Surveillance Report

2014

Canadian Blood Services
it's in you to give

Executive summary

We are pleased to present the third report for our stakeholders describing infectious disease surveillance. High quality and timely surveillance is key to the safety of the blood supply. This includes monitoring of transmissible disease markers that the blood is tested for (including bacteria), investigation of any reports of possible transfusion transmission, as well as a horizon scan for any new pathogens that may pose a risk now or in the future.

The most up-to-date tests for pathogens are used to identify infectious donations and prevent their release for patient use. In 2014, transmissible disease rates per 100,000 donations continued to be very low: HIV 0.4, Hepatitis C 6.1, Hepatitis B 5.8, HTLV 1.2 and Syphilis 3.5. Selective testing of donors at risk of Chagas' disease identified 5 positive donations, and there was 1 donation positive for West Nile Virus. The residual risk of a potentially infectious donation from a unit of blood also remains very low at 1 in 8 million donations for HIV, 1 in 6.7 million donations for HCV and 1 in 1.7 million donations for HBV. Lookback and traceback investigations did not identify any transfusion transmitted infections. Bacterial growth was identified in 8 platelet products.

Horizon scanning for emerging pathogens has identified no immediate threats to safety. Risk of a tick-borne disease, babesiosis, continues to be monitored. The parasite (*Babesia microti)* that causes babesiosis appears to be in the early stages of becoming established in a few places in Canada, especially in Manitoba. However, a 2013 study of over 10,000 blood donors did not identify any donors with antibody to *Babesia microti*. In a study of over 10,000 blood donors tested for Hepatitis E virus by PCR (polymerase chain reaction) none were positive, although in a subset of over 2000 donors 5.1% had a positive test for Hepatitis E antibody, indicating past exposure. A large outbreak of Ebola virus in West Africa prompted CBS to put together contingency plans to address risk from potentially infected people returning from West Africa. Starting in late 2013 and continuing through 2014, a large outbreak of a mosquito borne infection, Chikungunya virus, was seen in the Caribbean, extending into South and Central America. Although no cases of transfusion transmission have been reported to date, a travel survey of 8,908 blood donors was completed to facilitate policy formulation in case additional safety measures are required. From this it was estimated that about 39,000 (9.1%) donors traveled to the Caribbean in the previous year. Data from the travel survey as well as the natural history of Chikungunya virus

were used to estimate the risk of collecting a donation from an infected donor. The risk was extrememly low (less than 1 in 6 million donations).

In summary, transmissible disease continues to be very rare in Canadian Blood Services' donors. Ongoing surveillance will continue to play a prominent role in the safety of the blood supply.

Introduction

Safety of the blood supply from pathogens involves a multifaceted approach. Donor education materials on the internet and required reading just before donating explain risk factors for transmissible diseases and who should not donate. Before donating blood everyone must complete a health history questionnaire which includes questions about specific risk factors for transmissible diseases and answers are used to decide if people are safe to donate. All donations are tested for markers of transfusion transmissible agents including HIV (the AIDS virus), Hepatitis B (HBV) and Hepatitis C (HCV), Human T-Cell Lymphotropic Virus (HTLV) (a rare leukemia virus), Syphilis and West Nile Virus (WNV). In addition, donors at risk of Chagas' disease (which is acquired from the bite of an insect in Latin America) are tested, and all platelet products are tested for bacteria.

Canadian Blood Services carries out comprehensive surveillance of blood borne pathogens to monitor changing trends in known infections and to identify new infectious diseases. This information will allow us to put additional safeguards in place to reduce any risk to recipients of blood products. Surveillance includes monitoring of transmissible disease testing in blood donors, investigation of possible transfusion transmitted infections in blood recipients and horizon scanning for new, emerging pathogens. Although surveillance is conducted in "real time" over each year, final verification steps generally impose a short delay in producing a final report. This report describes Canadian Blood Services' approach to transmissible disease surveillance, as well as data for the calendar year of 2014.

1. Blood Donor Surveillance

The number of blood donations (whole blood and platelet and plasma apheresis) in donations from first time and repeat donors are shown in Figure 1. The majority of donations are from repeat donors (89.5%) with 10.5% of donations from new donors.

The "Classical" Pathogens

All blood donations are tested for transmissible diseases and are monitored in order to detect changes in trends. Details of screening tests used and dates of implementation are shown in Appendix 1. In Table 1 the number of positive donations and the rate is shown for 2014 by demographic groups. All transmissible disease positive donations occurred in whole blood donations (none in apheresis donations). As shown in Figure 2, the rate per 100,000 donations has decreased for most markers and the rate for repeat donations is extremely low. When a transmissible disease is detected, it is most often in a first time donation as these donors have not been tested previously and may have acquired the infection at any time in their life.

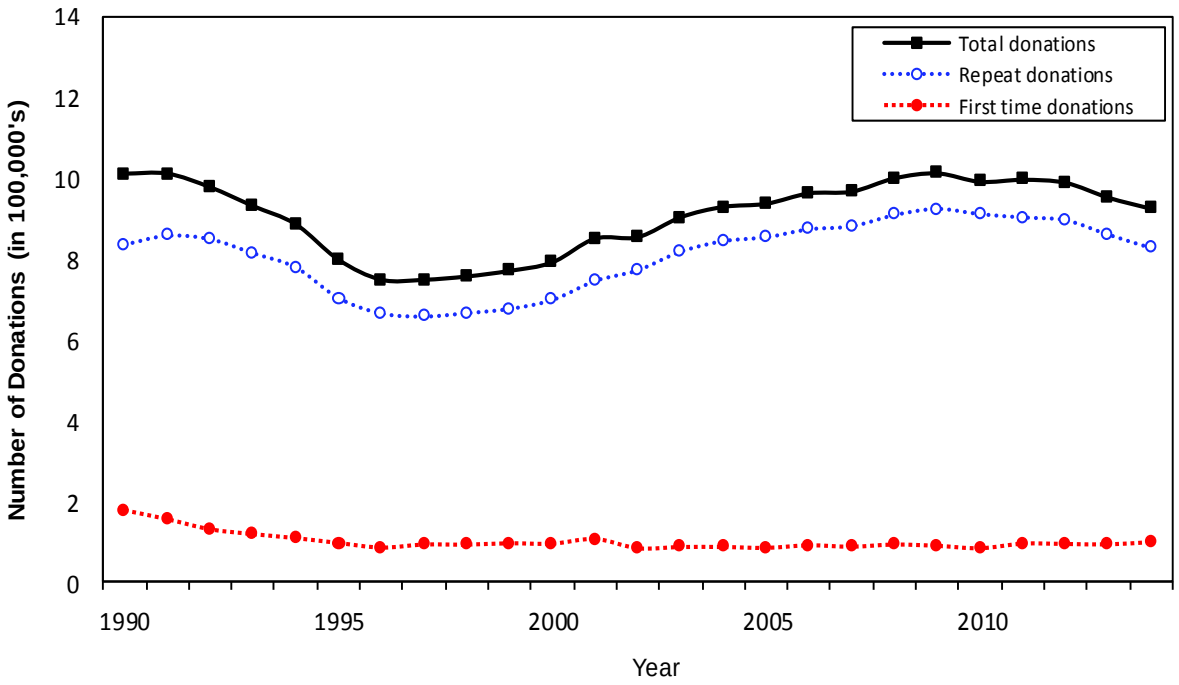
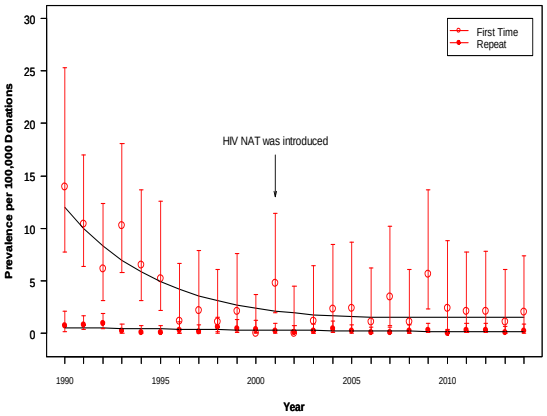


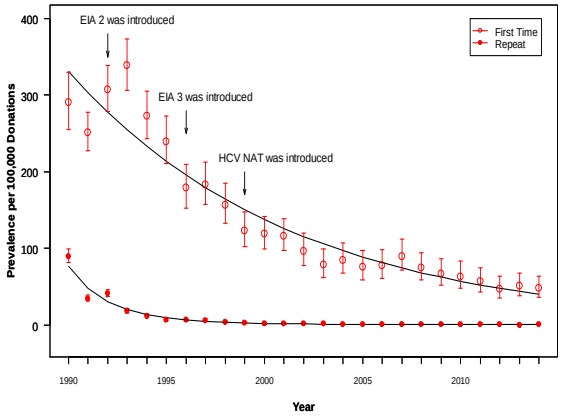
Figure 1 Donations in all Canadian Blood Services Regions, 1990-2014

Table 1 Confirmed positive donations and prevalence rates per 100,000 donations in 2014

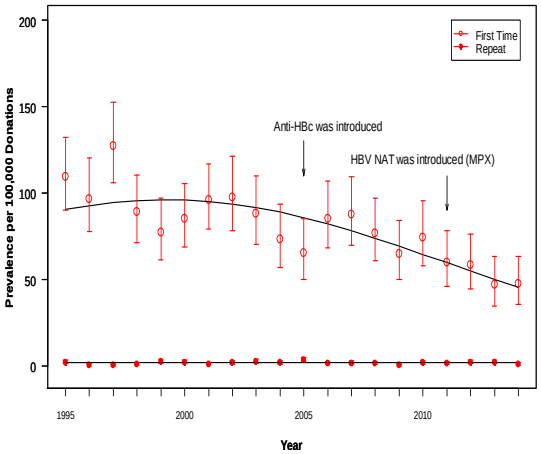
Characteristic	Number of Donations	Percent of Donations	HIV		HCV		HBV		HTLV		Syphilis	
			Pos	Rate	Pos	Rate	Pos	Rate	Pos	Rate	Pos	Rate
Donor status												
First time	97,274	10.5	2	2.1	47	48.3	46	47.3	9	9.3	29	29.8
Repeat	825,949	89.5	2	0.2	9	1.1	8	1.0	2	0.2	3	0.4
Sex												
Female	396,541	43.0	1	0.3	19	4.8	14	3.5	8	2.0	11	2.8
Male	526,682	57.1	3	0.6	37	7.0	40	7.6	3	0.6	21	4.0
Age												
17-29	209,701	22.7	1	0.5	11	5.3	18	8.6	3	1.4	3	1.4
30-39	133,413	14.5	2	1.5	7	5.3	13	9.7	1	0.8	6	4.5
40-49	164,367	17.8	1	0.6	10	6.1	11	6.7	0	-	9	5.5
50+	415,742	45.0	0	-	28	6.7	12	2.9	7	1.7	14	3.4
Total	**923,223**	**100.0**	**4**	**0.4**	**56**	**6.1**	**54**	**5.8**	**11**	**1.2**	**32**	**3.5**



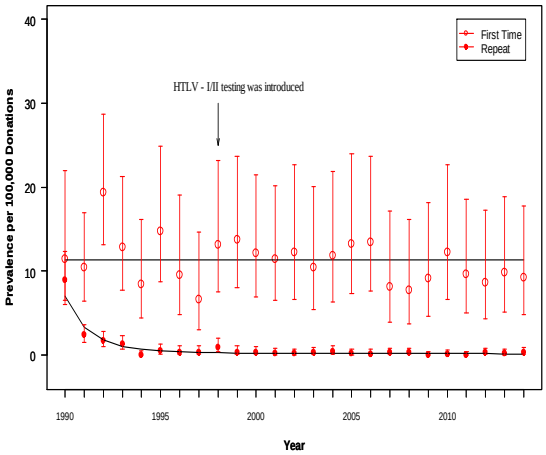
HIV prevalence per 100,000 donations
by donation status, 1990-2014



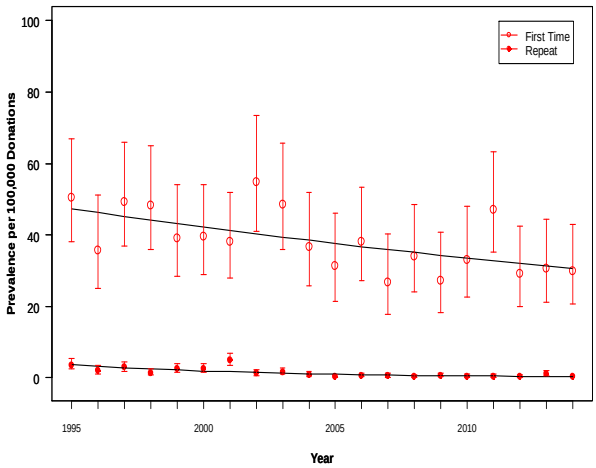
HCV prevalence per 100,000 donations
by donation status, 1990-2014



HBV prevalence per 100,000 donations
by donation status, 1994-2014



HTLV prevalence per 100,000 donations
by donation status, 1990-2014



Syphilis prevalence per 100,000 donations
by donation status, 1995 - 2014

Figure 2 Rate of HIV, HCV, HBV, HTLV and Syphilis in first-time and repeat donations (Note that these graphs have different scales on the y-axis)

All transmissible disease positive donations are destroyed and never released into inventory. The main source of risk is from blood donors with a very recently acquired transmissible disease that is too recent to be detected by testing, but may be transmitted by transfusion. This is called the "window period" of infection. With current state-of-the-art testing the window period is very short. For HIV and HCV an infection would be detected within 1 to 2 weeks of a donor being infected, and for HBV within one month. The residual risk of infection as shown in Table 2 is the estimated risk of a potentially infectious donation being made during the "window period", and is currently extremely low, but of course it can never be zero.

Table 2 Estimated residual risk of HIV, HCV and HBV

HIV	HCV	HBV
1 in 8 million donations	1 in 6.7 million donations	1 in 1.7 million donations

Risk Factors

Risk factor interviews are carried out with donors who test positive for transmissible diseases. For HIV the main risk factor is multiple sex partners. For HCV the main risk factors are a history of intravenous drug use or a sexual partner with a history of intravenous drug use, a history of blood transfusion (prior to testing the blood for HCV), having been in prison and being born in Africa or Asia where HCV is more common. For HBV the main risk factor was being born in Africa or Asia where HBV is more common. For HTLV the main risk factors were being born overseas (especially the Caribbean), as well as a history of other sexually transmitted diseases, and a history of blood transfusion. For Syphilis the main risk factor was a history of Syphilis. It should be noted that participation is voluntary and therefore there is only data for some donors, and that for many donors no risk factors were identified.

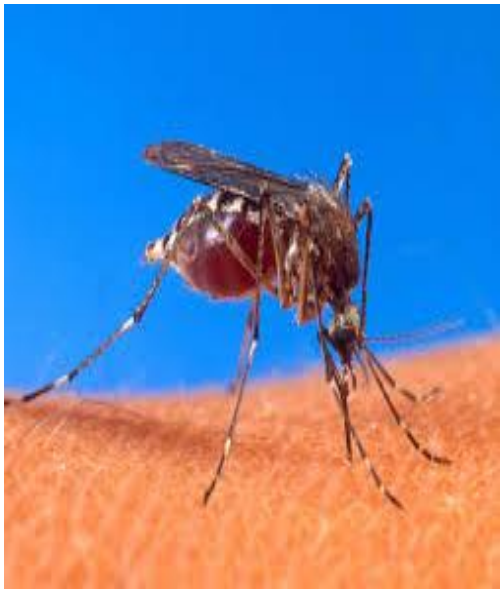
Chagas Disease *(Trypanosoma cruzi)*

Riduviid bug which carries *T. cruzi* (the parasite that causes Chagas' disease)

Chagas disease is caused by infection from a parasite called *Trypanosoma cruzi* (*T. cruzi*). People can become infected with it after being bitten by an insect that is found mainly in parts of Mexico, Central and South America but the *T. cruzi* parasite can also be passed on from an infected mother to her child during pregnancy and from an infected blood donor by blood transfusion. The insect is not able to live in Canada. Since May, 2009, Canadian Blood Services has been asking questions about risk of Chagas' disease on the donor health history questionnaire. Originally, platelets were not produced from at-risk donors followed in May, 2010 by implementation of testing of these donors for antibodies to *T. cruzi*. In 2014, there were 15,026 donations from donors with risk factors, and 5 had positive tests for *T. cruzi* antibody.

Regions of the world endemic for *T. cruzi*

West Nile Virus



West Nile Virus is a mosquito borne virus that has been present in North America since 1999 (in Canada since 2002). Although symptoms can be severe, they are usually mild and most people are not aware of their infection. All donations are tested in a minipool of 6 donations. However, to further reduce the risk, a risk assessment algorithm is applied to identify all donations from areas where West Nile Virus is active and these are tested as single units rather than in a minipool. In 2014, 1 donation tested positive for West Nile Virus. It was identified in September in London, Ontario. There were very few community cases in 2014.

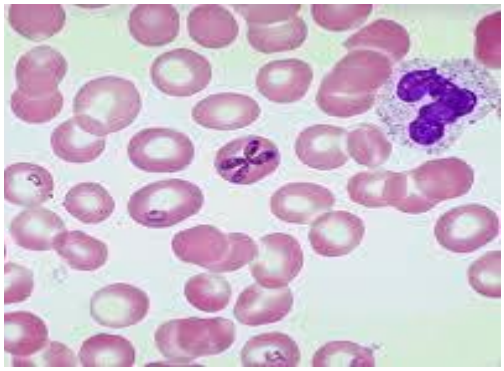
2. Surveillance for emerging pathogens

A central feature of surveillance is a horizon scan of potentially blood transmissible infectious diseases in the general community. It is important to be aware of emerging infectious diseases in other parts of the world as well as in Canada since international travel is commonplace and infections can rapidly enter from other countries. To ensure that potential risks are identified in a timely fashion, Canadian Blood Services needs to be connected with the latest infectious disease information at all times. Integral to this is active participation of Canadian Blood Services medical and scientific staff in public health and infectious disease professional organizations as well as monitoring of web sites and journals where new information is posted. In order to ensure readiness to act in the event of a new infectious disease threat, Canadian Blood Services maintains a plan to address pandemic influenza, which can be adapted to deal with other large outbreaks affecting staff and donors.

Babesiosis

Babesiosis is usually acquired from the bite of a tick (*Ixodes scapularis*), more commonly called the black-legged tick. Usually it causes mild flu-like symptoms, and many people are not even aware that they have had it. However, it can also be transmitted by blood transfusion from an infected donor, and infection in blood recipients can result in severe illness or death. To date babesiosis cases have been documented in the United States, mainly in the North Eastern States, but the number of reported cases has been increasing following the designation of this infection as a reportable disease in 2012, and over 150 infections in the USA are believed to have been acquired from a transfusion. The parasite appears to be in the early stages of becoming established in ticks in Canada, but to date only one human case acquired from tick exposure in Canada has been reported. In a 2013 study, 10,062 blood donations were tested from areas of potential risk and none were positive. At this time *Babesia microti* presents very low risk to the blood supply but ongoing vigilance is required.

Black-legged tick



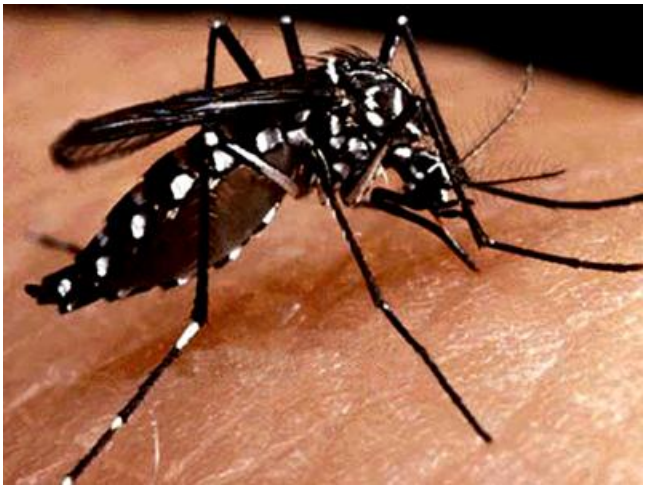
Babesia microti

Hepatitis E

Hepatitis E is relatively common in developing countries where it is spread through contaminated food and water. Healthy people often do not get very sick, generally clear the infection and often never know that they had it. However, blood recipients could become very ill. In a study 10,062 blood donations from various locations in Canada were tested for Hepatitis E virus (nucleic acid testing) and a subset of 2,048 donations were also tested for the antibody to Hepatitis E. None were positive for the virus, but 110 donations (5.1%) were positive for antibody. This indicates that some donors were likely infected with the Hepatitis E virus at some point in their lives, but had cleared the infection at the time of donation, so they did not pose a risk to blood recipients.

Chikungunya virus

Chikungunya virus is a mosquito borne virus that has been identified as the cause of outbreaks since the 1950's, mostly in Asia and Africa. Most infected individuals experience mild to moderate flu-like symptoms, but in severe cases debilitating joint pain occurs. Starting in late 2013, Chikungunya infections began to appear for the first time in the Americas, in particular the Caribbean, and a small number of Canadian travellers to the Caribbean developed infections. Although there is only a theoretical risk that Chikungunya virus could be transmitted by blood transfusion, and no transfusion transmitted cases have ever been reported, it is important to know how frequently donors travel to risk areas in case additional safety measures are required. In 2014 8,908 blood donors completed an on-line travel survey questionnaire, which showed that about 39,000 (9.1%) blood donors travelled to the Caribbean over a 12 month period but only about 6,500 donors (16.8%) would return to donate within 4 weeks of travel. Data from the travel survey as well as the natural history of Chikungunya virus were used to estimate the risk of a donation from an infected donor. The risk was extrememly low (less than 1 in 6 million donations).



Ebola Virus

Ebola virus is transmitted by direct contact with infected body secretions and causes fever, rash, vomiting and diarrhea and sometimes severe internal bleeding, resulting in death. There is an ongoing Ebola outbreak in West Africa, but in Canada the main risk is among individuals such as health care workers returning from West Africa. Donors returning from West Africa are already deferred for 12 months for malaria risk and so do not pose a risk to blood safety. However, CBS developed information for donors and staff to address risk from a donor if she/he was in contact with someone who had an Ebola infection in Canada. Questions which could be asked during donor screening, posters for the clinics, and information for the CBS website were prepared in case they were needed.

CBS has developed a protocol for collecting convalescent plasma (which contains antibodies to fight Ebola infection) from Canadian donors who have recovered from Ebola infection and are willing to donate for a specific infected recipient. An agreement has also been set up to access convalescent plasma from the U.S. if required by a Canadian hospital to treat someone with Ebola. Fortunately these circumstances have not arisen to date. The efficacy of this therapy is not established but is considered to be part of the treatment strategy for people infected with the Ebola virus.

Middle East Respiratory Syndrome

The Middle East respiratory syndrome (or MERS) was first reported in Saudi Arabia in 2012. It is caused by MERS-CoV, a coronavirus from the same family of viruses that caused the SARS outbreak in Toronto in 2003. So far over 980 cases of MERS-CoV have been reported, but they have all been linked to the Middle East (mostly Saudi Arabia). No cases have been reported in Canada to date.

3. New Initiatives

Pathogen Reduction

A study of a pathogen reduction system for platelet products is currently under way. The Mirasol Pathogen Reduction System for Platelets uses riboflavin (vitamin B_2) to inactivate many viruses, bacteria and parasites when exposed to ultraviolet light. It may also reduce the risk of graft versus host disease for platelet recipients. Before considering implementing such a system it is important to confirm that it does not reduce the effectiveness of the platelets to stop bleeding in patients. To do this, adult patients who have blood cancers and low platelets and who have volunteered to be in the study are randomly assigned to either receive the Mirasol pathogen reduced platelets or our regular platelets, and are being monitored for any adverse effects. This study is currently being carried out at selected hospitals in Canada and in the Netherlands and Norway. To date, over 442 platelet recipients have been enrolled in the study, including 98 from Canada. In total the study will involve over 600 platelet recipients.

Donor Re-entry Following a False Positive Transmissible Disease Test

Due to the sensitivity of the screening tests Canadian Blood Services uses, sometimes donors will test positive for a transmissible disease marker on initial testing, but the more specific confirmatory testing is negative. These are called 'false positives' and for many years these donors have been permanently deferred based on the screening result. Beginning in February, 2014 donors with false positive HIV, HCV or HBV results (those with a final interpretation of negative or indeterminate by confirmatory testing) were eligible to return to have a blood sample tested after a 6 month waiting period. If all testing is negative, then the donor is eligible to return to donate blood. Over 900 donors who were deferred for false positive results were identified for possible re-entry to date, of whom about 11% have returned to give a sample for testing. Of these about three quarters were eligible to return to donate.

Donor Eligibility Criterion for Male to Male Sex

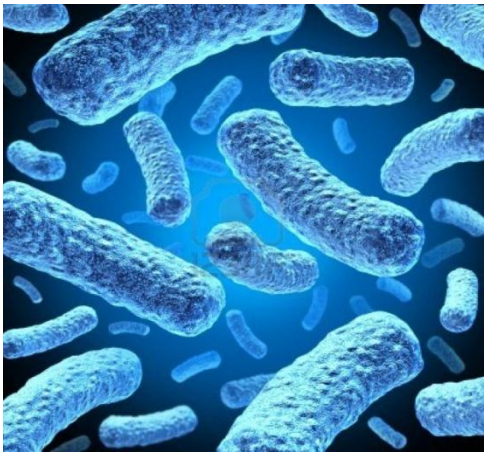
Since the 1980's men who have had sex with another man even once since 1977 were not eligible to donate blood to reduce the risk from HIV. With much improved donor testing and surveillance for emerging pathogens, following consultation with patient and community stakeholders, in July, 2013 male donors became eligible to donate if they have not had sex with another man in the past 5 years. Some other countries have implemented shorter deferral periods (for example 12 months in England and Australia) and have not seen any evidence of increased risk to the blood supply. The US FDA has indicated that they will modify regulatory guidance to permit a 12 month deferral period. Evaluation of the safety impact of the change to a 5 year deferral period will be carried out this summer, 2 years since it was put in place. Consultations with our stakeholder groups will then be undertaken to assess the potential to further reduce the deferral period. Any proposed change would then need to be approved by our regulator, Health Canada.

4. Lookback/Traceback

All cases of potential transfusion transmission of disease are investigated. When a donor tests positive for a transmissible disease, or if the donor reports a transfusion transmissible disease after donating (even if it is not one that would normally be tested for) a lookback file is opened. All previous donations are identified and hospitals are asked to contact the recipients of these donations to arrange testing. A traceback is initiated when a recipient is found to have a transmissible disease and it is queried as to whether it could have been from their blood transfusion. All blood products that the recipient received are identified by the hospital, and Canadian Blood Services attempts to contact the donors of these products to arrange testing.

There were 227 lookback files opened for donations that tested positive in 2014 (129 for donors that tested positive, 93 from public health notification and 5 identified during traceback investigation). Of these, 133 were from first time donors which had no previous donations to examine. The remaining 94 cases included 7 HIV, 67 HCV, 15 HBV, 2 HTLV and 3 Chagas. Of these, 65 cases were closed (all recipients that could be contacted were tested) and 29 cases were still open. No cases were associated with transfusion transmission. There were 90 traceback cases opened in 2014 (4 HIV, 76 HCV, 10 HBV, and 0 HTLV). Of these, 65 were closed (all donors that could be contacted were tested), and 25 remain open. There were no cases associated with transfusion transmission.

5. Bacteria



Bacteria in blood products usually come from the skin of donors during their blood donation, although occasionally they may originate from a systemic infection in the donor. The amount of contaminating bacteria is usually very low, but because platelet products are stored at room temperature the bacteria can multiply to reach high concentrations and then pose a serious risk to the recipient. Canadian Blood Services tests all apheresis and pooled platelet products for bacteria using the BacT/ALERT System in which a sample from the product is inoculated into culture bottles and monitored for growth for the full 5-day shelf life of the product. The product would be returned if any bacterial growth were detected and the product is still available (ie, has not been transfused or discarded). In 2014, 101,736 platelet products (21,719 apheresis and 80,017 pooled products) were tested of which 31 apheresis and 41 pooled products had initial positive results for bacterial growth in the culture bottle. From these, 2 and 6 cultures were confirmed as true bacterial contaminations, for apheresis and pooled products, respectively. In addition, 2 of the 41 pooled products with initial positive results were not confirmed as they were issued and/or transfused. This represents 10 products in total (0.98 per 10,000) with a chance of bacterial contamination with current testing, including both true positives and suspected positives.

6. References

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Implementation Dates of Testing

	Marker	Implementation Date*
1	**Syphilis**	1949
2	**HBV (Hepatitis B Virus)**	
	HBsAg	1972
	Anti-HBc	2005
	HBV NAT	2011
3	**HIV (Human Immunodeficiency Virus)**	
	Anti-HIV-1 EIA (Enzyme-linked Immunosorbent Assay)	1985
	Anti-HIV-1/2 EIA	1992
	HIV-1 p24 Antigen	1996 (discontinued in 2003)
	HIV-1 NAT	2001
	Anti-HIV-1/2 (including HIV-1 subtype O) EIA	2003
4	**HTLV (Human T-Lymphotropic Virus)**	
	Anti-HTLV-I	1990
	Anti-HTLV-I/II	1998
5	**HCV (Hepatitis C Virus)**	
	Anti-HCV EIA/ELISA	1990
	HCV NAT	1999
6	**WNV (West Nile Virus)**	
	WNV NAT	2003
7	**Chagas' disease (*Trypanosoma cruzi)* selective testing**	2010
8	**Bacteria**	
	BacT Alert	2004

*These are the dates that testing for the marker began. Tests have been upgraded as new versions of the test became available.