Transfusion and risk of infection in Canada: Update 2005

Canadian Paediatric Society

In Canada and other countries, many steps are taken to minimize the risk of infection through the transfusion of blood or blood products (1). However, the infection risk can never be zero because these are biological products that are taken from living donors who are never 'germ free' (2). This is in contrast to drugs that can be manufactured de novo under sterile conditions in a laboratory. The present note provides an update on transfusion infection risks in Canada. It replaces the 2004 note (3) and may be helpful to practitioners in discussions with patients and parents toward obtaining informed consent before blood or blood product administration.

A crucial step in enhancing safety is to carefully assess whether the patient will likely benefit from the administration of blood or blood products (ie, that the potential benefit outweighs the potential risks) (4). For example, a study in critically ill adults (5) showed that, in terms of outcomes, a restrictive transfusion policy in which red blood cells were transfused only if the hemoglobin concentration dropped below 70 g/L and hemoglobin concentrations were maintained at 70 g/L to 90 g/L is at least as effective and possibly superior to a liberal transfusion strategy in which red blood cells are transfused if the hemoglobin concentration fell below 100 g/L and hemoglobin concentration maintained at 100 g/L to 120 g/L. Similarly, a preliminary report has shown that a restrictive transfusion policy in very low birth weight infants (ie, hemoglobin kept in the range of 115 g/L to 75 g/L versus a more liberal policy with the range of 135 g/L to 85 g/L in high group) appears to be safe (6). The ongoing Transfusion Transmitted Injuries Surveillance System in Canada (Table 1), which looks for serious adverse events with receiving of blood or blood product infusions, has found that while there is a high degree of safety, there

TABLE 1
Types of adverse transfusion reactions*

	Blood components						
Adverse reaction	**RBC**	**Platelet**	**FFP**	**Cryoprecipitate**	**Granulocyte**	**Multiple blood components**	**Total, n (%)**
Major allergic/anaphylactic reaction	45	37	33	1	1	4	121 (35.2)
Circulatory overload	36	3	6	–	–	3	48 (14)
Acute hemolytic transfusion reaction	38	1	1	–	–	–	40 (11.6)
Transfusion-related acute lung injury	20	5	7	2	–	5	39 (11.3)
Bacterial contamination	15	18	6	–	–	–	39 (11.3)
ABO incompatibility	12	1	7	–	–	–	20 (5.8)
Hypotensive transfusion	9	2	1	–	–	1	13 (3.8)
Post-transfusion purpura	3	1	–	–	–	3	7 (2.0)
Delayed hemolytic transfusion	5	–	–	–	–	–	5 (1.5)
Viral infections	1	–	–	–	–	1	2 (0.6)
Parvovirus B19	1	–	–	–	–	–	1 (0.3)
West Nile virus	–	–	–	–	–	1	1 (0.3)
Rh incompatibility	1	–	–	–	–	–	1 (0.3)
Others	5	3	1	–	–	–	9 (2.6)
Hypocalcemia	–	1	–	–	–	–	1 (0.3)
Hyperkalemia	1	–	–	–	–	–	1 (0.3)
Severe hypertension	–	1	–	–	–	–	1 (0.3)
Atypical pain syndrome	1	1	–	–	–	–	2 (0.6)
Transfusion-associated dyspnea	1	–	1	–	–	–	2 (0.6)
Unknown	2	–	–	–	–	–	2 (0.6)
Total, n (%)	190 (55.2)	71 (20.6)	62 (18)	3 (0.9)	1 (0.3)	17 (4.9)	344 (100)

**Data from the Transfusion Transmitted Injuries Surveillance System program from April 1, 2001 to December 31, 2003 (Dr A Giulivi, Ms Nancy McCombie, personal communication). FFP Fresh frozen plasma; RBC Red blood cell*

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are still risks (albeit small) of both infection and other adverse events such as transfusion-related acute lung injury (7,8).

Besides the careful assessment of need, prior immunization with hepatitis B vaccine is an additional way to minimize risk from infection with this blood-borne pathogen for those who are likely to receive multiple blood transfusions in an elective situation.

While any infectious agent that has a blood phase has the potential to be transmitted by the transfusion of blood or blood products, the probability of infection in the recipient depends on a number of factors, including (5,9,10):

- The prevalence of the agent in the blood of the donor population;
- The tolerance of the agent to blood handling, storage and manufacturing procedures;
- The infectivity and pathogenicity of the agent;
- The recipient's health status;
- The effectiveness of donor screening or donor testing for the agent; and
- The effectiveness of the aseptic technique used in collecting the blood or blood product from the donor and in infusing the product into the recipient.

In Canada, the infectious disease risks of transfusion are minimized through multiple steps, including blood collection from volunteer unpaid donors, donor interview and selection procedures, careful aseptic technique procedures for collection and infusion, diversion of the first 40 mL of blood collected into a diversion pouch, donor screening by serological and other tests (Table 2) (including donor screening for West Nile virus [WNV] since 2003) (11), and viral inactivation procedures included in the manufacturing of plasma-derived products (Table 2) (12-15).

With WNV donor screening testing now in place, the risk of contamination in blood collected from donors during a WNV outbreak is estimated to be 1/400,000 to 1/600,000 or less (3). This measure reflects the sensitivity of the test and the prevalence of infection among donors in a given region. The incidence of WNV in Canada last year was low in all regions. During the 2004 WNV season, with the use of the screening process, no blood or blood product infusion related cases of WNV were detected.

As noted in Table 3, solvent/detergent procedures dissolve the lipid envelope of HIV, WNV, hepatitis B virus and hepatitis C virus, but they are not effective against nonlipid-enveloped viruses such as hepatitis A virus or parvovirus B19. Heat inactivation is effective against a wide range of viruses, including WNV, hepatitis A virus and parvovirus (15). The leukocyte reduction technique that is used by Canadian Blood Services and Héma-Québec to further improve the safety of the blood supply also reduces the infection transmission risk, particularly for cytomegalovirus (CMV) (14).

Table 4 identifies specific inactivation steps in the manufacture of different plasma-derived products that decrease viral infection risks. Of note, the majority of Factor VIII and Factor IX used in Canada are recombinant products that are not plasma derived and, hence, do not have the infectious risks of a blood product.

Unfortunately, the solvent/detergent and heat viral inactivation procedures noted in Table 3 cannot be used on red blood cells or platelets because neither can withstand these vigorous viral inactivation processes. Bacterial contamination of platelets is also a risk (greater than that with red blood cells) because platelets are stored at room temperature (22°C±2°C), which supports bacterial pathogen multiplication (16,17). Various strategies have been developed to try to minimize the risk of transfusion-associated sepsis, including enhanced aseptic collection and handling procedures (diversion pouches are now in place), pretransfusion bacterial detection systems, processing and storage enhancement procedures, and pathogen inactivation techniques (18).

TABLE 2
Testing of blood donors in Canada* by Canadian Blood Services (CBS) and Héma-Québec

HIV-type 1/2† group	Antibody/nucleic acid testing
Hepatitis B virus	HbsAg, Anti-HBc‡
HTLV type I/II	Antibody
Syphilis	Treponemal test/PK-TP
Hepatitis C virus	Antibody/nucleic acid testing
West Nile virus	Nucleic acid testing
Other§	CMV antibody on selected units only

**Dr Gilles Delage, Héma-Québec and Dr Heather Hume, CBS, personal communications; †While the PRISM HIV antibody test does detect HIV group O, donors are still asked questions related to travel to parts of the world where HIV-O infection is prevalent, until a change in practice is approved; ‡Antibody to hepatitis B core antigen (Anti-HBc) testing was introduced by Héma-Québec in 2003 and will be introduced by CBS in 2005; §Héma-Québec and CBS are developing bacterial culture testing for apheresis platelets. CMV Cytomegalovirus; HbsAg Hepatitis B surface antigen; HTLV Human T-lymphotropic viruses*

TABLE 3
Specific manufacturing procedures for virus inactivation or removal

Procedure	Agents inactivated	Agents not inactivated
Inactivation by heat	CMV, HAV, HBV, HCV, HIV, WNV, parvovirus B19	
Inactivation by solvent/detergent	CMV, HBV, HCV, HIV, WNV	HAV, parvovirus B19, enteroviruses
Ultrafiltration using 35 nm and 15 nm filters	Removes even small viruses but also macromolecules (eg, Factor VIII is decreased)	
Leukocyte depletion	Decreases CMV, HTLV type I, II	Non-WBC-associated viruses

CMV Cytomegalovirus; HAV Hepatitis A virus; HBV Hepatitis B virus; HCV Hepatitis C virus; HTLV Human T-lymphotropic viruses; WBC White blood cell; WNV West Nile virus

TABLE 4
Manufacturing steps to decrease infectious risks of plasma preparations and plasma-derived components

Plasma preparation	Virus risk preinactivation process(es)	Pools screened for HIV, HCV, HBV, and HTLV type I, II*	Further virus inactivation steps
Cryoprecipitate (a blood component – not a fractionation product)	++	Yes	None†
Factor VII	+	Yes	Heat inactivation ± solvent/detergent
Factor VIII	+	Yes	Heat inactivation ± solvent/detergent
Factor IX	+	Yes	Heat inactivation, solvent/detergent, chromatography, ultrafiltration
Antithrombin concentrates	+	Yes	Cohn fractionation, heat inactivation, chromatography
Albumin	+	Yes	Cohn fractionation, heat inactivation
Intravenous immunoglobulin products	+	Yes	Cohn fractionation, ± hydrolase, ± solvent/detergent, ± heat inactivation ± chromatography, nanofiltration, ± caprylate
Intramuscular immunoglobulin	+	Yes	Cohn fractionation, solvent/detergent, heat treatment, nanofiltration, ± chromatography
Specific antibody products‡	+	Yes	Cohn fractionation or ion exchange column chromatography, solvent/detergent, filtration ± heat inactivation

**Human T-lymphotropic viruses (HTLV) type I/II are cell-associated viruses, so they are not found in manufactured plasma-derived products and serological screening of source plasma is not required. Similarly, cytomegalovirus is primarily cell-associated and the manufacturing processes remove risk; †Hence, the risk of transmission of infection from cryoprecipitate is similar to the risk from blood and blood products, and greater than the risk from plasma-derived manufactured products; ‡eg, Hepatitis B virus (HBV) immune globulin, tetanus immune globulin, rabies immune globulin, Rh (D) immune globulin, etc. HCV Hepatitis C virus*

TABLE 5
Bacterial agents associated with acute infection during blood product transfusion

Blood component	Storage	Bacterial agent
Packed red cells	1°C to 6°C for 35 to 42 days	*Yersinia enterocolitica* and other Gram-negative organisms, including *Pseudomonas* species
Whole blood	1°C to 6°C for 35 to 42 days	Gram-negative organisms
Platelets	20°C to 24°C for 5 days	Skin flora (eg, *Staphylococcus epidermidis* diphtheroids), *Salmonella* species, *Escherichia coli, Enterococcus* species, *Clostridium* species, *Serratia marcescens*
Plasma	Frozen, once thawed can be held at 1°C to 6°C for 24 h	*Staphylococcus aureus* and *Pseudomonas aeruginosa*

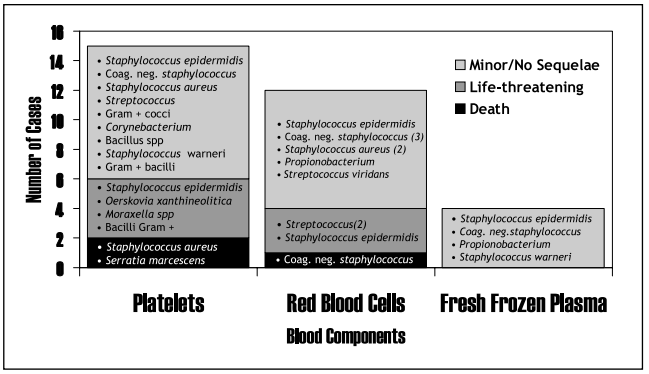

Figure 1) *Definite and probable cases of bacterial contamination (April 1, 2001 to September 30, 2003). Data from the Transfusion Transmitted Injuries Surveillance System program (Dr A Giulivi, Ms Nancy McCombie, personal communication). Coag neg Coagulase-negative*

In 2005, Canadian Blood Services will begin to implement the buffy coat method for the preparation of platelet pools with pretransfusion bacterial culture testing. Almost all reported acute infectious complications arising from blood product transfusion are associated with bacterial pathogens (16-18) (Table 5 and Figure 1). While the use of closed multicomponent plastic blood pack collection systems has helped to decrease the problem, contamination of platelet concentrates is still a concern (16,17). The risk of bacterial contamination of frozen components such as fresh frozen plasma and cryoprecipitates is low because the usual microbes (Table 5) are killed by freezing and other storage conditions. Where plasma has been found to be the source of infection, this was usually due to contamination of the water bath used to thaw the product (19). The use of microwave techniques or appropriate plastic covering specifically designed for this purpose minimizes this risk.

The estimated per unit risk of contamination in blood, blood products and manufactured plasma-derived products in Canada for a number of viral, bacterial, parasitic, prion and tick-borne agents are presented in Tables 6 and 7. In cases where Canadian data are not available, data from the United States and other countries have been included (4,9,13,20-21). As the data in Tables 7 and 8 show, the risks in Canada of transmitting infectious agents by blood, and especially, by plasma-manufactured products, are extremely low. To put it in context, a 1/3,000,000 risk is similar to that of being hit by lightning.

The risk estimates for the transmission of CMV remain complex (22). Although 40% to 70% of donors are CMV-positive, the risk of disease in nonimmunocompromised recipients is very low, while the risk of disease in immunocompromised and transplant patients is significant. For CMV seronegative recipients receiving seronegative organs or allogenic marrow, the risk of CMV infection in solid organ transplant recipients and in bone marrow transplant

TABLE 6
Estimated risk of infectious agent blood or blood products

Agents and products	Transfusion-transmitted	Pathogenic	Canadian estimated risk of contamination*
Viruses for which all blood donors are tested			
HIV†	Yes	Yes	<1/4,000,000
Hepatitis C virus†	Yes	Yes	<1/3,000,000
Hepatitis B virus†	Yes	Yes	1/275,000 to 1/1,000,000
HTLV† types I, II	Yes	Yes	<1/4,000,000
Other viruses			
Cytomegalovirus	Yes	Yes	Risks vary with donor/recipient‡
Parvovirus B19	Yes	Yes	1/10,000 to 1/15,000
GB virus C†§	Yes	Unknown	1–2 in 100; not known to be pathogenic
TTV†	Yes	Unknown	1/100; rarely pathogenic
SEN virus†	Yes	Unknown	1/100; not known to be pathogenic
HHV-8†	Unknown	Yes	Unknown
West Nile virus	Yes	Yes	1/400,000 to 1/600,000 during outbreak¶
Parasites			
Malaria	Yes	Yes	4 cases reported in Canada in the past 10 years
Chagas (*Trypanosoma cruzi*)	Yes	Yes	2 cases reported in Canada in past 15 years
Babesiosis (*Babesia microti*)	Yes	Yes	1 case reported in Canada in the past 15 years
Prion			
vCJD	Unknown	Yes	<1/10,000,000

**Risk of contamination refers to the potential residual risk of infection from the listed organisms in blood or blood products after proper screening and manufacturing processes have occurred; †Based on 3% to 5% of the Canadian population from the 17- to 65-year-old age group being blood donors. Based on reported cases from Public Health. Based on sensitivity and specificity of the tests used at Canadian Blood Services and Héma-Québec; ‡Cytomegalovirus infection risk is decreased by leukoreduction procedures (see text); §Formerly named Hepatitis G virus; ¶West Nile virus risk of 1/100,000 to 3/100,000 during an outbreak is an estimation given the sensitivity of the screening test and the prevalence of donor infection during an outbreak. HHV-8 Human herpes virus 8; HTLV Human T-lymphotropic viruses; TTV Transfusion transmitted virus; vCJD Variant Creutzfeldt-Jakob disease*

TABLE 7
Estimated risks of infectious agents in manufactured plasma-derived products

Agents	Historical evidence of transmission from plasma product	Pathogenic	Canadian estimated risk of contamination*
Viruses for which all blood donors are tested			
HIV	Yes	Yes	Less than 1/10 million
Hepatitis C virus	Yes	Yes	Less than 1/10 million
Hepatitis B virus	Yes	Yes	Less than 1/10 million
HTLV types I, II	Yes	Yes	Only theoretical risk
Other viruses			
Cytomegalovirus	No	Yes	Only theoretical risk
Parvovirus B19	Yes	Yes	Only theoretical risk if heat inactivated; otherwise, 1/100,000 to 1/1,000,000
West Nile virus	No	Yes	Much lower than 1/600,000, only theoretical risk
Parasites			
Malaria	No	Yes	Only theoretical risk
Chagas	No	Yes	Only theoretical risk
Babesiosis	No	Yes	Only theoretical risk
Prion			
vCJD	Unknown	Yes	Theoretical risk of less than 1/100,000,000

**Risk of contamination refers to the potential residual risk of infection from the listed organisms in plasma-derived products after proper screening and correct manufacturing processes have taken place. HTLV Human T-lymphotropic viruses; vCJD Variant Creutzfeldt-Jakob disease*

recipients is 2% to 3% and 20% to 50%, respectively, when non-WBC-reduced, unscreened blood components are given (14,22). This risk can be decreased with selection for seronegative donors and/or the use of leukocyte depletion filters (eg, the estimated risk of CMV infection for a bone marrow transplant recipient is only 2.4% when a leukocyte depletion filter is used) (14).

Although the risk of transmission of infectious agents through blood and plasma products is very low, the possibility of risk with a new or previously unrecognized agent is always present. Hence, an assessment of the potential transfusion risk must be made when a new agent is discovered or when new evidence comes to light. The two reports in 2004 from the United Kingdom of the possible transmission of variant Creutzfeldt-Jakob disease (one recipient asymptomatic) by transfusion of red blood cells donated by individuals 3.5 years and 18 months before the donors developed symptoms (23,24) combined with other evidence lead to a reassessment of the variant Creutzfeldt-Jakob disease transfusion risk and a shift of the risk from a theoretical possibility to a real, albeit very low, risk (25,26).

The experience gained from hepatitis C and HIV traceback and look-back programs, in which authorities have tried to trace transfusion recipients, have shown that many patients are unaware that they actually received a transfusion. No national electronic record of transfusions yet exists to facilitate any potential future tracing programs for a new transmittable agent. Therefore, it is important to ensure that transfused patients are aware that they received blood, blood products or manufactured plasma-derived products, and that the discharge or outpatient note adequately documents these transfusions and records the label code numbers for the specific products used.

The Transfusion Transmitted Injuries Surveillance System noted above, which has now been expanded to include all provinces and territories except Nunavut, will lead to an improvement in the quality and timeliness of risk estimates for blood-related infectious diseases and injuries. This system will provide firmer evidence for Canadian risk estimates that will be useful for providing counselling for informed consent.

The parent handout titled "When you child needs a transfusion" is available on our Web site <www.caringforkids.cps.ca>.

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The recommendations in this statement do not indicate an exclusive course of treatment or procedure to be followed. Variations, taking into account individual circumstances, may be appropriate. This article has also appeared in a previous issue of *Paediatrics & Child Health* (Paediatr Child Health 2005;10[3]:149-153)