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2019 - 2023

Ontario TTISS 5 Year Report

Transfusion Transmitted Injuries Surveillance System (TTISS) Five Year Report Summary 2019-2023

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Acknowledgement

Ontario's contribution to Canada's Transfusion Transmitted Injuries Surveillance System (TTISS) relies on the voluntary involvement of hospitals to report adverse transfusion events.

Dr. Andrew Shih, the director of the TTISS-ON, as of June 2024, is also the regional medical director of the Transfusion Medicine Service for the Hamilton Regional Laboratory Medicine Program.

In the last 10 years, the TTISS program has grown in Ontario to include all hospitals. This could not have been possible without the continuing participation of committed healthcare professionals responsible for reporting these adverse transfusion events and the input of those transfusion specialists involved in teaching, training and guiding practices in transfusion safety. Thank you for recognizing the importance of the program and contributing your time and effort to support TTISS and providing data on an ongoing basis. Without your cooperation and collaboration, this report would not be possible.

We would like to express our gratitude to the Blood Safety Contribution Program, Public Health Agency of Canada and Ontario's Blood Programs Coordinating Office at the Ministry of Health. They have provided us with funding, guidance and support throughout the program. In addition, many thanks to our colleagues and the staff at the Canadian Blood Services, Canada Vigilance Program, Health Canada, and ORBCoN for providing us with an avenue to grow and disseminate information.

Many thanks to the staff at Ontario's TTISS Coordinating Centre, located at McMaster University in Hamilton, including coordinators, biostatisticians and data entry personnel.

Lastly, I would like to thank Professor Nancy Heddle for her invaluable leadership provided to the program and Canadian hemovigilance.

Dr. Andrew Shih

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Michael G. Degroote Centre for Transfusion Medicine, McMaster University.

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Executive Summary

Transfusion Transmitted Injuries Surveillance System (TTISS) is a national hemovigilance system implemented by the Public Health Agency of Canada (PHAC) to monitor serious, moderate and selected minor adverse transfusion reactions (ATRs) related to blood components and blood products. The Ministry of Health (MOH) in Ontario and the Public Health Agency of Canada (PHAC) contracts the Michael DeGroote Centre for Transfusion Research Program (MCTR) at McMaster University to coordinate the TTISS activities in Ontario, though TTISS-ON is acknowledged to be a leader in hemovigilance in Canada.

The program is designed to capture ATRs related to all blood products comprised of blood components (red cells, plasma, platelets, cryoprecipitate) and blood products (immunoglobulin preparations, coagulation factors, and albumin).

There are 159 hospitals that transfuse blood products in Ontario. This report summarizes ATRs received from all 159 Ontario hospitals that voluntarily participated in the TTISS program during the period 2019 - 2023. All TTISS participating hospitals submit reportable ATRs (reportable to PHAC exclude minor allergic, delayed serological and febrile non-hemolytic reactions).

A subgroup of 28 hospitals, referred to as sentinel sites, report all ATRs including the non-reportable reactions listed above. The sentinel sites account for approximately 33.4% of all the transfusion activity in Ontario. Comprehensive reporting by sentinel sites allows for risk calculation for only blood components.

The report is divided into five sections consisting of an acknowledgment, executive summary, methodology, main report and appendices. The main report describes ATRs in connection with the following: blood products; blood components; sentinel sites and risk estimates; blood products; specific reaction types; and number of deaths.

The following report includes figures and tables of the 1,631 reportable ATRs (collected from all sites) and 2,104 non-reportable ATRs (collected100% from sentinel sites only), for a total of 3,735 ATRs submitted to TTISS Ontario between 2019 and 2023. Of the 1,631 reportable reactions from all TTISS participating sites, 1,123 (68.9%) were related to blood components, 499 (30.6%) related to blood product and 9 (0.5%) were from a combination of both blood components and blood products. Non-sentinel sites were encouraged to enter non-reportable reactions, if feasible, with 2,800 ATRs reported to TTISS-ON. In total, TTISS-ON received 6,085 ATRs.

Red blood cells were implicated in 849/1,123 (75.6%) of the reactions to blood components. ATRs associated with blood products were most frequently reported with IVIG (432; 86.6%).
The most frequent ATRs reported were; transfusion associated circulatory overload (TACO) reactions (n = 542, 33.2 %), severe allergic/anaphylactic/anaphylactoid reactions (n = 195, 12.0%), and IVIg headaches (n = 149, 9.1%). There were 54 (3.3%) ATRs not categorized and reported as “other” or “unknown”.

Overall, 706 (43.3%) of the 1,631 reportable ATRs were severe or life threatening; 547 (77.5%) of these were related to blood components and 159 (22.5%) were related to blood products. There were 28 related deaths, of which 24 were related to blood components and 4 associated with blood products.

Overview TTISS Reactions

There were 6,085 reactions reported during the period 2019 - 2023 calendar year. Minor reactions account for approximately 75% of all reactions (2,104/2787) reported from Sentinel Sites. Given Sentinel Sites account for approximately 35% of transfusion activity, the high rate of ATR reporting demonstrates a high level of additional engagement.

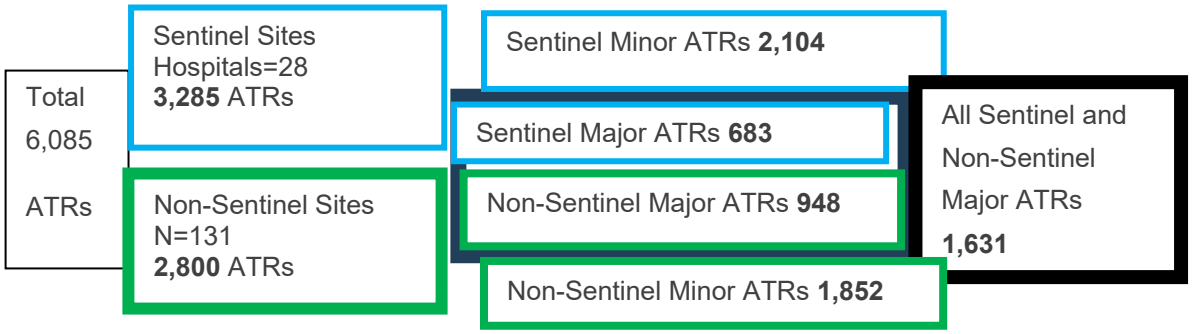
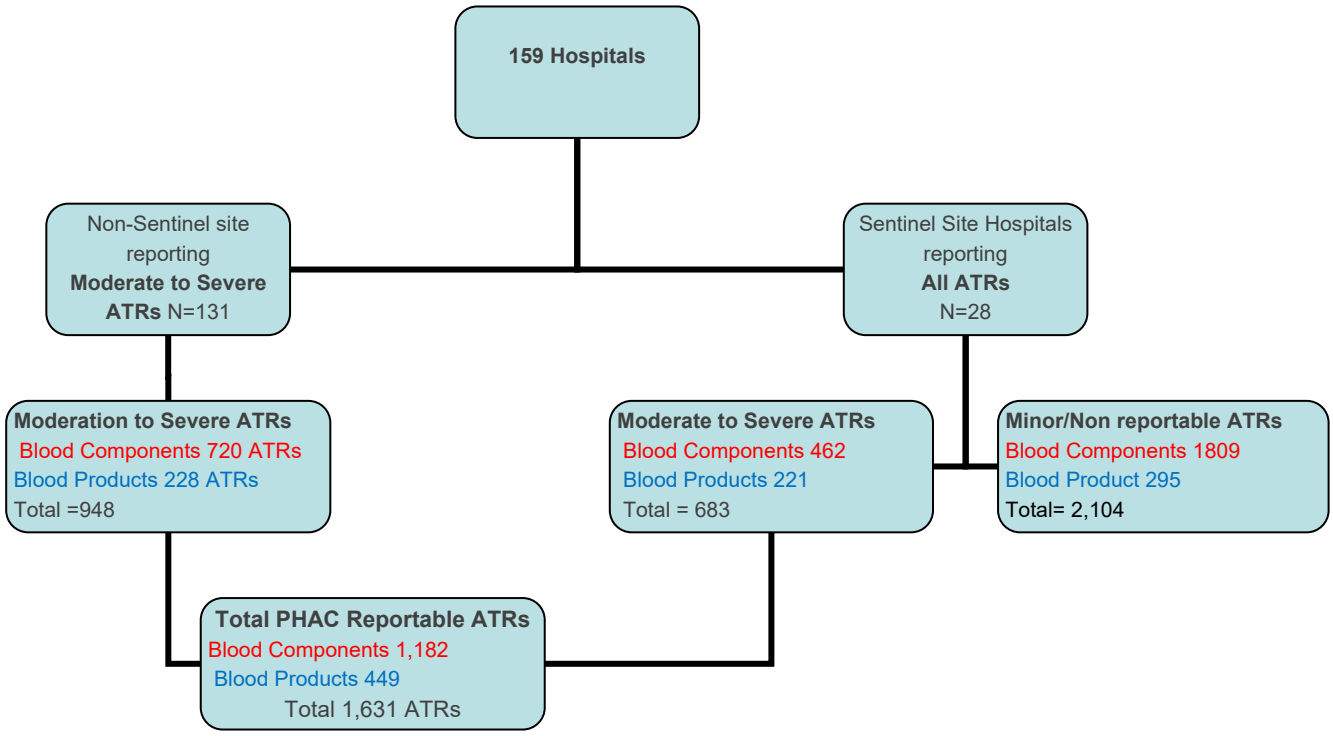


Figure i. Summary of ATR to blood components and blood components reported by Ontario Transfusion Transmitted Injuries Surveillance System (TTISS) to the public health agency of Canada.



Executive Summary

Key points derived from the tables and data below, are as follows:

1. Transfusion associated circulatory overload (TACO), (33%), severe allergic/anaphylactic/anaphylactoid, (12%), intravenous immune globulin (IVIg) headache, (9%) are, respectively, the three most common moderate-to-severe ATRs reported.

2. TACO and acute hemolytic reactions are highly associated with patient mortality and are not routinely reportable to Health Canada (HC) directly or via Canadian Blood Services (CBS). These reactions are reported TTISS. A notable proportion required either significant medical/surgical intervention and/or were life-threatening according to clinical adjudication in TTISS-ON data. TACOs should be reported to HC is requested when deemed “serious”. However very few of serious TACOs were found reported to HC-Canada Vigilance database for all of Canada.

3. ATR reporting has steadily increased while units of blood components have remained relatively constant. This increase in reporting most probably represents increased efforts to promote education and engagement from TTISS-ON sites to detect and report ATRs, further reflected in ATRs reported from all sites as well as training logs documenting that use is majorly by community-based hospitals.

4. Cases of “unknown/other” transfusion reactions were reviewed and classified, when possible. This category was commonly used when more than one transfusion reaction occurred. TTISS reports the most serious reaction. In 2024, hospitals will be able to choose more than one ATR.

5. Hypotension is a category on the TTISS form, while hypertension is not on the form and commonly reported as “other”. There were 38 (2%) that were reported as hypertension.

6. Febrile non-hemolytic reactions, delayed serological and minor allergic reactions are not reported to the Public Health Agency of Canada, but many are severe. In addition, they are commonly seen associated with other reactions such as TACO.

Methodology

A total of 2,239,251 blood components were transfused by 159 Ontario hospitals from 2019 - 2023. Hospitals participating in TTISS transfused 100% of those blood components over the 5-year period, as all 159 hospitals participated in TTISS, capturing 100% of components transfused. This has increased the number of reportable reactions by 27%, reporting 948 ATRs compared to 696 during the previous 5-year period (2014-2018).

Adverse transfusion reactions associated with blood transfusion are reported to the laboratory at individual hospital sites. These reactions are identified, severity is established and imputability determined using the national definitions. Imputability is categorized as definite, probable, possible, doubtful, ruled out, or not determined. For purposes of this report, those defined as doubtful and ruled out were not included (see appendix 3).

If the reaction is reportable according to the TTISS guidelines provided by PHAC, it is submitted to the Ontario TTISS office by direct entry into a web-based database. Submitted data does not include personal identifying information. The data is reviewed and assessed for completeness by the Ontario TTISS office staff. If additional information is required, the submitting hospital is contacted to provide the missing information. Cases initially classified as “Unknown” or “Other” are reviewed and, when possible, reclassified. Those cases that remain “Unknown” or “Other” were grouped together for this report to create one single new category of “Other/Unknown pain”.

Adverse event data is entered to PHAC into the online database CNPHI, after they are reviewed and completed, by the Ontario TTISS office.

The subgroup of hospitals (n=28) referred to as the “sentinel” sites that submit 100% of their non-reportable reactions (minor allergic, delayed serological, febrile non hemolytic), are required to provide the number of each blood component transfused annually allowing for a calculation of reaction risk per product transfused. The risk of ATRs associated with blood products is not calculated as hospitals do not report the denominator data for these products.

Figure ii: Ontario transfusion activity: Number of blood components transfused 2019 – 2023

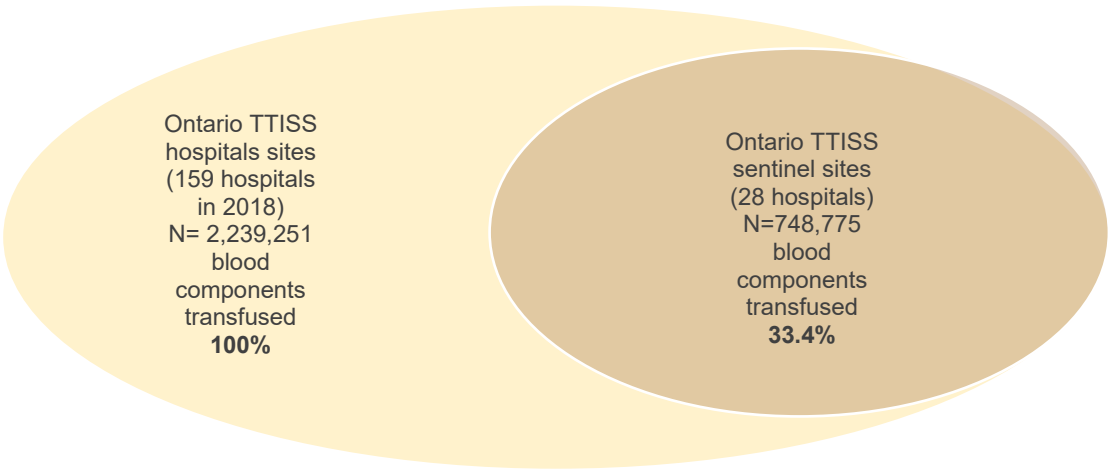


Figure 1 -Blood ATRs

Figure 1a: Number and percent of ATRs by reaction type for all reportable ATRS for Blood Components and Blood Products, N= 1,631

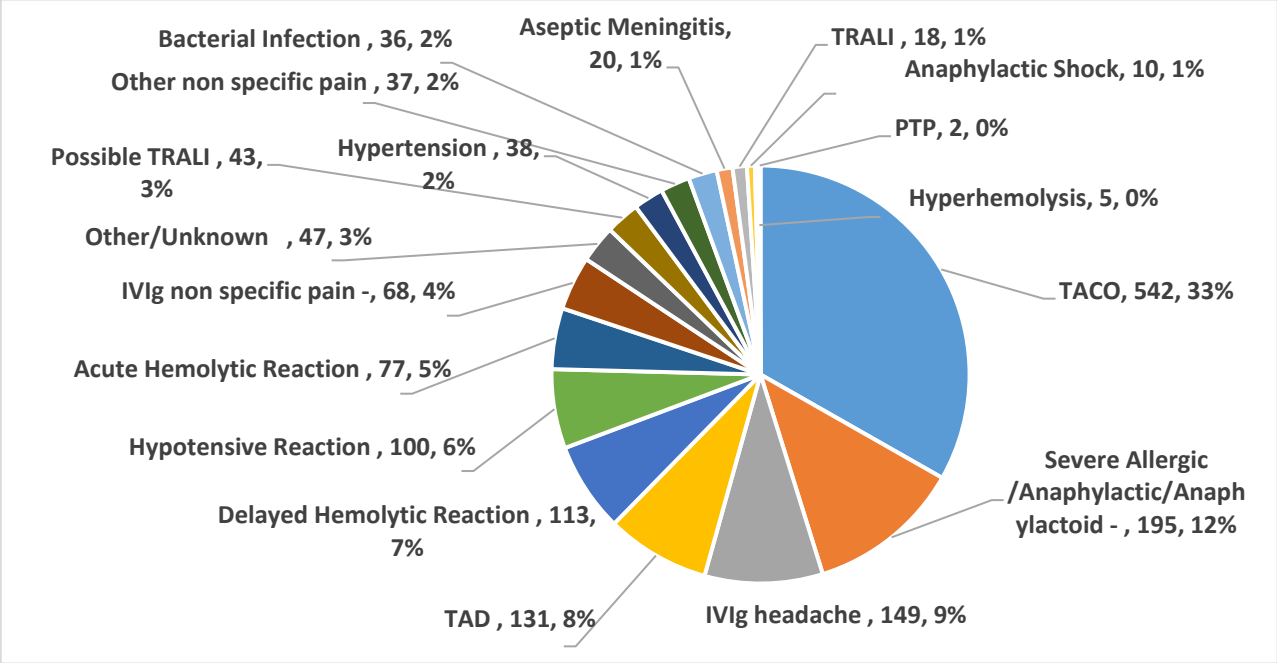


Table 1: Number and percent of ATRs by reaction type for all reportable ATRS for Blood Components and Blood Products, by Year N= 1,631

Hypertension is not a specific category of reaction on the TTISS form however, when reported as "other" TTISS reclassified this reaction as Hypertension resulting the 10 times increase in 2023.

ATRs	2019	2020	2021	2022	2023	Total	%
TACO	97	98	99	117	131	542	33%
Severe Allergic /Anaphylactic/Anaphylactoid -	51	36	38	32	38	195	12%
IVIg headache	37	16	20	35	41	149	9%
TAD	26	19	16	35	35	131	8%
Delayed Hemolytic Reaction	21	32	15	22	23	113	7%
Hypotensive Reaction	17	21	20	26	16	100	6%
Acute Hemolytic Reaction	16	6	18	21	16	77	5%
IVIg non specific pain -	19	17	11	10	11	68	4%
Other/Unknown (see appendix)	7	4	7	9	20	47	3%
Possible TRALI	6	15	13	5	4	43	3%
Hypertension	2	5	5	6	20	38	2%
Other non specific pain	6	11	11	4	5	37	2%
Bacterial Infection	12	6	6	6	6	36	2%
Aseptic Meningitis	6	3	4	2	5	20	1%
TRALI	5	3	4	3	3	18	1%
Anaphylactic Shock	3	0	3	3	1	10	1%
Hyperhemolysis	1	0	1	1	2	5	<1%
PTP	1	0	0	0	1	2	<1%
Total	**333**	**292**	**291**	**337**	**378**	**1,631**	**100%**

Blood ATRs – 1,631 ATRs

Table 2: Relationship of ATRS by reaction type for all reportable ATRS for Blood Components and Blood Products N= 1,631

Of the 1,631 ATRS reported, only 16.3% were classified as definitely related to the transfusion.

ATRs	Definite	Probable	Possible	Not Determ	Total
TACO	84	237	221	-	542
Severe Allergic /Anaphylactic/toid	37	90	68	-	195
IVIg headache	23	109	17	-	149
TAD	7	45	78	1	131
Delayed Hemolytic Reaction	55	17	34	7	113
Hypotensive Reaction	6	29	64	1	100
Acute Hemolytic Reaction	26	27	23	1	77
IVIg non specific pain	7	28	33	-	68
Other/Unknown	4	10	28	5	47
Possible TRALI,	2	4	37	-	43
Hypertension	-	17	21	-	38
Other non specific pain	4	14	18	1	37
Bacterial Infection	3	3	30	-	36
Aseptic Meningitis	5	11	4	-	20
TRALI	2	9	7	-	18
Anaphylactic Shock	1	1	8	-	10
Hyperhemolysis	-	1	4		5
PTP	-	-	2	-	2
Total	**266**	**652**	**697**	**16**	**1,631**

Table 3: Severity of ATRs by reaction type for all reportable ATRS for Blood Components and Blood Products N= 1,631

Of the 1,631 ATRS reported 43.3% were severe or life-threatening.

ATRs	Grade 1 (Non-Severe)	Grade 2 (Severe)	Grade 3 (Life-threatening)	Total
TACO	271	208	63	542
Severe Allergic /Anaphylactic/toid	61	105	29	195
IVIg headache	136	13	-	149
TAD	75	43	12	131
Delayed Hemolytic Reaction	67	43	4	113
Hypotensive Reaction	72	20	8	100
Acute Hemolytic Reaction	46	29	2	77
IVIg non specific pain	63	4	1	68
Other/Unknown	34	10	3	47
Possible TRALI,	2	26	15	43
Hypertension	35	3	-	38
Other non specific pain	34	3	-	37
Bacterial Infection	21	14	1	36
Aseptic Meningitis	5	15	-	20
TRALI	1	8	9	18
Anaphylactic Shock	2	5	3	10
Hyperhemolysis	-	5	-	5
PTP	-	2	-	2
Total	**925**	**556**	**150**	**1,631**

Blood ATRs – 1,631 ATRs

Blood and ATRs

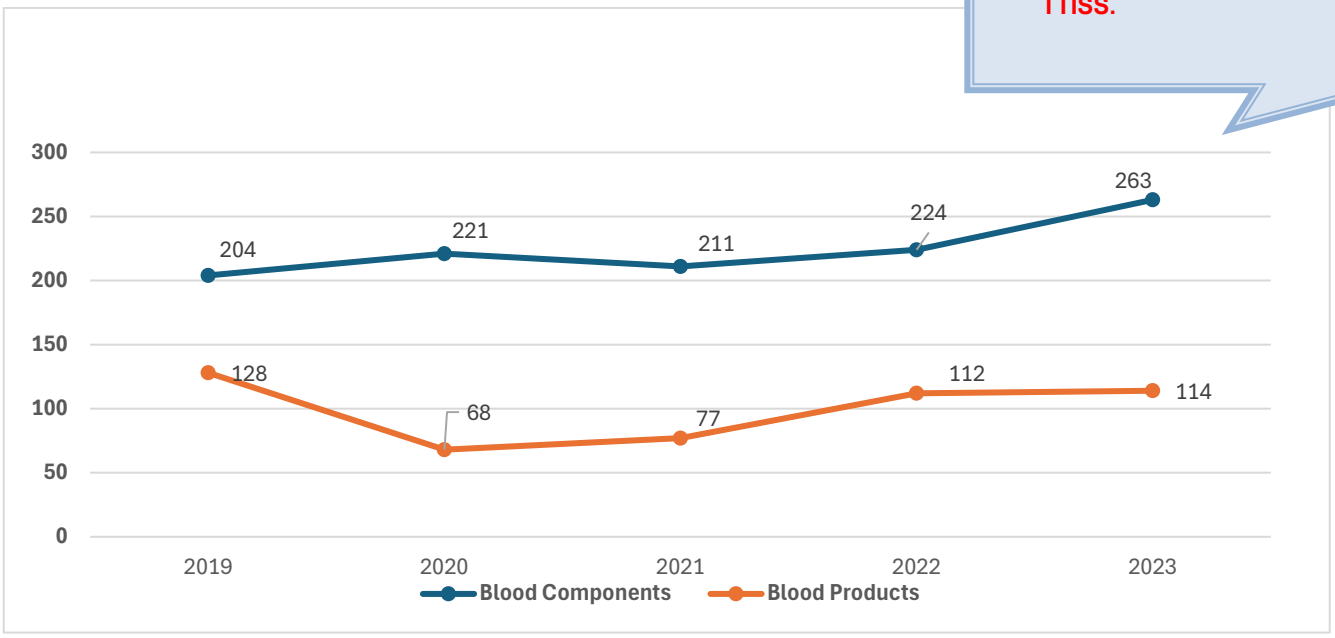
Total PHAC Reportable ATRs
For all blood products at all TTISS participating hospitals
Blood Components 1,123 ATRs
Blood Products 499 ATRs
Both Types 9 ATRs
Total 1,631 ATRs

Table 4: Adverse transfusion events (ATRs), N (%) by type of product and year.

Type of Transfused Product	2019		2020		2021		2022		2023		Total	
	N	%	N	%	N	%	N	%	N	%	N	%
Blood Components	204	61.3	221	75.7	211	72.5	224	66.5	263	69.6	1,123	68.9
Blood Products	128	38.4	68	23.3	77	26.5	112	33.2	114	30.1	499	30.6
Both Types	1	0.3	3	1.0	3	1.0	1	0.3	1	0.3	9	0.5
Total	**333**	**100**	**292**	**100**	**291**	**100**	**337**	**100**	**378**	**100**	**1,631**	**100**

- **Overall, 68.9% of ATRs reported to TTISS were associated with blood components.**
- **Number of ATRs reported has increased over the past 5 years due to increasing participation in TTISS.**

Figure 2: ATRS related to transfused blood per year (N=1,234).



Blood ATRs– 1,631 ATRs

Table 5a: Number and percent of ATRS by reaction type for Blood Components and Blood Products, N (%)

****SEE Appendix 1** for description of the 47 UNKNOWNS/OTHERS Reactions

- **The majority of the lung associated ATRS, TAD, TACO, TRALI and possible TRALI (XXX%) are associated with Blood Components**
- **The most frequently reported ATRs are TACO (33.2%)**

Adverse Transfusion Reaction	Blood Component		Blood Products		Both Product Types		Total of All Products	
	N	%	N	%	N	%	N	%
TACO	477	42.43	60	12.0	5	55.6	542	33.2
Severe Allergic /Anaphylactic/Anaphylactoid	135	12.0	59	11.8	1	11.1	195	12.0
IVIg headache	-	0.0	149	29.9	-	-	149	9.2
TAD	102	9.1	29	5.8	-	-	131	8.1
Delayed Hemolytic Reaction	89	7.9	23	4.6	1	11.1	113	6.9
Hypotensive Reaction	87	7.7	12	2.5	1	11.1	100	6.1
Acute Hemolytic Reaction	51	4.5	26	5.2	-	-	77	4.7
IVIg non specific pain	-	0	68	13.6	-	-	68	4.2
Unknown/Other**	23	2.1	24	4.8	-	-	47**	2.9
Possible TRALI,	41	3.6	2	0.4	-	-	43	2.6
Hypertension	25	5.3	13	2.6	-	-	38	2.3
Other non specific pain	26	2.3	11	2.2	-	-	37	2.3
Bacterial Infection	36	3.2	-	0	-	-	36	2.2
Aseptic Meningitis	-	0	20	4.0		-	20	1.2
TRALI	17	1.5	-	-	1	11.1	18	1.1
Anaphylactic Shock	8	0.7	2	0.4	-	-	10	0.6
Hyperhemolysis	4	0.4	1	0.2	-	-	5	0.3
PTP	2	0.2	-	-	-	-	2	0.1
Total	**1,123**	**100**	**499**	**100**	**9**	**100**	**1,631**	**100**

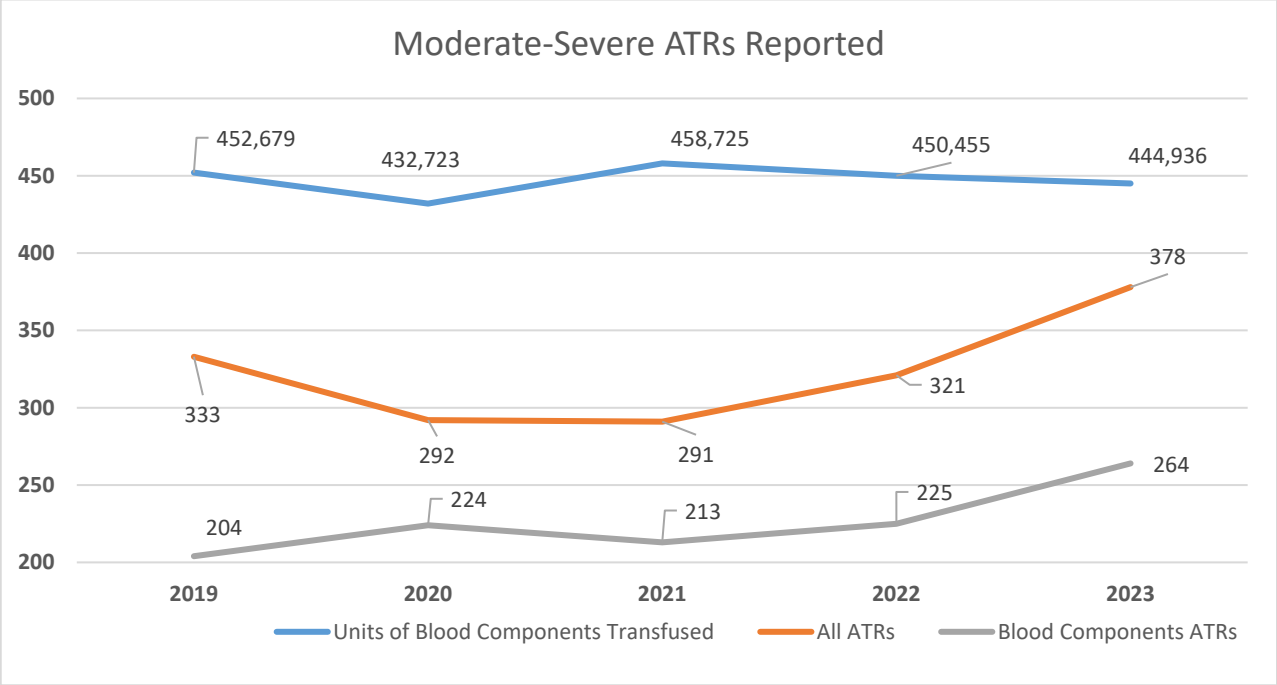
Transfusion Activity 2019 – 2023

Table 6: Blood Component transfusion activity in all Ontario hospitals, by year (N=159)
The table below shows the number of Blood Components transfused in Ontario. This denominator data is available for Blood Components and is not available for Blood Products.

- **2,239,251, blood components were transfused in Ontario from 2019 to 2023.**
- **All hospitals collect reportable ATRs (excludes minor allergic, delayed serologic and febrile non-hemolytic reactions).**

Blood Component	2019	2020	2021	2022	2023	Total
RBC	353,679	337,723	357,410	350,455	353,351	1,752,618
Plasma	44,367	42,376	44,590	41,880	29,376	202,589
Platelets	54,791	52,459	56,725	57,860	62,209	284,044
Total Components Transfused	452,837	432,558	458,725	450,195	444,936	2,239,251
TOTAL BC ATRs	**204**	**224**	**213**	**225**	**264**	**1130**

Figure 3: Blood Components transfused per year, all transfusion reactions, and Blood Component transfusion reactions.
Although transfusion activity remained constant, reporting of ATRS increased. This is likely due to better reporting.



Blood Components – 1,123 ATRs

Blood Components and ATRs

Total PHAC Reportable ATRs
For all blood at all TTISS participating hospitals
Blood Components 1,123 ATRs
Blood Products 499 ATRs
Both Product Types 9 ATRs
Total 1,631 ATRs

Figure 4: Blood Components that were associated with ATRs (N=1,123).

- **848 (76%) ATRs were associated with Red Blood Cells.**

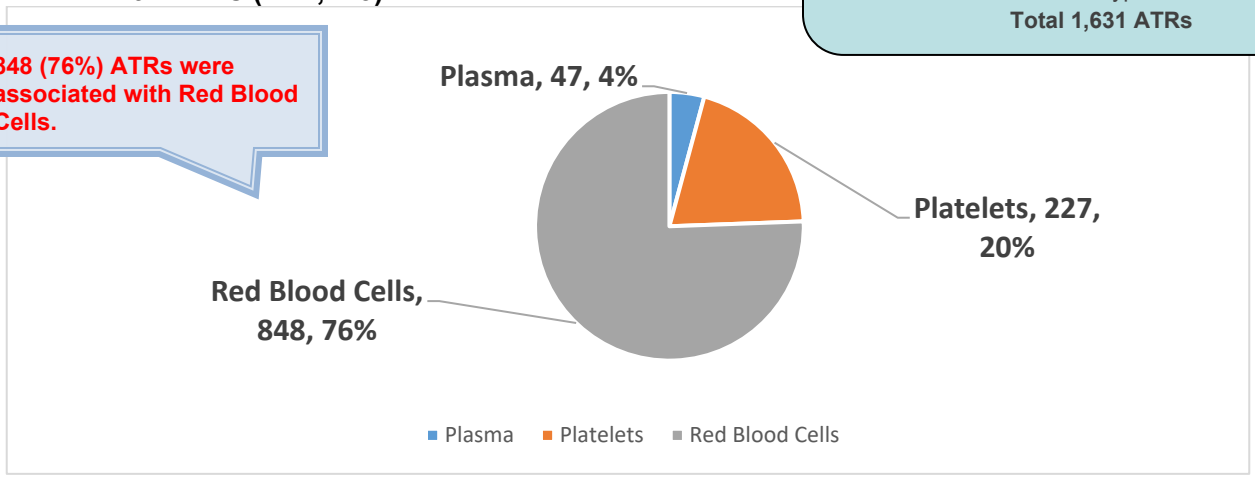


Table 7: The breakdown of ATRS associated with each Blood Component (N=1,123).
Of the 1,123 ATRS reported, 75.6% of all reactions are related to Red Blood Cells.

Type of Reaction	Red Blood Cells	Plasma	Platelets	Total
TACO	408	18	52	478
Severe Allergic /Anaphylactic/Anaphylactoid	40	17	78	135
TAD	75	3	24	102
Delayed Hemolytic Reaction	86	-	2	88
Hypotensive Reaction	72	-	15	87
Acute Hemolytic Reaction	42	-	9	51
Possible TRALI,	25	4	12	41
Bacterial Infection	21	1	14	36
Other non specific pain	19	2	5	26
Hypertension	24	-	1	25
Unknown/Other	18	-	5	23
TRALI	12	1	4	17
Anaphylactic Shock	3	1	4	8
Hyperhemolysis	4	-	-	4
PTP	-	-	2	2
Total	**849**	**47**	**227**	**1,123**

Blood Components – 1,123 ATRs

Figure 5: Relationship of ATRS to Blood Components (N=1,123).

- 54% of the ATRs were definitely or probably related to the Blood Component transfused.

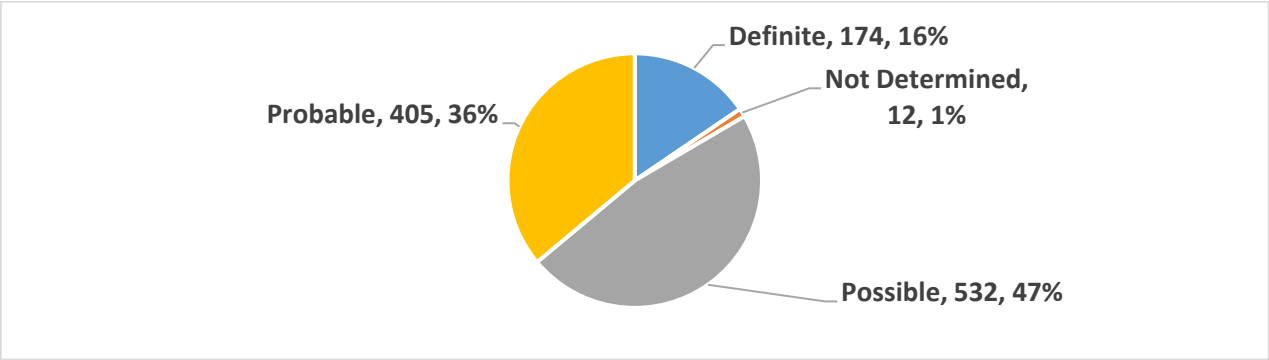


Table 8: Number and relationship of ATRS from 2019-2023 to Blood Component type.

Blood Component	Definite		Probable		Possible		Not Determined		Total	
	N	%	N	%	N	%	N	%	N	%
RBC	134	77.0	306	75.6	399	75.0	10	83.3	849	75.6
Plasma	11	6.3	17	4.2	19	3.6	-	-	47	4.2
Platelets	29	16.7	82	20,2	114	21.4	2	16.7	227	20.2
Total	**174**	**100**	**405**	**100**	**532**	**100**	**12**	**100**	**1,123**	**100**

Blood Components – 1,123 ATEs

- 557 (50%) of the ATRs were severe or life threatening.

Figure 6: Severity of ATRS for all Blood Components (N=1,123).

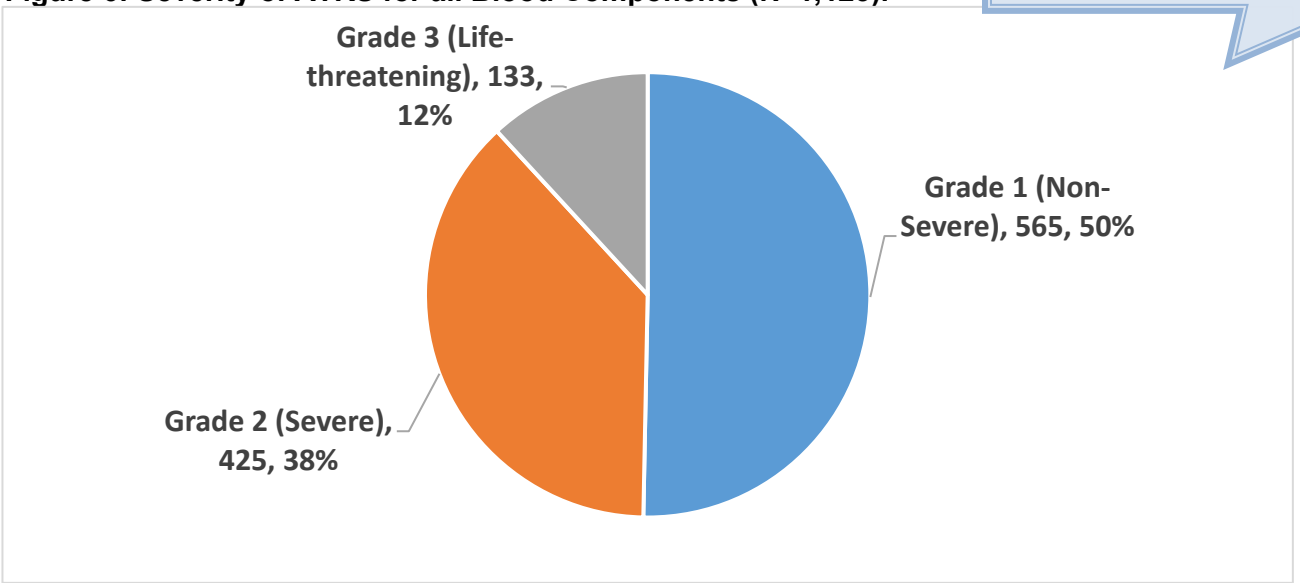


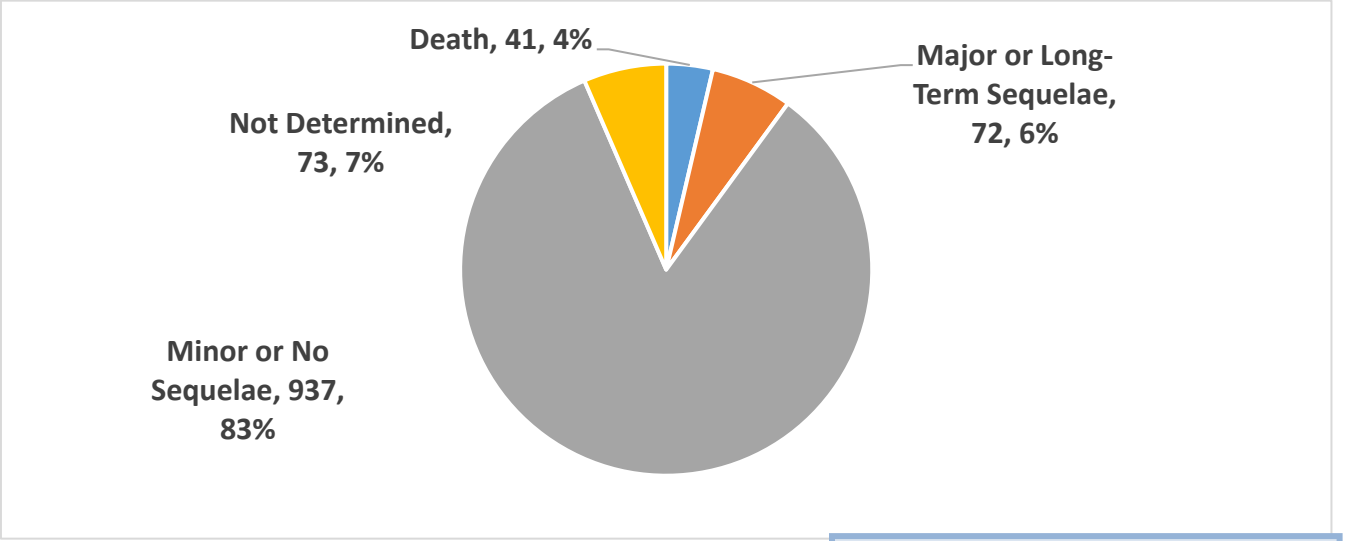
Table 9: Severity of ATRS for all Blood Components (N=1,123).

Of all the TACO reported, 52% were severe or life-threatening.

Type of ATR	Grade 1 (Non-Severe)	Grade 2 (Severe)	Grade 3 (Life-threatening)	Total
TACO	230	188	60	478
Severe Allergic /Anaphylactic/Anaphylactoid	36	77	22	135
TAD	59	33	10	102
Delayed Hemolytic Reaction	52	33	3	88
Hypotensive Reaction	63	16	8	87
Acute Hemolytic Reaction	33	16	2	51
Possible TRALI,	1	25	15	41
Bacterial Infection	21	14	1	36
Other non specific pain	25	1	-	26
Hypertension	24	1	-	25
Unknown	17	4	2	23
TRALI	1	7	9	17
Anaphylactic Shock	2	4	2	8
Hyperhemolysis	-	4	-	4
PTP	-	2	-	2
Total	**564**	**425**	**134**	**1,123**

Blood Components – 1,123 ATEs

Figure 7: Outcome of ATRS for all Blood Components (N=872).



- **There were 41 deaths reported of which 24 cases (58.5%) were believed to be related to the transfusion of blood components.**

Table 10: Death Outcomes of ATRs and Relationship to Transfusion for all blood components.

These ATRS were related to the transfusion however, the death outcome was not always related.

Type of ATRS and Death to Blood Components	Probable	Possible	Not Determined	Ruled out	Total
TACO	3	8	-	3	19
Possible TRALI	-	2	-	-	6
TAD	-	5	-	-	6
Delayed Hemolytic Reaction	-	1	-	1	2
Severe Allergic /Anaphylactic/Anaphylactoid	-	1	-	1	2
Acute Hemolytic Reaction	-	1	-	-	1
Anaphylactic Shock	-	-	-	1	1
Bacterial Infection	-	1	-	-	1
Hypotensive Reaction	-	1	-	-	1
TRALI	1	-	-	-	1
Unknown	-	-	1	-	1
Total	**4**	**20**	**1**	**6**	**41**

Blood Components – 1,123 ATEs

Table 11: Number of ATRS per year by reaction type, for Blood Components (N=1,123).

Type of Adverse Transfusion Reaction	2019	2020	2021	2022	2023	Total
TACO	83	94	87	97	117	478
Severe Allergic /Anaphylactic/Anaphylactoid	35	26	30	17	27	135
TAD	17	15	14	27	29	102
Delayed Hemolytic Reaction	14	29	9	19	17	88
Hypotensive Reaction	17	17	17	21	15	87
Acute Hemolytic Reaction	6	6	12	16	11	51
Possible TRALI,	5	15	13	4	4	41
Bacterial Infection	12	6	6	6	6	36
Other non specific pain	-	9	10	2	5	26
Hypertension	1	-	3	5	16	25
Unknown	5	2	3	4	9	23
TRALI	5	2	4	3	3	17
Anaphylactic Shock	2	-	3	2	1	8
Hyperhemolysis	-	-	1	1	2	4
PTP	1	-	-	-	1	2
Total	**203**	**221**	**212**	**224**	**263**	**1,123**

Risk Estimate - Sentinel Site ATR

Risk Calculations

Risk of experiencing a transfusion reaction to a blood component

The sentinel sites (28 of the 159 participating TTISS sites) report all transfusion reactions. The sentinel sites account for 33.4% of the transfusion activity captured by TTISS participating sites. There were 2,271 ATRs from blood components transfused reported from the sentinel sites, of which 1,809 of these were considered non-reportable according to PHAC guidelines. There were 683 reportable ATRs, of these, 462 were linked to blood components. Reporting of all ATRs by the sentinel sites allows for risk estimates to be calculated for those transfused for blood components. To make this calculation, using denominator data for each type of component transfused.

Table 12: Number of Blood Components transfused at the sentinel sites.

Blood Component	Blood Components Transfused by All Ontario 159 Hospitals	Blood Components Transfused by the 28 Sentinel TTISS Hospitals	
		N	%
Red Blood Cells (RBC)	1,752,618	550,301	31.4
FP Plasma + Cryosupernatant	202,589	71,797	35.4
Platelets	284,044	113,883	40.1
BC ATRs Reportable	720	462	64.2
BC ATRs non-reportable		1,809	-
Total	**2,239,251**	**748,775**	**33.4**

Table 13: Number of ATRS by type of Blood Component and risk estimate.

Blood Component	Sentinel Site Reportable ATRs	Sentinel Site Non-Reportable ATRs	Sentinel Site Total	Sentinel Sites Transfusion	Risk per Product Transfused
Red Blood Cells (RBC)	344	1,050	1,394	550,301	1:395
All Plasma	15	69	141	71,797	1:509
All Platelets	103	458	561	113,883	1:665
Total	**462**	**1,809**	**2,271**	**748,775**	**1:330**

Risk Estimate Summary – Sentinel Sites

Table 14: Risk of an ATRS by Blood Component and type of reaction.

Adverse Transfusion Event	Red Blood Cells (550,301)		Plasma (71,797)		Platelets (113,883)		Total (748,775)	
	N	Risk	N	Risk	N	Risk	N	Risk
TACO	177	1:3,109	5	1:14,359	27	1:4,217	209	1:3,582
Severe Allergic /Anaphylactic	20	1:27,515	5	1:14,359	39	1:2,920	64	1:11,699
TAD	24	1:22,929	2	1:35,899	12	1:9,490	38	1:19,704
Delayed Hemolytic Reaction	35	1:15,722	-	-	1	1:113,883	36	1:20,799
Hypotensive Reaction	26	1:21,165	-	-	5	1:22,776	31	1:24,154
Hypertension	20	1:27,515	-	-	1	1:113,883	21	1:35,655
Acute Hemolytic Reaction	14	1:39,307	-	-	4	1:28,470	18	1:41,598
Other non specific pain	8	1:68,787	1	1:71,797	4	1: 28,470	13	1:57,588
Bacterial Infection	7	1:78,614	-	-	4	1: 28,470	11	1:68,070
Possible TRALI,	4	1:137,575	2	1:35,899	4	1:28,470	10	1:74,878
TRALI	3	1:183,433	-	-	1	1:113,883	4	1:187,193
Anaphylactic Shock	2	1:275,150	-	-	1	1:113,883	3	1:249,591
Other/Unknown	4	1:137,575	-	-	-	-	4	1:187,193
Total Reportable	**344**	**1:1,600**	**15**	**1:4,787**	**103**	**1:1,105**	**462**	**1:1,620**
Febrile Non-Hemolytic	863	1:638	42	1:1,710	437	1:260	1,142	1:656
Minor Allergic	152	1:3,620	15	1:4,786	264	1:431	631	1:1186
Delayed Serological	35	1:15,722	-	-	1	1:113,883	36	1:20,799
Total Non-Reportable	**1,050**	**1:524**	**57**	**1:1,260**	**702**	**1:162**	**1,809**	**1:413**
Total (Risk of Any Type of ATR)	**1,394**	1:395	**72**	**1:997**	**805**	1:141	**2,271**	**1:330**

Total PHAC Reportable ATrs
All blood products at all TTISS participating hospitals
Blood Components1,123 ATEs
Blood Products 499ATRs
Both Product Types 7 ATEs
Total 1,631 ATEs

Blood Products

Table 15: Number (%) of ATRS, by year, related to Blood Products(N=499)

Type of Transfused Product	2019		2020		2021		2022		2023		Total	
	N	%	N	%	N	%	N	%	N	%	N	%
IVIG	111	86.7	58	85.3	62	79.5	97	87.4	104	91.2	432	86.6
Albumin	8	6.3	6	8.8	9	11.5	9	8.1	9	7,9	41	8.2
Other BP	2	1.6	1	1.3	2	1.3	3	2.7	-	-	8	1.6
Other Immune	2	1.6	2	1.3	2	2,6	-	-	1	0.9	7	1.4
RhIG Rh	2	1.6	1	8.2	2	2,6	0.9	-	-	-	6	1.2
Coag Factor	3	2.3	-	-	1	1.3	0.9	4.2	-	-	6	1.22
Total	**128**	**100**	**68**	**100**	**78**	**100**	**111**	**100**	**114**	**100**	**499**	**100**

- **432(86.6%) ATRs attributed to Blood Products occur with IVIG.**

Table 16: Type of ATRS related to Blood products(N=499)

Type of Reaction	IVIG Intravenous	Albumin	Coagulation Factor	Other Immune Globulin	Other Plasma Derivatives	RhIG Rh Immune Globulin	Total
IVIg headache	149	-	-	-	-	-	149
IVIg non specific pain	67	-	-	1	-	-	68
TACO	37	22	-	-	1	1	61
Severe Allergic	33	14	5	2	4	1	59
TAD	27	1	-	1	-	-	29
Acute Hemolytic Reaction	24	-	-	-	-	2	26
Delayed Hemolytic	23	-	-	-	-	-	23
Aseptic Meningitis	20	-	-	-	-	-	20
Hypertension	13	-	-	-	-	-	13
Unknown	15	1	-	2	1	-	19
Hypotensive Reaction	9	1	-	-	-	2	12
Other non specific pain	8	1	-	1	1	-	11
Chest Tightness	4	-	-	-	-	-	4
Anaphylactic Shock	1	1	-	-	-	-	2
Possible TRALI,	1	-	-	-	1	-	2
Hyperhemolysis	1	-	-	-	-	-	1
Total	**432**	**41**	**5**	**7**	**8**	**6**	**499**

Blood Product

Figure 8: Relationship of ATRS from Blood Products (N=308).

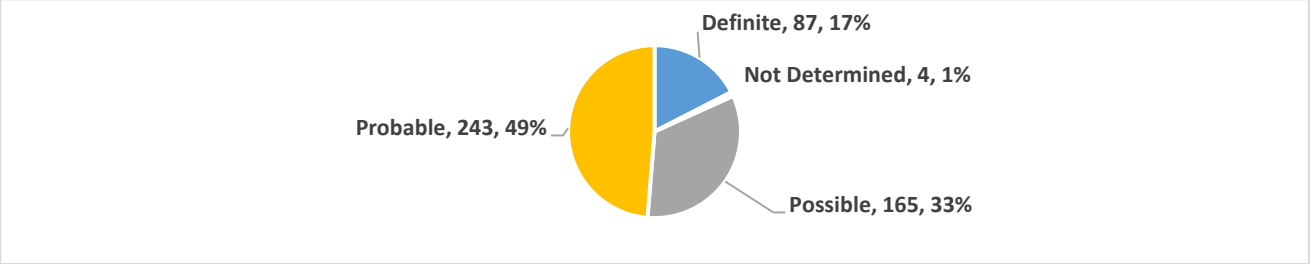


Table 17 Relationship of ATRs and blood product (N=499).

Blood Product	Definite	Probable	Possible	Not Determined	Total
IVIG	72	221	135	4	432
Albumin	6	13	22	-	41
Other Plasma Derivatives	2	3	3	-	8
Other Immune Globulin	4	2	1	-	7
RhIG Rh Immune Globulin	1	3	2	-	6
Coagulation Factor	2	1	2	-	5
Total	**87**	**243**	**165**	**4**	**499**

Table 18: Relationship of ATRs and type of ATR (N=499).

Type of ATR	Definite	Probable	Possible	Not Determined	Total
IVIg headache	23	109	17	-	149
IVIg non specific pain	7	28	33	-	68
TACO	11	22	28	-	61
Severe Allergic /Anaphylactic/	17	25	17	-	59
TAD	-	10	18	1	29
Acute Hemolytic Reaction	10	9	6	1	26
Delayed Hemolytic Reaction	7	6	9	1	23
Aseptic Meningitis	5	11	4	-	20
Unknown	3	6	10	1	20
Hypertension	-	4	9	-	13
Hypotensive Reaction	2	4	6	-	12
Other non specific pain	1	6	4	-	11
Other results of investigation	-	2	1	-	3
Anaphylactic Shock	-	-	2	-	2
Possible TRALI,	1	-	1	-	2
Hyperhemolysis	-	1	-	-	1
Total	**87**	**243**	**165**	**4**	**499**

Blood Product

Figure 9: Severity of ATRs from Blood Product Transfused

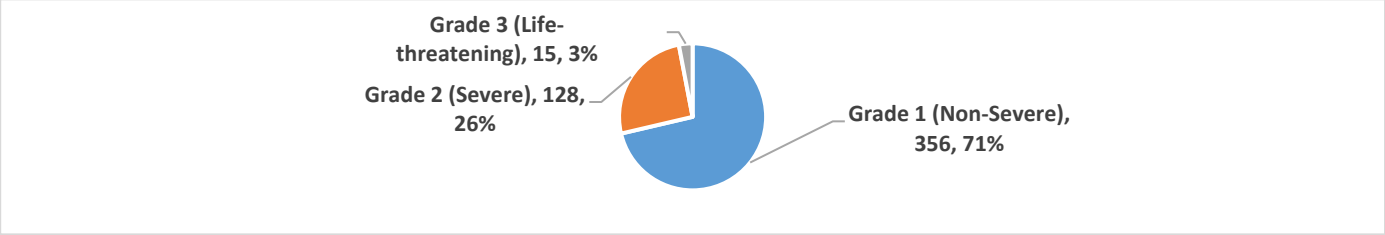


Table 19 Severity of ATRs related to Blood Product (N=499)

Blood Product	Grade 1 (Non-Severe)	Grade 2 (Severe)	Grade 3 (Life-threatening)	Total
IVIG Intravenous Immune globulin	320	105	7	432
Albumin	22	13	6	41
Other Plasma Derivatives	4	4	-	8
Other Immune Globulin	5	1	1	7
RhIG Rh Immune Globulin	2	3	1	6
Coagulation Factor	3	2	-	5
Total	**356**	**128**	**15**	**499**

Table 20: Severity and Type of ATR related to Blood Products (N=499)

Type of Reaction	Grade 1 (Non-Severe)	Grade 2 (Severe)	Grade 3 (Life-threatening)	Total
IVIg headache	136	13	-	149
IVIg non specific pain	63	4	1	68
TACO	40	18	3	61
Severe Allergic /Anaphylactic	24	28	7	59
TAD	16	11	2	29
Acute Hemolytic Reaction	13	13	-	26
Delayed Hemolytic Reaction	14	9	-	23
Unknown	16	6	1	23
Aseptic Meningitis	5	15	-	20
Hypertension	11	2	-	13
Hypotensive Reaction	8	4	-	12
Other non specific pain	9	2	-	11
Anaphylactic Shock	-	1	1	2
Possible TRALI,	1	1	-	2
Hyperhemolysis	-	1	-	1
Total	**356**	**128**	**15**	**499**

Blood Product

- There were 4 deaths related to a Blood Product

Figure 10: Outcome of ATRs related to Blood Product (N=499)

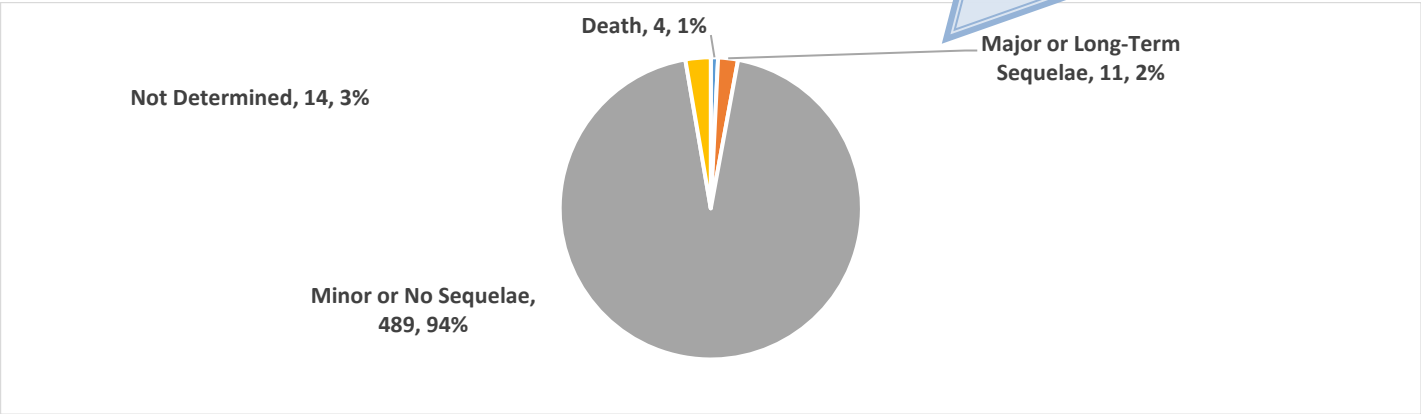


Table 21: Outcome of ATEs related to IVIG (N=308)

Type of ATR/Relationship to Death	Definite	Possible	Doubtful	Total
Anaphylactic Shock	-	1	-	1
Severe Allergic /Anaphylactic/Anaphylactoid	1	-	-	1
TACO	-	-	1	1
TAD	-	1	-	1
Total	**1**	**2**	**1**	**4l**

Do we want to put incompatible transfusions here??

Type of ATR - AHTR

Table 22: Acute hemolytic transfusion reactions relationship and blood (AHTR), (N=77).

Table 11A: Relationship of AHTR to Transfusion										
Type of Blood	**Definite**		**Probable**		**Possible**		**Not Determined**		**Total**	
	N	**%**	**N**	**%**	**N**	**%**	**N**	**%**	**N**	**%**
Red Blood Cells	14	53.9	15	55.6	13	56.5	-	-	42	54.6
IVIG	10	38.5	8	29.6	5	21.7	1	100	24	31.2
Platelets	2	7.6	3	45.8	4	17.4	-	-	9	11.7
RhIG Rh Immune Globulin	-	-	1	11.1	1	4.4	-	-	2	2.6
Total	**26**	**100**	**27**	**100**	**23**	**100**	**1**	**100**	**77**	**100**

Table 23: Acute hemolytic transfusion reactions severity and blood (AHTR), (N=77).

Table 11B: Severity of AHTR										
Type of Product	**Grade 1 (Non-Severe)**		**Grade 2 (Severe)**		**Grade 3 (Life Threatening)**		**Not Determined**		**Total**	
	N	**%**	**N**	**%**	**N**	**%**	**N**	**%**	**N**	**%**
Red Blood Cells	28	60.9	14	48.2	-	0	-	-	42	54.5
IVIG	12	26.1	12	41.4	-	0	-	-	24	31.2
Platelets	5	10.9	2	69.0	2	100	-	-	9	11.7
RhIg	1	2.3	1	34.4		0	-	-	2	2.6
Total	**6**	**100**	**26**	**100**	**2**	**100**	**-**	**-**	**77**	**100**

Type of ATR - DHTR

Table 24: Delayed hemolytic transfusion reactions (DHTR), (N=113).

Table 24: Relationship of DHTR to Transfusion										
Type of Blood Product	**Definite**		**Probable**		**Possible**		**Not Determined**		**Total**	
	N	**%**	**N**	**%**	**N**	**%**	**N**	**%**	**N**	**%**
Red Blood Cells	48	87.3	11	64.7	24	70.6	5	71.4	88	20.4
IVIG	7	12.7	6	35.3	9	26.5	1	14.3	23	1.8
Platelets	-	-	-	-	1	2.9	1	14.3	2	0.8
Total	**55**	**100**	**17**	**100**	**34**	**100**	**7**	**100**	**113**	**100**

Table 25: Delayed hemolytic transfusion reactions (DHTR), (N=113).

Table 12B: Severity of DHTR										
Type of Blood Product	**Grade 1 (Non-Severe**		**Grade 2 (Severe)**		**Grade 3 (Life Threatening)**		**Not Determined**		**Total**	
	N	**%**	**N**	**%**	**N**	**%**	**N**	**%**	**N**	**%**
Red Blood Cells	51	76.1	33	78.6	4	45.2	-	-	88	77.9
IVIG	14	20.9	9	21.4	-	-	-	-	23	20.4
Platelets	2	3.0	-	-	-	-	-	-	2	1.7
Blood/Derivatives	-	-	-	-	-	-	-	-	-	-
Total	**67**	**100**	**42**	**100**	**4**	**100**	**-**	**-**	**113**	**100**

Type of ATR - Severe Allergic

Table 26: Severe Allergic / Anaphylactic / Anaphylactoid Reactions (N=176).

Table 13A: Relationship of Severe Allergic / Anaphylactic / Anaphylactoid to Transfusion										
Type of Blood Product	**Definite**		**Probable**		**Possible**		**Not Determined**		**Total**	
	N	**%**	**N**	**%**	**N**	**%**	**N**	**%**	**N**	**%**
Red Blood Cells	7	18.9	18	26.5	16	17.8	-	-	41	21.0
Plasma	3	8.1	7	10.3	7	7.8	-	-	17	8.7
Platelets	10	27.0	40	58.8	28	31.1	-	-	78	40.0
IVIG	8	21.6	17	25.0	8	8.9	-	-	33	16.9
Other Ig	1	2.7	1	1.5	-	-	-	-	2	1.0
Coagulation Factor	2	5.4	1	1.5	2	2.2	-	-	5	2.6
Albumin	4	10.8	4	5.9	6	6.7	-	-	14	7.2
Other Blood Product	2	5.4	1	1.5	2	2.2	-	-	1	0.5
RhIG Rh Immune Globulin		-	1	1.5	-	-	-	-	1	0.5
Total	**37**	**100**	**68**	**100**	**90**	**100**	**0**	**100**	**195**	**100**

Table 27: Severity of Severe Allergic / Anaphylactic / Anaphylactoid Reaction										
Type of Blood Product	**Grade 1 (Non-Severe)**		**Grade 2 (Severe)**		**Grade 3 (Life Threatening)**		**Not Determined**		**Total**	
	N	**%**	**N**	**%**	**N**	**%**	**N**	**%**	**N**	**%**
Red Blood Cells	12	19.7	21	20.0	8	27.6	-	-	41	21.0
Plasma	4	6.6	9	8.6	4	13.8	-	-	17	8.7
Platelets	21	34.4	47	44.8	10	34.5	-	-	78	40.0
IVIG	13	21.3	18	17.1	2	6.9	-	-	33	16.9
Other Ig	2	3.3	-	-	-	-	-	-	2	1.0
Coagulation Factor	3	4.9	2	1.9	-	- 17.2	-	-	5	2.6
Albumin	4	6.6	5	4.8	5	-	-	-	14	7.2
Other Blood Product	2	3.3	2	1.9	-	-	-	-	4	2.1
RhIG Rh Immune Globulin	-	-	1	1.0	-	-	-	-	1	0.5
Total	**61**	**100**	**105**	**100**	**29**	**100**	**-**	**-**	**195**	**100**

Type of ATR –TRALI & Possible TRALI

Table 28: Possible Transfusion-Related Acute Lung Injury

Table 14A: Relationship of TRALI Transfusion										
Type of Blood Product	**Definite**		**Probable**		**Possible**		**Not Deter**		**Total**	
	N	**%**	**N**	**%**	**N**	**%**	**N**	**%**	**N**	**%**
Red Blood Cells	1	50.0	6	66.7	6	85.7	-	-	13	72.2
Plasma	-	-	1	11.1	-	-	-	-	1	5.6
Platelets	1	50.0	2	22.2	1	14.3	-	-	4	2.2
Total	**2**	**100**	**9**	**100**	**7**	**100**	**-**	**-**	**18**	**100**

Table 29: Severity of TRALI										
Type of Blood Product	**Grade 1 (Non-Severe)**		**Grade 2 (Severe)**		**Grade 3 (Life Threatening)**		**Not Determined**		**Total**	
	N	**%**	**N**	**%**	**N**	**%**	**N**	**%**	**N**	**%**
Red Blood Cells	1	57.8	5	65	7	80	-	-	13	63.6
Plasma	-	21.1	-	15	1	-	-	-	1	15.9
Platelets	-	21.1	3	15	1	20	-	-	4	18.2
Total	**1**	**100**	**8**	**100**	**9**	**100**	**-**	**-**	**18**	**100**

Table 14: Transfusion-Related Acute Lung Injury - Possible TRALI

Table 30: Relationship of Possible TRALI to Transfusion										
Type of Blood Product	**Definite**		**Probable**		**Possible**		**Not Deter**		**Total**	
	N	**%**	**N**	**%**	**N**	**%**	**N**	**%**	**N**	**%**
Red Blood Cells	1		3		21		-	-	25	
Plasma	-		1		3		-	-	4	
Platelets	1		-		12		-	-	412	
IVIg	1		-		1		-	-	-	
Total	**3**	**100**	**4**	**100**	**37**	**100**	**-**	**-**	**43**	**100**

Table 31Severity of Possible TRALI										
Type of Blood Product	**Grade 1 (Non-Severe)**		**Grade 2 (Severe)**		**Grade 3 (Life Threatening)**		**Not Determined**		**Total**	
	N	**%**	**N**	**%**	**N**	**%**	**N**	**%**	**N**	**%**
Red Blood Cells	-	57.8	15	65	10	80	-	-	25	63.6
Plasma	-	21.1	4	15		-	-	-	14	15.9
Platelets	1	21.1	6	15	5	20	-	-	12	18.2
IVIg	1		1		-		-	-	2	
Total	**2**	**100**	**26**	**100**	**15**	**100**	**-**	**-**	**43**	**100**

Type of ATR- TAD

Table 32: Transfusion-Associated Dyspnea (TAD), (N=45).

Table 15A: Relationship of TAD to Transfusion								
Type of Blood Product	**Definite**		**Probable**		**Possible**		**Total**	
	N	**%**	**N**	**%**	**N**	**%**	**N**	**%**
Red Blood Cells	6	85.7	27	60.0	42	53.2	75	57.3
Plasma	-		-		3	3.8	3	2.3
Platelets	1	14.3	8	17.8	15	19.0	24	18.3
IVIG	-		9	20.0	18	22.8	27	20.6
Other Immune Globulin	-		1	2.2	-		1	0.8
Albumin	-		-	-	1	1.2	1	0.8
Total	**7**	**100**	**45**	**100**	**79**	**100**	**131**	**100**

Table 33: Severity of TAD								
Type of Blood Product	**Grade 1 (Non-Severe**		**Grade 2 (Severe)**		**Grade 3 (Life Threatening)**		**Total**	
	N	**%**	**N**	**%**	**N**	**%**	**N**	**%**
Red Blood Cells	47	62.7	20	45.5	8	51.6	75	51.1
Plasma	3	4.0	-	-	-	6.5	3	6.7
Platelets	9	12.0	13	29.5	2	29	24	31.1
IVIG	15	20	10	22.7	2	9.7	27	6.7
Other Immune Globulin	-	-	1	2.3			1	
Albumin	1	1.3	-	-	-	3.2	21	4.4
Total	**75**	**-**	**44**	**100**	**12**	**100**	**131**	**100**

Type of ATR - TACO

Table 34: Transfusion-Associated Circulatory Overload (TACO), (N=540).

Table 16A: Relationship of TACO to Transfusion										
Type of Blood Product	**Definite**		**Probable**		**Possible**		**Not Determined**		**Total**	
	N	**%**	**N**	**%**	**N**	**%**	**N**	**%**	**N**	**%**
Red Blood Cells	55	65.5	190	86.0	164	69.1	-	-	409	75.5
Plasma	8	9.5	6	2.7	5	2.1	-	-	19	3.5
Platelets	10	11.9	19	8.7	24	10.1	-	-	53	9.8
IVIG	9	10.7	11	5.0	17	7.2	-	-	37	6.8
Albumin	2	2.4	9	4.1	11	4.5	-	-	22	4.0
Blood Products	-	-	1	0.5	-	-	-	-	1	0.2
RhIG Rh Immune Globulin	-	-	1	0.5	-	-	-	-	1	0.2
Total	**84**	**100**	**221**	**100**	**237**	**100**	**-**	**100**	**542**	**100**

Table 35: Severity of TACO										
Type of Blood Product	**Grade 1 (Non-Severe)**		**Grade 2 (Severe)**		**Grade 3 (Life Threatening)**		**Not Determined**		**Total**	
	N	**%**	**N**	**%**	**N**	**%**	**N**	**%**	**N**	**%**
Red Blood Cells	201	74.1	158	76.0	50	79.4	-	-	409	75.5
Plasma	7	2.6	10	4,8	2	3.2	-	-	19	3.4
Platelets	23	8.5	22	10.6	8	12.7	-	-	53	9.8
IVIG	25	9.2	11	5.3	1	1.5	-	-	37	6.9
Albumin	14	5.2	7	3.3	1	1.5	-	-	22	4.0
Other Blood Product	1	0.4	-	-	-		-	-	1	0.2
RhIG Rh Immune Globulin	-	-	-	-	1	1.5	-	-	1	0.2
Total	**271**	**100**	**208**	**100**	**63**	**100**	**-**	**-**	**542**	**100**

Deaths

- **Reportable reactions, there was 27 related deaths**

Table 36: Probable and Possible Deaths to ATRs

Related Deaths	Red Blood Cells	Plasma	Platelets	IVIG	Total
TACO	8	2	1	-	11
TAD	4	-	1	1	6
Possible TRALI,	2	-	-	-	2
Severe Allergic /Anaphylactic/Anaphylactoid	1	-	-	1	2
Acute Hemolytic Reaction	1	-	-	-	1
Anaphylactic Shock	-	-	-	1	1
Bacterial Infection	-	-	1	-	1
Delayed Hemolytic Reaction	1	-	-	-	1
Hypotensive Reaction	1	-	-	-	1
TRALI	1	-	-	-	1
Total	**19**	**2**	**3**	**3**	**27**

Appendices

Appendix 1

List of 47 Unknown/Others

Adverse Transfusion Reaction	Number
Chest Tightness	10
Tachycardia/cardiac event	7
Nausea and/or vomiting	6
Tachycardia	3
TACO/TRALI like symptoms	2
Lip numbness or tinging	2
Hypotension	2
Cardiac Arrest	2
Positive blood culture	1
Paresthesia	1
Not stated	1
Increased temp	1
Hypothermia	1
Hypertension	1
Dyspnea/wheezing	1
Blurred vision	1
Acute Kidney Injury	1
Transfusion Associated Electrolyte Exacerbation	1
Major Skin Reaction	1
Hypocalcemia	1
Dizziness	1
Total	47

Appendix 2
List of Reportable and Non Reportable Transfusion Reactions

Reportable ATRs	**Reportable ATRs**
Acute Hemolytic Transfusion Reaction	Incompatible Transfusion Reactions
Delayed Hemolytic Transfusion Reaction	Post Transfusion Purpura (PTP)
Anaphylactic Shock	Hypotensive Reaction
Severe/Anaphylactic/Anaphylactoid	Intravenous immunoglobulin (IVIg) headache
Aseptic Meningitis	Other/Unknown Pain Reaction
Bacterial Infection	TA-GVHD
Viral Infection	Severe Allergic/Anaphylactic/Anaphylactoid
Other Infection	**Non-Reportable ATRs**
Transfusion Related Acute Lung Injury (TRALI)	
Possible TRALI	Delayed Serological Transfusion Reaction
Transfusion Associated Dyspnea (TAD)	Febrile Non Hemolytic Reaction
Transfusion Associated Circulatory Overload (TACO)	Minor Allergic Reaction
Hemochromatosis	

Appendix 3
List of Abbreviations

AHTR	Acute Hemolytic Transfusion Reaction
ATR	Adverse Transfusion Reaction
CBS	Canadian Blood Services
DHTR	Delayed Hemolytic Transfusion Reaction
MOHLTC	Ministry of Health and Long-term Care
ORBCoN	Ontario Regional Blood Coordinating Network
PHAC	Public Health Agency of Canada
Possible TRALI	Possible Related Acute Lung Injury
PTP	Post-Transfusion Purpura
RBC	Red Blood Cells
TACO	Transfusion Associated Circulatory Overload
TAD	Transfusion Associated Dyspnea
TRALI	Transfusion Related Acute Lung Injury
TTISS	Transfusion Transmitted Injuries Surveillance System
IVIG	Intravenous Immunoglobulin

Appendix 4
List of Surveillance Definitions[1]

Relationship to Product (Imputability)	
Definite	Clinical and/or laboratory event within a time frame consistent with the administration of the blood, blood component or plasma derivative and was proven by investigation to have been caused by transfusion.
Probable	Clinical and/or laboratory event occurred within a time frame consistent with the administration of the blood, blood component or plasma derivative and did not seem to be explainable by any other cause.
Possible	Clinical and/or laboratory event occurred within a time frame consistent with the administration of the blood, blood component or plasma derivative but could be explained by concurrent disease(s) or by the administration of a drug or other agent.
Severity: Severity was initially classified into four categories including death (as Grade 4) which was subsequently reclassified as life-threatening. The death was categorized as an outcome and relationship between transfusion and death was assessed.	
Life-threatening (Grade 3)	The recipient required major intervention following the transfusion (i.e. vasopressors, intubation, and transfer to intensive care).
Severe (Grade 2)	The recipient required in-patient hospitalization or prolongation of hospitalization directly attributable to the event; or the adverse event resulted in persistent or significant disability or incapacity; or the adverse event necessitated medical or surgical intervention of preclude permanent/significant damage or impairment of body function.
Non-severe (Grade 1)	The recipient may have required medical intervention (i.e. symptomatic treatment) but lack of such would not result in permanent damage or impairment of body function.
Outcome	
Death	Death was directly or indirectly transfusion-related.
Major or long-term sequelae	Transfused patient developed an infection with persistent infectious agent or any other long-term sequelae including difficulties with future transfusions.
Minor or no sequelae	Transfused patient developed antibodies to low-medium frequency antigens or any other minor reaction

[1]Public Health Agency of Canada. TTISS -2006-2012 Report, Centre for Communicable Diseases and Infection Control, PHAC, 2014