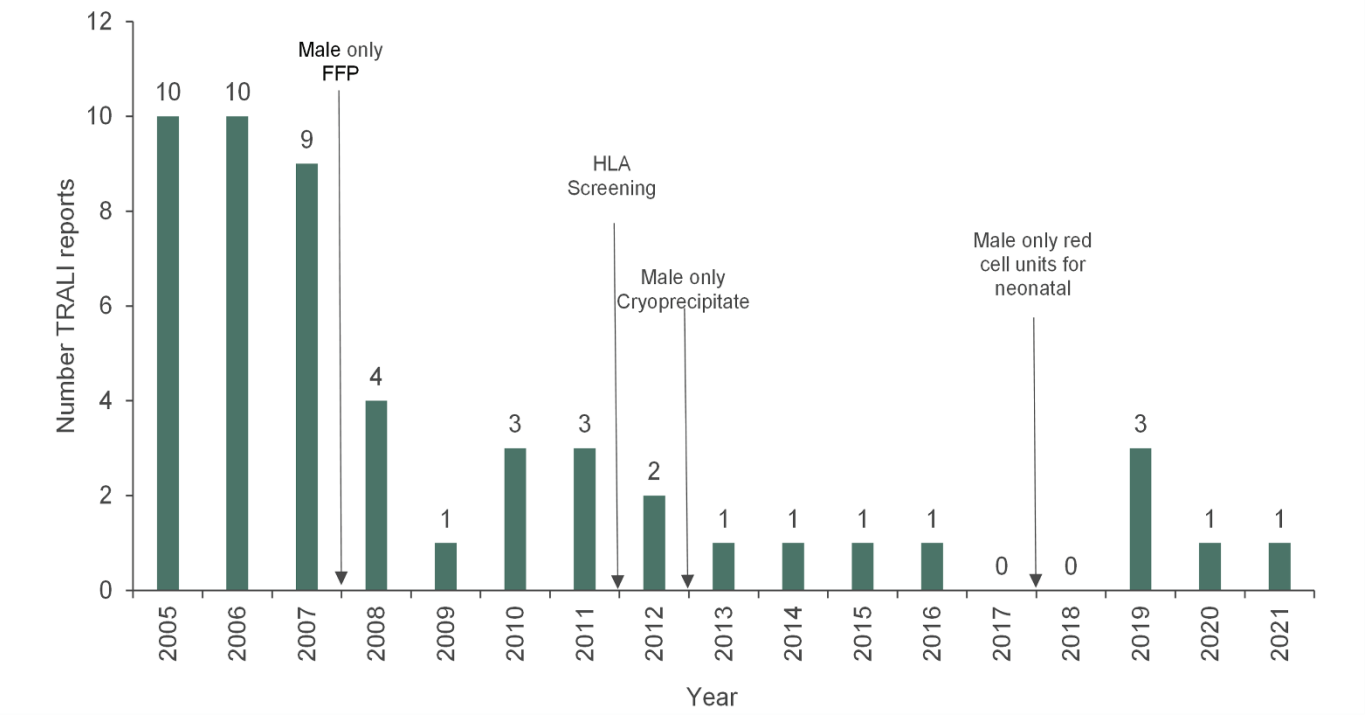
3.5.1 TRANSFUSION-RELATED ACUTE LUNG INJURY (TRALI)

New acute lung injury (ALI) in a patient with no evidence of ALI prior to transfusion. Acute onset during or within 6 hours of completion of transfusion, hypoxaemia (PaO2/FiO2 <300 mmHg, oxygen saturation <90% on room air, or other clinical evidence), bilateral infiltrates on frontal chest radiograph, no left atrial hypertension or other evidence of circulatory overload, no temporal relationship to an alternative risk factor for ALI.

Since 2005, 51 cases of TRALI have been reported to the Haemovigilance Programme. NZBS has taken a number of steps to reduce the risk of TRALI over that time and this has seen a dramatic fall in numbers of cases reported. Numbers of reported TRALI events now remain low: one event of severity grade 2 was reported in 2021.

Figure 3.5.1-1 shows the measures introduced by NZBS since 2007 to reduce the incidence of TRALI.

Figure 3.5.1-1: Annual TRALI reactions 2005 to 2021



Comparison of data from the last eight years with the years before any risk reduction measures were implemented (2005-2007), shows how the proportions of components implicated in TRALI have changed. In the earlier years, FFP was the most commonly implicated component at 38%. In the last eight years it has dropped to 9% of implicated components (Table 3.5.1-1). It should be noted that platelets in PAS have now replaced platelets in plasma, hence the proportion of these implicated is now higher than that for platelets in plasma.

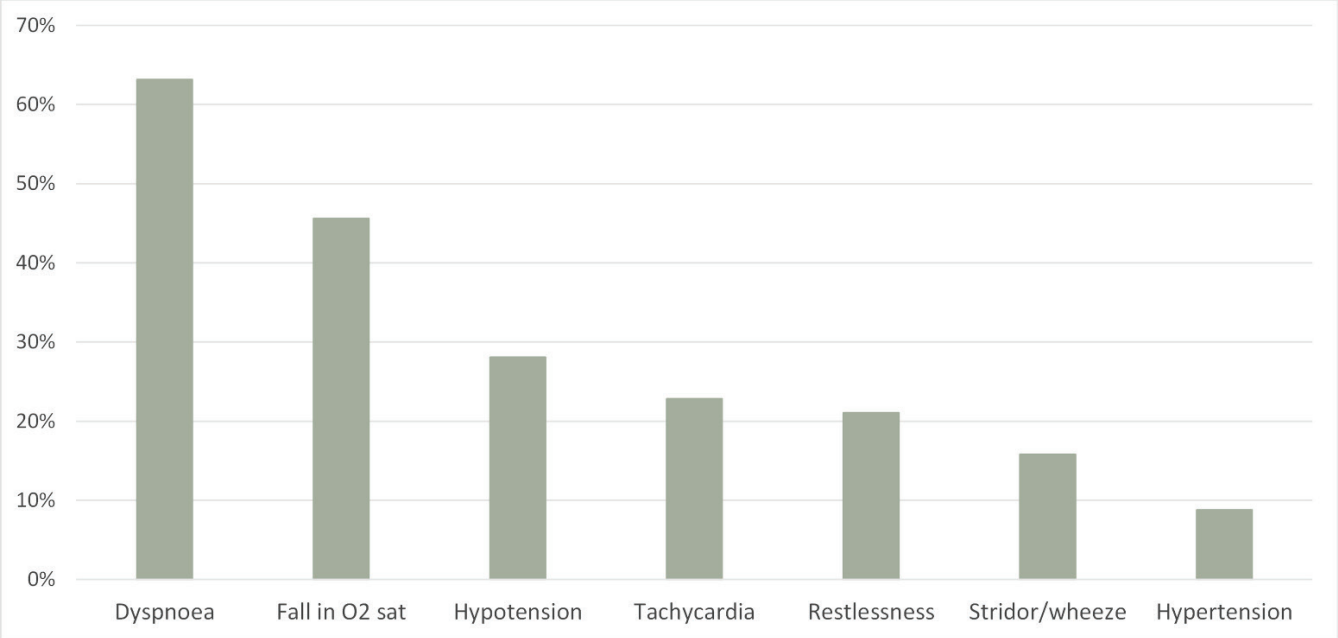
Table 3.5.1-1: Comparison of components implicated in TRALI over time

	Red Cells	FFP	Platelets in plasma	Platelets in PAS	Cryoprecipitate
2005 – 2007	33%	38%	24%	N/A*	4%
2014 – 2021	45%	9%	9%	27%	9%

** Platelets in PAS were not manufactured during this period.*

The distribution of signs and symptoms in all 51 cases is shown in Figure 3.5.1-2.

Figure 3.5.1-2: Distribution of TRALI signs and symptoms 2005 – 2021

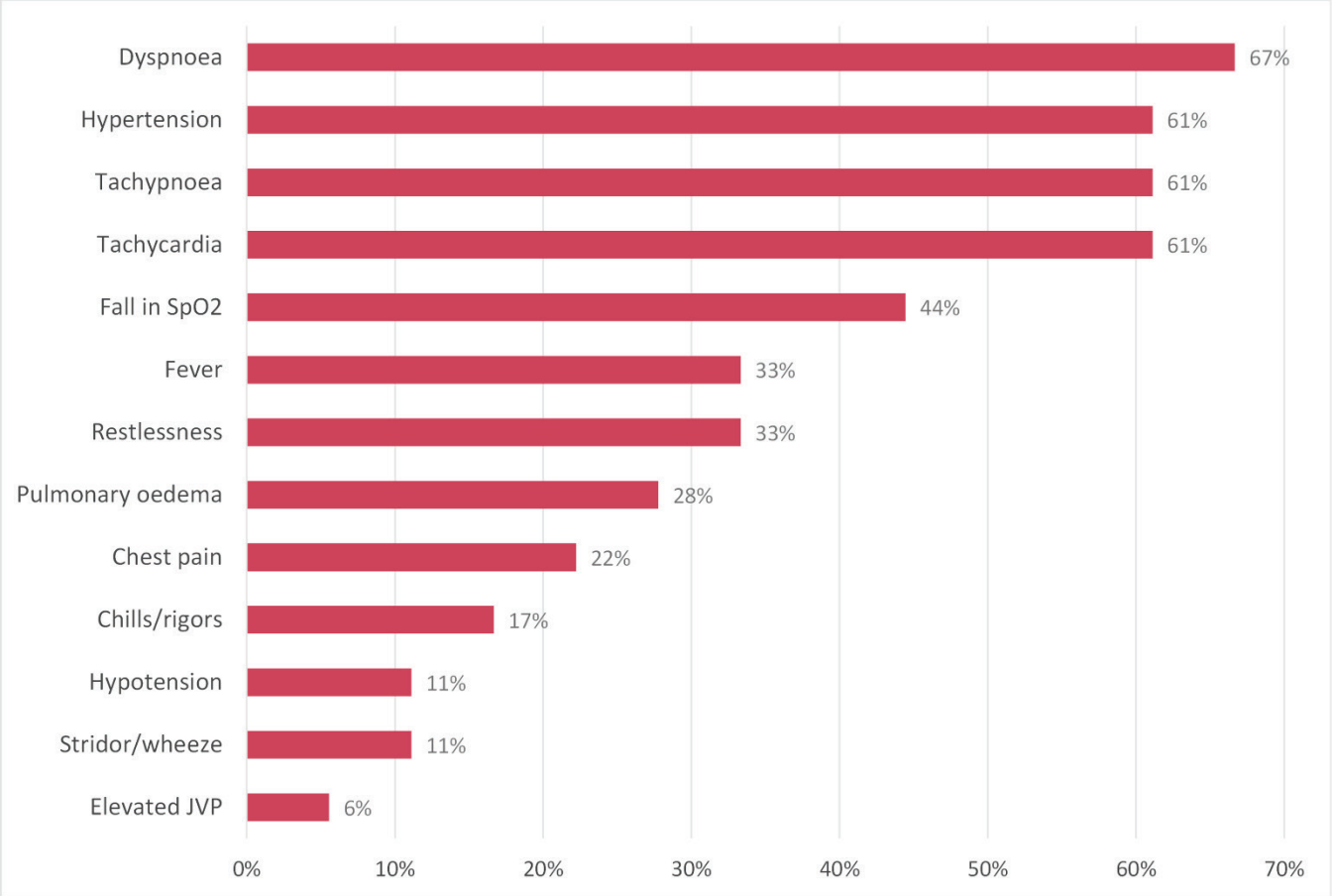


3.5.2 TRANSFUSION-ASSOCIATED CIRCULATORY OVERLOAD (TACO)

Surveillance case definition (extract from ISBT TACO definition[3]):
Acute or worsening respiratory compromise and/or evidence of pulmonary oedema (A and/or B below) during or up to 12 hours after transfusion and presence of a total of 3 or more of the criteria below:
Acute or worsening respiratory compromise
Evidence of acute or worsening pulmonary oedema
Evidence for cardiovascular system changes not explained by the patient's underlying medical condition,
Evidence of fluid overload
Supportive result of a relevant biomarker e.g. an increase of B type natriuretic peptide level (e.g., BNP or NT-pro BNP) above the age group-specific reference range and greater than 1.5 times the pretransfusion value.

During 2021, there were 18 reported TACO events (5.4% of total events). Three were non-severe, ten were severe and five were life-threatening. The signs and symptoms identified in these cases are shown in Figure 3.5.2-1.

Figure 3.5.2-1: TACO signs and symptoms as a percentage of TACO cases 2021



[3] *ISBT Working Party on Haemovigilance, IHN and AABB. Transfusion-associated circulatory overload (TACO) Definition. (2018)*

Over the last ten years there have been 155 reports of TACO reactions received. Red cells are the most frequently implicated component (Table 3.5.2-1).

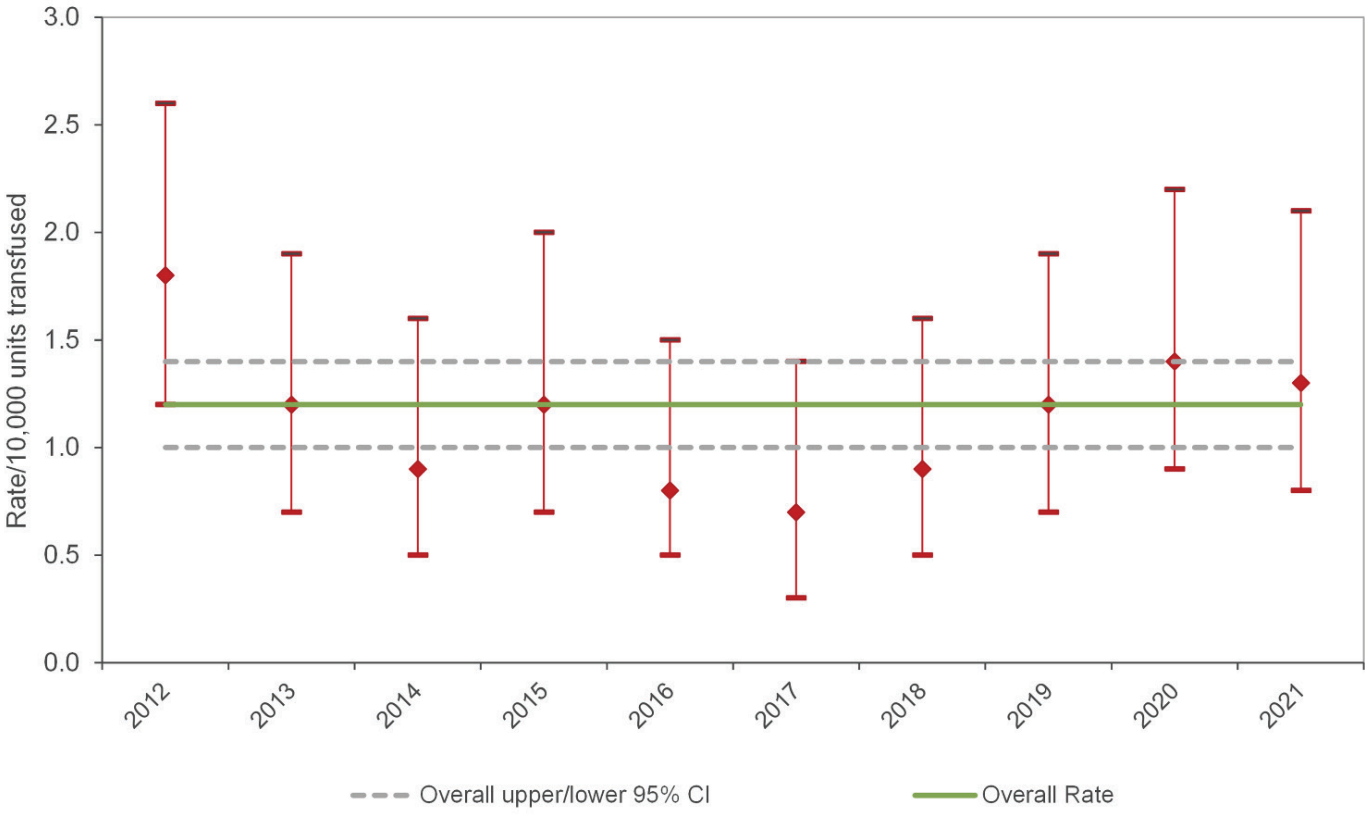
Table 3.5.2-1: Components implicated in TACO reactions 2012 – 2021

		Implicated Components*				
Period	TACO Reports	Red Cells	Platelets	FFP	Cryo-precipitate	Other
2012 – 2021	155	143	23	10	4	2
% of components		78.6%	12.6%	5.6%	2.3%	1.1%

** Some reactions are associated with the transfusion of more than one component type.*

Reporting rates for TACO have been variable over the last ten years (Figure 3.5.2-2). This may be partly because cases of TACO are not well recognised. This is an area where NZBS plans to do some work on raising awareness about TACO risks and the need to report TACO reactions.

Figure 3.5.2-2: Annual rate of reported TACO reactions (with 95% CI) 2012 – 2021



Over the last ten years TACO accounted for 4.4% of all reactions, but over a quarter of severe reactions and over two-thirds of those that resulted in death (Table 3.5.2-2).

Table 3.5.2-2: Severe TACO reactions 2012 – 2021

		Severity Grade			
		Grade 2 (Severe)	Grade 3 (Life-Threatening)	Grade 4 (Death)	Total
All adverse reactions	Number	284	43	11	338
TACO reactions	Number	76	14	8	98
	Percentage of reactions	26.8%	32.6%	72.7%	29.0%

CASE STUDY

Transfusion-related ATAK complex - double trouble with transfusion?

In three recent cases - two of whom had had RBC and one a platelet transfusion - an initial transfusion reaction occurred that suggested an allergic transfusion reaction. One developed an extensive rash; another, significant hypotension; the third, bilateral wheezes and a choking sensation in the throat. All had treatment for a severe allergic reaction. Two received adrenaline, and the third metaraminol (an adrenoreceptor agonist). Shortly after treatment the reaction changed to something resembling transfusion-associated circulatory overload (TACO). The chest X-rays in all were consistent with TACO. In one, there was echocardiographic evidence of Takotsubo cardiomyopathy or syndrome (TS). In another, echocardiography was done 18 hours post-event and global left ventricular impairment was seen. In the third, echocardiography was not done.

These cases suggest the possibility that a severe transfusion reaction that is not TACO may precipitate TACO. Thus some transfusions, in some patients, may deliver a 'double whammy'. This may be through the development of TS – a cause of acute, reversible, heart failure. TS typically presents with chest pain or shortness of breath. Ventricular wall dysfunction occurs, and characteristic echocardiographic abnormalities. ECG and biochemical features suggest cardiac ischaemia. 'Stressors' such as hypotension, asthma attacks, accidents, medical procedures, pain, bad news, etc. may precipitate it. Catecholamines such as adrenaline are believed to play a central role. They cause direct toxicity to the myocardium, and also coronary artery spasm, and increased cardiac workload. Catecholamines (e.g. noradrenaline) and stress-related neuropeptide Y are believed to play central roles in TS causing not only cardio-inhibitory effects but also acute microvascular dysfunction. Interestingly, asthma exacerbation, especially after treatment (short-acting ß2 adrenergic receptor agonist, adrenaline and intubation), is well described as a TS trigger.

Kounis syndrome (KS) is an acute coronary syndrome precipitated by severe allergic events. In KS, it is postulated that mast cell mediators such as histamine, platelet-activating factor, cytokines, and so on cause coronary artery spasm, atheromatous plaque rupture or coronary artery stent thrombosis. Drugs, foods, etc., although not yet blood or its derivatives, have been implicated. Clinical, biochemical, ECG and angiographic features overlap allergic reactions and cardiac ischaemia. Lately, the ATAK (Adrenaline-takotsubo-anaphylaxis-Kounis) complex, which overlaps TS and KS, has been described. Exogenous adrenaline may also play a role. One other such case is reported. There, a 48-year-old post-menopausal woman developed acute reversible heart failure with the features of TS, following urticaria and pruritus, whilst having a platelet transfusion. No adrenaline was given, but the authors postulate that adrenergic and histaminergic elements may have combined to produce the effect on the heart.

Thus, in some patients the 'perfect storm' compounded of,

1. borderline cardiac function,
2. catecholamine release (secondary to the stress of the underlying disorder, the transfusion, and the transfusion reaction),
3. histamine release (in allergic transfusion reaction),
4. the treatment of the allergic transfusion reaction with adrenaline
5. recent or ongoing volume overload

may be sufficient to precipitate or exacerbate TACO.

Careful consideration of cases with similar features is needed. Potential precipitating factors are modifiable or preventable. Further information and discussion can be found in the following article:

Badami KG. Transfusion double whammy? Adrenaline-takotsubo-anaphylaxis-Kounis complex post transfusion? Vox Sang. 2022;1–4 (DOI: 10.1111/vox.13257)

3.5.3 TRANSFUSION-ASSOCIATED DYSPNOEA (TAD)

Respiratory distress within 24 hours of transfusion that does not meet the criteria of TRALI, TACO, or allergic reaction and is not explained by the patient's underlying condition.

In 2021, 17 adverse reactions were classified as TAD. Cumulative data for the last ten years is shown in Table 3.5.3-1.

Table 3.5.3-1: Annual TAD reactions 2012 – 2021

Year	TAD Events	Total Units Transfused	Frequency	Rate / 10,000 Units Transfused (95%CI)
2012	15	149,668	1:9,978	1.0 (0.6 to 1.7)
2013	26	136,995	1:5,269	1.9 (1.3 to 2.8)
2014	4	135,135	1:33,784	0.3 (0.1 to 0.8)
2015	2	132,060	1:66,030	0.2 (0 to 0.6)
2016	8	130,185	1:16,273	0.6 (0.3 to 1.2)
2017	14	127,765	1:9,126	1.1 (0.6 to 1.9)
2018	11	130,361	1:11,851	0.8 (0.5 to 1.5)
2019	20	135,093	1:6,755	1.5 (0.9 to 2.3)
2020	9	131,308	1:14,590	0.7 (0.3 to 1.3)
2021	17	134,440	1:7,908	1.3 (0.8 to 2.0)
Total	**126**	**1,343,010**	**1:10,659**	**0.9 (0.8 to 1.1)**

CASE STUDY

TAD during plasma exchange

A 14-year-old child was undergoing plasma exchange following severe rejection for the deceased donor kidney transplant he had received about 9 months earlier. The reason for the kidney transplant was a background of end stage renal failure secondary to posterior urethral valves. The child had been on peritoneal dialysis since August 2018. The prognosis was guarded in the view of the transplanted kidney now being at risk of failing due to rejection.

One of the modalities of treatment involves doing a series of plasma exchanges combined with immunosuppression with a view to reduce/remove host antibodies causing the rejection. This requires replacing the patient's plasma, usually with albumin solution or FFP or sometimes a mixture of both, as in this case. The 17th plasma exchange on this young patient started at about 8:20 am with stable vital observations until the last of the four bags of FFP was about half transfused.

There was a change in the recordings with an increase in the respiratory rate from a baseline of 18 breaths/min to 25 breaths/min and increase in the pulse from 91 beats/min to 135 beats/min. There was no change in the oxygen saturations, blood pressure or the temperature. The patient remained asymptomatic, but a decision was made to stop the plasma exchange and rinse back was started. There were no further adverse events reported and the patient's pulse rate settled.

The exchanges are done under the direct supervision of a trained nurse from NZBS. Therefore, it was possible to get an accurate picture of what had happened in this case, with records available to review when the case was reported to haemovigilance.

The differential diagnoses to be excluded in this case were TACO and TRALI.

The plasma exchange was being done on a Monday and the patient had been at home over the weekend. There is little chance of fluid overload with plasma exchange as they are mostly always euvolemic. The changes in vital parameters were of short duration and settled soon after stopping the exchange. Both TACO and TRALI were thus ruled out in this case and a diagnosis of exclusion, Transfusion Associated Dyspnoea, was attributed to this incident.

3.6 HAEMOLYTIC AND SEROLOGIC TRANSFUSION REACTIONS

3.6.1 ACUTE HAEMOLYTIC TRANSFUSION REACTIONS (AHTR)

A reaction in which symptoms and clinical or laboratory signs of increased red cell destruction occur at any time up to 24 hours following the transfusion of blood or a blood component.

Three AHTRs were reported in 2021, two of which were due to passively acquired red cell antibodies in paediatric patients. The third was a very unusual case of microangiopathic haemolytic anaemia (MAHA). The cases are described in Table 3.6.1-1.

Table 3.6.1-1: AHTRs 2021

Type of reaction	Patient	Description
Passive anti-A,B	4-month-old male	Paediatric oncology patient, group AB RhD Positive. Five units of group O neonatal platelets suspended in plasma administered over 4 days. DAT was positive on the last day of transfusion. The infant's Hb was 81 on the third day of transfusion but on day 4 it fell from 67 g/L at 06:05 to 44 g/L at 16:25. Bilirubin rose from 13 µmol/L at 06:05 to 30 µmol/L at 18:00 on day 4.
Passive anti-B	7-year-old male	A unit of group O platelets causing an allergic reaction and haemolysis in a group B child. See case study below.
Non-immune haemolysis	38-year-old female	This patient had an unusual non-immune haemolytic event with a history of uterine bleeding and a previous haemolytic event that also appeared to be triggered by transfusion. A complement-mediated microangiopathic haemolytic anaemia (MAHA) is considered likely. This case occurred at the end of the year, and a second similar reaction occurred in early 2022. At time of publishing, results of further investigations are awaited. The case will be discussed further in the 2022 annual report.

CASE STUDY

Passive anti-B haemolysis in a child

A seven-year-old B RhD positive male child was admitted to the Paediatric Oncology Unit with Hb 50 g/L and platelet count 12 x 10^9/L. One unit of O RhD positive platelets was administered in the evening, followed by a unit of B RhD positive red cells, to allow a bone marrow examination to be done for a suspected diagnosis of acute leukaemia. The immediate post-platelet transfusion period was noted to be uneventful, however, shortly thereafter, the child complained of general itchiness and described "feeling weird". He was reviewed by the Registrar, who considered the reaction unlikely due to the platelet transfusion. Further complaints of abdominal pain on palpation were voiced but an initial offer to treat it by paracetamol was refused.

The red cell transfusion was started approximately 5 hours after the platelet transfusion, in the early hours of the next morning. This was accompanied by a 2.2 °C rise in temperature, restlessness and anxiety. The only vital sign change notes in the transfusion reaction report was an increase in the respiratory rate from 17 breaths/min baseline to 23 breaths/min after. About two-thirds of the unit was transfused before it was stopped and advice sought about the possibility of a transfusion reaction.

Later that morning, the haemoglobin was noted to have risen to 72 g/L. The two reactions to blood components were discussed with the on-call TMS. The first reaction to platelets was deemed to be allergic. The second reaction was thought to be haemolytic and further blood investigations were suggested, which included full blood count and film, repeat group & screen, direct antiglobulin test (DAT), bilirubin, haptoglobin, LDH, reticulocytes, coagulation screen, C3 & C4 levels and urine for haemoglobinuria.

The investigations were conclusive of an acute episode of haemolysis with DAT positive, C3d only, but the eluate was negative. There was a rise in bilirubin levels from a baseline level of 5 µmol/L to 46 µmol/L. It was concluded that the O RhD Positive unit of platelets, caused an allergic reaction and acute haemolysis due to passive anti-B in the platelet unit.

Points of interest:

1. An unusual scenario where a single blood component caused two different acute transfusion reactions.

2. Haemolysis due to Anti-B in plasma occurs much less frequently than with Anti-A. The haemolysin screening method consists of a single dilution step against AB red cells, which also does not pick up any IgM antibodies. This is of significance when group O blood components are given to either Group A or B recipients as both anti-A & anti-B antibodies can be both IgG & IgM.

3. A useful discussion with the on-call Transfusion Registrar led to correct differential diagnosis and correct investigations being ordered in a timely manner.

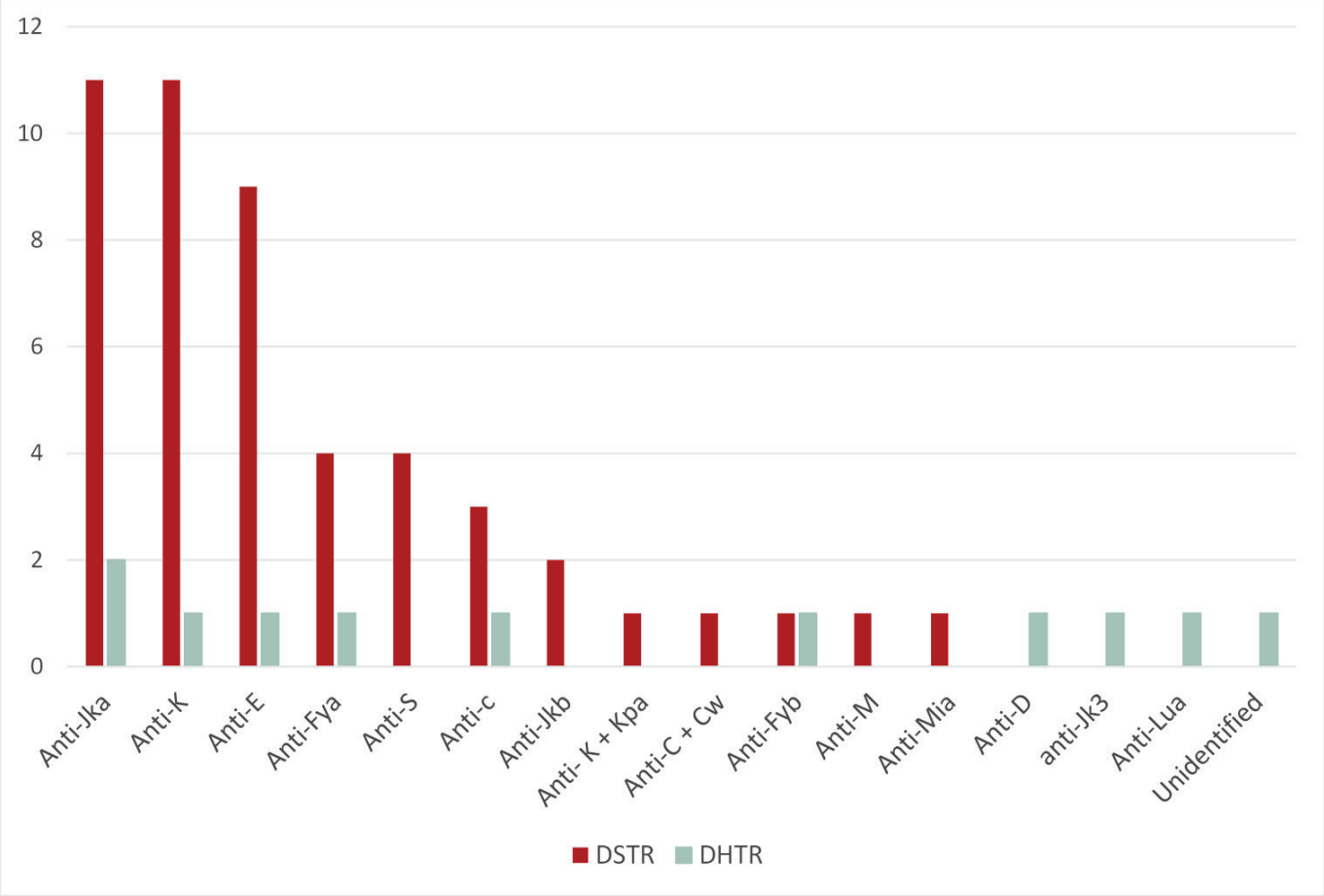
3.6.2 DELAYED HAEMOLYTIC/SEROLOGIC TRANSFUSION REACTIONS (DHTR / DSTR)

A DHTR usually manifests between 24 hours and 28 days after a transfusion and clinical or laboratory features of haemolysis are present. Signs and symptoms are similar to AHTR but are usually less severe. DHTR may sometimes manifest as an inadequate rise of post-transfusion haemoglobin level or unexplained fall in haemoglobin after a transfusion. Blood group serology usually shows abnormal results.

DSTR should be considered when, after a transfusion, there is demonstration of clinically significant antibodies against red blood cells which were previously absent (as far as is known) and the DAT is positive but there are no clinical or laboratory features of haemolysis.

During 2021, there were two DHTR reports received and twelve DSTR reports. Fig 3.6.2-1 details the specificities of the blood group antibodies implicated in the DHTR and DSTR events over the last five years.

Figure 3.6.2-1: DHTR and DSTR by red cell antibody specificity 2017 – 2021



3.7 OTHER TRANSFUSION REACTIONS

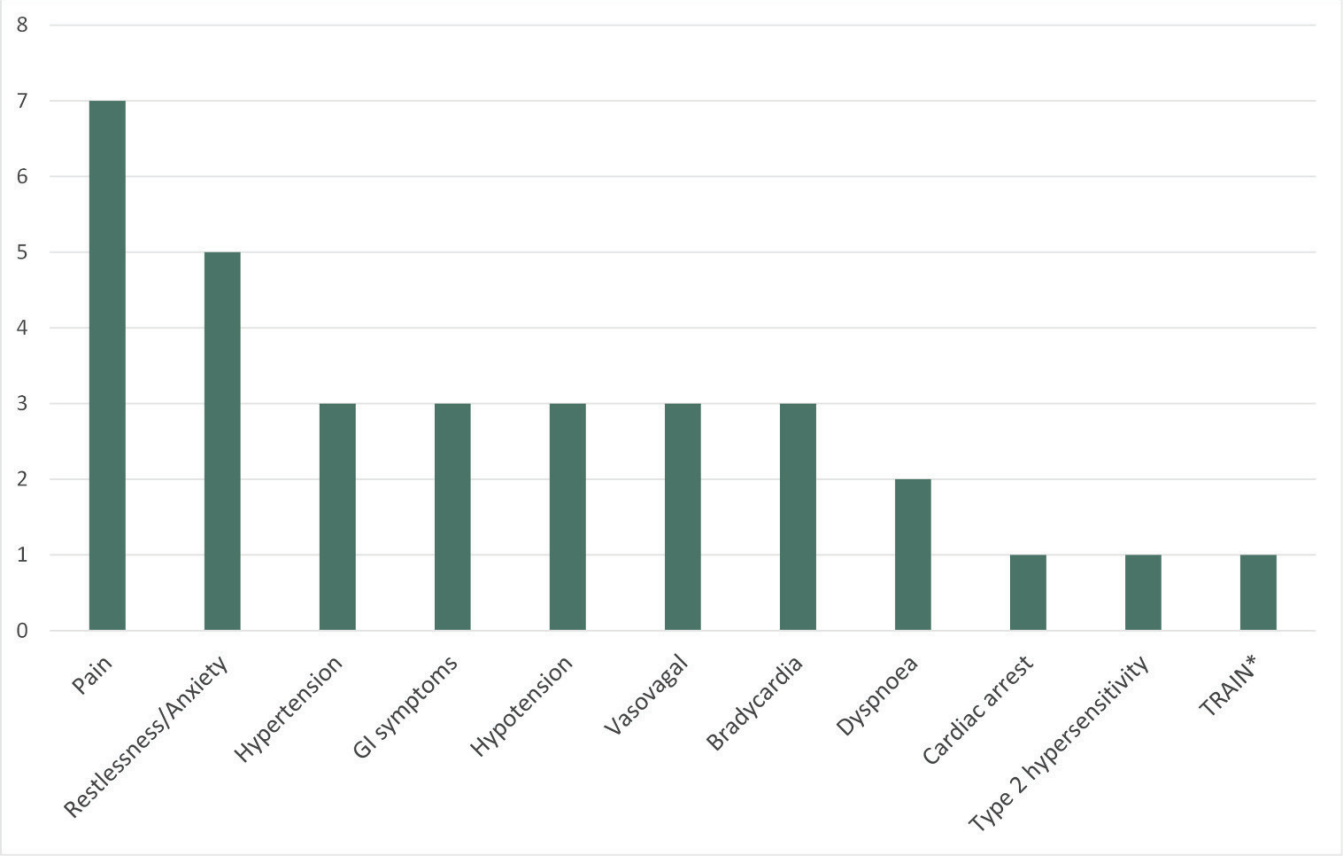
3.7.1 UNCLASSIFIABLE COMPLICATIONS OF TRANSFUSION (UCT)

Occurrence of an adverse effect or reaction temporally related to transfusion, which cannot be classified according to an already defined event, with no risk factor other than transfusion.

During 2021, there were 18 reports of adverse reactions which could not be classified into a definitive category, ten in females and eight in males.

A wide range of signs and symptoms can be seen in UCTs. In 2021 there were 32 signs and symptoms reported for the 18 events (Figure 3.7-1).

Figure 3.7-1: Numbers of signs and symptoms reported in UCT cases 2021



** TRAIN = Transfusion-related autoimmune neutropenia*

3.7.2 HAEMOSIDEROSIS

Transfusion-associated haemosiderosis is being defined as a blood ferritin level of > 1000 µg/L, with or without organ dysfunction in the setting of repeated RBC transfusions.

To date the Haemovigilance Programme in NZ has not received any reports of haemosiderosis. This is an important complication of chronic transfusion that may not be being detected in some patient groups. We are aware of one hospital that is amending its transfusion consent form to include information for patients about the risks of chronic transfusion.

3.8 REPORTS INVOLVING PAEDIATRIC PATIENTS

During 2021, there were 21 ATRs reported involving recipients aged 15 years and younger (Table 3.8-1).

Although 17 (81%) of the reactions occurred in males in 2021, the gender split in 2020 was more even: 14 females and 12 males. The rate of events in paediatric patients was 25.1/10,000 units transfused. This is slightly lower than 2020 (35.8).

Table 3.8-1: ATRs in paediatric patients by event type, rate, gender and severity 2021

Event Type	Number	Percentage of Events	Rate/10,000 units transfused	Gender		Severity Score	
				Female	Male	1	2
Allergic	9	42.9%	10.7	1	8	7	2
FNHTR	7	33.3%	8.4	3	4	7	-
AHTR	2	9.5%	2.4	-	2	2	-
TAH	1	4.8%	1.2	-	1	1	
TAD	1	4.8%	1.2	-	1	1	
UCT	1	4.8%	1.2	-	1	1	
Total	**21**		**25.1**	**4**	**17**	**19**	**2**

The two severe events were allergic reactions.

Table 3.8-2: Frequency and rate of paediatric ATRs by component type 2021

Component	Events*	Units transfused	Frequency	Rate/10,000 units transfused (95% CI)
Platelets	12	2,403	1:200	49.9 (27.5 to 88.1)
Red cells	9	4,780	1:531	18.8 (9.3 to 36.4)
Plasma	2	808	1:404	24.8 (0.6 to 96)
Cryoprecipitate	2	390	1:195	51.3 (1.5 to 197.6)

** Some reactions are associated with the transfusion of more than one component type.*

Errors and near misses related to children are described in Chapter 4.

3.9 RARE ADVERSE TRANSFUSION REACTIONS

3.9.1 POST-TRANSFUSION PURPURA (PTP)

Thrombocytopenia arising 5 - 12 days following a transfusion of cellular blood components with findings of antibodies in the patient directed against Human Platelet Antigen (HPA) system.

No cases of PTP were reported in 2021.

Only two cases of PTP have been reported to the National Haemovigilance Programme since 2005, one in 2019 and one in 2020.

3.9.2 TRANSFUSION-ASSOCIATED GRAFT-VERSUS-HOST DISEASE

TA-GVHD is a clinical syndrome characterised by symptoms of fever, rash, liver dysfunction, diarrhoea, pancytopenia and findings of characteristic histological appearances on biopsy occurring 1-6 weeks following transfusion with no other apparent cause. The diagnosis of TA-GVHD is further supported by the presence of chimerism.

No cases of TA-GVHD were reported in 2021 and none have been reported since the National Haemovigilance Programme began in 2005.

3.10 TRANSFUSION-TRANSMITTED INFECTIONS (TTIs)

3.10.1 DONOR INFECTIOUS DISEASE SCREENING

In New Zealand, all blood donations are screened for HBsAg, HBV DNA, anti-HCV, HCV RNA, anti-HIV-1/2, HIV RNA and syphilis antibody. All new donors are also tested for anti-HTLV-I/II. Additional testing is performed on selected donations, e.g., CMV IgG antibody for fetal and neonatal transfusions, Trypanosoma cruzi (Chagas Disease) and malarial antibody tests in donors who may pose a risk due to residence and/or travel to affected areas.

During 2021, 91,327 donors were tested. Of these, 83% were repeat donors and 17% were first-time donors (previously untested). Numbers and rates of confirmed positive infectious markers for 2021 are shown in Table 3.10.1-1.

Table 3.10.1-1: Donors with confirmed positive infectious markers 2021

		HBV	HBV Occult	HCV	HIV	Syphilis	HTLV I/II
Number	First-time donors (n = 15,527)	2	0	9	1	16	0
	Repeat donors (n =75,800)	0	22	1	0	8	-
	Total donors (n = 91,327)	2	22	10	1	24	0
Rate per 10,000 donors	First-time donors	1.3	0	5.8	0.6	10.3	0
	Repeat donors	0	2.9	0.1	0	1.1	-
	All donors	0.2	2.4	1.1	0.1	2.6	0

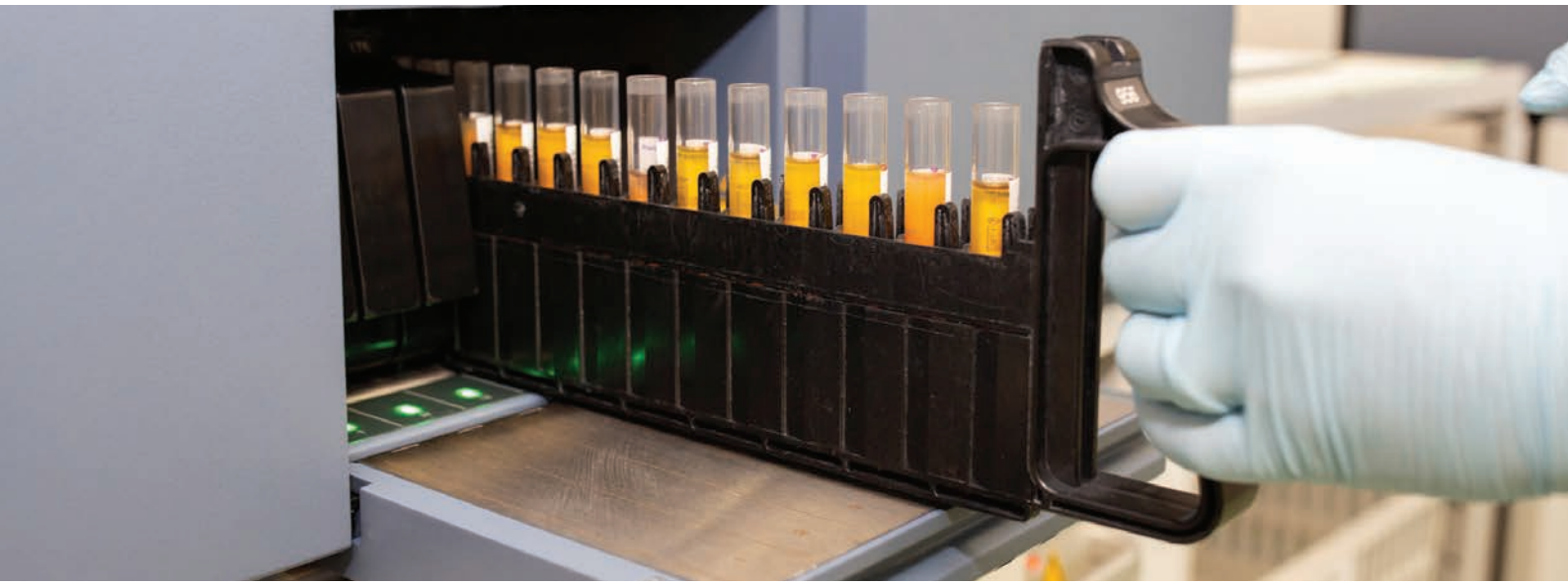
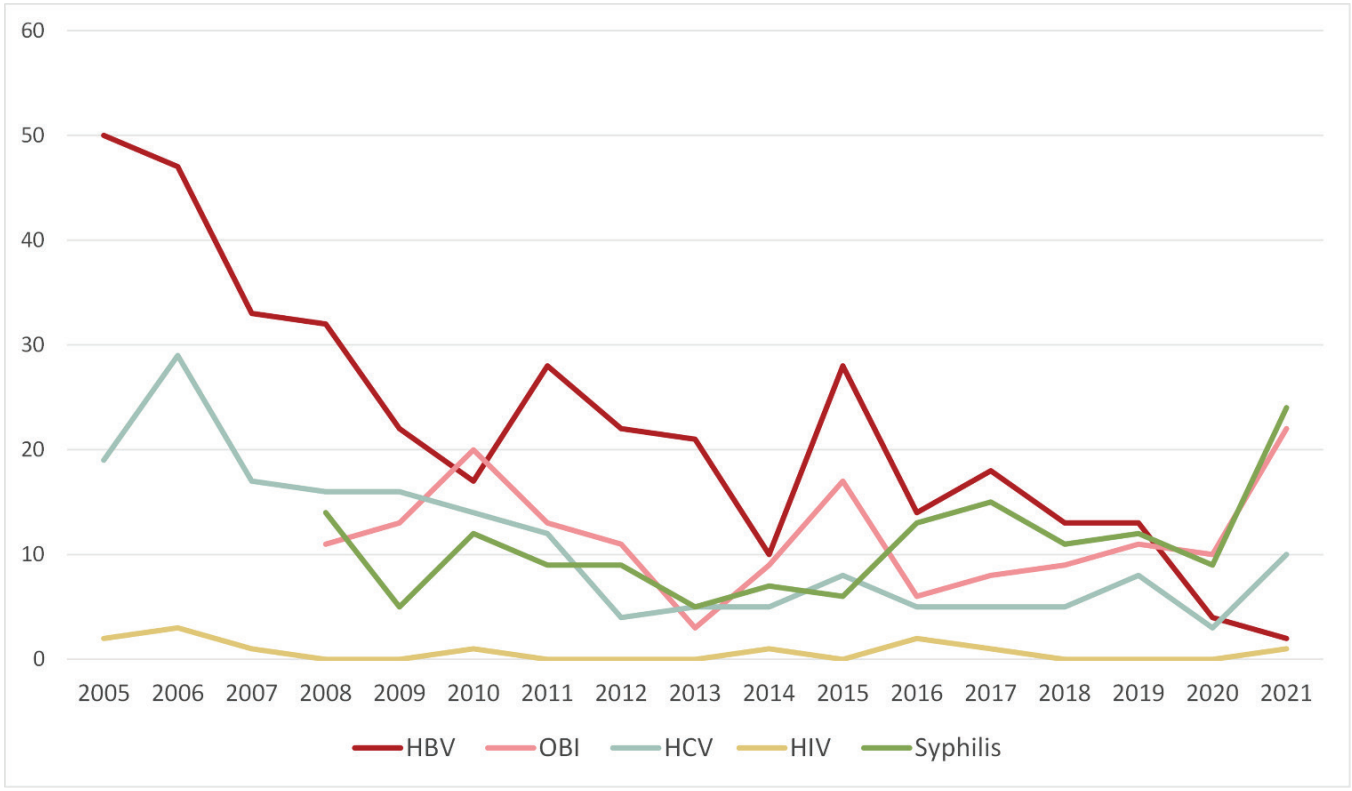


Figure 3.10.1-1 shows numbers and trends of confirmed positive infectious markers in donors since 2005. The number of HBV infections (HBsAg positive) detected in donors has been trending downwards since 2005. This continued into 2021, despite a significant increase in plasma collections over the previous two years.

Cases of occult hepatitis B (OBI) in donors also more than doubled from 2020. Occult hepatitis B is generally characterised by detectable HBV DNA, negative HBsAg, positive hepatitis B core antibody and low levels of hepatitis B surface antibody. OBI is still the most frequent reason for conducting donor-triggered lookback.

The number of syphilis infections detected in donors has been trending upwards since 2013 and the number detected in 2021 was more than double that in 2020. This is a reflection of the increasing incidence of syphilis in the community in New Zealand over the same period. Although the public health data appear to show a decrease in community incidence from mid-2019, the national testing laboratory, ESR, explains that the Covid-19 pandemic has caused a "highly unusual, rapid change in the epidemiology of many infectious diseases"[4] .

Figure 3.10.1-1: Annual number of donors with confirmed positive infectious markers 2005 – 2021



[4] *ESR STI Dashboard interpretation document, 2020.*
https://www.esr.cri.nz/assets/Uploads/ESR-STI-Dashboard-interpretation-2020-Q2.pdf

3.10.2 LOOKBACK

All cases of potential transfusion transmitted infections are investigated by NZBS. Lookback may be donor-triggered or recipient-triggered.

Donor-triggered lookback

- *A donor, who has previously tested negative for NZBS mandatory infectious marker screening, is repeat reactive on the current donation and confirmed positive for an infection. All previous donations in the preceding 24 months are traced. Clinicians of living recipients are notified and asked to undertake appropriate testing on the recipient. For occult hepatitis B infections (OBI) lookback extends back as far as donor records allow.*
- *A donor or healthcare provider notifies NZBS that a donor has developed signs or symptoms of an infection after a donation indicating that his/her donation may have been infectious.*

In 2021, 15 donors were identified as requiring donor triggered lookbacks: one syphilis and 14 OBI. Post transfusion test results were obtained on 46/78 (59%) living recipients.
No conclusive transmissions were identified (Table 3.10.2-1).

Table 3.10.2-1: Summary of donor-triggered lookbacks conducted in 2021

Lookbacks conducted	15
Total recipients	165
Living recipients	78
Recipient test results obtained	46
Confirmed positive recipients*	0

** Two inconclusive results were received.*

Recipient-triggered lookback

NZBS is informed that a recipient of blood components or products has developed a reactive laboratory test result and/or disease symptoms indicating that a blood component or product may have been infectious for HBV, HCV, HIV, HTLV, a bacterial infection or any other infection that may be transmitted through blood transfusion. Archived samples of these donations are re-tested and confirmatory testing is carried out. Implicated donors are traced and asked to provide samples for retesting if they have not donated or have not been retested since their implicated donation.

In 2021, one potential transmission of HBV was reported in a patient with relapsing myeloma post HPC transplant. The investigation was inconclusive. One donor had anti-HBc with an anti-HBs of >300 IU/L. A reactivation of the infection in the patient could not be ruled out.

3.10.3 BACTERIAL TESTING OF PLATELET COMPONENTS

NZBS performs pre-release sampling for bacterial culture on all platelet components. This provides NZBS with an indication of bacterial contamination rates in its donations. This practice is carried out in a number of countries, although there are slight variations in practice, such as timing of sampling, volume of inoculum and duration of incubation. NZBS samples platelet components on day 2 (at least 36 hours after collection), inoculates 8 mL into each of the aerobic and anaerobic culture bottles and incubates to day 7.

Initial positives are further tested to confirm the result and identify the organism. The following AABB definitions[5] are used for the classification of test results:

Initial positive	Positive or abnormal (out of range) initial test
False positive	Positive on initial test & both the remainder of unit negative & recipient has no clinical or microbiological evidence of sepsis
Indeterminate	Positive on the initial test and either no confirmatory test was performed or results could not be interpreted
True positive	Positive on initial test and confirmatory test - the confirmatory test must be culture-based and be performed on a different sample than the culture bottle or other sample used for the initial test e.g. a sample source for the confirmatory test could be the original platelet component. A subculture of the initial positive culture is not an adequate sample for this purpose. If transfused: the remainder of component is positive or recipient has sepsis or positive blood culture with the same organism.

A total of 14,915 platelet pools and apheresis platelet donations were tested in 2021 (Table 3.10.3-1). 61 units were initial positive and, of these, 20 were confirmed as true positive (0.13% of the total number tested).

Table 3.10.3-1: Platelet bacterial culture summary 2021

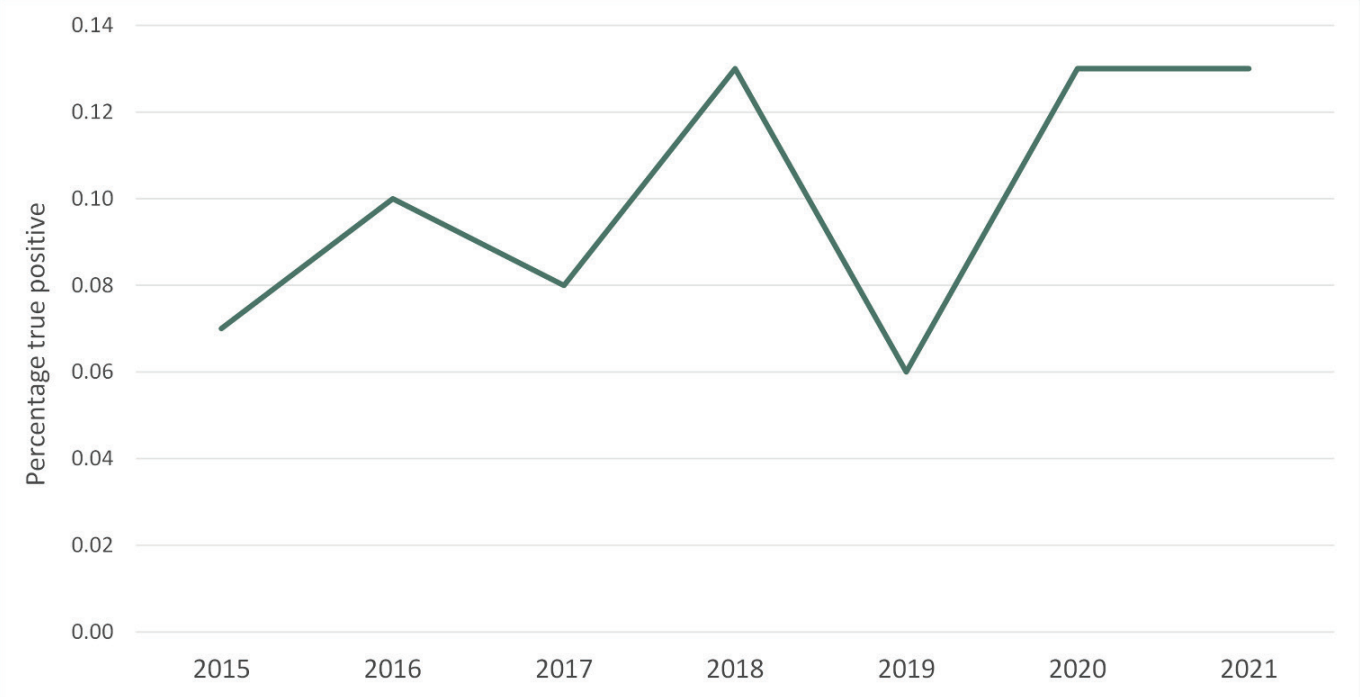
Result	Number of units*	Percentage of number tested
Number tested	14,915	
Non-reactive	14,854	99.59 %
Initial positive	61	0.41 %
False positive	26	0.17 %
Indeterminate	15	0.10 %
True positive	20	0.13 %

** For platelet testing, one unit is either one platelet pool or one apheresis platelet donation that may be subsequently split.*

[5] *AABB Association Bulletin #04-07: Actions following an initial positive test for possible bacterial contamination of a platelet unit (2014).*

The EDQM Guide[6] indicates that contamination rates at or below 0.2% are generally reported in surveillance studies. NZBS bacterial contamination rates have remained below 0.14% since testing began in 2015 (Figure 3.10.3-1).

Figure 3.10.3-1: Confirmed positive bacterial culture rates 2015 – 2021



Seven of the true positive units were transfused and all were platelet pools (Table 3.10.3-2). NZBS medical staff followed up with the clinical teams of the seven recipients. No sepsis was reported in any of the patients.

Table 3.10.3-2: Bacterial species identified in confirmed positive cases 2021

Species	Number	
	Total	Transfused
Cutibacterium acnes	11	5
Staph epidermidis	2	0
Staph capitis	3	1
Staph saccharolyticus	1	0
Strep agalactiae	1	0
E coli	1	0
Propionibacterium sp	1	1
Total	20	7

[6] *Guide to the preparation, use and quality assurance of blood components. European Directorate for the Quality Medicines & Healthcare of the Council of Europe (2020).*

NZBS takes steps to reduce the risk of bacterial contamination of components. These include a standardised and validated skin disinfection process and diverting the first 30 mL of blood drawn into a sample diversion pouch for filling tubes for testing. However, contamination from skin flora can never be completely eliminated.

No cases of bacterial sepsis in a transfusion recipient were reported to the Haemovigilance unit for investigation during 2021.

CHAPTER 4

ERROR REPORTS

04 ERROR REPORTS

Error and near miss reports in this chapter relate to blood components and fractionated products, and are separate from the request form and sample labelling errors reported in section 4.5.

Although reporting rates for errors and near misses are still low, 2021 shows an increase in the total number compared with the previous four years. There were 96 errors and near misses reported in 2021 compared with 51 in 2020 (see Figure 2-3, Chapter 2).

For the NZBS Blood Banks, error and near miss data can be extracted from the NZBS incident reporting system. For hospitals and non-NZBS Blood Banks the Haemovigilance Office relies on clinicians and health professionals to notify all occurrences of these incidents through their organisation. Reports received from non-NZBS Blood Banks tend to be only the more serious errors such as IBCT. Currently, near misses are rarely reported.

It is encouraging to note there is a growing awareness of the need to report wrong blood in tube events (WBIT) and we are starting to receive these from some non-NZBS Blood Banks.

Most errors and near misses reported occurred in the clinical area (70 out of 96). The largest category was WBITs, followed by those involving errors with RhD immunoglobulin (anti-D). See summary in Table 4-1.

Table 4-1: Error and near miss summary 2021*

Error	Clinical error	Blood Bank Error	Error total	Error %
Incorrect blood component transfused (IBCT)	2	2	4	4.2
Incorrect fractionated product administered	1	1	2	2.1
Anti-D errors and near misses	9	7	16	16.7
Storage and handling errors	10	1	11	11.4
Avoidable transfusions	2	-	2	2.1
Avoidable delays	-	4	4	4.2
Near misses	3	11	14	14.5
Wrong Blood in Tube (WBIT)	43	-	43	44.8
Total	**70**	**26**	**96**	**100**

** Excluding sample and form labelling errors.*

There are nine Transfusion Nurse Specialists (TNSs) in New Zealand, six employed by NZBS and three by DHBs. They work closely with hospital staff to provide advice and some education on all aspects of the transfusion process. They have a key role in following up on errors and assisting with investigations. During 2021, Covid-19 related restrictions reduced education opportunities and access to clinical areas, and this has delayed some improvements planned by NZBS.

4.1 INCORRECT COMPONENT/PRODUCT ADMINISTERED

Transfusion of a blood component or product that was intended for another patient, or one that did not meet the patient's requirements.

4.1.1 INCORRECT BLOOD COMPONENT TRANSFUSED (IBCT)

During 2021, there were four IBCT events reported, compared with ten reported in 2020. The IBCT events for 2021 are detailed in Table 4.1.1-1.

Table 4.1.1-1: IBCT events 2021

IBCT type	Reason	Origin	Number
SRNM Special requirements not met *(Unintentional transfusion of blood that did not meet the specific requirements for the patient)*	Irradiated blood not transfused. Blood Bank not informed of requirement.	Clinical	1
	Antigen positive red cells transfused to patient with anti-e.	Laboratory	1
	21-day-old red cells transfused to a patient with a documented requirement for fresh blood.	Laboratory	1
WCT Wrong component transfused *(Transfusion of wrong patient, wrong component, or wrong group)*	Emergency O RhD negative red cells transfused when crossmatched blood was available.	Clinical	1
TOTAL			**4**

4.1.2 INCORRECT FRACTIONATED PRODUCT ADMINISTERED

There were two reports of an incorrect fractionated product being administered in 2021.

Table 4.1.2-1: Incorrect fractionated product events 2021

Error	Error Location
A patient was prescribed and approved to receive Privigen® but because a protocol had not been entered in the computer system, Intragam® P was issued and administered in error.	Blood Bank
A patient was given one bottle of Intragam® P labeled for a different patient. No harm occurred because the patient receiving the product had also been prescribed Intragam® P.	Clinical

4.2 ANTI-D ERRORS AND NEAR MISSES

Thirteen errors and three near misses involving anti-D were reported in 2021 compared with eight errors and one near miss in 2020 (see Table 4.2-1).

Table 4.2-1: Anti-D errors and near misses 2021

Error	Clinical error	Blood Bank error	Error total
Anti-D administered to an RhD positive woman	4	-	4
Anti-D administered to a woman with immune anti-D	-	2	2
Anti-D administered to the mother of an RhD negative baby	1	-	1
Anti-D administered to the wrong patient	3	-	3
Incorrect route of administration	1	-	1
Anti-D not administered with RhD positive components (when indicated)	-	1	1
Anti-D storage and handling error	-	1	1
Anti-D near miss	-	3	3
Not given when indicated or administered late	-	-	-
Wrong dose of anti-D administered	-	-	-
Total	**9**	**7**	**16**

Typically, Blood Bank errors include misreading the request form, accidentally picking the wrong dose of product from inventory and not checking for or not being aware of the procedure for women with immune anti-D.

Clinically, the main errors are a result of either not properly checking patient identification or not properly checking details on the patient history, such as blood group and antibody status. In all three cases where product was administered to the wrong patient, identification was not properly checked. Of the four cases where anti-D was administered to an RhD Positive woman, two involved the same woman. We have received anecdotal information from some hospital staff that protocols for patient identification are not routinely followed in the maternity wards. This may be because midwives are familiar with their own patients and therefore neglect the patient identification process. Hospitals should take steps to ensure that midwives using their facilities adhere to patient identification policies. It also appears that midwives do not always have reliable access to patient laboratory test results. This is crucial when making decisions around anti-D requirements and all hospitals should ensure midwives have access to the information they require.

The errors involving patient identification in the maternity setting are also evident in the wrong blood in tube data, section 4.4.1.

4.3 OTHER ERRORS

4.3.1 STORAGE AND HANDLING ERRORS

Administration of the correct blood component or product to the intended patient, where handling or storage errors may have affected component or product safety.

Storage and handling errors include administration of expired components or products and errors in the administration process.

Table 4.3.1-1: Storage and handling errors 2021

Error		Error Location	Error total
Blood components			
Administration errors	No blood filter used with giving set *(note 1)*	Clinical	4
	Incorrect infusion rate	Clinical	2
Storage errors	Red cells stored in freezer prior to transfusion (see case study below)	Clinical	1
Expired component	Expired FFP issued and transfused	Blood Bank	1
Subtotal			**8**
Fractionated Products			
Administration errors	Incorrect infusion rate – Privigen® *(note 2)*	Clinical	2
	Incorrect route of administration: IM RhD immunoglobulin administered subcutaneously	Clinical	1
Subtotal			**3**
Total storage and handling errors			**11**

Notes:

1. In some hospitals, blood giving sets with in-line filters were recalled and replaced with sets without in-line filters. This resulted in some staff forgetting to connect a filter to the new set.

2. Privigen® is an intravenous immunoglobulin that is not as widely used in NZ as Intragam® P. It is more concentrated than Intragam® P is therefore administered at a lower infusion rate. Staff who are not familiar with it sometimes administer Privigen® at the same rate as Intragam® P. CSL Behring has now made information cards available that highlight the difference in infusion rates.

STORAGE AND HANDLING CASE STUDY

Freezer storage of red cells prior to transfusion

A 67-year-old male with a complex medical history, presented to ambulatory care for a semi-acute elective transfusion. His haemoglobin had been trending down (98 g/L), after receiving chemotherapy one week prior, but fell to 69 g/L over a 48-hour period due to ongoing gastrointestinal bleeding at home. He was feeling acutely breathless, hypotensive and severely fatigued on arrival. Reticulocytes noted to be 131 $x10^9$/L.

Because the hospital where the transfusion took place does not have an on-site Blood Bank, three units of compatible red cells were shipped from the local Blood Bank provider. The hospital has an approved blood refrigerator on site to store red cells received from the Blood Bank. The refrigerator is located in the theatre area, next to a domestic chest freezer.

The red cells arrived on site at 11:45 and the first of the three units was taken directly to ambulatory care for immediate transfusion to the patient. The remaining two units were placed into the theatre chest freezer by the receiving staff, with the receipt-to-inventory documentation completed correctly. The first unit was administered without event, over the prescribed two-hour timeframe. The second unit was retrieved from the theatre freezer at 13:50 and transfusion commenced just after 14:00.

At 15:50 the theatre co-ordinator accessed the freezer, immediately noting a unit of red cells within. The attached label provided the identity of the intended recipient and without delay it was established the patient was currently receiving red cells on-site. Theatre called the ambulatory care team instructing them to cease the transfusion immediately, thereafter notifying NZBS and seeking Transfusion Medicine Specialist advice.

By the time 214 mL of the second unit had been administered, 31 mL remained. The team were advised to admit the patient for 24-hour observation, monitor the vital signs and take regular blood samples, specifically for renal function and any evidence of haemolysis. The patient remained stable, with a creatinine of 48 µmol/L. Despite a congenital single kidney, the patient escaped injury or harm from gross haemolysis due to storage of the red cells below 2°C.

The remainder of unit two (stored in the freezer for two hours) and the third semi-frozen unit retrieved from the freezer after four hours, were returned to the Blood Bank. On testing, remarkably, neither had any evidence of red cell haemolysis, the critical risk of uncontrolled storage and freezing. It was concluded the age of the domestic freezer, due for imminent replacement, may have been the reason the red cells didn't freeze completely.

Root cause

Because of perceived clinical urgency, there was a deviation from the normal practice of receiving blood into the hospital blood refrigerator. This resulted in a staff member, unfamiliar with the correct process, inadvertently placing two units in the freezer instead of the refrigerator. The same staff member retrieved unit two, not noticing the coldness of the unit or that the freezer was not the usual place for inventory.

Response

It was encouraging to note that the hospital was quick to respond to this error. They worked closely with the NZBS Transfusion Nurse Specialist to thoroughly investigate the error and identify appropriate remedial action.

Recommendations

1. Review and update documented polices and processes to ensure the process for receipt of blood is clear

2. Update educational requirements. Ensure all staff involved in the transfusion chain know and understand the rationale for a policy and process of blood receipt and storage, and the consequence of deviation.

3. Include the process in new staff induction and introduce physical orientation to the blood refrigerator.

4. Audit all refrigerators on site. Add clear labelling to the blood refrigerator.

5. Label theatre freezer with “Not for blood storage”. Consider relocating freezer to avoid confusion.

6. Report the event, to ensure all staff have the chance to learn from this.

Learnings

It is crucial that all staff involved in the transfusion chain are trained, that processes are clear and physical tasks are designed to reduce the chance of error.

4.3.2 AVOIDABLE TRANSFUSIONS

Where administration of a suitable blood component or product is intended, but the decision leading to the administration is flawed.

There were two instances of avoidable transfusion reported in 2021, as there were in 2020.

Table 4.3.2-1: Avoidable transfusions 2021

Error
Pre-operative transfusion of FFP to a patient with no record of a coagulation deficiency.
Transfusion of platelets intended to be given pre-chemotherapy, but chemotherapy was not given that day and no platelet count was done to check the increment after the transfusion.

4.3.3 AVOIDABLE DELAYS

Where an avoidable delay in provision of blood components or products affected patient care.

Four avoidable delays were recorded in 2021.

Table 4.3.3-1: Avoidable delays 2021

Error	Error Location
5.5-hour delay in providing phenotyped blood for intra-uterine transfusion, due to miscommunication between the Blood Bank and the Blood Centre over which unit was the correct phenotype.	Blood Bank and Blood Centre
Insufficient dose of Intragam® P issued to a remote hospital resulting in overnight shipping of further product and requiring the patient to return the next day.	Blood Bank
Delay in issuing urgent phenotyped blood to a neonate because of communication errors at handover and confusion with the NHI number of the baby.	Blood Bank
Delay in providing urgent blood for a baby on ECMO resulted in a clear prime having to be performed. This lowered the baby's Hb and required red cell transfusion leading to the baby receiving significantly more fluid than necessary.	Blood Bank

4.4 NEAR MISS EVENTS

A deviation from standard procedures or policies that is discovered before administration commences and that could have led to a wrong transfusion or a reaction in a recipient if administration had occurred.

During 2021, there were 14 near miss events identified from the NZBS incident management system (eight in 2020) and one reported from a DHB Blood Bank (one in 2020). These events are summarised in Table 4.4-1. Near misses related to wrong blood in tube are addressed separately in section 4.4.1. Those related to anti-D are reported in section 4.2.

Table 4.4-1: Near miss events by error type and location 2021

Near Miss Type	Location of near miss	Number
Product/component requested for wrong patient.	Clinical	3
Wrong product/component issued	Blood Bank	4
Wrong group component issued	Blood Bank	3
Wrong dose issued (Intragam® P)	Blood Bank	1
Wrongly labeled product/component issued	Blood Bank	3
TOTAL		**14**

Typically, in New Zealand, an initial Blood Bank Request Form is sent with the pre-transfusion testing sample to the Blood Bank in advance of blood being required. When the blood is needed for transfusion a different request form is sent for issue of the blood. In all three near miss cases that occurred in clinical areas, the wrong patient label had been applied to the form sent to Blood Bank to request issue of the blood. Two of these cases occurred in theatre because labels from a previous case were left in the theatre.

It is important that hospitals have processes to clear all of a patient's identifying information from the operating theatre before the next case proceeds.

Errors in the Blood Bank typically involve distractions or interruptions at critical points in the process, such as issuing.

4.4.1 WRONG BLOOD IN TUBE (WBIT) EVENTS

- *Blood is taken from the wrong patient and is labeled with the intended patient's details*
- *Blood is taken from the intended patient, but labeled with another patient's details*

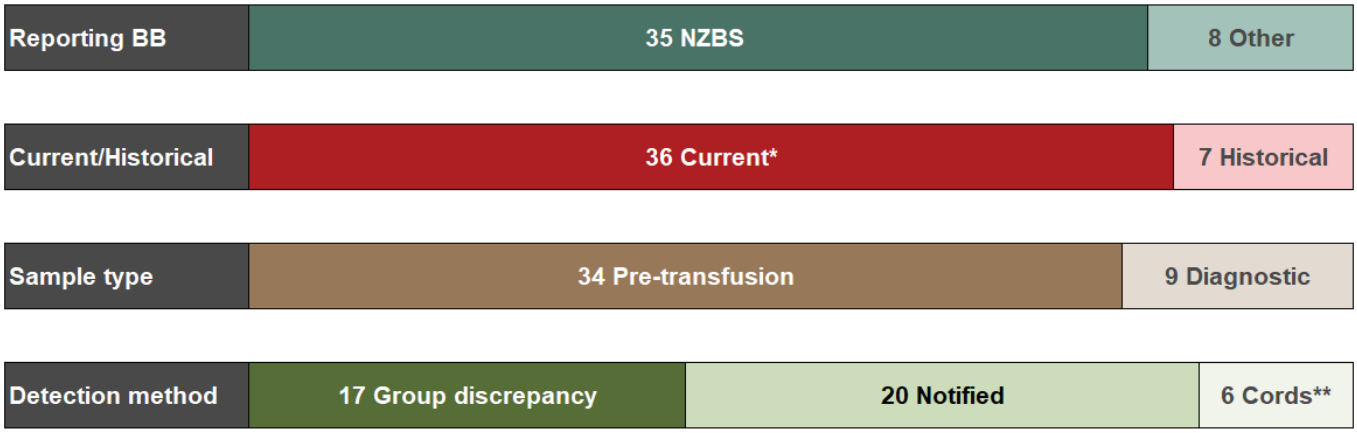
The way NZBS collects WBIT data has been evolving and this is reflected in the increase in WBIT numbers this year. In August 2021 a new electronic method was introduced in NZBS Blood Banks for reporting WBITs. During the introduction of this process, Blood Bank staff were reminded that the reporting criteria for WBITs have changed. Prior to 2020 only WBITs detected by blood group discrepancy on pre-transfusion samples were counted. From 2020 we have included diagnostic samples as well as those WBITs identified by notification from the ward and those where a cord blood sample is labeled with maternal details. Since this approach has been implemented it is interesting to note that less than half of all WBITs reported are detected by a blood group discrepancy. This is an important reminder that the Blood Bank cannot detect all WBITs and the most dangerous WBITs are those that are not detected.

During 2021, 43 WBIT events were reported, compared with 22 reported in 2020. Of these, 36 were current, i.e. the error occurred in 2021, and the remainder were historical, i.e. the error occurred prior to 2021. Ten of the current WBITs were detected by blood group discrepancy.

Most of the WBIT errors on diagnostic samples (6 out of 9) were cord blood samples that had been labeled with maternal details.

Figure 4.4.1-1 shows an overview of the 43 WBITs by reporting Blood Bank, current or historical, sample type and detection method.

Figure 4.4.1-1: Overview of 43 WBIT events by category 2021



** 1 sample in this category was a historical WBIT(error occurred with a previous sample) but the error occurred during the same admission.*

*** Cord blood sample labeled with maternal details. An Apt and Downey test can be used to confirm that the sample is cord blood.*

Table 4.4.1-1 provides a closer look at the current WBITs by hospital and detection method. It also includes the number of WBITs that resulted from an error at patient admission.

Table 4.4.1-1: Current WBITs by hospital, detection method and admission error 2021

		Method of detection			
Site	Current WBITs	Blood group discrepancy	Reported by ward/ collector	Cord blood error	Hospital admission error
Auckland	13	4	9	-	2
Christchurch	6	2	4	-	1
Wellington	2	-	-	2	3
Palmerston North	4	1	2	1	-
Rotorua	3	-	-	3	-
Waikato	2	1	1	-	-
Middlemore	2	1	1	-	-
North Shore	2	1	1	-	-
Dunedin	1	-	1	-	-
Tauranga	1	-	1	-	1
Total	**36**	**10**	**20**	**6**	**7**

New Zealand has a National Health Index (NHI) that assigns a unique NHI number to each person who receives healthcare across New Zealand. The NHI number is portable across all health services and hospitals. The success of the system relies on health providers linking patients to the correct NHI number each time they present. On occasion, a patient's identity is not properly checked on admission to hospital and a patient is linked to the incorrect NHI number. Seven WBITs in 2021 were caused by a patient being linked to the wrong NHI number at the current or a previous admission. This can be particularly problematic for patients with common surnames. These errors can be very complex and time consuming for the clinical team to correct.

For Transfusion Nurse Specialists to know where to direct education, it is important to be able to identify which roles are involved in making WBIT errors. The new WBIT reporting system within NZBS has started to capture the role of the sample collector. In 2021, roles for 26 of the 36 current WBITs were identified. See Table 4.4.1-2.

Table 4.4.1-2: Current WBITs by hospital and role of sample collector 2021

Site	Nurse	Midwife	Doctor	Unknown
Auckland	6	1	2	4
Christchurch	2	2	1	1
Wellington	-	1	-	1
Palmerston North	-	2	-	2
Rotorua	3	-	-	-
Waikato	-	1	-	1
Middlemore	1	1	-	-
North Shore	-	1	1	-
Dunedin	-	1	-	-
Tauranga	-	-	-	1
Total	**12**	**10**	**4**	**10**

We note that the number of errors made by midwives and nurses are similar. While there is currently insufficient data to draw any conclusions from this, it will be monitored over time as more data are accumulated. We are aware of at least one hospital where pre-labelling of blood collection tubes is common practice in the maternity ward, despite contravening hospital policy. Hospitals should ensure that midwives follow hospital policy for identifying patients and labelling samples.

Hand label sample with:
Family name and given name
Date of birth / NHI
Date and time taken
Signature of collector

The following analyses of current WBITs, in Tables 4.4.1-3 and 4.4.1-4, are based on NZBS data only as data from other hospitals is currently under-reported.

Table 4.4.1-3: Frequency of NZBS current WBITs detected by group discrepancy 2021

Site	Detected WBITs	Historic groups	WBIT frequency*	WBIT rate per 10,000 samples* (95% CI)
Auckland	4	40,876	1:7,222	1.4 (0.5 to 3.2)
Christchurch	2	18,639	1:6,586	1.5 (0.3 to 4.8)
Wellington	0	18,630	-	-
Palmerston North	1	7,176	1:5,071	2.0 (0 to 9.6)
Waikato	1	18,744	1:13,247	0.8 (0 to 3.7)
Dunedin	0	7,464	-	-
Total	**8**	**111,529**	**1:9,852**	**1.0 (0.5 to 1.8)**

** Corrected to account for silent errors (correction factor = 1.415).*

The frequencies and rates above are corrected using a correction factor of 1.415. This is derived from New Zealand blood group frequencies to account for the proportion of samples for which there is no historical blood group on record and the chance that two patients have the same blood group.

The corrected error rate can be used to estimate the number of silent WBITs, i.e. those that were not detected because the two patients involved in the error had the same blood group or because there was no historical group on record. For the data set in Table 4.4.1-3 it was estimated that there were seven silent WBITs.

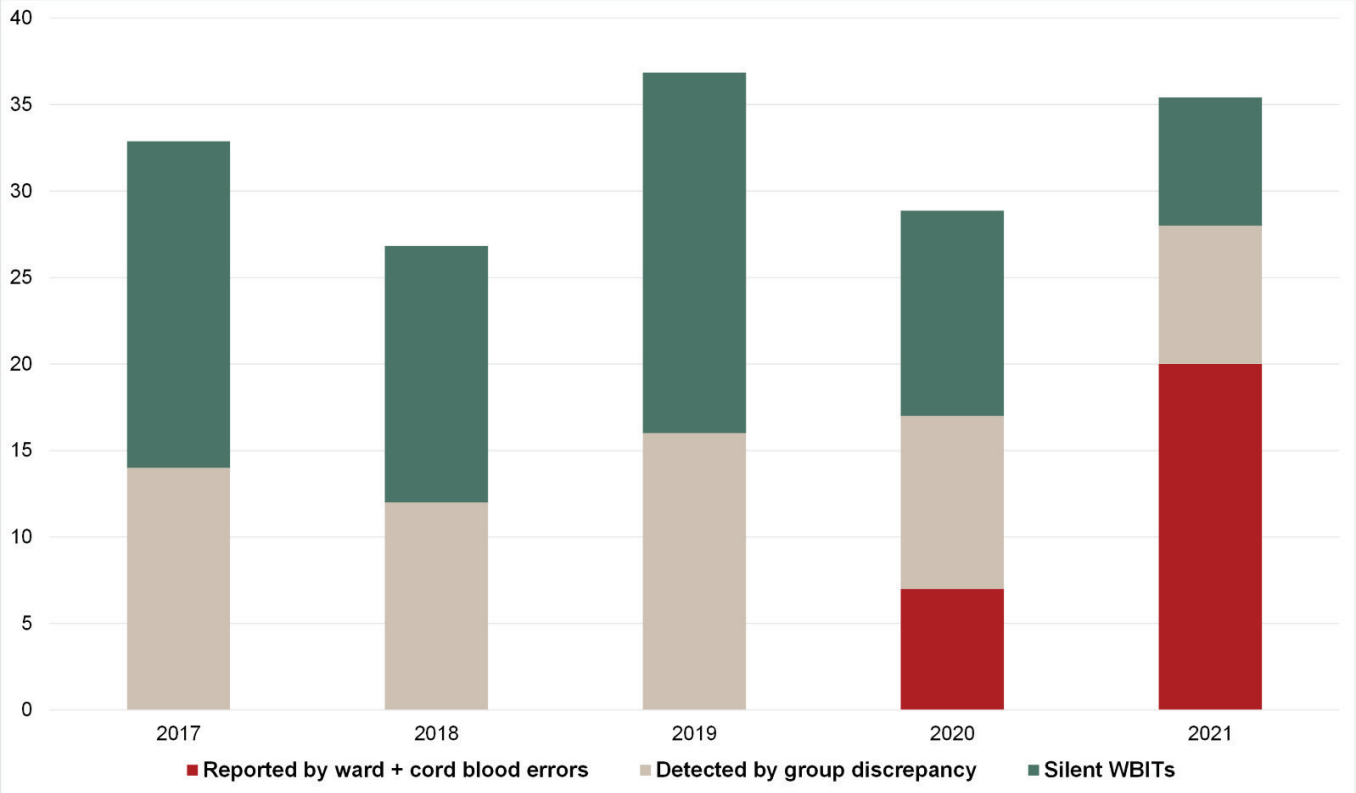
Those current WBITs not detected by group discrepancy are shown in Table 4.4.1-4. This includes those reported by the ward/collector and cord blood samples labeled with maternal details.

Table 4.4.1-4: Frequency of NZBS current WBITs not detected by group discrepancy 2021

Site	Detected WBITs	Historic groups	WBIT frequency	WBIT rate per 10,000 samples (95% CI)
Auckland	9	54,299	1:6,033	2.3 (0.8 to 3.2)
Christchurch	4	27,132	1:6,783	2.1 (0.4 to 3.9)
Wellington	2	25,265	1:12,633	1.1 (0 to 3.1)
Palmerston North	3	9,794	1:3,265	4.3 (0.6 to 9.5)
Waikato	1	24,816	1:24,816	0.6 (0 to 2.5)
Dunedin	1	10,513	1:10,513	1.3 (0 to 6)
Total	**20**	**151,819**	**1:7,591**	**1.9 (0.8 to 2)**

The relative numbers of current WBITs detected by group discrepancy, those not detected by group discrepancy and silent WBITs are shown in Figure 4.4.1-2.

Figure 4.4.1-2: Numbers of current WBITs reported by NZBS, by type 2017 – 2021*



** Non-blood group discrepant WBITs have only been reported since 2020*

The problem of WBITs has been discussed at length in the literature. It is a difficult problem to eliminate, even with electronic systems. However, NZBS has noticed a lack of systematic investigation by hospitals into the causes of these errors. While talking to the person who made the error is the easiest and most common response to these incidents, this approach is ineffective because, in most cases, the sample collector is already aware of the correct procedure.

Another concern is that many hospitals do not regard these to be serious errors as no patient harm occurred. It is crucial for hospitals with repeated WBITs to understand there will likely be WBITs occurring that will be undetectable by Blood Bank and can potentially cause serious harm. There has been a death in New Zealand in the last six years due to WBIT.

The UK Healthcare Safety Investigation Branch published a report into the WBIT problem in 2019[7]. The report provides a number of insights into the issues that contribute to incorrect labelling and would make a useful resource for hospitals investigating their own WBIT problem. Examples of contributing factors are things such as interruptions while labelling and having no place to label effectively at the patient's bedside. It is important to note that the scope of any investigation should include the admission process as our data indicates admission errors are a common cause of WBIT.

NZBS believes there are likely to be steps hospitals can take to reduce the incidence of WBITs without having to introduce costly electronic bedside systems.

[7] *Healthcare Safety Investigation Branch. Wrong Patient Details on Blood Sample. Sept 2019*
https://www.hsib.org.uk/investigations-and-reports/wrong-patient-details-on-blood-sample/

4.5 REQUEST FORM AND SAMPLE LABELLING ERRORS

The total number of samples registered in New Zealand in 2021 was 336,222. There were sample and/or request form labelling errors associated with 12,879, i.e. a national frequency of 1:26 samples. Of all samples with errors, 4,987 (38.7%) required recollection, indicating that a lot of time is wasted by Blood Bank and hospital staff either correcting labels or recollecting samples.

NZBS has developed detailed acceptance criteria for the labelling of pre-transfusion testing blood samples and request forms. These criteria are based on the Australian & New Zealand Society of Blood Transfusion (ANZSBT) Guidelines[8]:

Request Form Hand-written or pre-printed label	Sample Must be hand-written
Full name	Family name and one or more given names (not abbreviated)
National Health Index (NHI) number and/or date of birth	NHI number and/or date of birth
Gender	Signature or initials of collector
Patient's location	
Details of request (group and screen, blood products etc.)	
Name or signature or other identifier of person completing the form	
Signed declaration by sample collector that • The patient was positively identified prior to collection • Sample labeled before leaving the patient	
Date and time of sample collection written on sample or form	

[8] *Transfusion Science Standing Committee of the Australian and New Zealand Society of Blood Transfusion. Guidelines for transfusion and immunohaematology laboratory practice (2020).*

The action required for a sample or request form with an error depends on the severity of the error. Errors are classified major, moderate or minor. The following are typical examples:

Deficiency type	Typical Example	Usual action
Major	• Unlabelled sample • NHI and DOB missing • Labeled with pre-printed label • Patient ID on form different from that on sample	Reject and recollect
Moderate	• Patient details illegible on sample but legible on form • First name replaced by initials or nickname • Form OR sample not signed	Correction by collector
Minor	• Single character addition/omission in one name • Given name/family name transposed	Verify details and correct in BB

During 2021, NZBS reviewed its sample acceptance criteria to make them clearer and stricter. The original intention was to implement the new requirements in 2022 with a supporting Positive Patient ID campaign to enhance communication and education in hospitals. The impact of Covid-19 in hospitals has delayed this programme.

Sample and request form labelling error rates, by sample status recorded in eTraceline, are shown in Figure 4.5-1.

Figure 4.5-1: Request form and sample labelling error rate by eTraceline sample status 2021

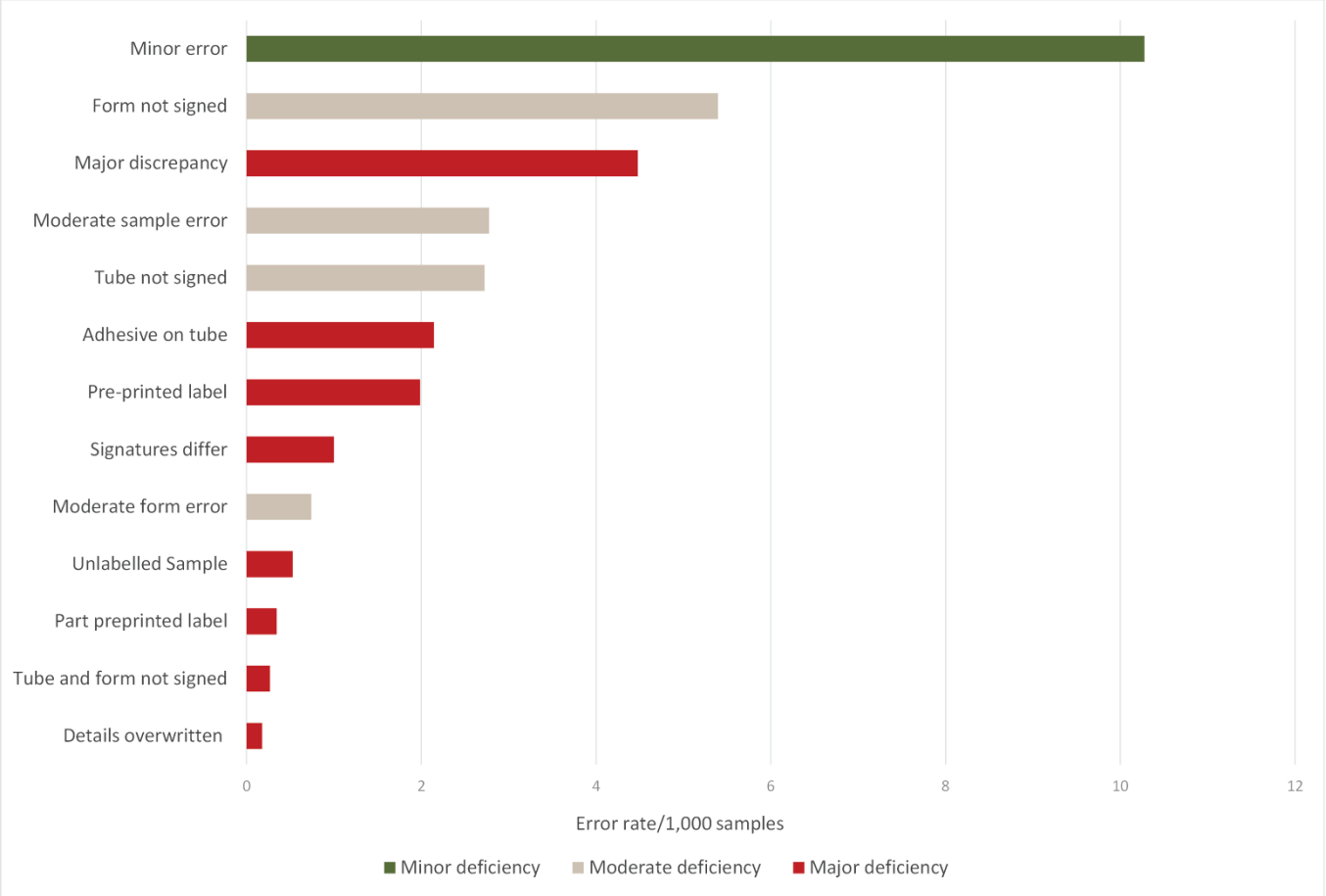


Table 4.5-1 shows error rates by Blood Bank in three groups, based on numbers of samples tested and in ascending order of rate within each group. It should be noted that labelling errors occur at the collection point and each Blood Bank may receive samples from more than one hospital.

Table 4.5-1: Request form and sample labelling errors by Blood Bank 2021

Site	Blood Bank	Errors	Total Samples	Error frequency	Error rate/1000 samples (95% CI)
Large (>10,000 samples)	Taranaki	202	11,905	1:59	17.0 (14.8 to 19.5)
	Auckland	1,320	59,966	1:45	22.0 (20.9 to 23.2)
	North Shore	577	24,849	1:43	23.2 (21.4 to 25.2)
	Dunedin	345	12,036	1:35	28.7 (25.8 to 31.8)
	Tauranga	387	12,467	1:32	31.0 (28.1 to 34.2)
	Christchurch	1,091	31,142	1:29	35.0 (33 to 37.1)
	Middlemore	1,527	35,513	1:23	43.0 (40.9 to 45.2)
	Wellington	1,326	29,404	1:22	45.1 (42.8 to 47.5)
	Palmerston North	522	11,145	1:21	46.8 (43.1 to 50.9)
	Waikato	1,834	28,609	1:16	64.1 (61.3 to 67)
	Whangarei	634	10,092	1:16	62.8 (58.2 to 67.7)
	Hawkes Bay	1,101	16,295	1:15	67.6 (63.8 to 71.5)
Medium (2,000-10,000 samples)	Gisborne	38	4,514	1:119	8.4 (6.1 to 11.6)
	Wairau	47	2,141	1:46	22.0 (16.5 to 29.1)
	Waitakere	156	6,764	1:43	23.1 (19.7 to 26.9)
	Timaru	51	2,057	1:40	24.8 (18.8 to 32.5)
	Masterton	98	3,884	1:40	25.2 (20.7 to 30.7)
	Whanganui	105	2,668	1:25	39.4 (32.6 to 47.4)
	Nelson	217	4,869	1:22	44.6 (39.1 to 50.7)
	Southland	256	5,197	1:20	49.3 (43.7 to 55.5)
	Hutt Valley	422	7,867	1:19	53.6 (48.9 to 58.8)
	Whakatane	111	2,040	1:18	54.4 (45.3 to 65.2)
	Rotorua	394	5,547	1:14	71.0 (64.6 to 78.1)
Small (<2,000 samples)	Auckland Ref Lab	20	1,884	1:94	10.6 (6.8 to 16.4)
	Kaitaia	5	308	1:62	16.2 (5.8 to 38.5)
	Thames	16	681	1:43	23.5 (14.2 to 38.1)
	Oamaru	3	124	1:41	24.2 (5.1 to 71.8)
	Te Nikau (Grey)	32	1,030	1:32	31.1 (22 to 43.7)
	Kawakawa	15	428	1:29	35.0 (20.9 to 57.5)
	Taupo	15	369	1:25	40.7 (24.3 to 66.5)
	Dunstan	12	285	1:24	42.1 (23.5 to 72.9)
	Tokoroa	0	51	-	-
	Taumarunui	0	49	-	-
	Te Kuiti	0	41	-	-
	Dargaville	0	1	-	-
	National	**12,879**	**336,222**	**1:26**	**38.3 (37.7 to 39)**

CHAPTER 5

PHARMACOVIGILANCE

05 PHARMACOVIGILANCE

During 2021, 49 adverse event reports related to fractionated human plasma products were received, 34 of which were related to intravenous immunoglobulin (Intragam® P and Privigen®). This pattern is similar to previous years.

Classification for these events is based on the following categories:

Causality	Severity
Excluded	Non-severe
Unlikely	
Possible	
Probable	Severe – cases that are life-threatening or result in death, disability or prolonged hospitalisation.
Certain	

Adverse event reports associated with six fractionated plasma products were received during 2021 (Table 5-1).

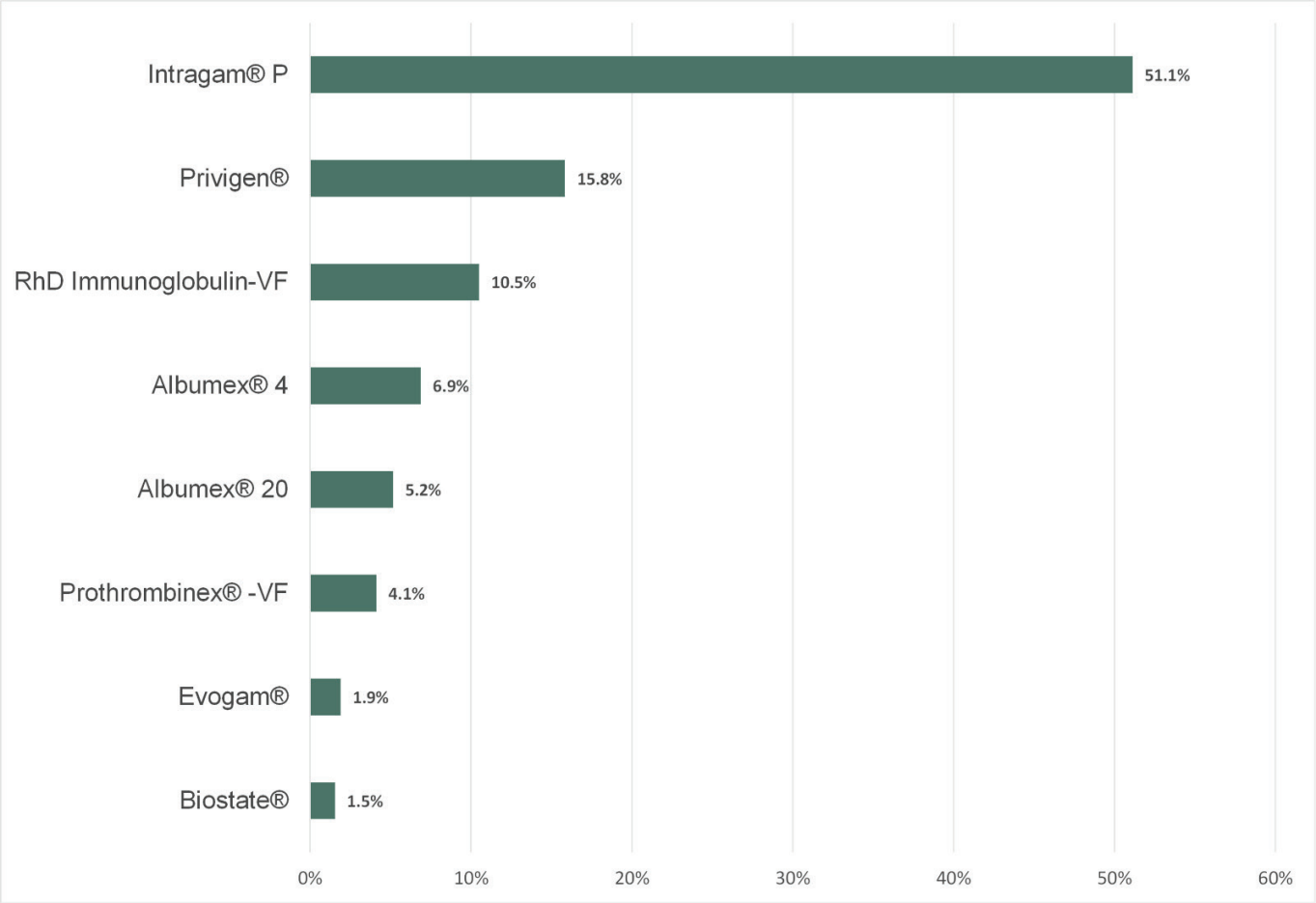
Table 5-1: Fractionated products issued and adverse event reports received 2021

Product	Dose	Number of vials Issued	Total amount of product issued	Adverse events reported
Intragam® P	12 g	30,445	401 kg	20
	3 g	11,726		
Privigen®	20 g	2,882	70 kg	14
	10 g	915		
	5 g	673		
Albumex® 20	100 mL	12,839	1290 L	5
	10ml	650		
Evogam®	3.2 g	14,821	55kg	1
	0.8 g	9,858		
Rhophylac®	1500 IU	16	24 x 10^3 IU	1
Rh(D) Immunoglobulin-VF	625 IU	8,518	5.7 x 10^6 IU	8*
	250 IU	1,698		

** All Rh(D) Immunoglobulin events were errors*

The proportion of reports received for Intragam® P is consistently higher than for other immunoglobulins because of the higher volumes issued. Figure 5-1 shows the products responsible for most adverse reactions, as a percentage of the total reports received between 2007 and 2021.

Figure 5-1: Proportion of adverse events associated with fractionated products 2007 – 2021 (Products with >1% of reports)



The following human plasma derived products were issued during 2021 but no adverse event reports were received:

Immunoglobulins	Haemostasis products*
Albumex® 4	FEIBA NF®
Berirab® P (Rabies Immunoglobulin)	Fibrogammin® (FXIII)
Biostate®	Hemoleven® (FXI)
Hepatitis B Immunoglobulin-VF	Koate-DVI® (FVIII)
Hizentra® (SC Immunoglobulin)	Prothrombinex®-VF (FII, FIX, FX)
HyperHEP® B (IM Immunoglobulin)	RiaSTAP® (Fibrinogen)
HyQvia® (SC Immunoglobulin)	Thrombotrol®-VF (ATIII)
Tetanus Immunoglobulin-VF	**Other**
Zoster Immunoglobulin-VF	BERINERT® (C1 Esterase inhibitor) Zemaira® (alpha1-proteinase inhibitor)

** NZBS also issues some recombinant haemostasis products. Adverse reactions to these would normally be reported directly to the New Zealand Centre for Adverse Reactions Monitoring (CARM).*

The most frequently reported reactions to fractionated products over the last five years have been allergic reactions. This is illustrated in Figure 5-2, which shows each adverse event type as a percentage of the 242 reports received over the last five years.

Figure 5-2: Adverse event types as a percentage of reports received 2017 – 2021 (all causalities)

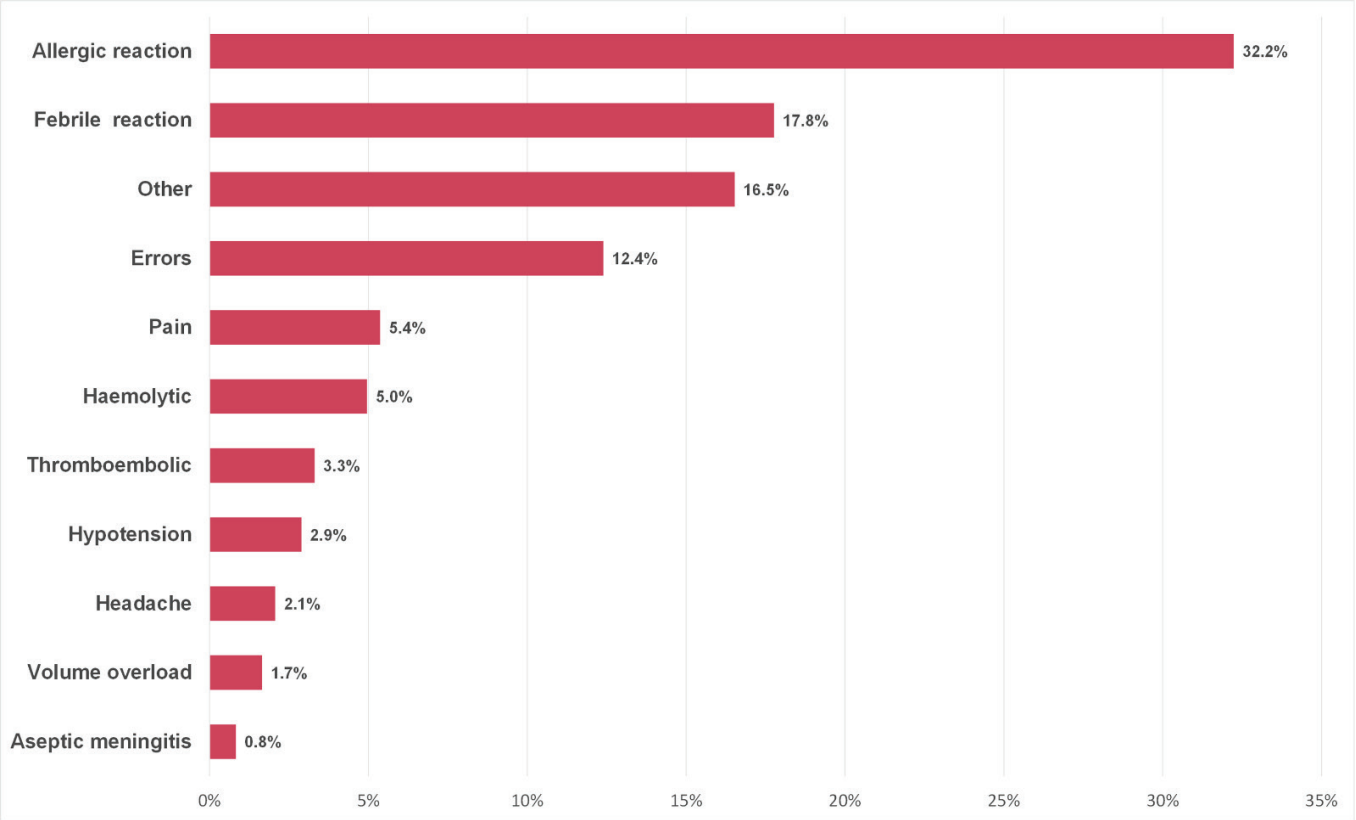


Table 5-2 shows that there were slightly more febrile reactions than allergic reactions reported in 2021, although allergic reactions were the most commonly reported reaction to Intragam® P.

Table 5-2: Adverse event types by product 2021 (all causalities)

Product	Allergic	Febrile	Pain	Haemolytic	Thrombo-embolic	Volume overload	Incorrect infusion rate*	Anti-D error*	Other
Intragam® P	10	5	1	0	2	2	0	0	0
Privigen®	1	5	1	1	0	0	2	0	4
Albumex® 20	0	3	0	0	0	0	0	0	2
Evogam®	0	0	1	0	0	0	0	0	0
Rhophylac®	0	0	0	1	0	0	0	0	0
Rh(D) Immuno-globulin-VF	0	0	0	0	0	0	0	8	0
Total	**11**	**13**	**3**	**2**	**2**	**2**	**2**	**8**	**6**

** Anti-D and infusion rate errors are discussed in further detail in Sections 4.2 and 4.3.*

Excluding anti-D errors and infusion rate errors, 34 events were assessed as having a causality of possible, probable or certain and six of these were severe reactions. Table 5-3 shows this information by product.

Table 5-3: Severe case numbers for reports with causality possible, probable or certain 2021

Product	Causality Possible to Certain	Severe
Intragam® P	18	4
Privigen®	11	1
Albumex® 20	3	0
Evogam®	1	0
Rhophylac®	1	1
Total	**34**	**6**

Two of the severe cases associated with Intragam® P were thromboembolic events. One of these is described in the following case study.

CASE STUDY

Possible pulmonary embolism due to intravenous immunoglobulin

A 48-year-old female had been receiving intravenous immunoglobulin (Intragam® P) since July 2016 for treatment of chronic inflammatory demyelinating polyneuropathy (CIDP). Her mobility was restricted and at times she required crutches and wheelchair assistance. Her weight was 130 kg and height was 166 cm. She had been receiving 120 g of Intragam® P over two days every two weeks.

In March 2021 she presented to the outpatient clinic for her scheduled infusion but complained that she had developed shortness of breath and chest pain five to seven days after the last infusion. Following a CT pulmonary angiogram investigation, a large proximal pulmonary embolus was diagnosed. Rivaroxaban was prescribed, Intragam® P treatment was withheld in the interim and a possible serious adverse event associated with Intragam® P was reported.

While investigating this with the patient, a past history of a similar episode was disclosed. A suspected pulmonary embolus in March or April of the previous year wasn't confirmed by CT scan, but D-Dimer was significantly raised. Prior to the most recent event she had complained of unexplained back pain following Intragam® P infusions and stated she often suffered from nausea and headaches following infusions. These adverse events were never reported to blood bank. Prior to Intragam® P infusions the patient was in the practice of taking paracetamol and loratadine prophylactically.

After further discussions with the Transfusion Medicine Specialist, Neurologist and patient, a diagnosis of a possible thromboembolic episode (pulmonary embolus) due to Intragam® P was made. Due to increasing symptoms and further reduced mobility in this woman, it was decided to recommence Intragam® P at a lower dose, nine weeks post-diagnosis of the pulmonary embolism.

Intravenous immunoglobulin has been associated with thromboembolic events but the causality in this event was determined to be only possible, as there were other factors involved including limited mobility, wheelchair use, sedentary lifestyle and a significantly increased BMI.

New Zealand Blood Service encourages clinicians and nurses to report all events suspected to be caused by blood components and products regardless of severity or frequency.

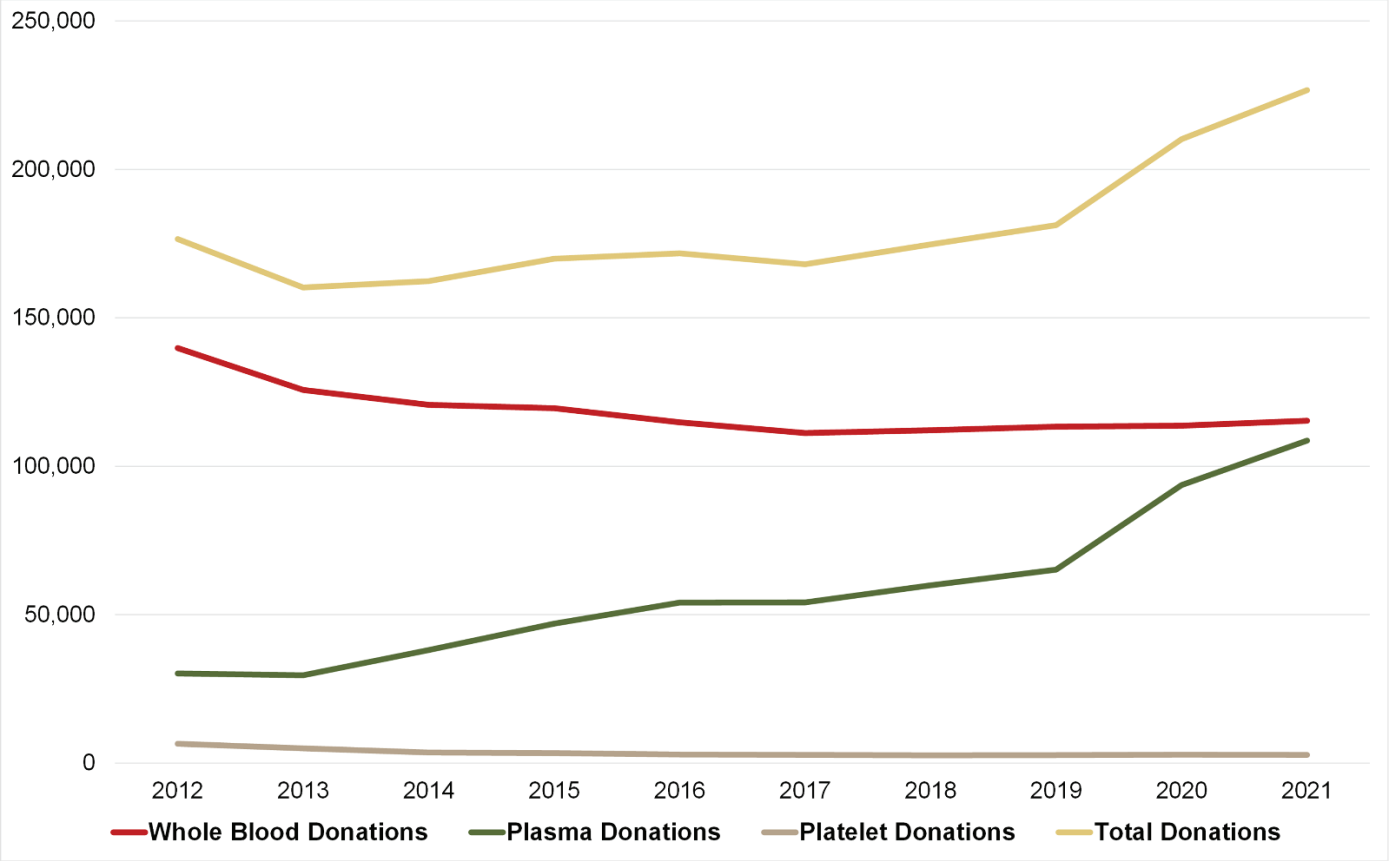
CHAPTER 6

DONOR VIGILANCE

06 DONOR VIGILANCE

The annual numbers of blood donations by donation type over the last ten years are shown in Figure 6-1. While the number of whole blood donations has remained steady for the last five years, the ever-increasing demand for intravenous immunoglobulin products has resulted in a 260% increase in plasmapheresis donations over the last ten years.

Figure 6-1: Annual number of blood donations by donation type 2012 - 2021



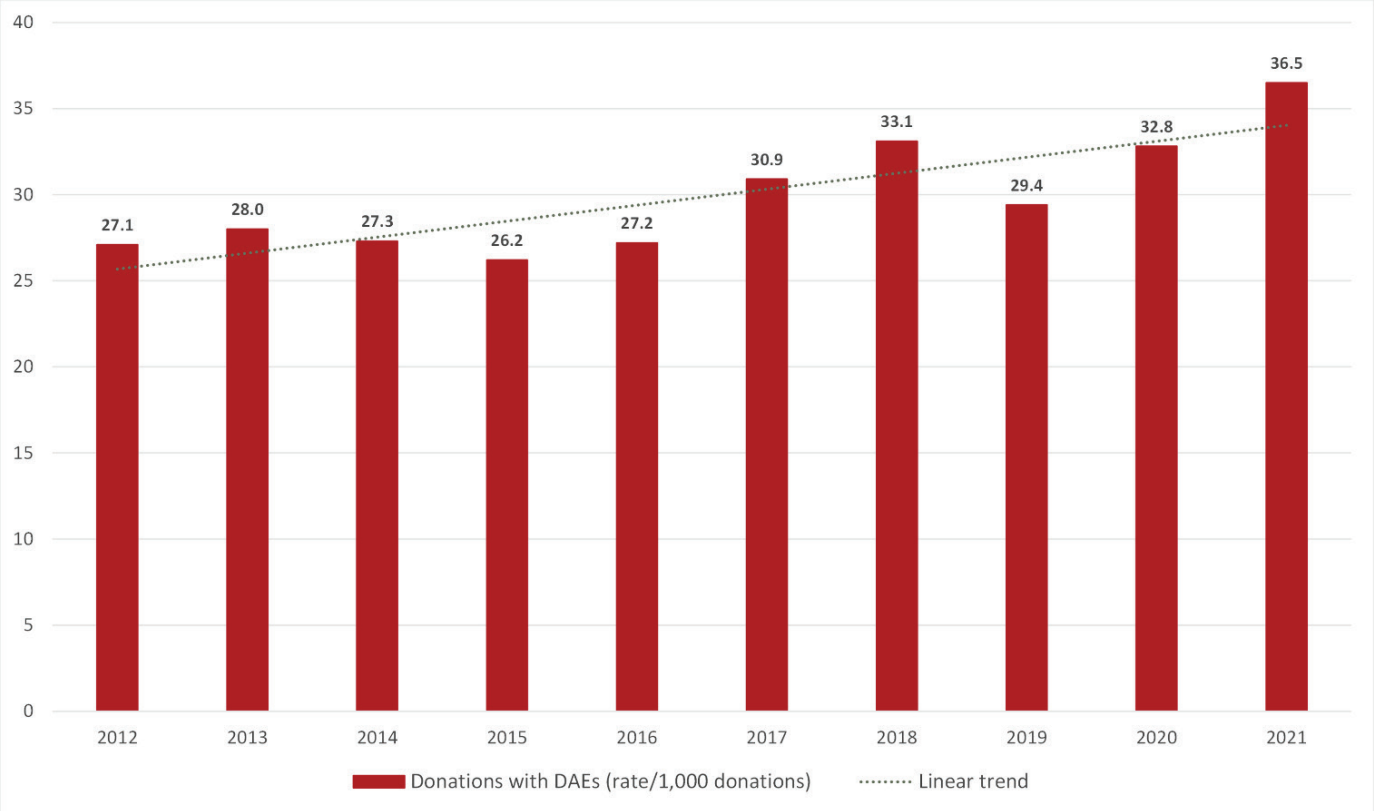
A total of 226,738 donations were collected in 2021. Adverse event reports were received in relation to 8,275 donations from 7,553 donors.

Table 6-1 shows the rate of donations with adverse events for 2021 and Figure 6-2 shows rates over the last ten years. Over that period the reporting rate has increased by 35%.

Table 6-1: Adverse event rates by donation type 2021

Donation type	Donations with adverse events	Total Donations	Frequency	Rate / 1,000 Donations (95%CI)
Whole Blood Donation	4,359	115,315	1:26	37.8 (36.7 to 38.9)
Plasmapheresis	3,736	108,669	1:29	34.4 (33.3 to 35.5)
Plateletpheresis	180	2,754	1:15	65.4 (56.7 to 75.2)
Total	**8,275**	**226,738**	**1:27**	**36.5 (35.7 to 37.3)**

Figure 6-2: Adverse event rate/1,000 donations 2012 – 2021



NZBS uses the following ISBT categories for complications related to blood donation[9].

A. Local symptoms:
- A1. Blood outside vessel
- A2. Arm pain
- A3. Localised infection/inflammation
- A4. Other major vessel injury

B. Vasovagal reactions

C. Related to apheresis

D. Allergic reactions

E. Other serious complications

F. Other

Vasovagal reactions and haematomas were the most frequently reported events in 2021 (see Table 6-2). This is consistent with previous years. Figure 6-3 shows that vasovagal reactions are much more common in whole blood donors than apheresis donors, but that haematomas are more common in apheresis donors.

Table 6-2: Adverse events by reaction type* 2021

ISBT Category	Event type	Number of events	Rate per 1,000 donations (95% CI)
B	Vasovagal	4,254	20.239 (19.645 to 20.850)
A1	Haematoma	3,137	14.925 (14.415 to 15.452)
A2	Painful Arm	515	2.450 (2.248 to 2.671)
F	Other Complications	284	1.351 (1.203 to 1.518)
A2	Nerve Irritation / Injury	146	0.695 (0.590 to 0.817)
A1	Re-bleeding	112	0.533 (0.442 to 0.641)
D	Local Allergic Reaction	29	0.138 (0.095 to 0.199)
A1	Arterial Puncture	7	0.033 (0.015 to 0.070)
A3	Thrombophlebitis	4	0.019 (0.005 to 0.051)
D	Generalised Allergic Reaction	4	0.019 (0.005 to 0.051)
A3	Cellulitis	2	0.010 (0 to 0.037)
E	Other Serious Complications	1	0.005 (0 to 0.030)
A4	Other Major Vessel Injury	0	-

** Apheresis-specific complications excluded, i.e. citrate reactions*

[9] *Working Group on Donor Vigilance of the ISBT Working Party on Haemovigilance in collaboration with IHN and the AABB Donor Haemovigilance Working Group. Standards for Surveillance of Complications Related to Blood Donation. (2014)*

Figure 6-3: Adverse events with frequency >0.1/1,000 donations, by donation type 2021

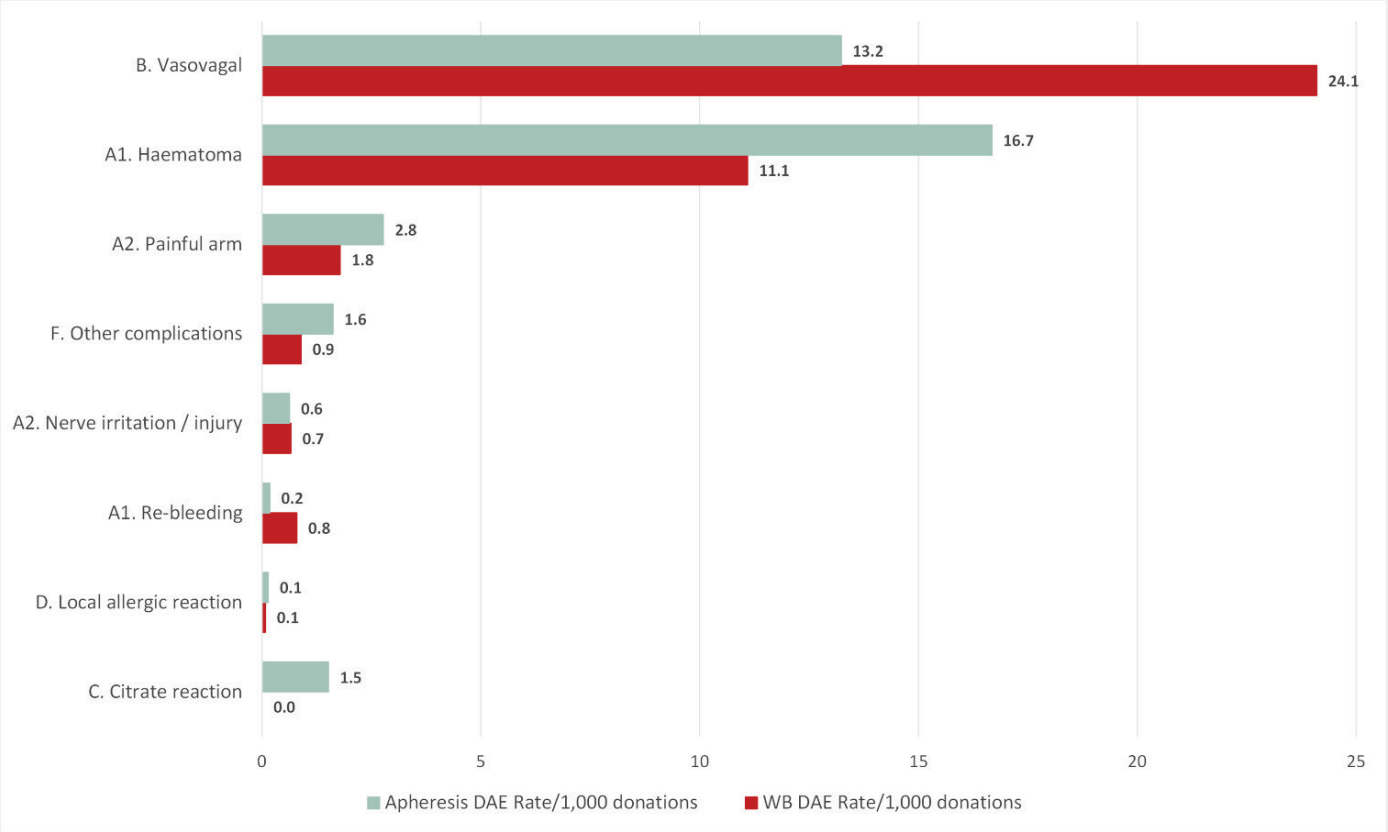
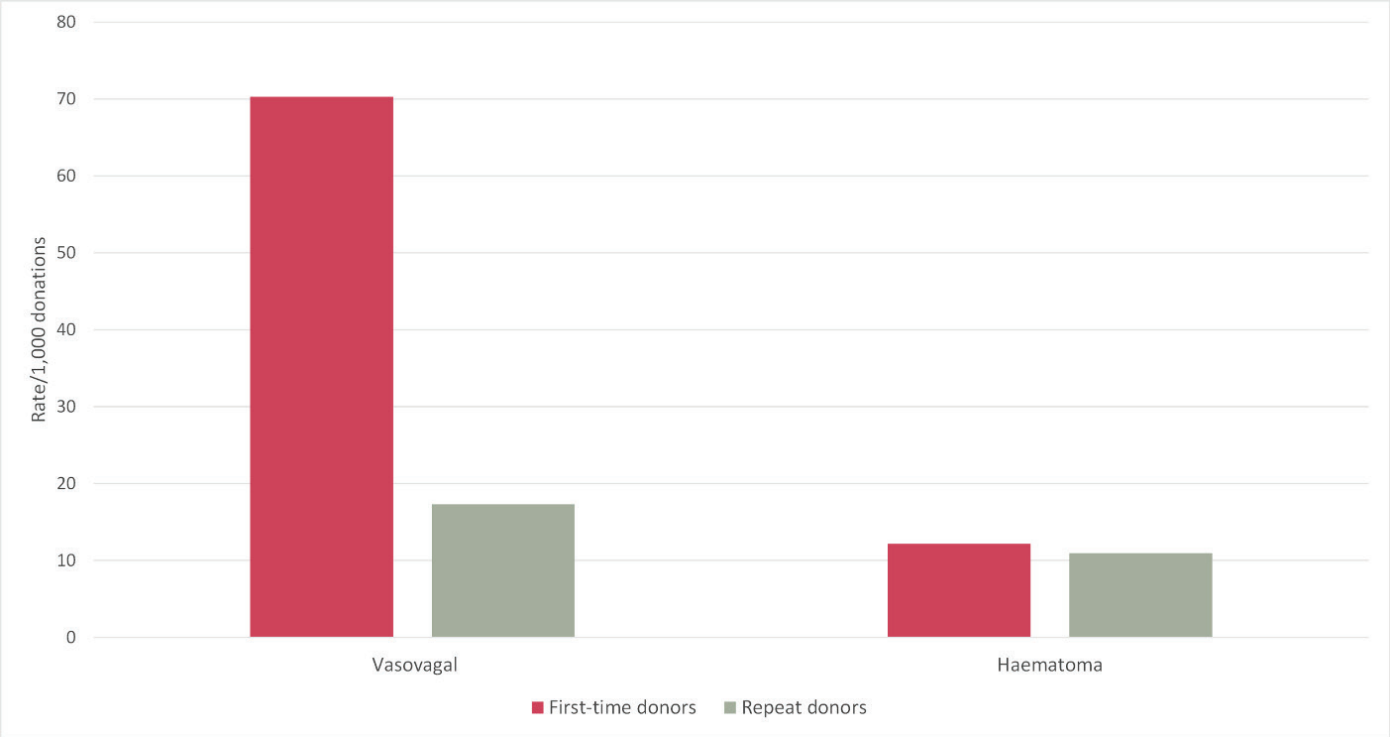


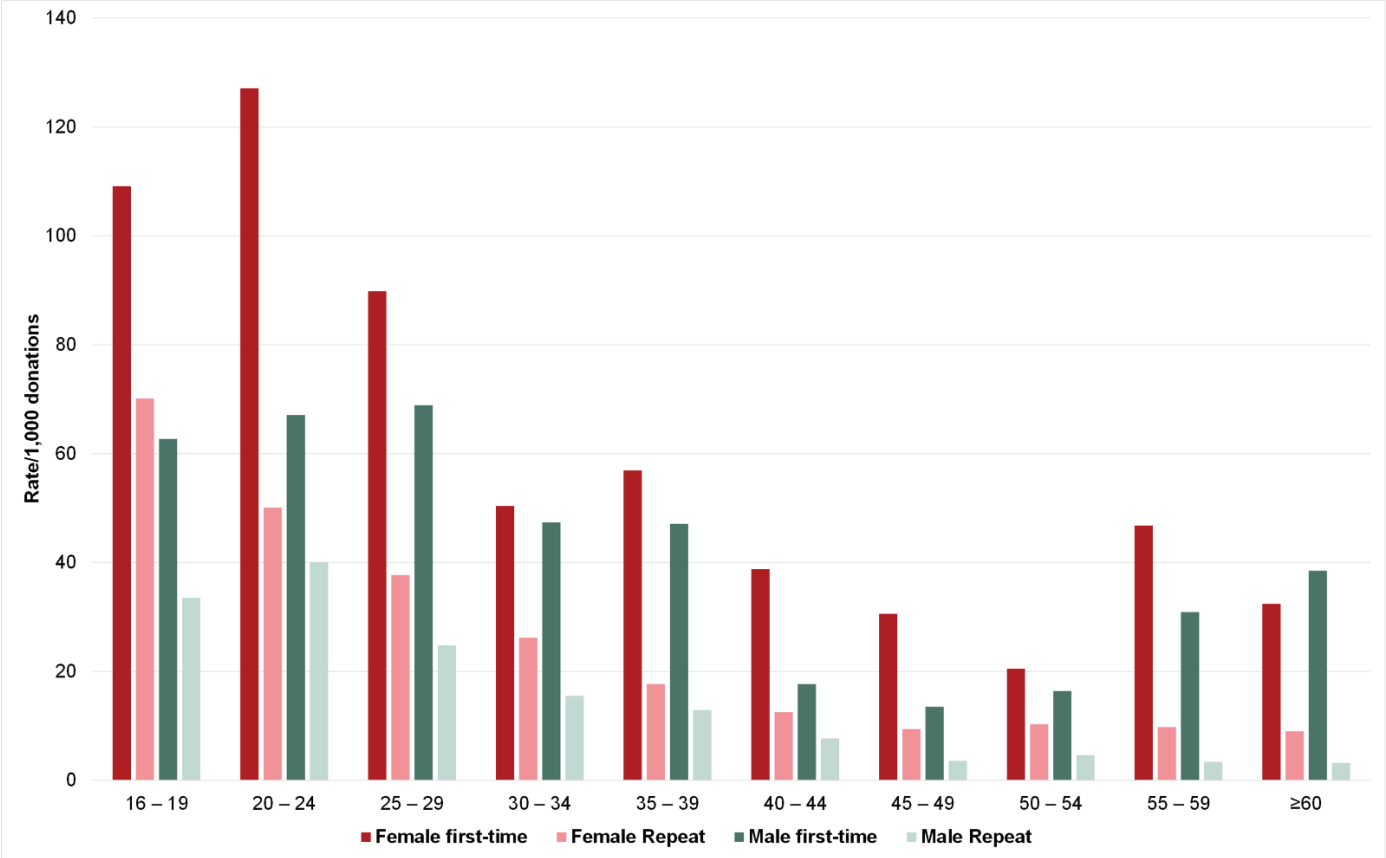
Figure 6-4 shows that while haematomas occur at similar rates in first-time and repeat donors, immediate vasovagal reactions occur four times as frequently in first-time donors. This partly explains why vasovagal reaction rates are lower in apheresis donors than whole blood donors as the percentage of first-time apheresis donors is also lower.

Figure 6-4: Haematoma and immediate vasovagal rates in first-time and repeat donors 2021



Vasovagal rates also differ by gender and age. Younger donors and females are more likely to experience vasovagal reactions (Figure 6-5).

Figure 6-5: Immediate vasovagal reaction rates in WB donors by gender and age group 2021



CHAPTER 7

DATA SUPPLEMENT

DATA SUPPLEMENT

This supplement contains additional data for some sections of the Haemovigilance Annual Report 2021. Where the data relates to Figures in the main report, this has been indicated in italics in the Table title.

2. Haemovigilance Overview

Supplementary Table 2-1: Haemovigilance reports received, and blood components transfused, in the last ten years *(Refer Fig 2-1)*

Note: error reports were previously included in this table. These have now been removed.

	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021
Total components transfused	149,668	136,995	135,135	132,060	130,185	127,765	130,361	135,093	131,308	134,440
Annual change of total components transfused (%)	-1.5%	-8.5%	-1.4%	-2.3%	-1.4%	-1.9%	2.0%	3.6%	-2.8%	2.4%
Total Haemovigilance reports	506	473	440	449	391	408	436	519	574	549
Annual change of total Haemovigilance reports (%)	1.2%	-6.5%	-7.0%	2.0%	-12.9%	4.3%	6.9%	19.0%	10.6%	-4.4%
Number of Haemovigilance reports per 10,000 components transfused	34	35	33	34	30	32	33	38	44	41
Number of individual patients	465	429	411	412	369	362	394	452	518	493

2.1 BLOOD COMPONENTS TRANSFUSED

Supplementary Table 2.1-1: Number of blood components transfused annually 2013 – 2021 ***(refer Figs 2.1-1 and 2.1-2)***

Blood Component	2013	2014	2015	2016	2017	2018	2019	2020	2021
Red Cells	103,565	102,718	99,915	98,535	95,979	95,438	98,614	97,874	100,791
Red Cells-Neo	1,664	1,553	1,260	1,327	1,466	1,412	1,361	1,378	1,603
Total Red Cells	**105,229**	**104,271**	**101,175**	**99,862**	**97,445**	**96,850**	**99,975**	**99,252**	**102,394**
Platelets	12,571	11,985	11,912	12,790	13,115	13,914	14,387	13,316	14,117
Platelets-Neo	817	616	621	624	685	601	650	510	691
Total Platelets	**13,388**	**12,601**	**12,533**	**13,414**	**13,800**	**14,515**	**15,037**	**13,826**	**14,808**
Fresh Frozen Plasma	13,528	13,400	13,172	11,821	12,141	13,542	13,954	12,212	10,797
Fresh Frozen Plasma-Neo	175	151	162	161	131	196	125	214	262
Total Fresh Frozen Plasma	**13,703**	**13,551**	**13,334**	**11,982**	**12,272**	**13,738**	**14,079**	**12,426**	**11,059**
Cryoprecipitate	4,167	4,198	4,482	4,463	4,147	5,279	5,968	5,804	6,179
Cryodepleted Plasma	508	514	536	464	101	175	34	0	0
Total Components	**136,995**	**135,135**	**132,060**	**130,185**	**127,765**	**130,557**	**135,093**	**131,308**	**134,440**

Supplementary Table 2.1-2: Components transfused per 1000 population 2013 – 2021 ***(Refer Figs 2.1-3 and 2.1-4)***

Component	2013	2014	2015	2016	2017	2018	2019	2020	2021
Red Cells	23.7	23.1	21.9	21.2	20.2	19.8	20.1	19.5	20.0
Platelets	3.0	2.8	2.7	2.8	2.9	3.0	3.0	2.7	2.9
Fresh Frozen Plasma	3.1	3.0	2.9	2.5	2.5	2.8	2.8	2.4	2.2
Cryoprecipitate	0.9	0.9	1.0	0.9	0.9	1.1	1.2	1.1	1.2
Cryodepleted Plasma	0.1	0.1	0.1	0.1	0.0	0.0	0.0	0.0	0.0
All Components	30.8	29.9	28.7	27.6	26.5	26.6	27.1	25.8	26.2
Population (millions)	**4.4**	**4.5**	**4.6**	**4.7**	**4.8**	**4.9**	**5.0**	**5.1**	**5.1**

Supplementary Table 2.1-3: Components transfused by DHB 2021

DHB	Red cells	FFP	Cryo	Platelets	Total
Auckland	19,684	3,718	2,130	6,202	31,734
Bay of Plenty	4,303	217	138	218	4,876
Canterbury	13,350	1,372	488	1,692	16,902
Capital and Coast	9,136	1,057	855	1,724	12,772
Counties Manukau	9,096	1,084	235	434	10,849
Hawkes Bay	3,526	360	66	140	4,092
Hutt Valley	1,771	66	29	25	1,891
Lakes	1,865	93	57	78	2,093
MidCentral	626	225	138	519	508
Nelson Marlborough	3,646	145	42	162	3,995
Northland	3,238	230	20	284	3,772
South Canterbury	1,130	40	9	59	1,238
Southern	6,260	600	326	779	965
Tairawhiti	692	35	8	17	752
Taranaki	2,201	128	47	78	454
Waikato	10,172	1,213	1,486	2,061	14,932
Wairarapa	731	24	4	20	779
Waitemata	6,046	432	95	282	6,855
West Coast	657	10	3	24	694
Whanganui	1,264	10	3	10	1,287
Grand Total	**102,394**	**11,059**	**6,179**	**14,808**	**134,440**

2.2 RECIPIENTS OF BLOOD COMPONENT

Supplementary Table 2.2-1: Annual numbers of recipients of components by year* 2015 to 2021 ***(Refer Figs 2.2-1 and 2.2-2)***

Component	2015	2016	2017	2018	2019	2020	2021
Red cells	23,437	22,620	22,884	22,534	23,056	23,509	24,621
	-3.7%	*-3.5%*	*1.2%*	*-1.5%*	*2.3%*	*2.0%*	*4.7%*
Fresh Frozen Plasma	3,198	2,551	2,399	2,487	2,418	2,208	2,249
	10.4%	*-20.2%*	*-6.0%*	*3.7%*	*-2.8%*	*-8.7%*	*1.9%*
Platelets	2,764	3,154	3,104	3,187	3,279	3,198	3.257
	-13.4%	*14.1%*	*-1.6%*	*2.7%*	*2.9%*	*-2.5%*	*1.8%*
Cryoprecipitate	1,155	1,195	1,158	1,301	1,301	1,401	1,480
	-2.3%	*3.5%*	*-3.1%*	*12.3%*	*12.3%*	*-3.7%*	*5.6%*

** percentage change from previous year in italics*

Supplementary Table 2.2-2: Age group distribution of male and female recipients 2017 to 2021 ***(Refer Figs 2.2-3 and 2.2-4)***

Male recipients (count)										
Age group (yrs)	**0 - 4**	**5 - 14**	**15 - 24**	**25 - 34**	**35 - 44**	**45 - 54**	**55 - 64**	**65 - 74**	**75 - 84**	**85+**
Red cells	2,164	650	1,118	1,470	1,710	3,248	6,451	10,397	10,748	6,383
FFP	432	105	297	304	372	700	1,278	1,659	1,299	354
Platelets	800	271	305	293	396	908	1,874	2,427	1,520	311
Male recipients (percentage)										
Age group (yrs)	**0 - 4**	**5 - 14**	**15 - 24**	**25 - 34**	**35 - 44**	**45 - 54**	**55 - 64**	**65 - 74**	**75 - 84**	**85+**
Red cells	3.6%	1.1%	1.9%	2.4%	2.8%	5.4%	10.7%	17.3%	17.8%	10.6%
FFP	0.7%	0.2%	0.5%	0.5%	0.6%	1.2%	2.1%	2.8%	2.2%	0.6%
Platelets	1.3%	0.4%	0.5%	0.5%	0.7%	1.5%	3.1%	4.0%	2.5%	0.5%
Female recipients (count)										
Age group (yrs)	**0 - 4**	**5 - 14**	**15 - 24**	**25 - 34**	**35 - 44**	**45 - 54**	**55 - 64**	**65 - 74**	**75 - 84**	**85+**
Red cells	1,626	771	3,380	7,391	5,474	5,062	6,088	9,146	10,259	8,303
FFP	369	113	264	588	482	466	673	838	699	239
Platelets	588	220	229	356	385	642	1,002	1,236	754	204
Female recipients (percentage)										
Age group (yrs)	**0 - 4**	**5 - 14**	**15 - 24**	**25 - 34**	**35 - 44**	**45 - 54**	**55 - 64**	**65 - 74**	**75 - 84**	**85+**
Red cells	2.4%	1.1%	5.0%	10.9%	8.1%	7.5%	9.0%	13.5%	15.1%	12.2%
FFP	0.5%	0.2%	0.4%	0.9%	0.7%	0.7%	1.0%	1.2%	1.0%	0.4%
Platelets	0.9%	0.3%	0.3%	0.5%	0.6%	0.9%	1.5%	1.8%	1.1%	0.3%

3. ADVERSE TRANSFUSION REACTION REPORTS

3.1.1 IMPUTABILITY

Supplementary Table 3.1.1-1: Adverse transfusion reactions by imputability 2011-2021 *(Refer Fig 3.1.1-1)*

	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020*	2021*
Total reactions	514	532	507	463	460	404	429	448	532	574	549
Possible, probable, certain	442	442	436	357	363	326	302	320	398	385	335
Excluded or unlikely	72	90	71	106	97	78	127	128	134	189	214
Percent excluded/unlikely	14.0%	16.9%	14.0%	22.9%	21.1%	19.3%	29.6%	28.6%	25.2%	32.0%	39.0%

** transfusion-related errors have been removed from 2020 and 2021 data only*

Supplementary Table 3.1.1-2: Adverse transfusion reactions by event type and imputability 2021 *(Refer Fig 3.1.1-2)*

Reaction type	Excluded	Unlikely	Possible	Probable	Certain	Total	Imputability > 2
FNHTR	69	115	130	40	5	359	175
Allergic	2	2	23	29	29	85	81
UCT	10	5	16	2	0	33	18
TAD	2	3	12	5	0	22	17
TACO	0	1	11	5	2	19	18
DSTR	1	0	0	2	10	13	12
TAH	3	1	6	2	0	12	8
AHTR	0	0	0	2	1	3	3
DHTR	0	0	0	1	1	2	2
TRALI	0	0	1	0	0	1	1
Total	**87**	**127**	**199**	**88**	**48**	**549**	**335**

3.1.3 ADVERSE TRANSFUSION REACTION TYPES

Supplementary Table 3.1.3-2: Frequency of adverse transfusion reaction types by blood component 2021

Reaction Type	Red cells	Fresh frozen plasma	Platelets apheresis PAS	Platelets pooled PAS	Cryoprecipitate
FNHTR	1:560	1:2,212	1:975	1:625	1:3,099
Allergic	1:1,896	1:335	1:406	1:551	1:885
TACO	1:4,654	-	1:4,873	1:9,369	-
Hypotension	1:17,066	-	-	1:3,123	-
UCT	1:5,689	-	1:2,437	1:3,123	-
TAD	1:6,400	1:11,059	-	1:9,369	-
DSTR	1:4,452	-	-	-	-
PTP	-	-	-	-	-
AHTR	1:51,197	-	1:2,437	-	-
DHTR	1:20,479	-	-	-	-
TRALI	-	-	-	1:9,369	-
Units transfused	**102,394**	**11,059**	**4,873**	**9,369**	**6,197**

3.1.6 REPORTING BY DISTRICT HEALTH BOARD

Supplementary Table 3.1.6-1: Adverse transfusion reaction reports by DHB (imputability >2) 2021 ***(refer Fig 3.1.6-2)***

Size	District Health Board	ATRs	Units Transfused	Frequency	Rate / 10,000 units transfused (95%CI)
Large (>10,000 units transfused)	Capital and Coast	50	12,772	1:255	39.1 (29.6 to 51.7)
	Waikato	39	14,932	1:383	26.1 (19.0 to 35.8)
	Counties Manukau	26	10,849	1:417	24.0 (16.2 to 35.3)
	Canterbury	38	16,902	1:445	22.5 (16.3 to 30.9)
	Auckland	66	31,734	1:481	20.8 (16.3 to 26.5)
Medium (3,000-10,000 units transfused)	MidCentral	17	4,508	1:265	37.7 (23.1 to 60.8)
	Nelson Marlborough	13	3,995	1:307	32.5 (18.4 to 56.2)
	Bay of Plenty	15	4,876	1:325	30.8 (18.2 to 51.2)
	Waitemata	18	6,855	1:381	26.3 (16.3 to 41.8)
	Hawkes Bay	10	4,092	1:409	24.4 (12.6 to 45.6)
	Southern	17	7,965	1:469	21.3 (13.1 to 34.4)
	Northland	6	3,772	1:629	15.9 (6.4 to 35.6)
Small (<3,000 units transfused)	Hutt Valley	6	1,891	1:315	31.7 (12.8 to 70.9)
	Lakes	6	2,093	1:349	28.7 (11.5 to 64.0)
	Wairarapa	2	779	1:390	25.7 (0.6 to 99.5)
	South Canterbury	2	1,238	1:619	16.2 (0.4 to 62.8)
	West Coast	1	694	1:694	14.4 (0 to 89.8)
	Taranaki	2	2,454	1:1227	8.1 (0.2 to 31.7)
	Whanganui	1	1,287	1:1287	7.8 (0 to 48.5)
	Tairawhiti	0	752	-	-
	Total	**335**	**134,440**	**1:401**	**24.9 (22.4 to 27.7)**

3.2 FEBRILE NON-HAEMOLYTIC TRANSFUSION REACTIONS

Supplementary Table 3.2-3: Distribution of FNHTR symptoms 2010-2021

Signs/Symptoms	Number of reports	Percentage
Chills/rigors	1077	37.3%
Hypertension	393	13.6%
Tachycardia	294	10.2%
Fever	262	9.1%
Restlessness	243	8.4%
Dyspnoea	219	7.6%
Nausea/vomiting	92	3.2%
Chest pain	68	2.4%
Hypoxaemia	61	2.1%
Stridor/wheeze	57	2.0%
Hypotension	49	1.7%
Tachypnoea	43	1.5%
Urticaria	27	0.9%

3.5.1 TRANSFUSION-RELATED ACUTE LUNG INJURY (TRALI)

Supplementary Table 3.5.1-2: Distribution of symptoms reported in 51 cases* 2005-2021 *(Refer Fig 3.5.1-2)*

Signs/Symptoms	2005-2021 (number of reports)
Dyspnoea	36
Fall in O2 saturation	26
Hypotension	16
Tachycardia	13
Restlessness	12
Stridor/wheeze	9
Hypertension	5

**** Multiple symptoms per case***

3.5.2 TRANSFUSION-ASSOCIATED CIRCULATORY OVERLOAD (TACO)

Supplementary Table 3.5.2-4: Annual TACO events 2012 – 2021 *(Refer Fig 3.5.2-2)*

Year	Number of events	Units Transfused	Frequency	Rate/10,000 Units Transfused (95%CI)
2012	27	149,668	1:5,543	1.8 (1.2 to 2.6)
2013	16	136,995	1:8,562	1.2 (0.7 to 1.9)
2014	12	135,135	1:11,261	0.9 (0.5 to 1.6)
2015	16	132,060	1:8,254	1.2 (0.7 to 2.0)
2016	11	130,185	1:11,835	0.8 (0.5 to 1.5)
2017	9	127,765	1:14,196	0.7 (0.3 to 1.4)
2018	12	130,361	1:10,863	0.9 (0.5 to 1.6)
2019	16	135,093	1:8,443	1.2 (0.7 to 1.9)
2020	18	131,308	1:7,295	1.4 (0.9 to 2.2)
2021	18	134,440	1:7,469	1.3 (0.8 to 2.1)
Total	**155**	**1,343,010**	**1:8,665**	**1.2 (1.0 to 1.4)**

5. Pharmacovigilance

Supplementary Table 5-4: Adverse events by fractionated product: 2007 – 2021 ***(Refer Fig 5-1)***

Product	Number of Reports	Percentage
Intragam® P	297	51.1%
Privigen®	92	15.8%
Rh(D) Immunoglobulin-VF	61	10.5%
Albumex® 4	40	6.9%
Albumex® 20	30	5.2%
Prothrombinex® -VF	24	4.1%
Evogam®	11	1.9%
Biostate®	9	1.5%
Intragam® P & Privigen®	4	0.7%
MonoFIX® -VF	2	0.3%
Tetanus Immunoglobulin-VF	2	0.3%
Berinert®	1	0.2%
Evogam® & Intragam® P	1	0.2%
FEIBA NF®	1	0.2%
Hepatitis B Immunoglobulin-VF	1	0.2%
NextGen® 16% Immunoglobulin	1	0.2%
Normal Immunoglobulin-VF	1	0.2%
RiaSTAP®	1	0.2%
Zoster Immunoglobulin-VF	1	0.2%
Total	**581**	

6. Donor vigilance

Supplementary Table 6-3: Annual number of blood donations by donation type 2005 – 2021 ***(Refer Fig 6-1)***

	Whole Blood		Plasmapheresis		Plateletpheresis		Total	
Year	Donors	WB Donations	Donors	Plasma Donations	Donors	Platelet Donations	Donors	Total Donations
2005	95,382	156,684	1,227	6,479	979	5,098	97,588	168,261
2006	91,929	151,934	2,647	12,880	957	5,148	95,533	169,962
2007	88,584	150,308	4,064	23,514	957	5,493	93,605	179,315
2008	90,364	152,760	4,190	26,985	1,009	5,998	95,563	185,743
2009	89,159	151,689	3,012	18,106	1,143	6,578	93,314	176,373
2010	89,623	153,044	3,407	18,243	1,136	6,499	94,166	177,786
2011	86,986	147,093	4,723	28,886	1,119	6,491	92,828	182,470
2012	83,040	139,845	5,037	30,179	1,138	6,527	89,215	176,551
2013	75,069	125,684	5,078	29,585	830	4,942	80,977	160,211
2014	72,754	120,668	5,910	38,099	595	3,570	79,259	162,337
2015	71,511	119,554	7,586	46,983	555	3,377	79,652	169,914
2016	69,857	114,779	8,789	54,059	425	2,878	79,071	171,716
2017	66,871	111,188	9,121	54,125	415	2,766	76,407	168,079
2018	67,407	112,162	10,243	59,895	436	2,648	78,086	174,705
2019	68,297	113,329	11,785	65,192	448	2,682	80,530	181,203
2020	68,832	113,699	17,267	93,669	611	2,823	80,801	210,191
2021	68,926	115,315	20,687	108,669	553	2,754	85,501	226,738

Supplementary Table 6-4: Donation related adverse events by donation type 2021 *(Refer Fig 6-3)*

	WHOLE BLOOD (115,315 Donations)				APHERESIS (111,423 donations)			
Event type	**No of events**	**% of events**	**Frequency**	**Rate/1,000 donations (95% CI)**	**No of events**	**% of events**	**Frequency**	**Rate/1,000 donations (95% CI)**
B. Vasovagal	2779	63.81%	1:41	24.10 (23.23 to 25.00)	1475	35.80%	1:76	13.24 (12.58 to 13.93)
A1. Haematoma	1279	29.37%	1:90	11.09 (10.50 to 11.71)	1858	45.10%	1:60	16.68 (15.94 to 17.44)
A2. Painful Arm	206	4.73%	1:560	1.79 (1.56 to 2.05)	309	7.50%	1:361	2.77 (2.48 to 3.10)
F. Other Complications	103	2.37%	1:1,120	0.89 (0.74 to 1.08)	181	4.39%	1:616	1.62 (1.40 to 1.88)
A1. Re-bleeding	92	2.11%	1:1,253	0.80 (0.65 to 0.98)	20	0.49%	1:5,571	0.18 (0.11 to 0.28)
A2. Nerve Irritation / Injury	76	1.75%	1:1,517	0.66 (0.53 to 0.83)	70	1.70%	1:1,592	0.63 (0.50 to 0.80)
D. Local Allergic Reaction	9	0.21%	1:12,813	0.08 (0.04 to 0.15)	16	0.39%	1:6,964	0.14 (0.09 to 0.24)
A1. Arterial Puncture	5	0.11%	1:23,063	0.04 (0.02 to 0.11)	2	0.05%	1:55,712	0.02 (0 to 0.07)
A3. Thrombophlebitis	2	0.05%	1:57,658	0.02 (0 to 0.07)	2	0.05%	1:55,712	0.02 (0 to 0.07)
D. Generalised Allergic Reaction	1	0.02%		0.01 (0 to 0.05)	3	0.07%	1:37,141	0.03 (0.01 to 0.08)
A3. Cellulitis	0	-	-	-	2	0.05%	1:55,712	0.02 (0 to 0.07)
E. Other Serious Complications	0	-	-	-	1	0.02%	1:111,423	0.01 (0 to 0.06)
A4. Other Major Vessel Injury	0	-	-	-	0	-	-	-
C. Citrate Reaction	-	-	-	-	169	4.10%	1:659	1.52 (1.30 to 1.76)
C. Haemolysis	-	-	-	-	2	0.05%	1:55,712	0.02 (0 to 0.07)

Supplementary Table 6-5: Whole blood donation related adverse events by reaction type in first-time and repeat donors 2021 ***(Refer Fig 6-4)***

	First-time donors (n=13,926)				Repeat donors (n=99,773)			
Event type	**No of events**	**Percentage of events**	**Frequency**	**Rate/1,000 donations**	**No of events**	**% of events**	**Frequency**	**Rate/1,000 donations**
B. Vasovagal	1,039	80.42%	1:14	70.28	1740	53.33%	1:58	17.31
A1. Haematoma	180	13.93%	1:82	12.18	1099	33.68%	1:91	10.93
A2. Painful Arm	31	2.40%	1:477	2.10	175	5.36%	1:574	1.74
A2. Nerve Irritation / Injury	9	0.70%	1:1,643	0.61	67	2.05%	1:1,500	0.67
A1. Re-bleeding	3	0.23%	1:4,928	0.20	89	2.73%	1:1,130	0.89
A1. Arterial Puncture	0	-	-	-	5	0.15%	1:20,106	0.05
D. Local Allergic Reaction	3	0.23%	1:4,928	0.20	6	0.18%	1:16,755	0.06

Supplementary Table 6-6: Whole blood adverse events by donor age group 2021

Event type	No of events	No of donations	Frequency	Rate/1,000 donations (95% CI)
16 - 19	674	7,056	1:10	95.5 (88.9 to 102.6)
20 - 24	826	9,977	1:12	82.8 (77.5 to 88.4)
25 - 29	759	12,291	1:16	61.8 (57.6 to 66.1)
30 - 34	477	11,450	1:24	41.7 (38.1 to 45.5)
35 - 39	343	10,018	1:29	34.2 (30.8 to 38)
40 - 44	251	9,956	1:40	25.2 (22.3 to 28.5)
45 - 49	233	10,718	1:46	21.7 (19.1 to 24.7)
50 - 54	256	10,954	1:43	23.4 (20.7 to 26.4)
55 - 59	242	10,548	1:44	22.9 (20.2 to 26)
≥60	494	22,347	1:45	22.1 (20.3 to 24.1)
All	**4,555**	**115,315**	**1:25**	**39.5 (38.4 to 40.6)**

Supplementary Table 6-7: First-time and repeat donor whole blood vasovagal events by donor age group and gender 2021 *(Refer Fig 6-5)*

		First-time donors (n=13,926)		Repeat donors (n=99,773)	
Age group (years)	**Gender**	**Frequency**	**Rate/1,000 donations (95% CI)**	**Frequency**	**Rate/1,000 donations (95% CI)**
16 – 19	Female	1:9	109.1 (97.1 to 122.4)	1:14	70.1 (58.5 to 83.8)
	Male	1:16	62.7 (52.9 to 74.0)	1:30	33.5 (24.2 to 46.1)
20 – 24	Female	1:8	127.1 (110.1 to 146.3)	1:20	50.1 (44.6 to 56.3)
	Male	1:15	67.1 (50.8 to 88.0)	1:25	40.1 (33.2 to 48.4)
25 – 29	Female	1:11	89.8 (74.8 to 107.5)	1:27	37.7 (33.4 to 42.6)
	Male	1:15	68.9 (54.2 to 87.1)	1:40	24.8 (20.2 to 30.4)
30 – 34	Female	1:20	50.4 (37.5 to 67.4)	1:38	26.2 (22.2 to 30.9)
	Male	1:21	47.4 (34.6 to 64.6)	1:65	15.5 (12.2 to 19.5)
35 – 39	Female	1:18	56.9 (41.0 to 78.3)	1:56	17.7 (14.3 to 21.9)
	Male	1:21	47.1 (32.6 to 67.5)	1:78	1 2.9 (9.8 to 16.8)
40 – 44	Female	1:26	38.8 (24.9 to 59.4)	1:80	12.5 (9.8 to 16.0)
	Male	1:57	17.7 (8.4 to 35.2)	1:130	7.7 (5.4 to 10.9)
45 – 49	Female	1:33	30.6 (17.8 to 51.1)	1:106	9.4 (7.2 to 12.3)
	Male	1:74	13.5 (4.8 to 32.2)	1:276	3.6 (2.1 to 6.0)
50 – 54	Female	1:49	20.5 (9.7 to 40.6)	1:97	10.3 (8.0 to 13.3)
	Male	1:61	16.4 (5.9 to 39.0)	1:216	4.6 (3.0 to 7.1)
55 – 59	Female	1:21	46.8 (27.4 to 77.7)	1:102	9.8 (7.6 to 12.8)
	Male	1:32	30.9 (12.7 to 67.4)	1:291	3.4 (2.0 to 5.7)
≥60	Female	1:31	32.4 (14.5 to 66.7)	1:111	9.0 (7.4 to 10.9)
	Male	1:26	38.5 (17.3 to 78.7)	1:312	3.2 (2.3 to 4.5)
Total	Female	1:12	81.8 (76.0 to 87.9)	1:48	20.8 (19.7 to 22.0)
	Male	1:20	51.2 (46.1 to 56.8)	1:93	10.7 (9.8 to 11.7)
Overall		**1:15**	**68.1 (64.2 to 72.3)**	**1:61**	**16.4 (15.6 to 17.2)**