Health Canada Santé Canada

Canada

Canadian Transfusion Adverse Event Reporting System Analysis of Data 2001-2003

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A collaborative project of the Division of Blood Safety Surveillance and Health Care Acquired Infections[1], Marketed Health Products Directorate[2], Biologics and Genetic Therapies Directorate[2], Health Canada, Ottawa, Ontario; Provincial/Territorial Blood Surveillance Offices[2] and Canadian Blood Manufacturers[2]

Background

- A voluntary surveillance system, the Transfusion Transmitted Injuries Surveillance System (TTISS) started in 1999 in Canada to collect and analyze data on moderate and severe adverse events resulting from the administration of blood components and plasma derivatives.
- The TTISS is a Canadian National Surveillance System.

Objective

- To describe the adverse transfusion reactions reported to the TTISS from 1 April 2001 to 30 September 2003.

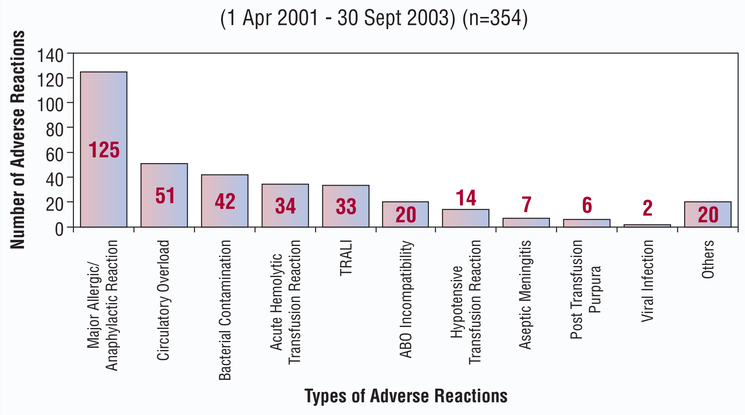
Methods

- Case definitions, data elements, a reporting form, a database and reporting protocols are nationally adopted to collect the adverse events of transfusion.
- Adverse events collected are investigated at participating hospitals and then forwarded to their provincial/territorial office.
- Validated non-nominal adverse events that met TTISS requirements are then transferred to Health Canada on a quarterly basis.
- A quarterly and ad hoc review of the reported data is conducted and adverse transfusion reactions are summarized for presentations and inclusion in a yearly national report.

Results

Number of Adverse Transfusion Reactions Reported to Health Canada

(1 Apr 2001 - 30 Sept 2003) (n=354)



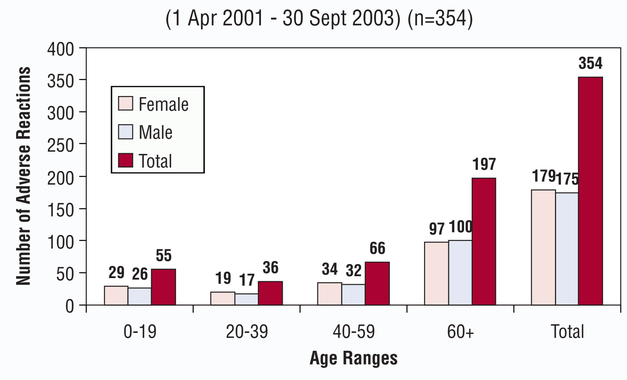
Types of Adverse Transfusion Reactions Reported by Period

(1 Apr 2001 - 30 Sept 2003) (n=354)

Adverse Reactions	Apr-Dec 2001 (9 months)	Jan-Dec 2002 (12 months)	Jan-Sept 2003 (9 months)	Total (%)
Major Allergic/Anaphylactic Reaction	27	57	41	125 (35.3%)
Circulatory Overload	16	20	15	51 (14.4%)
Bacterial Contamination	11	20	11	42 (11.9%)
Acute Hemolytic Transfusion Reaction	11	11	12	34 (9.6%)
TRALI	5	19	9	33 (9.3%)
ABO Incompatibility	9	8	3	20 (5.6%)
Hypotensive Transfusion Reaction	2	10	2	14 (4.0%)
Aseptic Meningitis	2	3	2	7 (2.0%)
Post Transfusion Purpura	–	1	5	6 (1.7%)
Viral Infections	1	1	–	2 (0.6%)
Parvovirus B19	1	–	–	1 (0.3%)
West Nile Virus	–	1	–	1 (0.3%)
Others	5	7	8	20 (5.6%)
Delayed Hemolytic/Serologic Transfusion Reaction	2	3	6	11 (3.1%)
Platelet Alloimmunization	–	2	2	4 (1.1%)
Hypocalcemia	–	1	–	1 (0.3%)
Hyperkalemia	0	1	0	1 (0.3%)
Severe Hypertension	1	–	–	1 (0.3%)
Intrauterine death	1	–	–	1 (0.3%)
Unknown	1	–	–	1 (0.3%)
TOTAL	**89**	**157**	**108**	**354 (100%)**

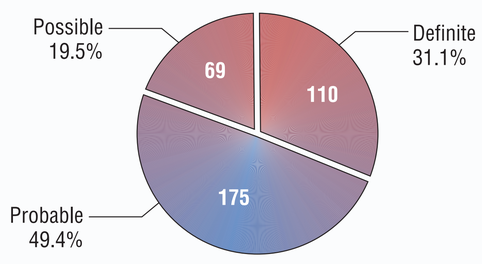
Distribution of Adverse Transfusion Reactions by Age and Gender

(1 Apr 2001 - 30 Sept 2003) (n=354)



Adverse Transfusion Reactions by Relationship to Transfusion

(1 Apr 2001 - 30 Sept 2003) (n=354)



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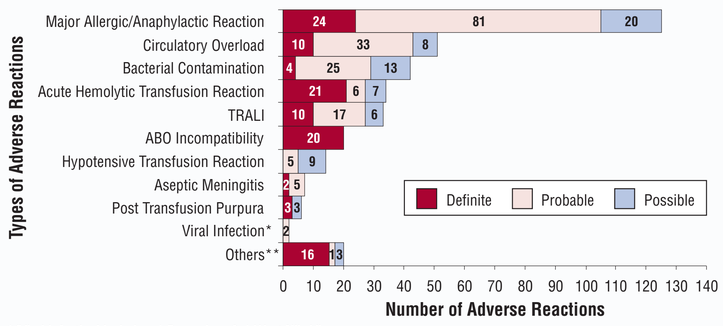


* 'Viral Infection' includes: 1 Parvovirus & 1 West Nile Virus

** 'Others' includes: Delayed Hemolytic/Serologic Transfusion Reaction, Platelet Alloimmunization, Hypocalcemia, Hyperkalemia, Severe Hypertension, Intrauterine Death, Unknown

Definite, Probable & Possible Adverse Transfusion Reactions by Severity of Outcome

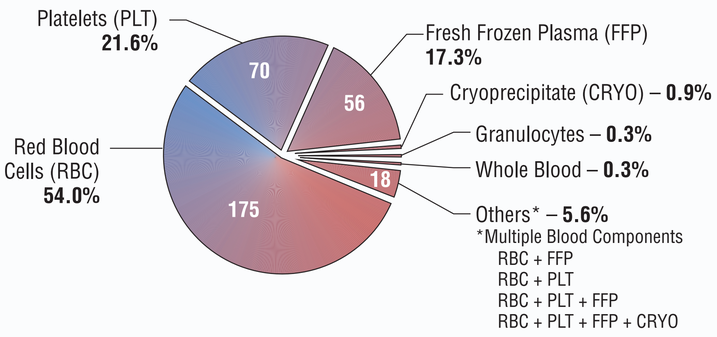
(1 Apr 2001 - 30 Sept 2003) (n=353*)

Adverse Reactions	Death	Life-Threatening	Long-term Sequelae	Minor/ No Sequelae	Not Determined	Total
Major Allergic / Anaphylactic Reaction*	1	67	1	53	2	124
Circulatory Overload	2	49	–	–	–	51
Bacterial Contamination	4	8	–	30	–	42
Acute Hemolytic Transfusion Reaction	1	13	3	17	–	34
TRALI	4	24	–	5	–	33
ABO Incompatibility	–	2	1	15	2	20
Hypotensive Transfusion Reaction	1	2	7	4	–	14
Aseptic Meningitis	–	–	–	6	1	7
Post Transfusion Purpura	2	3	–	1	–	6
Viral infections	1	–	–	1	–	2
Parvovirus B19	–	–	–	1	–	1
West Nile Virus	1	–	–	–	–	1
Others	3	7	10	–	–	20
Delayed Hemolytic/Serologic Transfusion	–	5	6	–	–	11
Platelet Alloimmunization	–	–	4	–	–	4
Hypocalcemia	–	1	–	–	–	1
Hyperkalemia	–	1	–	–	–	1
Severe Hypertension	1	–	–	–	–	1
Intrauterine Death	1	–	–	–	–	1
Unknown	1	–	–	–	–	1
TOTAL #	**19**	**175**	**22**	**132**	**5**	**353**
TOTAL %	**5.4%**	**49.6%**	**6.2%**	**37.4%**	**1.4%**	**100.0%**

* Severity not reported for one case

Distribution of Blood Components Suspected to be Associated with Adverse Transfusion Reactions

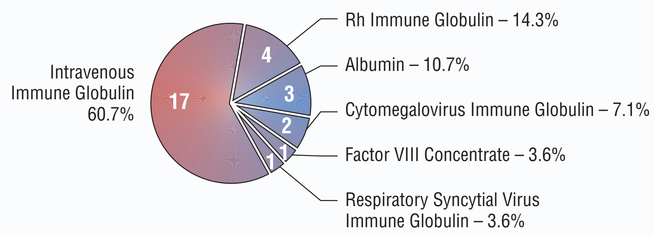
(1 Apr 2001 - 30 Sept 2003) (n=324**)



** Blood products received not reported/available for 2 cases

Distribution of Plasma Derivatives Suspected to be Associated with Adverse Transfusion Reactions

(1 Apr 2001 - 30 Sept 2003) (n=28)



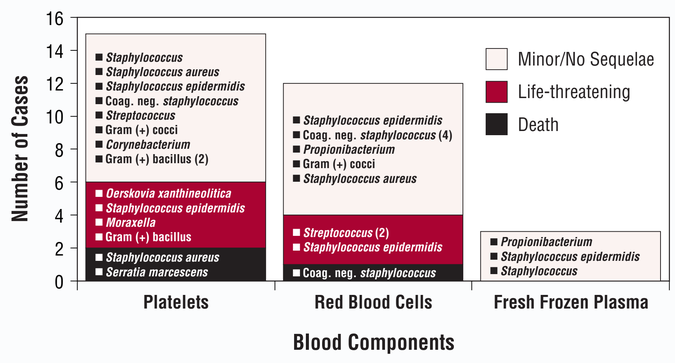
Suspect Blood Products in Bacterial Contamination Cases

(1 Apr 2001 - 30 Sept 2003) (n=42)

Blood Products	Number of Cases	Percentage (%)
Red Blood Cells	18	42.9%
Platelets	19	45.2%
Fresh Frozen Plasma	5	11.9%
Total #	**42**	**100.0%**

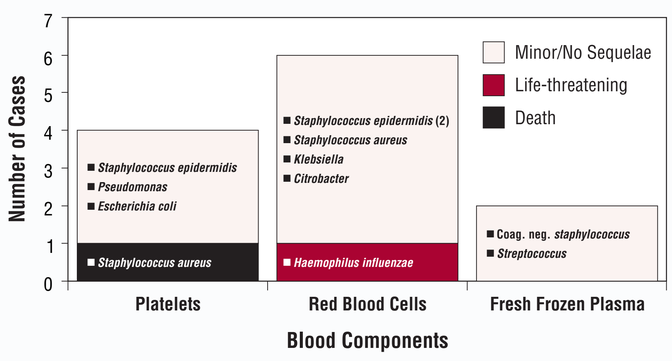
Definite and Probable Cases of Bacterial Contamination

(1 Apr 2001 - 30 Sept 2003) (n=30)



Possible Cases of Bacterial Contamination

(1 Apr 2001 - 30 Sept 2003) (n=12)



Fatal Events Reported According to Their Relationship to Transfusion

(1 Apr 2001 - 30 Sept 2003) (n=19)

Fatal Events	Relationship to Transfusion						
	Definite	Probable	Possible	Doubtful	Ruled Out	Unknown	Total
TRALI	1	2	1	–	–	–	4
Bacterial Contamination	1	2	1	–	–	–	4
Post Transfusion Purpura	1	1	–	–	–	–	2
Circulatory Overload	–	–	1	1	–	–	2
Acute Hemolytic Transfusion Reaction	1	–	–	–	–	–	1
Anaphylactic Reaction	–	1	–	–	–	–	1
Viral Infection	–	–	–	–	–	1	1
West Nile Virus	–	–	–	–	–	1	1
Hypotensive Transfusion Reaction	–	–	–	–	1	–	1
Others	–	1	2	–	–	–	3
Severe Hypertension	–	1	–	–	–	–	1
Intrauterine Death	–	–	1	–	–	–	1
Unknown	–	–	1	–	–	–	1
Total	4	7	5	1	1	1	19

Conclusions

(1 Apr 2001 – 30 Sep 2003)

- Major Allergic/Anaphylactic reactions were the largest proportion of adverse reactions reported to the TTISS.
- Circulatory Overload, Bacterial Contamination, Acute Hemolytic Transfusion Reactions, TRALI and ABO Incompatibility continue to occur.
- Proportion of bacterial contamination related to platelets was about the same as to red blood cells.
- Transfusion was definitely or probably attributed as the cause of death in 11 out of 354 reported adverse reactions (3%).
  - However, this data should be interpreted with caution:
    - Denominator data was not yet available for the calculation of rates of adverse reactions.
    - Underreporting may be possible.
    - Steps are being taken to validate the higher proportion of cases probably related to transfusion.
- New measures to reduce the risk of bacterial contamination such as the use of diversion pouches to sequester the first few mL of blood donation have been implemented in Canada; the effectiveness of this can evaluated in the future.

Acknowledgements

Provinces/Territories	Names
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Alberta	M. Swaters*
Northwest Territories	R. Greig*
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Blood Manufacturers	**Names**
Canadian Blood Services	T. Alport*
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Working Groups	**Names**
* National TTISS Working Group	N. McCombie (chairperson)
** National Data Review Working Group	B. Larke (chairperson), R. Dodd, J. Saldanha, R. Nair, H. Hume

Transfusion Transmitted Injuries Section's Website

http://www.hc-sc.gc.ca/pphb-dgspsp/hcai-iamss/tti-it/index.html

TTISS Transfusion Transmitted Injuries Surveillance System
SSIT Système de surveillance des incidents transfusionnels

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