Surveillance Report 2019

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Executive Summary

We are pleased to present the eighth annual report describing transmissible blood-borne infection surveillance. High quality and timely surveillance is central to the safety of the blood supply. This includes monitoring of transmissible disease markers that the blood is tested for (including bacteria) and investigation of any reports of possible transfusion transmission, as well as a horizon scan for any new pathogens that may pose a risk.

Infectious Risk Monitoring

The most up-to-date tests for pathogens are used to identify infectious donations and prevent their release for patient use. In 2019, transmissible disease rates per 100,000 donations continued to be very low: HIV 0.5, hepatitis C (HCV) 5.6, hepatitis B (HBV) 8.5, HTLV 0.9 and syphilis 4.1. Selective testing of donors at risk of Chagas' disease identified 1 positive donation, and there were 4 donations positive for West Nile Virus. Residual risk estimates of a potentially infectious donation from a unit of blood are very low at 1 in 12.9 million donations for HIV, 1 in 27.1 million donations for HCV and 1 in 1.4 million donations for HBV. Lookback and traceback investigations did not identify any transfusion transmitted infections. Bacterial growth was identified in 183 platelet products. Of 552 potential peripheral stem cell or bone marrow donors tested, 2 (0.36%) were positive for antibody to hepatitis B core antigen. Of 507 samples from mothers donating stem cells collected from the umbilical cord and placenta (called "cord blood") after their babies were born, none were positive for any marker.

Horizon scanning for emerging pathogens monitors potential 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. Travelers and former residents from malaria risk areas are temporarily deferred for malaria risk. In addition, a 3 week deferral for any travel outside Canada, the USA and Europe reduces risk from short term travel related infections, such as Zika virus. A novel coronavirus was identified in Wuhan, Hubei Province, China in November. By the end of 2019 planning was in progress to address travel risk and risks within Canada that may arise. Note: Safety and sufficiency of the blood supply has been successfully maintained over the early COVID-19 pandemic (at time of release of this report, June 2020).

Non-infectious monitoring

Giving blood is very safe, and serious reactions in donors are quite rare. However, some donors have vasovagal reactions (faint or pre-faint reactions) during or shortly after donation. A Donor Wellness initiative was implemented in March 2019 in which all donors were offered water and salty snacks before donating, and instructions on muscle tension exercises to do during donation. These are expected to reduce vasovagal (feeling faint) reactions and help donors to feel well after donating. Vasovagal reactions decreased from 18.8 to 16.2 per 10,000 whole blood donations.

Iron depletion is relatively common in female donors and people who donate frequently. Iron stores are not currently being measured in donors. However, iron deficiency can progress to a drop in donor hemoglobin, and donors may then fail their pre-donation hemoglobin screen. In order to help prevent iron deficiency, in 2017 the minimum waiting time between whole blood donations for females was increased from 56 days to 84 days which contributed to a decrease in deferrals. The minimum hemoglobin for males was increased from 125 g/L to 130 g/L resulting in a small and transient increase in deferrals.

The Diagnostic Services Laboratories at Canadian Blood Services provide prenatal testing for some pregnant women, including all pregnancies in several provinces, and for some patients with complex transfusion needs. In 2019 1,257 red blood cell antibodies were identified in pregnant women that could put their fetus at risk of hemolytic disease on the fetus/newborn and 1,102 red cell antibodies were identified in patients who may need special matching for transfusion.

1. 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 infections and who should not donate. Before donating blood, everyone must complete a health history questionnaire which includes questions about specific risk factors for transmissible infections. This is followed by an interview with trained staff to decide if the person is eligible to donate blood. All donations are tested for markers of transfusion transmissible agents including HIV (human immunodeficiency virus or the AIDS virus), hepatitis B (HBV) and hepatitis C (HCV), human T-cell lymphotropic virus (HTLV) (a rare cause of leukemia) and syphilis. West Nile virus (WNV) testing is done during the at-risk period of the year (spring, summer and fall) and in at risk-travelers during the winter season. In addition, donors at risk of Chagas' disease (which is transmitted by the bite of an insect in Latin America) are tested, and all platelet products are tested for bacteria.

Surveillance includes monitoring of transmissible infection testing in donors, investigation of possible transfusion transmitted infections in recipients and horizon scanning for new, emerging pathogens. Monitoring the safety of donors is also essential. 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 surveillance of transmissible blood-borne infection surveillance and donor safety, as well as data for the calendar year of 2019.

2. Blood Donor Surveillance

The number of allogeneic blood donations (whole blood and platelet and plasma apheresis) from first time and repeat donors are shown in Figure 1. The majority of donations are from repeat donors (88.9%) with 11.1% of donations from new donors.

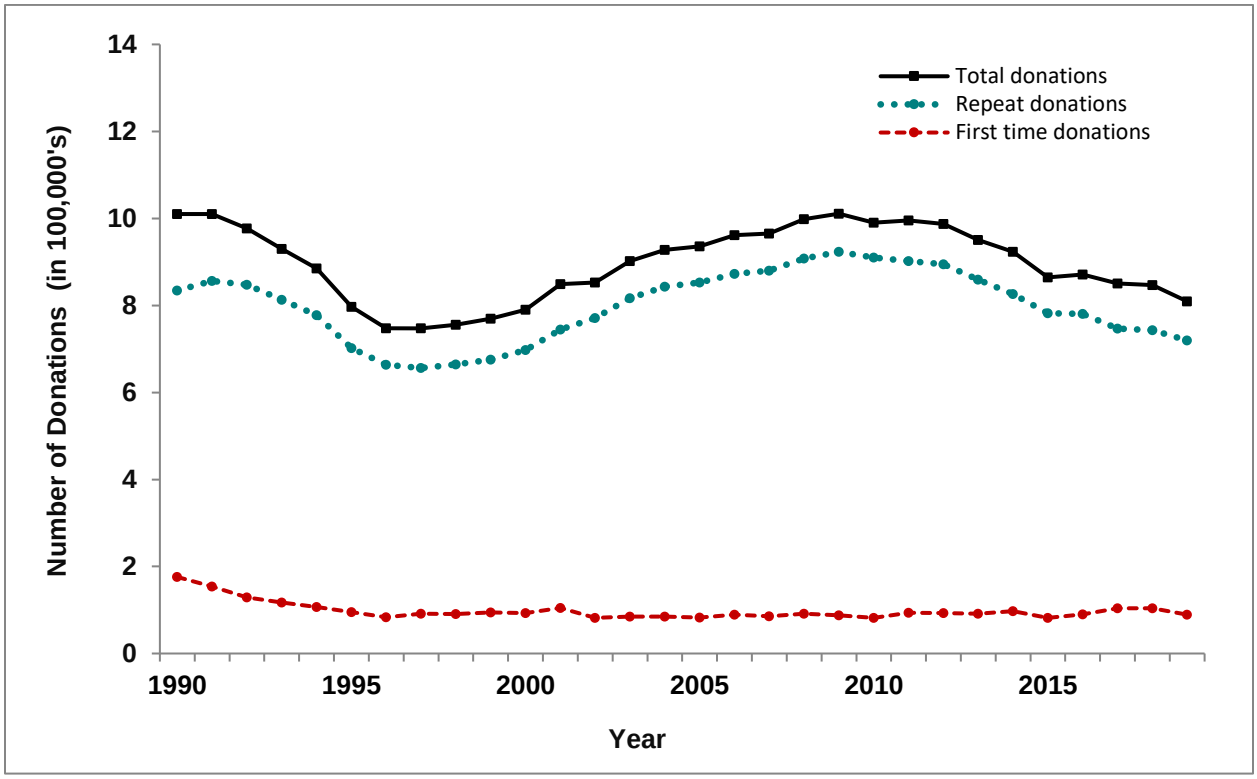


Figure 1 Donations in all Canadian Blood Services Regions, 1990-2019

The "Classical" Pathogens

Details of screening tests used, and dates of implementation are shown in Appendix 1. In Table 1 the numbers of positive donations and the rates of positive tests per 100,000 donations are shown for 2019 by demographic groups. All transmissible infection positive donations occurred in whole blood donations (none in apheresis donations). The rate per 100,000 donations has decreased for most markers and the rate for repeat donations is extremely low (see Appendix 2). When a transmissible infection is detected, it is most often in a first time donor as these donors have not been tested previously and may have acquired the infection at any time in their lives. Importantly, although the proportion of first time donors has increased in recent years, there has been no increase in infectious markers.

Table 1 Confirmed positive donations and prevalence rates per 100,000 donations in 2019

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	88,596	11.1	2	2.3	43	48.5	60	67.7	5	5.6	20	22.6
Repeat	712,685	88.9	2	0.3	2	0.3	8	1.1	2	0.3	13	1.8
Sex												
Female	342,621	42.8	2	0.6	13	3.8	21	6.1	3	0.9	11	3.2
Male	458,660	57.2	2	0.4	32	7.0	47	10.3	4	0.9	22	4.8
Age												
17-29	171,786	21.4	0	-	2	1.2	17	9.9	0	-	8	4.7
30-39	143,608	17.9	3	2.1	7	4.9	23	16.0	2	1.4	11	7.7
40-49	129,671	16.2	1	0.8	8	6.2	10	7.7	2	1.5	8	6.2
50+	356,216	44.5	0	-	28	7.9	18	5.1	3	0.8	6	1.7
Total	**801,281**	**100**	**4**	**0.5**	**45**	**5.6**	**68**	**8.5**	**7**	**0.9**	**33**	**4.1**

All transmissible infection positive donations are destroyed. The main source of risk is when a blood donor acquired the infection too recently to be detected by testing. This is called the "window period" of infection. With current 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 is the estimated risk of a potentially infectious donation being given during the "window period". These estimates (based on 2016 -2018 data) are shown in Table 2. The risk 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 12.9 million donations	1 in 27.1 million donations	1 in 1.38 million donations

Risk Factors

Risk factor interviews are carried out with donors who test positive for transmissible infections. The main risk factors are shown in Table 3. HIV infections are very rare in donors; therefore it is difficult to generalize the risk factors. It should be noted that participation is voluntary and therefore there are only data for some donors, and that for many donors no risk factors were identified.

Table 3 Risk factors for infectious disease in blood donors

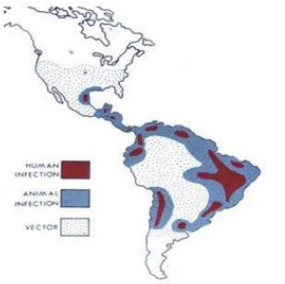
Infection	Risk Factor
HIV	High risk heterosexual partners Male to male sex
HCV	History of intravenous drug use History of blood transfusion (prior to testing) Been in prison Born in Africa or Asia
HBV	Born in Africa or Asia
HTLV	Born overseas (especially Caribbean) History of other sexually transmitted disease History of blood transfusion
Syphilis	Previous history of syphilis

Note: Not all donors are interviewed

Chagas Disease (*Trypanosoma cruzi*)

Chagas disease is caused by infection with a parasite called *Trypanosoma cruzi* (*T. cruzi*). People can become infected with it after being bitten by an insect in parts of Mexico, Central and South America. The *T. cruzi* parasite can also be passed on from mother to child during pregnancy and by blood transfusion. In 2019, there were 20,804 donations from donors with risk factors, and 1 had a positive test for *T. cruzi* antibody.

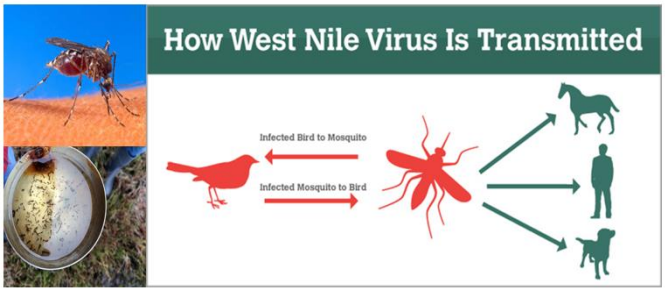
Riduviid bug which carries *T. cruzi* (the parasite that causes Chagas' disease)



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. During spring, summer and fall, donations are routinely tested in a mini-pool of 6 donations. However, to further reduce the risk, an algorithm is applied to identify all donations from areas where West Nile virus is active, and these are tested as single donations. In 2019, 397,314 donations were tested over the spring/summer/fall when all donations were tested, and 1 donation was positive, identified in July in Ontario. With only travelers tested over the winter, 66,391 donations (from Jan 1 to May 27, and November 24 to December 31, 2019) were tested and 3 were positive. All three donors recently had vaccine for Japanese encephalitis, known to cross-react with the West Nile virus test as was one additional donation from the summer.



3. Surveillance for Emerging Pathogens

A horizon scan of potentially blood borne infections in the general community ensures rapid revision of donor policies to maintain safety. Even before a new infectious disease is reported in Canada, we are aware of emerging infectious agents by monitoring outbreaks in other parts of the world. International travel is commonplace, and infections can rapidly enter from other countries. To ensure that potential risks are identified, Canadian Blood Services needs to be connected with the latest infectious disease information at all times. Canadian Blood Services medical and scientific staff participate in public health and infectious disease professional organizations and monitor web sites and journals where new information is posted. When appropriate the Alliance of Blood Operators (ABO) Risk Based Decision Making Framework can be used to facilitate policy decision making. This ensures that relevant assessments including infection risk to recipients, operational impact of strategies, stakeholder input and health economics are considered.

Potential infectious risks within Canada

Ongoing surveillance of a range of infectious agents that could emerge as a threat within Canada are being monitored. Three that have prompted additional studies or actions are described here.

Coronavirus Disease 2019 *(COVID-19)*

Towards the end of 2019 a new coronavirus was identified in Wuhan, Hubei Province, China. More than 80,000 people were infected. People with *COVID-19* infection develop respiratory illness that can last up to 2 weeks or longer. While many cases are asymptomatic or mild and people recover fully, some people become extremely ill and even die. By the end of 2019 there was concern that people outside of China may become infected from travelers, and concerns of a pandemic were raised. There is currently no evidence that *COVID-19* is blood transmissible. However, there are concerns about infectious risks to donors and to staff from attending donor clinics and risks to the adequacy of the blood supply if donors decide to avoid donation during the pandemic. Canadian Blood Services has a pandemic response plan which formed the starting base for addressing these concerns. By the start of 2020 risk assessment and preparation to activate the plan had commenced.

Babesiosis

Babesiosis comes from the bite of the black-legged tick (*Ixodes scapularis*). 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, and infection in blood recipients can result in severe illness or death. To date babesiosis cases in the general population have been reported mainly in the North Eastern and Upper Midwest parts of the United States where more than 1,500 cases per year are reported. Cumulatively more than 200 infections in the United States are believed to have been acquired from a transfusion. In Canada the parasite is found in small numbers of ticks. A 2013 study at Canadian Blood Services and Héma-Québec tested 13,993 blood donations and none were positive. In 2013 one human case in the community from local tick exposure was reported. Ongoing public health surveillance of ticks suggests no increase in risk, but a donor study was carried out in 2018 involving more donors. One of 50,752 samples tested from southerly areas across Canada was positive by *B. microti* nucleic acid testing (NAT, donated in Manitoba and indicating an active infection) and of 14,758 samples tested for antibody to *B. microti*, 4 in Southwestern Ontario were positive (but negative by NAT, indicating likely resolved infection at some time in the past). In 2019 a donor developed illness after donating and was diagnosed with *B. microti* infection, likely infected in southern Manitoba. No recipients were infected from the donation. Risk mitigation strategies are being considered using the ABO Risk Based Decision Making Framework. Canadian Blood Services, Héma-Québec, and experts from the Public Health Agency of Canada and academic institutions are working together to estimate the risk of *B. microti* in Canada to inform decision making.

Hepatitis E (HEV)

Hepatitis E is common in developing countries where it is spread through contaminated food and water. People can also be infected from eating undercooked pork. Similar to hepatitis A, healthy people often do not get very sick, generally clear the infection and never know they had it. However, blood recipients could become very ill. A 2013 study at Canadian Blood Services and Héma-Québec showed that 5.1% of donations were positive for antibody (indicating a previous infection with Hepatitis E) but none were positive for the virus. In 2015 a larger study (over 50,000 donations) with a more sensitive test identified 1 in 4,615 HEV positive donations. However, most were later stage infections with low concentrations of virus thus less likely to be infectious. The risk is lower than in some countries in Europe that have testing in place. The ABO Risk Based Decision Making Framework was used to consider strategies to address risk.

The decision was to enhance physician awareness of HEV and enhance adverse event and donor surveillance.

Travel related infections

Donors who travel may return with infections that could be transmitted by blood (see Figure 2). Most are only a risk for a period of time after returning until they are eliminated from the donor's bloodstream. Malaria risk is present in parts of the Caribbean, Mexico, Central and South America, Asia and Africa. Donors are deferred after travel to risk areas for 12 months, enough time to develop symptoms. Former residents of endemic areas are deferred for 3 years because there is a chance they may be infected longer without symptoms. Other tropical mosquito-borne infections such as dengue virus have long been present in sunny destinations frequented by Canadians, but in recent years there have been outbreaks of others such as Chikungunya virus and Zika virus not previously seen in the Caribbean, Mexico, Central and South America. Risk to the blood supply was determined to be very low based on quantitative risk assessment. However, to address future travel risks as of 2016 Canadian Blood Services defers all donors who have travelled anywhere outside of Canada, the USA or continental Europe for 3 weeks after travel. Other travel risks such as for variant-Creutzfeldt Jakob disease (vCJD) have longer deferrals. vCJD is acquired from eating infected meat (Bovine Spongiform Encephalitis, or BSE, known as "Mad Cow Disease") in England and other European countries during the years of the BSE epidemic in cattle. Donors are deferred for time spent in those countries while infected meat may have been available. Infectious risks in other countries are closely monitored to decide if further action is needed. In 2019 a new coronavirus (*COVID-19*) was identified in China. For more details, see section above.

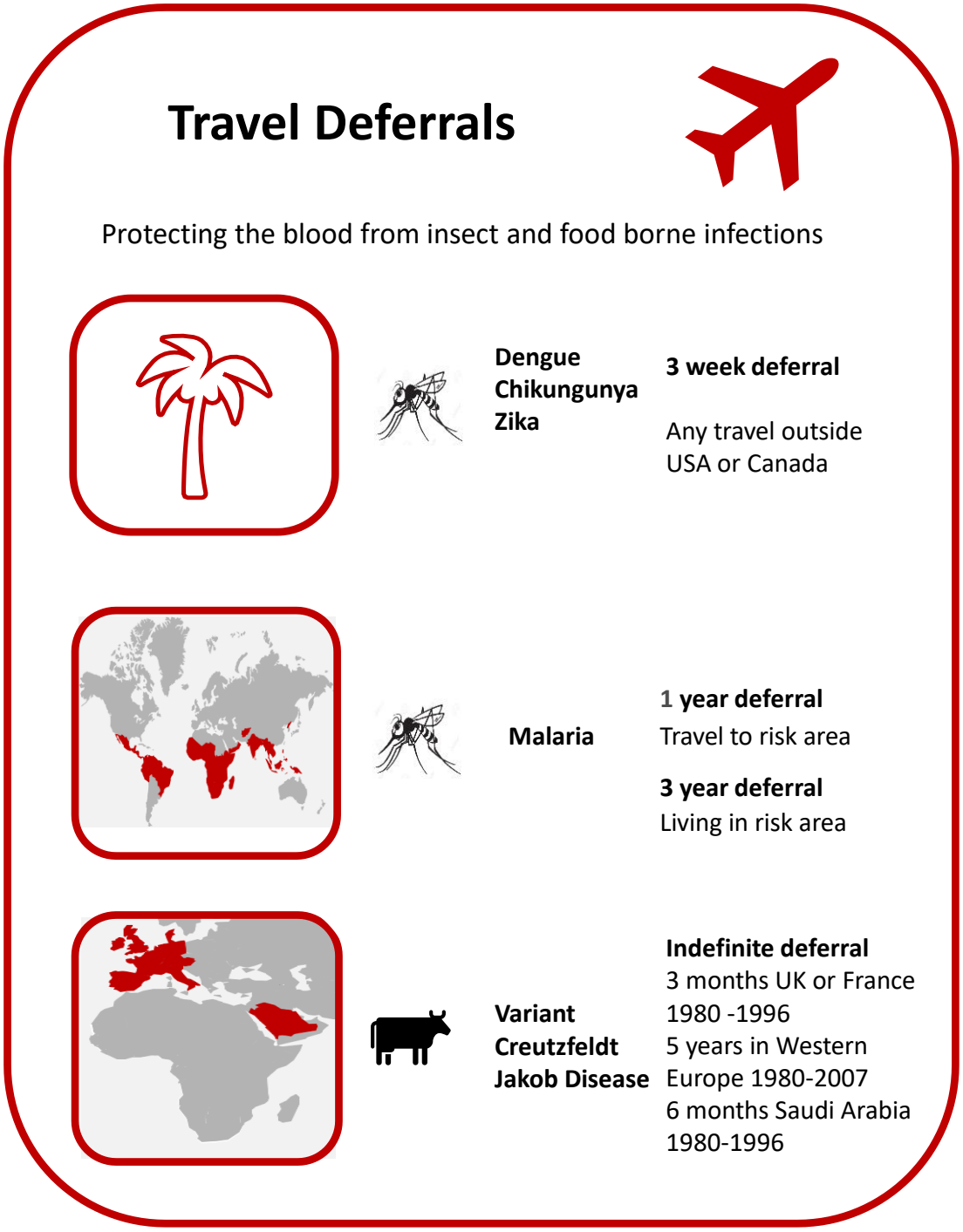


Figure 2 Key travel deferrals in place to reduce risk of transmissible infections.

4. Bacteria

Bacteria in blood products usually come from the skin of donors during their blood donation, although occasionally they may come from the donor's bloodstream. The number of bacteria is usually very low, but because platelet products are stored at room temperature, 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 an aerobic (presence of oxygen) culture bottle and an anaerobic (absence of oxygen) culture bottle and monitored for growth for 7 days. If any bacterial growth is detected in the culture bottles, the product is not issued if it is still in inventory at Canadian Blood Services, or if it is recalled and returned to Canadian Blood Services from the hospital blood bank (i.e., has not been transfused or discarded). In 2019, 109,222 platelet products (16,318 apheresis and 92,904 pooled products) were tested, of which 101 apheresis and 390 pooled products had initial positive results for bacterial growth in the culture bottles. From these, 10 and 100 cultures were confirmed as true bacterial contaminations, for apheresis and pooled products, respectively. In addition, 9 apheresis and 64 pooled products with initial positive results were not confirmed as they were issued and/or transfused. This represents 183 products in total (16.8 per 10,000) with a chance of bacterial contamination with current testing, including both true positives and suspected positives.

5. 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 of AIDS/HIV transmission. With much improved donor testing and surveillance for emerging pathogens the deferral period has been gradually reduced, moving to 5 years in 2013, to 1 year in 2016 and to 3 months in 2019. HIV rates did not increase following any of these changes, although more time is needed to adequately assess post-3-month deferral (see Figure 3). Anonymous donor compliance surveys showed that shortening the deferral period allowed more MSM to donate blood and donor compliance was not adversely affected (see Figure 3). With these data the risk associated with reducing the deferral to 3 months was estimated to be 1 in 34.2 million donations (1 in 225,534 million, 8.7 million). Another compliance survey is planned for 2020/2021 to assess the impact of the 3-month deferral. Many countries have switched from lifetime to shorter time deferrals, mostly 1 year. England has a 3 month deferral, and France and the Netherlands have 4 month deferrals.

Canadian Blood Services is committed to ongoing revision of this policy, ideally to find a way to more finely define donor sexual risk rather than deferring all sexually active MSM. In January of 2017 Canadian Blood Services and Héma-Québec hosted a meeting which included Canadian researchers in gay men's health, regulatory staff (Health Canada and the USA Food and Drug Administration), stakeholders and international experts. The attendees brainstormed to identify the key areas of research needed to assess the safety of potential changes to the deferral. Canadian Blood Services and Héma-Québec then launched a competitive grant program to allocate funding provided by Health Canada to Canadian researchers. To date, 15 research projects are being funded in this grant program. For more information see: https://blood.ca/en/research/our-funded-research-projects?combine=msm

A meeting of grant-holders, regulatory staff (Health Canada and the USA Food and Drug Administration), stakeholders and international experts was convened in November 2019 at which research results were presented. A report will be made available in 2020.

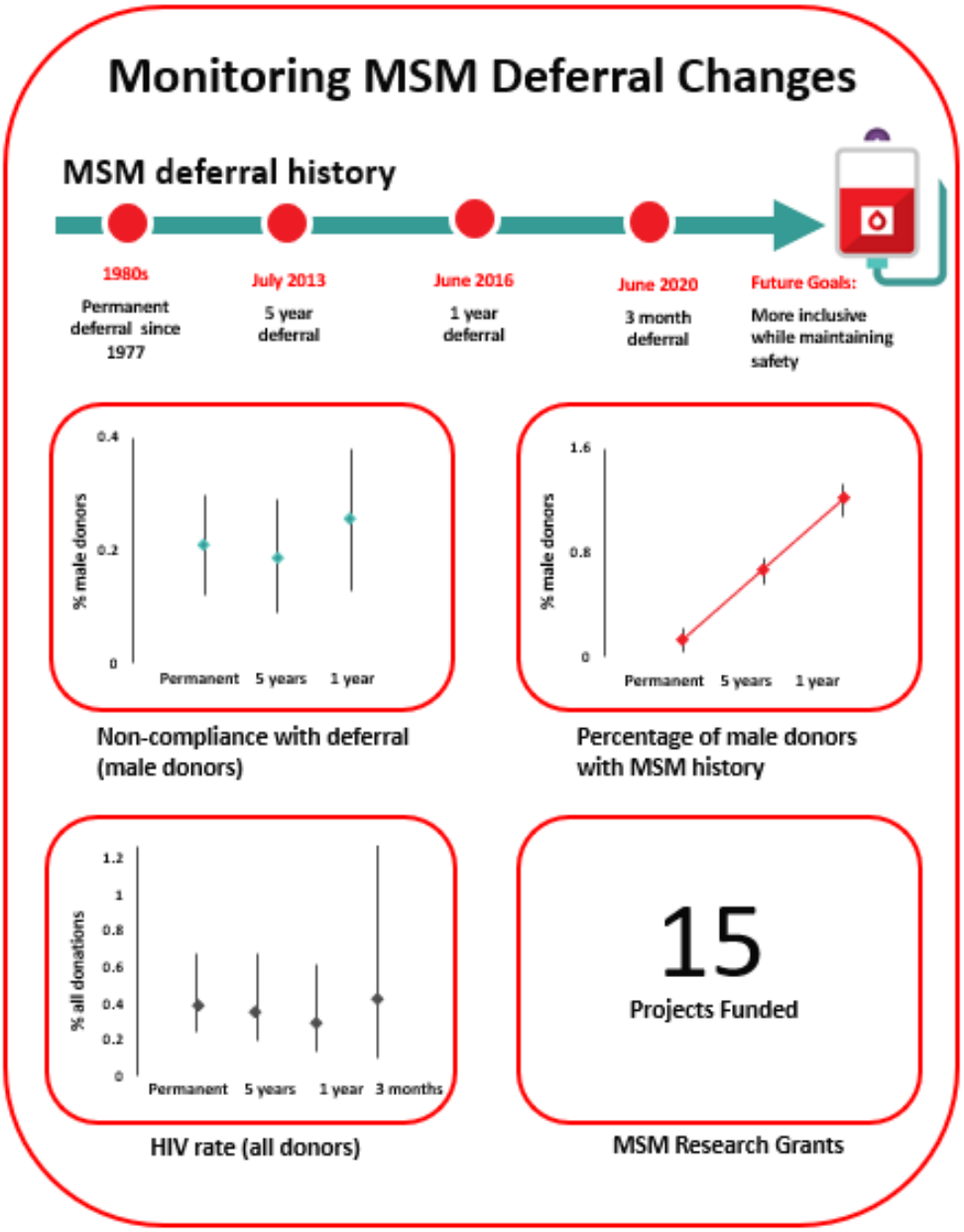


Figure 3 Increased eligible MSM donors but no change in non-compliance with the deferral or HIV rates as the duration of deferral periods was decreased.

6. Lookback/Traceback

All cases of potential transfusion transmission of disease are investigated. The Lookback / Traceback Program is notified 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 investigation is initiated when previous or historical 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 transfusion was confirmed and it is queried as to whether it could have been from their blood transfusion. Hospitals provide a list of all blood products that the recipient received, and Canadian Blood Services attempts to contact the donors of these products to arrange testing unless current test results are available.

In 2019, there were 55 lookback cases that required investigation. This included 6 HIV, 43 HCV, and 2 HBV, 2 HTLV and 0 WNV, 1 Babesia, 0 Chagas, 1 HEV cases (12 for donors that tested positive with in-house testing, 43 from external testing or public health notification and 0 identified during traceback investigation). Of these 45 were cases closed (all recipients that could be contacted were tested). The remaining 10 cases were still open. There were 16 open cases from previous years that were closed in 2019. No closed cases were associated with transfusion transmission. There were 47 traceback cases that required investigation received from external sources in 2019 (5 HIV, 38 HCV, 4 HBV, and 0 HTLV). Of these, 31 were closed (all donors that could be contacted were tested), and 16 remain open. There were also 15 cases from previous years closed. There were no closed cases associated with transfusion transmission.

7. Blood Stem Cells

Blood stem cells can multiply to renew themselves; the new cells develop into blood cells such as red cells, white cells and platelets. In adults, they are found mainly in the marrow of large bones, with a few cells in the bloodstream. The cord blood of newborn babies, taken from the umbilical cord and placenta after the delivery of a healthy baby, is also very rich in stem cells. Blood stem cells can therefore be obtained from the bone marrow, from circulating blood (called peripheral blood stem cells) or from the umbilical cord (cord blood) after a baby is born. Blood stem cells are very important in treating various types of diseases such as leukemia, lymphoma and multiple myeloma. Canadian Blood Services has a coordinated national stem cell program

which includes adult registrants and banked cord blood units. Infectious disease testing for stem cells includes the same markers tested for whole blood donations.

Canadian Blood Services Stem Cell Registry

Canadian Blood Services' Stem Cell Registry is a registry of Canadians who have volunteered to donate either bone marrow or peripheral blood stem cells should a recipient need it at some time in the future. Potential registrants complete a questionnaire which includes risk factors for transmissible infections and are tested for their Human Leukocyte Antigen (HLA) profile. In 2019 there were about 457,000 registrants in the registry. In total, 552 registrants were identified as potential matches for recipients and had additional testing. Of these, two (0.36%) were reactive for antibody to hepatitis B core antigen (anti-HBc). For comparison, about 1% of first-time whole blood donors are reactive for this marker. All tested registrants had negative results for all other infectious disease markers.

Canadian Blood Services' Cord Blood Bank

Canadian Blood Services' Cord Blood Bank collected cord blood at four sites in Canada in 2019. Participating mothers at these hospitals who volunteer to donate their baby's cord blood complete a questionnaire about medical conditions that could be passed on to a recipient, as well as risk factors for transmissible infections. If the donation is suitable for transplantation (i.e., has enough stem cells) with negative results for all infections, the cells are frozen and stored until a recipient needs them. In 2019, there were 507 blood samples from mothers tested and none were positive for any infections tested.

8. Donor Safety

Donor Reactions

Canadian Blood Services takes many precautions to make sure that giving blood is safe for donors. These include a health screening questionnaire and a hemoglobin fingerstick screen, as well as providing refreshments and monitoring the donor after donating. Most donors do not have any problems during or after their donation, but it is important to keep track of any incidents that happen so that donor care can be improved. Definitions of reactions are shown in Table 4.

The Donor Wellness Initiative

Since late March 2019 all donors were encouraged to eat salty snacks and drink water provided at the donation clinic before donating, although these were being gradually introduced before that date. Salty snacks and water can help to reduce vasovagal (faint) reactions. Donor instructions to carry out muscle tension exercises while donating were also provided. These can also reduce the risk of a vasovagal reaction. Also, in March the amount of time donors was required to wait before getting up after donating decreased from 5 minutes to 2 minutes in line with practice of many blood operators in the US. It was anticipated that the wellness initiatives would more than compensate for any risk of reactions.

Reaction rates per 10,000 whole blood donations in 2019 are shown in Figure 4 with those in 2018 for comparison. Moderate vasovagal reactions were lower ($p<0.001$) and severe reactions trended downwards, but the change was not statistically significant ($p = 0.16$). People more likely to experience a reaction are first time donors, young donors (17-25 years old) and female donors. The reaction reporting system is oriented towards capturing moderate and severe reactions. Most reactions are mild, such as feeling faint or bruising at the needle site, but these are only recorded if mentioned by the donor at some point after donation. A further breakdown of fainting reactions (both moderate and severe) in whole blood donors by sex and donation history is provided in Table 5. Due to small numbers in each group these are not significantly different from those reported in 2018 ($p>0.05$).

There was an increase in the number of re-bleeds reported in 2019 (See Figure 5, $p<0.001$). This could be related to donors getting up from donating more quickly than before and a change in the procedure used to stop bleeding after donation. These reactions do not pose a serious health risk but may be distressing or bothersome for the donor. Clinic staff are encouraging donors to apply pressure to the venipuncture site after donating. Additional training on the new procedure was implemented due to the higher rate of donor rebleed reactions. Cardiovascular events are very rare. It is difficult to know if cardiovascular events that happen shortly after donation are in any way related to donation, or simply happened by chance in the 24 hours after donation.

Table 4 Reaction and definitions

Reaction	Definition
Vasovagal	Donor loses consciousness (faint reactions)
Moderate	Unconscious less than 60 seconds and no complications
Severe	Unconscious more than 60 seconds or complications
Major Cardiovascular Event	Chest pain or heart attack within 24 hours of blood donation, may or may not be related to donation
Re-bleed	The phlebotomy site starts to bleed after donation
Nerve Irritation	Needle irritation or injury of a nerve during phlebotomy. Usually described as sharpshooting pain, arm tingling or numbness
Inflammation/Infection	Redness or infection at the needle site, usually seen several days after donating
Local Allergic Reaction	Rash from skin cleaning solution or dressing, with raised vesicles on the skin
Arm Pain	Usually due to blood pressure cuff, tourniquet or arm position
Bruise/Hematoma	Temporary dark color of the skin due to blood leakage from blood vessel at time of phlebotomy
Arterial Puncture	Needle inserted in an artery instead of a vein

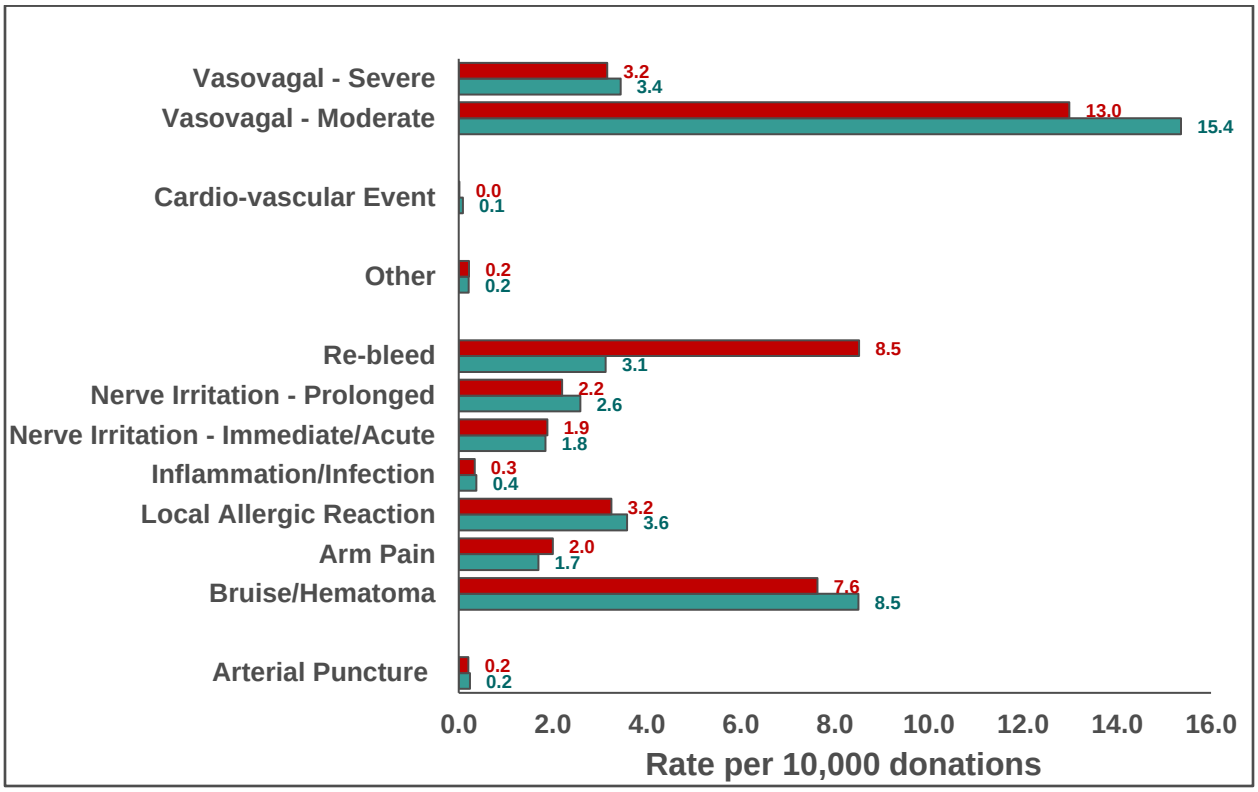


Figure 4 Reaction rates per 10,000 whole blood donations in 2019 (red) and 2018 (green)

Table 5 2019 Fainting (vasovagal) reactions (per 10,000 collections)

	Moderate & Severe (all)		Associated with injury	
Donation Status	**Male**	**Female**	**Male**	**Female**
First Time	51.6	78.8	1.1	2.7
Repeat	5.4	17.2	0.4	0.8

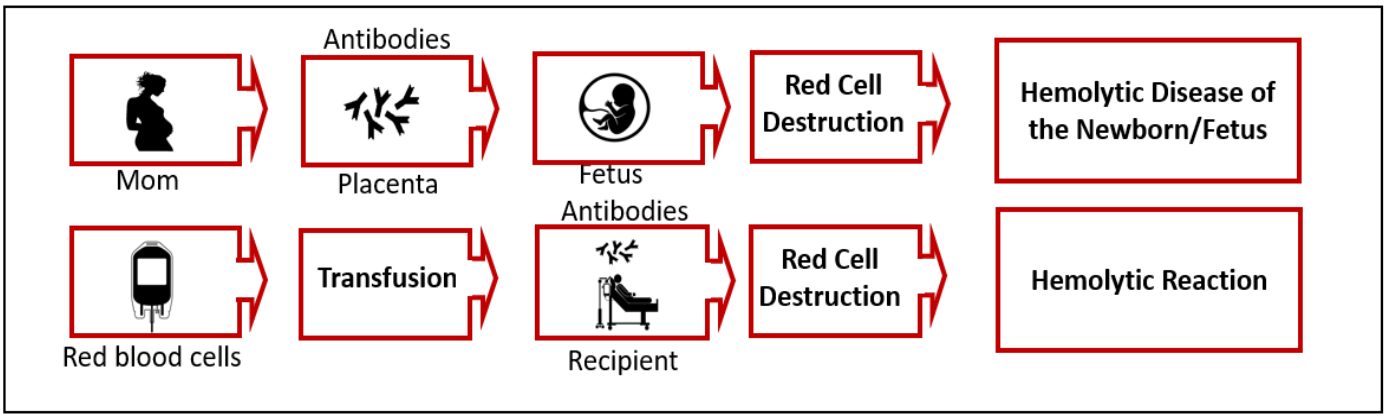
*all comparisons are statistically significant among moderate & severe reactions combined ($p<0.05$). For reactions associated with injury only FT vs repeat females and repeat male's vs repeat females were significantly different.

Donor Hemoglobin and Iron

The most common reason for a donor deferral at the collection site is a failed hemoglobin fingerstick screen. Low hemoglobin is often related to low iron stores. Iron is needed to make hemoglobin which carries oxygen in red blood cells. Studies at Canadian Blood Services showed that iron stores are often lower in females and are further reduced by frequent donation in both females and males. Males with borderline hemoglobin are also more likely to have lower iron stores. To reduce the chance of developing iron deficiency, the minimum wait time between whole blood donations for females was increased from 56 days to 84 days in 2017. This longer interdonation period allows females more time to build back their iron stores and return to their baseline hemoglobin levels. Hemoglobin deferral rates have gradually decreased in female donors from about 13.5% of donation attempts to 7.0% ($p<0.001$). In 2017 the minimum hemoglobin for male donors was increased from 125 to 130 g/L to align with a healthy hemoglobin in males which is higher than for females. As a result, the hemoglobin deferral rate in males initially increased from 1.4% to 2.3% but has now dropped back to 1.5%. There was an overall net decrease in hemoglobin deferrals due to the large decrease in females.

Information about iron and the safety of blood donation can be found at www.blood.ca as well as in the 'What you must know to give blood' pamphlet provided to all donors prior to every donation.

9. Diagnostic Services



The Diagnostics Services Laboratories provide patient testing, mainly for pregnant women (Perinatal Laboratories) and patients receiving blood transfusions (Crossmatch/Reference Laboratories). Some Canadian Blood Services Diagnostic Services Laboratories provide all of these services.

Perinatal Laboratories

The Perinatal Laboratories provide testing of pregnant women for blood group and antibodies to red blood cells. Some antibodies can cause hemolytic disease of the fetus/newborn. The goal is to 1) identify Rh negative pregnant women and recommend treatment to prevent developing anti-D antibodies, and 2) identify pregnant women with risky antibodies to monitor their pregnancy and treat as needed. Testing of fathers, newborns and fetuses is also sometimes done. In 2019 1,257 women had red blood cell antibodies; the most common ones that could put their baby at risk are shown in Figure 5.

Maternal	97.79%
Paternal	0.84%
Cord	1.38%

198,147 Samples Tested

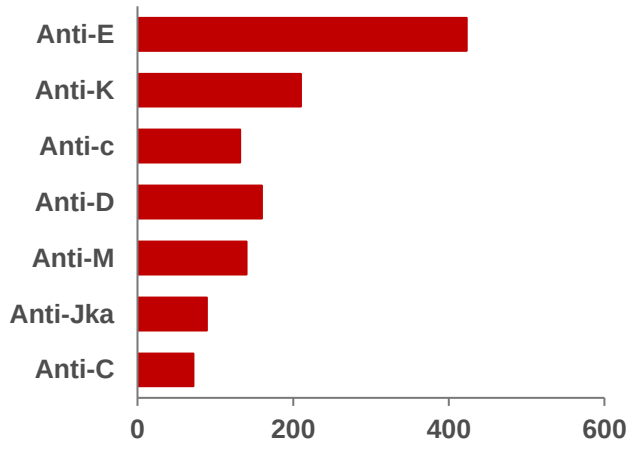


Figure 5 Number of clinically significant perinatal antibodies, 2019

Crossmatch/Reference Laboratories

The reference laboratories provide testing of patients for blood groups which must match the donor blood to be transfused. They also carry out antibody investigations for patients who may have unusual red blood cell antibodies and need special matching of blood for transfusion. Figure 6 shows the frequency of different antibodies in pre-transfusion patients (1,102 patients). Patients who have rare antibodies/antigens may be difficult to match for transfusion. The National Platelet Immunohematology Platelet Reference Lab in Winnipeg, Manitoba assists health care providers manage thrombocytopenic patients by HLA and HPA typing and investigation for HLA and HPA.

For more detail see https://blood.ca/en/hospital-services/laboratory-services/surveys

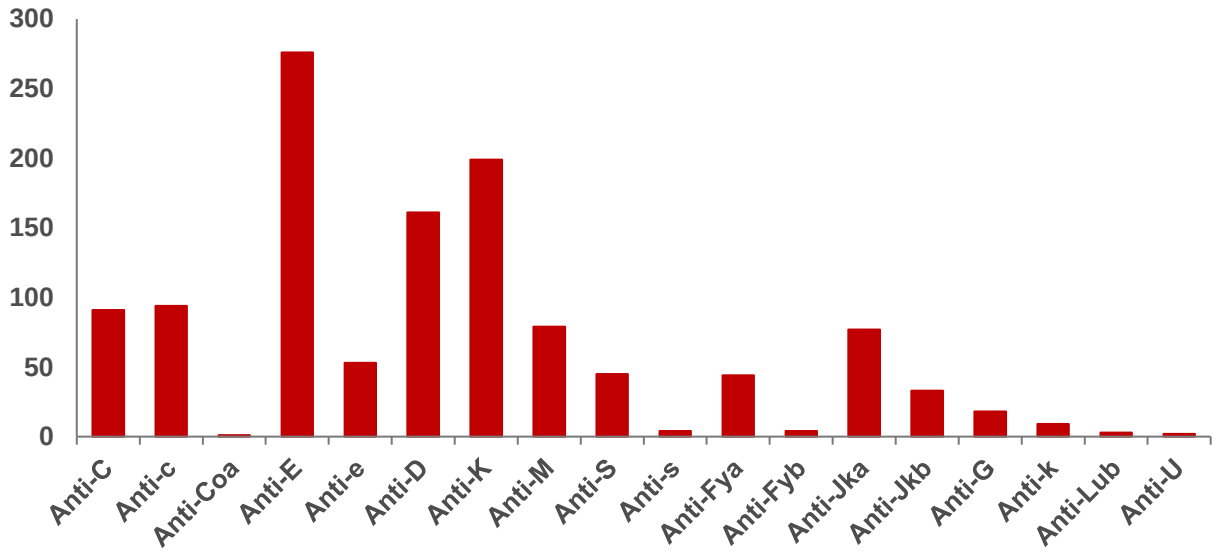


Figure 6 Number of reference antibodies, 2019

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APPENDIX I

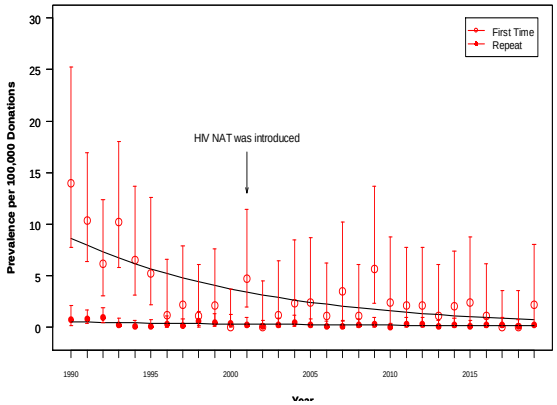
Implementation Dates of Testing

	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
	BacT Alert modified for 7 day platelets	2017

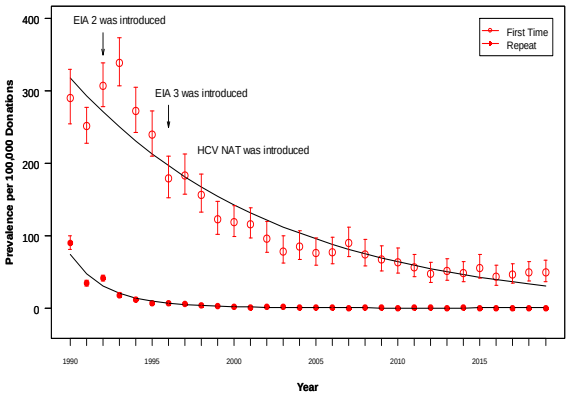
*These are the dates that testing for the marker began. Tests have been upgraded as new versions of the test became available.

APPENDIX II

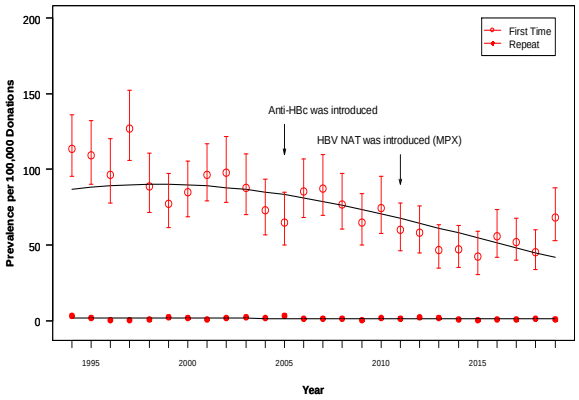
Rate of HIV, HCV, HBV, HTLV and syphilis in first-time and repeat donations (Note that these graphs have different scales on the y-axis)



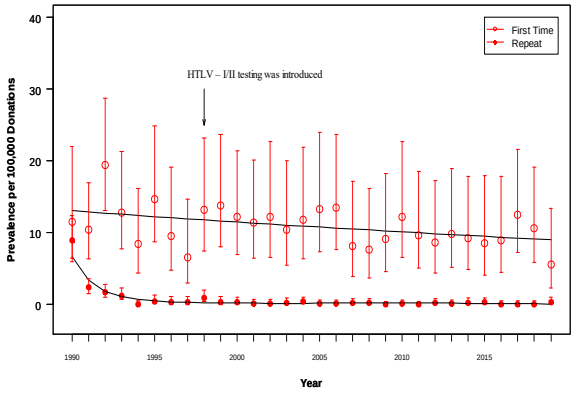
HIV prevalence per 100,00 donations by donation status, 1990-2019



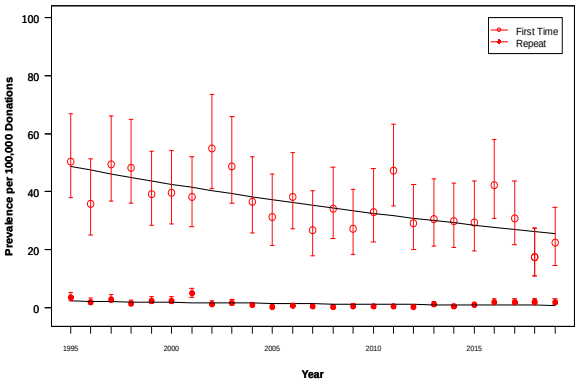
HCV prevalence per 100,000 donations by donation status, 1990-2019



HBV prevalence per 100,000 donations by donation status, 1994-2019



HTLV prevalence per 100,000 donations by donation status, 1990-2019



Syphilis prevalence per 100,000 donations by donation status, 1990-2019