Transfusion-transmissible infections in Australia

2019

Surveillance Report

Australian Red Cross Lifeblood

UNSW SYDNEY

Kirby Institute

This publication is available online at:
http://www.kirby.unsw.edu.au and
http://www.transfusion.com.au

Recommended citation:
Transfusion-transmissible infections in Australia: 2019 Surveillance Report. Kirby Institute, UNSW Sydney, and the Australian Red Cross Lifeblood; 2019

Requests for further information should be addressed to:

Dr Laila Khawar
Research officer, Surveillance, Evaluation and Research Program
The Kirby Institute, UNSW Australia
+61 2 9385 9201 I lkhawar@kirby.unsw.edu.au

Or,

Dr Clive Seed
Senior Blood Safety Analyst, Donor and Product Safety (DAPS) Policy Unit
Australian Red Cross Lifeblood
+61 8 6213 5913 I cseed@redcrossblood.org.au

ISSN 2203-0751 (Online)

edited by

Clive Seed, Laila Khawar, Veronica Hoad, Claire Styles, and Rebecca Guy

The Australian Red Cross Lifeblood

in collaboration with

The Kirby Institute, UNSW Australia

Acknowledgements

The report was prepared by the following investigators of the Kirby Institute[1] and the Australian Red Cross Lifeblood[2].

Edited by	Clive Seed[1], Laila Khawar[2], Veronica Hoad[1], Claire Styles[1] and Rebecca Guy[2]
Chief investigators	Sue Ismay[1], Clive Seed[1] and Rebecca Guy[2]
Associate investigators	Skye McGregor[2] and Joanne Pink[1]

The following Australian Red Cross Lifeblood and Kirby Institute staff are acknowledged for their contribution to this report and ongoing surveillance activities:

- Donor Services and Manufacturing staff involved in donor assessment or blood donation testing for transfusion-transmissible infections
- Medical Services staff medical officers undertaking donor counselling and risk factor assessment
- Ashley Henshaw and the Manufacturing Testing teams
- Medical Services Lookback committee
- Glen Shuttleworth
- Philip Kiely, Michael Thomas, Anthea Cheng and the members of the Donor and Product Safety Policy Unit
- Jonathan King, Epidemiologist, Kirby Institute.

Australian governments fund the Australian Red Cross Lifeblood to provide blood, blood products and services to the Australian community

Foreword

This report is jointly produced by the Australian Red Cross Lifeblood (Lifeblood) and the Kirby Institute via the Surveillance, Evaluation and Research Program, which is responsible for monitoring the pattern of transmission of HIV, viral hepatitis, and specific sexually transmissible infections in Australia. This is the ninth report that summarises donation testing data, and incidence and prevalence trends for transfusion-transmissible infections (TTIs) among Australian blood donors. While it is an important Lifeblood resource, it is also intended to be a reference document for organisations and individuals interested in the occurrence of transfusion-transmissible infections in Australia and the effectiveness of Lifeblood's infectious disease blood safety strategy. The data in the report is current at the time of publication and all efforts have been undertaken to confirm its accuracy, however subsequent data updates may occur, and users must consider this.

Ensuring donations do not transmit infectious diseases is a key priority of Lifeblood. Blood donors are required to complete a questionnaire every time they donate to assess their risk of exposure to significant TTIs. The questionnaire for first-time donors includes basic demographic information, as well as questions regarding lifetime exposures to certain risk events. Repeat donors within a two-year time frame are required to complete a shorter questionnaire. The questionnaire is reviewed and those assessed as being at high risk of recent exposure are deferred from donating. Subsequent to satisfactorily completing the assessment process, donors proceed to donate. The current regulatory standard applicable in Australia requires each blood donation to be tested for significant TTIs which can potentially cause infection in the donation recipient (see Supporting Information for details). A timeline of introduction of specific screening tests for Australian blood donors is provided in Supplementary Table 1. If a TTI is detected, the blood donation is removed from the donor pool and the donor undergoes a post-donation interview.

For the purpose of this report the term TTI refers to infections for which there is mandatory blood donation testing. Mandatory tests differ between donations for fresh blood components (i.e. HIV, HBV, HCV, HTLV, syphilis) and plasmapheresis donations, which are exclusively sent for fractionation (i.e. HIV, HCV and HBV only). Consistent with previous years, the overall number of TTIs detected remained very low in 2018 (n=151). Of these, 87% were either hepatitis B (HBV) or hepatitis C (HCV) virus. Reflecting the effectiveness of donor screening strategies, the prevalence of infection in first-time donors in 2018 continues to be substantially (13-28 times) lower than the estimated national population prevalence. Eight (5.3%) of all infections in 2018 were determined to be incident (newly acquired) based on a past negative test within the last twelve months for the same TTI. Incident infections are the most concerning from a blood safety perspective, as in contrast to prevalent infections they are more likely to be in the so-called testing 'window period' making them undetectable by the screening test(s). Notably, there was no significant trend observed for incidence rates of any of the TTIs for the five-year study period, 2014-2018.

As window period infections cannot be detected by testing but can be prevented if the donor discloses risk behaviour leading to deferral from donation, Lifeblood is highly reliant on donor truthfulness. Of the TTIs detected in 2018, 19% had risk factors identified in their post-donation interview which were not disclosed in their initial donation interview (termed 'noncompliance'). While this rate has been fairly stable in the past decade, there has been a fluctuating trend in recent years. As minimising noncompliance is an organisational imperative, Lifeblood continually reviews the donor assessment process for potential improvements. Internationally, electronic (computer-assisted) interviews have demonstrated the capability to provide improved compliance. Accordingly, Lifeblood has successfully piloted an electronic donor questionnaire (PeDQ) for regular plasmapheresis donors at several plasma collection sites with plans to expand this process to other collection sites.

Contents

Glossary

Active syphilis
Defined by reactivity on treponemal and nontreponemal syphilis testing, with or without clinically apparent infection (i.e. excluding past treated infections). This definition is no longer in use (see 'Potentially infectious syphilis') but is included as previous reports and trend data used this definition.

Apheresis
The collection procedure for plasma and/or platelets which separates whole blood into its components and returns remaining components to the donor, using automated separation technology.

First time donor
A donor who has not previously donated blood or blood products in Australia.

Hepatitis B virus (HBV) positive:
The person has either tested positive to hepatitis B surface antigen, hepatitis B DNA or to both:

Hepatitis B surface antigen (HBsAg) positive: HBsAg is a HBV protein and a positive result indicates the presence of HBV in the blood. This means the person is currently infected with HBV and can transmit the infection to others (infectious). Most adults who acquire HBV clear the virus within a few months, and their HBsAg test result will be negative after that time. Some people remain infected and continue to test positive for HBsAg. If, after 6 months, the person still tests positive for HBsAg, the infection is considered chronic.

Hepatitis B deoxyribonucleic acid (HBV DNA) positive: HBV DNA assays are used to monitor response to treatment, assess the likelihood of maternal-to-child transmission of HBV, and to detect the presence of occult hepatitis B virus infection (i.e. infection in someone who tests HBsAg negative). If positive, it could either mean:

- The virus is multiplying in a person's body and he or she is highly contagious.
- In case of chronic HBV infection, the presence of viral DNA means that a person is possibly at increased risk of liver damage.

Hepatitis C virus (HCV) positive:
The person has either tested positive to antibodies to HCV, HCV RNA or both as defined below:

Antibodies to hepatitis C (anti-HCV) positive: The person has tested positive for antibodies to hepatitis C virus in the blood, but the results should be interpreted carefully. A positive anti-HCV could mean the person is a chronic carrier of HCV, has been infected but has resolved infection, or is recently (acutely) infected. The HCV RNA test, described below, can help differentiate between current or resolved infection.

Hepatitis C ribonucleic acid (HCV RNA) positive: RNA is the genetic material of the virus, and the qualitative test determines whether the virus is present. A positive test means that the person is currently infected. A negative HCV RNA test in the presence of anti-HCV indicates resolved infection.

Intravenous drug user
Defined in the context of blood donation as: "used drugs" in the past 5 years by injection or been injected, even once, with drugs not prescribed by a doctor or a dentist.

Incidence
The rate of newly acquired infection among repeat donors.

Incident donor
A positive repeat donor whose most recent previous donation was within the last 12 months and tested negative for the same TTI, excluding donors with occult hepatitis B virus infection (OBI), and HCV antibody positive/RNA negative donors deemed to be 'partial seroreverters' (see definitions on page 9).

Putative risk factor
A potential route of infection for positive donors reported at the post-donation interview.

Infectious syphilis
Syphilis infection of less than 2 years' duration in the general population diagnostic setting.

Lapsed donor
A repeat donor who has not donated blood in the past 2 years.

Noncompliance
Disclosure of information post-donation that would have led to deferral from donation had it been disclosed on the questionnaire.

Occult HBV infection (OBI)
A form of chronic HBV infection characterised by undetectable HBsAg, low/intermittently detectable levels of hepatitis B DNA and usually detectable anti-HBc in the bloodstream.

Prevalence
Prevalence is defined as the number of positive donations per 100 000 donations; it is calculated separately for all and first-time blood donors.

Positive donor
A donor confirmed (by additional testing as necessary) to have the relevant transfusion-transmissible infection.

Potentially infectious syphilis (PIS)
This is a blood safety specific surveillance definition designed to capture donors who are at theoretical risk of transmitting syphilis by blood transfusion. PIS includes repeat donors if they had seroconverted within the last two years (TPHA negative to positive) with a positive confirmatory result, or had a history of syphilis treatment since their last TPHA non-reactive donation and infectious syphilis cannot be conclusively ruled out at the time of that donation, or were previously known to have past treated syphilis and subsequently had possible reinfection (four-fold RPR titre rise). PIS includes first time donors if screening and confirmatory tests for treponemal antibodies were positive, in addition to RPR titre >8 or clinical evidence (signs of syphilis) or recent contact with a confirmed case.

Repeat donor
A donor who has donated in Australia on at least one occasion prior to the current donation.

Transfusion-transmissible infection (TTI)
Any infection that can be transmitted to a recipient via transfused blood components. In the context of this report this refers to TTIs for which Lifeblood undertakes testing, i.e. HIV, HCV, HBV, HTLV and syphilis.

Window period
The duration of the period from infection to the time point of first detection in the bloodstream. The window period varies depending on the infection and the test used.

Seroconversion
The time period during which a specific antibody develops and becomes detectable in the blood. Following seroconversion, a person tests positive for the antibody using tests that are based on the presence of antibodies.

Seroreversion
The progressive loss of antibody in a previously seropositive individual to the point the antibody is consistently undetectable ('seroreverter') or only intermittently detectable ('partial seroreverter').

Summary of the main findings

General characteristics of blood donors in Australia

1. Over the ten year period 2009-2018, there were over 13 million blood donations collected in Australia with an average of 1.3 million donations per year. Over the past ten years, 2009-2018, there has been no significant change in the total number of donations (see Methodological Notes for details). Total blood donations in 2018 increased by 5% (representing 70 160 more donations) compared to 2017, most of which were plasma donations.
2. Of the 'age-eligible' Australian population (aged between 16-80 years), approximately 2.4% donated blood during 2018.
3. On average, first-time and repeat donors comprised 14.5% and 85.5% of all blood donors in Australia over the period 2009-2018, respectively. The ratio of first-time donors has declined gradually over the past ten years, from 17.6% in 2009 to 13.8% in 2013 and 11.9% in 2018. Male donors constitute 49.0% of all donors in 2018, which is almost identical to their proportional representation of 49.5% among the Australian general population aged 16-80 years.

Trends in transfusion-transmissible infections in Australian blood donors

A blood donation which is found to be positive for one of the TTIs which Lifeblood tests for is discarded and the donor is counselled and referred for medical follow-up.

1. In 2018, a total of 150 blood donors were detected as having a TTI for which testing is in place, namely, hepatitis B virus (HBV), hepatitis C virus (HCV), human immunodeficiency virus (HIV), human T-lymphotropic virus (HTLV), or potentially infectious syphilis. In 2018, one donor was infected by more than one TTI (HBV and HCV co-infection), making a total of 151 TTIs detected. In the ten-year period 2009-2018 a total of 1 875 TTIs were detected.
2. Consistent with the long-term pattern, the most common TTI was HBV, followed by HCV. Of all the donations positive for a TTI in 2018, 87.4% were positive for either HBV or HCV, a slight increase from 84.8% in 2017.
3. Overall HTLV was the least common infection among all donors in 2018, with just three donors testing positive. In the ten-year period 2009-2018, HTLV was the least common infection among all donors (39 positive donors); and HIV was the least common infection in the first-time donors (20 positive donors).
4. Although representing only 11.9% of the donor population, first-time blood donors contributed approximately 68% of TTIs in Australia in 2018. This ratio has remained relatively stable since 2009 (77%-82% range), except for years 2014 and 2018 where first-time blood donors contributed to a record low of 67% and 68% of the total TTIs, respectively. The decline in 2014 was due to an increase in the proportion of lapsed donors who had made their last donation prior to 1990 (the year HCV testing was commenced) and therefore they had not previously been tested for HCV. In 2018, the majority of repeat donors who tested positive for HCV (80.9%) were antibody positive without detectable HCV RNA, presumably representing past resolved infections.
5. No transfusion-transmitted HIV, HCV, HTLV or syphilis infections were reported in Australia during 2009-2018.
6. Consistent with previous years, in 2018, the prevalence of TTIs was substantially lower among first-time blood donors (13-28 times) compared with national prevalence estimates for 2017 for HBV and HCV, and for 2018 for HIV.

HBV infection among Australian blood donors

1. There were 79 HBV infections detected among all donations in 2018 (62 in first-time donors and 17 in repeat donors).
2. Of all TTIs detected, HBV continued to have the highest prevalence among first-time donors.
3. The prevalence of HBV infection among first-time donors in 2018 has relatively increased by 11% as compared to 2017, 76.2 versus 68.6 per 100 000 donations, respectively. This equates to 0.08% of the total first-time donations in 2018, which is 13 times lower than the estimated 1.0% reported in national HBV surveillance data for 2017.
4. Among the 79 HBV infections, 24 (11 first-time and 13 repeat donors) were classified as occult HBV (OBI) based on the detection of HBV DNA without HBsAg. Most donors (19) with OBI in 2018 were males and had an average age of 51 years. The majority of donors (58.3%) with OBI in 2018 were born in Asia.
5. Incident HBV donors continue to be rare with only two recorded nationally in 2018, giving an incidence rate of 0.6 per 100 000 donor-years of observation. Although this is double the reported rate in 2017, there was no significant temporal trend in HBV donor incidence nationally or in any state/territory during the ten-year study period 2009-2018.
6. In 2018, HBV positive donors were slightly younger as compared to all donors (41 years versus the mean age 43 years), more likely to be male (76% in hepatitis B positive donors versus 49% in all donors) and more likely to be born in the Asia-Pacific Region. These characteristics are consistent with reporting in previous years.
7. The most common putative risk factor for HBV positive donors during the five-year period, 2014-2018, was ethnicity/country of birth (89%). In Australia 38% of people living with hepatitis B were born in the Northeast/Southeast Asia.[1]
8. No transfusion-transmitted HBV infections were recorded in 2018. Three probable cases were reported in the 2008-2015 period (see Transfusion-transmissible infections in Australia 2017 Surveillance Report for details).

HCV infection among Australian blood donors

1. There were 53 HCV infections detected among all donors in 2018 (32 in first-time donors and 21 in repeat donors). The proportion of HCV RNA positive (potentially infectious) donors was 32% (40% in 2017). This figure has incrementally declined from around 75% when HCV RNA donation testing was introduced in 2000.
2. HCV was the second most common infection found in first-time blood donors after HBV.
3. During 2009-2018, there has been a significant decrease in HCV prevalence in first-time donors in Australia, from 0.06% of the total first-time donations in 2009 to 0.04% in 2018. This translates to a decrease of 33% from 58.6 per 100 000 first-time donations in 2009 to 39.3 per 100 000 first-time donations in 2018. The 0.04% first-time donor prevalence in 2018 is 19 times lower than the 0.7% reported for HCV national surveillance data for 2017. This decreasing trend is consistent with the national HCV new-diagnoses notification rate (from 53 per 100 000 in 2008 to 43 per 100 000 in 2017).
4. In 2018, there were 21 repeat donors who tested positive but only three met the incidence definition. The average incidence rate of HCV among previously negative repeat donors during 2014-2018 was very low at 0.70 per 100 000 donor-years of observation (see Methodological Notes for details). HCV incidence has shown no significant trend during the study period, 2014-2018.
5. In 2018, the mean age of HCV positive donors was 45 years compared to 43 years for all donors. Unlike previous years where HCV positive donors were more likely to be male as compared to all donors, in 2018 the percentage distribution of males is comparable in HCV positive donors versus all donors (50.9% versus 48.9%). The majority (75%) of HCV positive donors were born in Australia.
6. The most common putative risk factor reported by donors with HCV infection during 2014-2018 was injecting drug use (25%), followed by a history of tattoo/piercing (22%). Note this reporting does not confirm causation and background tattoo prevalence should be considered. In comparison, injecting drug use (82.7%) and country of birth/ethnicity and other blood to blood contact (each 2.4%) were the three most dominant routes of exposure in cases of newly acquired hepatitis C infection reported in national notification data in 2017.[1]
7. No transfusion-transmitted HCV infections were reported in Australia during 2009-2018.

HIV infection among Australian blood donors

1. There were seven HIV infections detected among all donations in 2018 (four first-time and three repeat donors).
2. The prevalence of HIV infection among first-time donors during 2009-2018 remained very low at 1.8 per 100 000 donations (or 0.002% of the total first-time donations) and comparatively much lower than hepatitis B (77.2 per 100 000 donations) and hepatitis C (48.1 per 100 000 donations). However, no significant trend was observed for prevalence rates for HIV infection during this time. The 0.002% HIV prevalence in first-time donor is 28 times lower than the 0.1% prevalence reported for HIV national surveillance data for 2018.
3. There is nearly a three-fold increase in the incidence of HIV in 2018 as compared to 2017, 0.9 per 100 000 donor-years of observation in 2018 versus 0.3 per 100 000 donor-years of observation in 2017. However, this single year increase is not statistically significant and there is no significant trend in the 2014-2018 period.
4. In 2018, the mean age of HIV positive donors (n=7) was 32 years as compared to 43 years for all donors. Like HBV, HIV positive donors were more likely to be male as compared to all donors (71% vs 49%). Contrasting 2017 where the majority (67%) were Australian-born, in 2018, 71% were born overseas.
5. The most common reported route of exposure for donors with HIV infection during 2014-2018 was male-to-male sex (32%), followed by heterosexual sex partners with known risks or known to be positive (23%). This compares to the new HIV diagnoses notification data in Australia where men who have sex with men accounted for 62% of new HIV diagnoses in Australia in 2018, followed by heterosexual sex (22%).[2]
6. No transfusion-transmitted HIV infections were reported in Australia during 2009-2018.

HTLV infection among Australian blood donors

1. There were three HTLV infections detected among all donations in 2018 (two in first-time donors and one in a repeat donor).
2. The prevalence of HTLV infection among first-time donors during 2009-2018 has remained low at 3.4 per 100 000 donations and has shown no significant trend. Population prevalence for HTLV is unknown; therefore, comparison of prevalence rates among first-time donors and the general population is not possible.
3. The HTLV incidence among repeat Australian donors in 2018 was zero as it was for the five-year period 2014-2018.
4. In 2018, the mean age of the three donors with HTLV infection was 38 years; two were males and two were born overseas.
5. The most common putative risk factor for donors with HTLV infection during 2014-2018 was ethnicity or country of birth (73%). There are no data to compare risk factors in the general population.
6. No transfusion-transmitted HTLV infections were reported in Australia during 2009-2018.

Potentially infectious syphilis (previously ‘active syphilis’) infection among Australian blood donors

1. There were nine potentially infectious syphilis infections (3 first-time and 6 repeat donors) detected in 2018.
2. Despite a recent increase, the prevalence of active/potentially infectious syphilis in first-time donors has shown no significant change over time in the past ten years, 2009-2018, or in the past five years, 2014-2018.
3. The mean age of potentially infectious syphilis positive donors in 2018 was 42 years (compared to 43 years for all donors); and they were more likely to be male as compared to all donors (89% versus 49%).
4. The most common reported route of exposure by donors with active/potentially infectious syphilis during 2015-2018 period was having a partner with an unspecified risk (42%).

Donor compliance

1. Of the TTI-positive donors in 2014-2018, 20% (155 donors) were identified as 'non-compliant' in that they had risk factors identified during their post-donation interview that would have deferred them from donating had they disclosed them at the pre-donation interview. Proportionally, first time donors were overrepresented accounting for 67% (104 donors).
2. The non-compliance rate of all TTI-positive donors has fluctuated in the past decade between 14.8 and 25.0%. The non-compliance rate among TTI-negative donors is not determined on a regular basis; however, results from a large national survey from 2012-13 showed a comparatively much lower rate of non-compliance (in the range of 0.05-0.29%). See *Additional Information* section for more information.

Malaria testing

1. In 2018, a total 108 783 donations were tested for malaria antibody of which 1 538 (1.4%) were repeatedly reactive for malaria antibodies.
2. There were no reported cases of transfusion-transmitted malaria during 2018, with the last reported Australian case occurring in 1991.

Bacterial pre-release testing for platelets

1. In 2018, 127 (0.10%) of a total 124 399 screened platelet units had confirmed bacterial contamination.
2. The species most frequently isolated was *Cutibacterium acnes*, a commensal skin organism of low pathogenicity which is rarely (if ever) associated with septic transfusion reactions[3]. The next most common group was coagulase-negative staphylococci, which along with propionibacteria are usually considered skin contaminants.
3. Confirmed positive pathogens included *Enterococcus faecalis* (2 isolates), *Lactococcus garvieae*, *Serratia marcescens* (2 isolates), *Streptococcus dysgalactiae* and *Streptococcus pneumoniae* (2 isolates).
4. ChloraPrep was used for skin decontamination from January to May 2018. Between May and July 2018, ChloraPrep was replaced by SoluPrep swabs. Due to an excessive number of hypersensitivity reactions in donors, SoluPrep swabs were replaced by SoluPrep wipes in December 2018.
5. On 10 September 2018, the duration of incubation of bacterial contamination screening samples was reduced from 7 days to platelet expiry (5 days). An internal post-implementation review suggested that this had little impact on either the proportion of propionibacteria isolated or the overall contamination detection rate.
6. No septic transfusion reactions were recorded due to platelets, however there was one non-fatal transmission of *Yersinia enterocolitica* in a red cell component.

Emerging infections

1. Along with the ongoing risk from local dengue virus outbreaks and seasonal WNV outbreaks in Europe, outbreaks of Ebola virus, MERS-CoV and Zika virus were also monitored during 2018-2019.
2. The risk to the blood supply posed by donors returning from Ebola virus and Zika virus outbreak areas is managed by deferring donors (Ebola) or restricting donations to plasma sent for fractionation for an appropriate period (Zika).

List of figures and tables

List of figures

List of tables

List of Supplementary Tables

This page intentionally left blank

Abbreviations

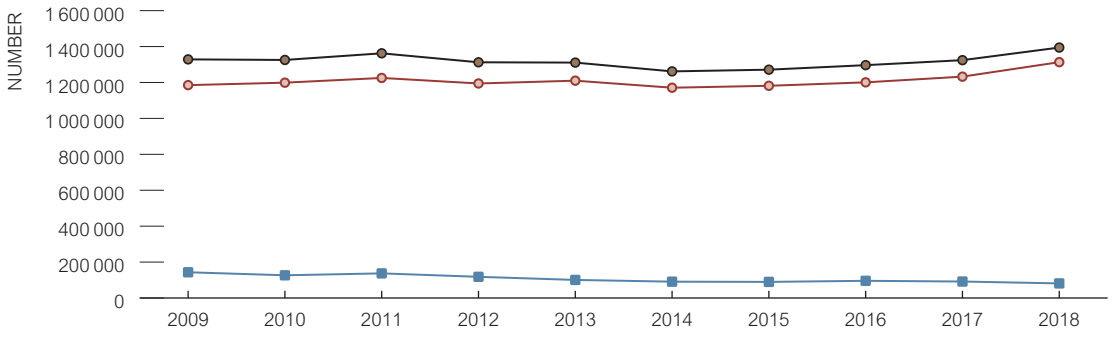
anti-HBc	antibody to hepatitis B core antigen
anti-HBe	antibody to hepatitis B e antigen
anti-HBs	antibody to hepatitis B surface antigen
anti-HeV	antibody to Hendra virus
A(H7N9)	avian influenza H7N9 virus
HBsAg	hepatitis B surface antigen
EVD	Ebola virus disease
HBeAg	hepatitis B e antigen
HBsAg	hepatitis B surface antigen
HBV	hepatitis B virus
HCV	hepatitis C virus
HeV	Hendra virus
HIV	human immunodeficiency virus
HTLV	human T-lymphotropic virus
IDU	intravenous drug user
MERS-CoV	Middle East respiratory syndrome coronavirus
NAT	nucleic acid testing
OBI	occult hepatitis B virus infection
SARS-CoV	severe acute respiratory syndrome-related coronavirus
STIs	sexually-transmissible infections
TTIs	transfusion-transmissible infections
WNV	West Nile virus
WP	window period
YFV	yellow fever virus
YF	yellow fever
ZIKV	Zika virus

Main Findings

Blood donors in Australia

Over 13 million donations were tested for TTIs in Australia during the ten-year period 2009-2018 with an average of 1.3 million donations per year. In 2018, the number of donations has increased by 5% as compared to 2017 reaching nearly 1.4 million donations. The majority of this increase reflects an expansion in plasma collections to meet increasing demand for plasma-derived blood products. Over the entire ten year period there was no significant trend in numbers of donations (Figure 1) (see Methodological Notes for details). Notably, from September 2016, in accordance with regulatory requirements, plasma donations from repeat donors collected solely for the manufacture of plasma-derived blood products were no longer tested for HTLV or syphilis resulting in differing total test numbers. A total of 0.78 million donations were tested for HTLV and syphilis in 2018, as compared to 1.39 million for HBV, HCV and HIV.

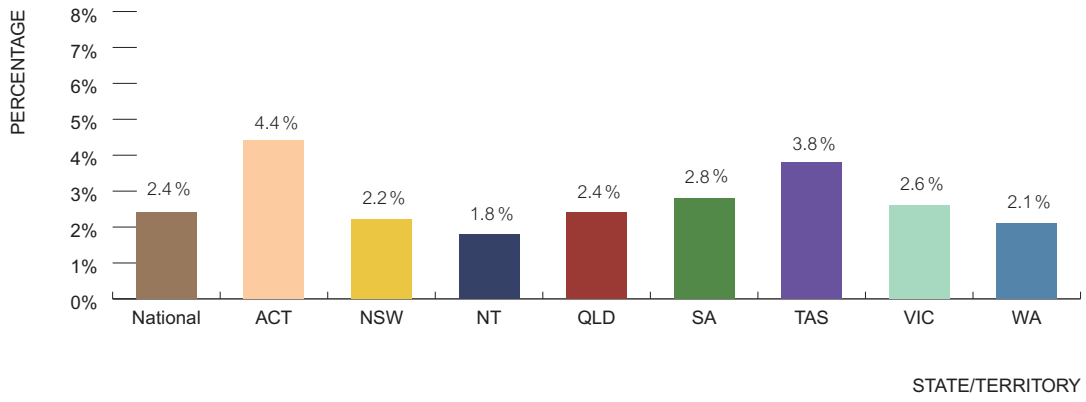
Figure 1 Number of blood donations in Australia by year of donation, 2009-2018



	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018
Total	1.33 M	1.33 M	1.36 M	1.31 M	1.31 M	1.26 M	1.27 M	1.30 M	1.32 M	1.39 M
First-time	0.14 M	0.13 M	0.14 M	0.12 M	0.10 M	0.09 M	0.09 M	0.10 M	0.09 M	0.08 M
Repeat	1.19 M	1.20 M	1.23 M	1.19 M	1.21 M	1.17 M	1.18 M	1.20 M	1.23 M	1.31 M

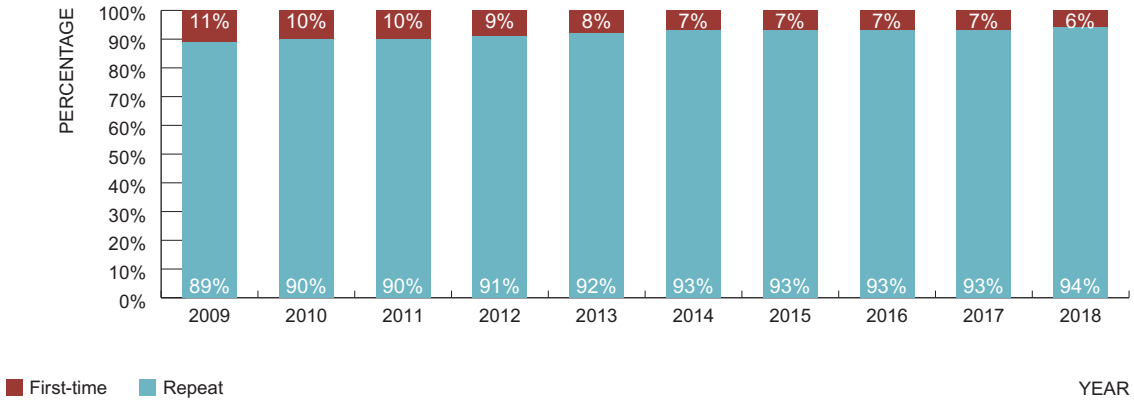
In 2019, 2.4% of the general population who were aged between 16-80 years (age-eligible to donate) donated blood in Australia. Together, New South Wales, Queensland and Victoria accounted for more than 76% of all blood donations. The jurisdiction where the greatest proportion of the age-eligible local population donated blood in 2018 was the Australian Capital Territory (4.4%), followed by Tasmania at nearly 4% (Figure 2).

Figure 2 Percentage of age eligible general population who donated blood in 2018, by state/territory



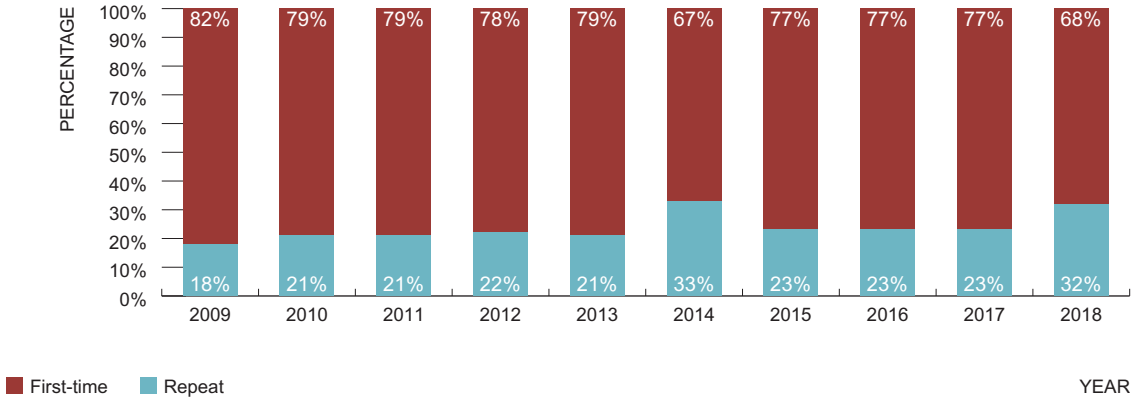
As in previous years, more than 90% of all donations in 2018 were from repeat donors (Figure 3). In the past ten years, 2009-2018, there has been a gradual decrease in percentage of donations by first-time donors, from 11% in 2009 to 6% in 2018. While first-time blood donors represented only 12% of the donor population, and 6% of the total donations, they contributed the majority (68%) of TTIs in Australian blood donors in 2018, reflecting detection of prevalent infections rather than incident infections (Figure 4).

Figure 3 Percentage of donations made by first time and repeat donors among all blood donations in Australia, 2009-2018



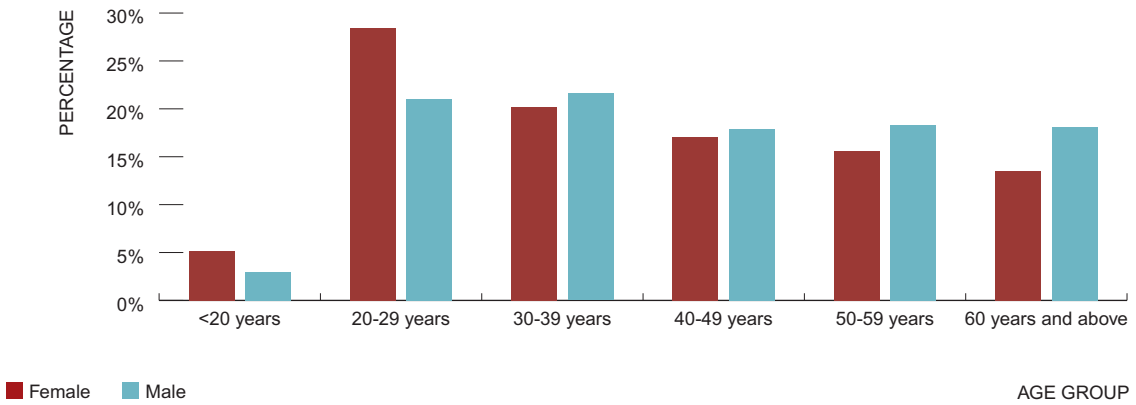
Overall in the past ten years, there has been a steady increase in the proportion of repeat donors among all TTI-positive blood donations in Australia, from 18% in 2008 to 21% in 2013 to 32% in 2018 (Figure 4). The increase in 2014 (33%) is explained by an anomaly in the rate of returning 'lapsed' donors, who had made their last donation prior to 1990, undergoing HCV testing for the first time (HCV testing was implemented in 1990). The substantial increase in 2018 in the proportion of repeat donors with a TTI has resulted from an increase in detection of all TTIs from 2017, except syphilis. Nearly 80% of these repeat donors were positive for either HBV or HCV, with the largest increase secondary to an increase in HCV infections in repeat donors. The majority of HBV positive repeat donors had occult hepatitis B (76%), a form of chronic HBV infection characterised by undetectable surface antigen and usually low levels of HBV DNA. In addition, the majority of repeat HCV positive donors (over 80%) were HCV antibody positive without detectable HCV RNA, likely signifying past resolved infections. The increase in the TTI-positive repeat donor proportion in the past ten years is probably multi-factorial and influenced by the declining HCV prevalence among first-time donors, and the implementation of HBV DNA testing in 2010 which detected a cohort of previously unidentified repeat donors with occult HBV infection. Importantly, the proportional increase in TTI-positive repeat donors is not reflective of an increase in TTI incidence, which has been stable or declining.

Figure 4 Percentage of first time and repeat donations among all TTI-positive blood donations in Australia, 2009-2018



Among all blood donors who donated in 2018, 51.0% were females and 48.9% were males. There was a higher proportion of females among younger age groups (less than 20 years and 20-29 years), and a higher proportion of males in donors 30 years and above (Figure 5). Nearly 33% of donors were aged 50 years and above; the median age of male and female donors was 42 and 38 years, respectively.

Figure 5 Distribution of blood donors in Australia by age group and sex, 2018



Trends in TTIs in blood donors – incidence, prevalence, demographic characteristics and risk factors

This section focuses on the trends in prevalence and incidence of TTIs during the ten-year period 2009-2018 overall in Australia, and trends observed in state/territory jurisdictions. In addition, association of demographic characteristics with presence of TTIs for the year 2018 and the five-year period 2014-2018 will be discussed. Putative risk factors associated with positive blood donors in Australia are also reported for the five-year period, 2014-2018. The findings are presented in respective sections by infection.

Blood donors are a subset of the general population, so to provide a context for the report the epidemiology of each relevant TTI in Australia is also discussed in respective sections. This includes a brief description of the number of people living with TTIs in Australia by the end of 2017, trends in the last ten years, notifications of newly diagnosed TTIs in Australia, and risk exposure categories associated with respective infections. Of note, the 2018 general population data were not available for HBV, HCV and infectious syphilis at the time of the report preparation. Therefore, for these infections, comparisons were made with the 2017 data. The information is drawn from the HIV, viral hepatitis and sexually transmissible infections in Australia: Annual Surveillance Report 2018.[1]

Of note, prevalence is defined as the frequency and proportion of infection among all blood donors, and first-time blood donors, separately; whereas incidence is the rate of newly acquired infection among repeat donors. It is important to note that given the low donor incidence rates nationally and in all jurisdictions, individual year variation should be interpreted with caution. This is particularly relevant to the 2014-18 incidence data where a stricter definition (negative test within the past 12 months) applies. Poisson regression analysis was used to calculate incidence rate ratios (IRRs) and their 95% confidence intervals. A p-value of less than 0.05 was considered statistically significant.

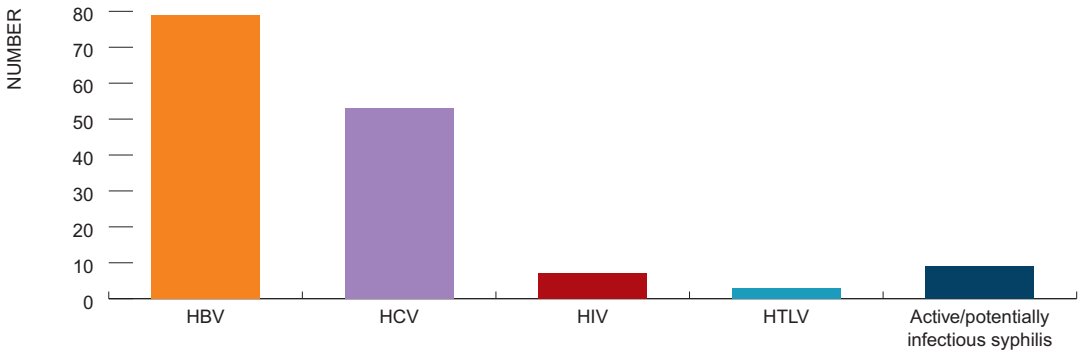
Lifeblood assesses the incidence rate of newly acquired infection in donors since this correlates directly with the risk of transmission. Incident donors (formerly 'seroconverters') are defined as 'positive repeat donors whose last donation tested negative for the same TTI within the last twelve months' (with some exceptions; see glossary). Incident donors were previously defined as repeat donors with any previous negative tests. The term 'incident donor' reflects that the definition encompasses a test pattern indicative of recently acquired infection.

During the past ten years, 2009-2018, a total of 1 875 donations (1 444 in first-time and 431 in repeat donations) were positive for at least one of the TTIs subject to mandatory donation testing. Of these, 1 754 were positive for HBV, HCV and HIV (13.3 per 100 000 donations), and 121 (1.0 per 100 000 donations) were positive for active/potentially infectious syphilis and HTLV. As noted above, due to a different total number of donations tested for these infections during the last ten years 2009-2018, (13.1 million donations for HBV, HCV and HIV, as opposed to 11.8 million donations tested for HTLV and syphilis), these data are presented separately (Table 1A and 1B). Of these, 91.0% of the donations were positive for either HBV or HCV. As noted above, overall in the past ten years, there has been a steady increase in the proportion of repeat donors among all positive blood donations in Australia, from 18% in 2009 to 21% in 2013 to 32% in 2018 (Figure 4). This increase, in part, could also be explained by the increasing proportion of repeat donations among all donations.

In 2018, a total of 150 donors were found positive for at least one of the TTIs subject to mandatory donation testing; one donor was positive for HBV and HCV infections, making a total of 151 TTIs detected in 2018. Overall, HBV and HCV were the two most frequent TTIs identified in Australian blood donors in 2018, together contributing to 87.4% of all infections (Figure 6). This proportion has decreased by a relative 5.8% as compared to 92.8% in 2009, suggesting a declining trend in the prevalence of HBV and HCV in all donors. HBV and HCV were also the most frequent TTIs in both first-time and repeat donors.

As outlined in the 2018 report, the method for calculating incidence has been modified due to a change in the process for calculating the donor-years of observation (DYO) and includes the inter-donation intervals from the reporting year only. Previous reports used two years of inter-donation interval data. Therefore, the incidence calculations cannot be directly compared to previous reports (see Methodological notes for details). For this reason, updated data are presented for a five-year period, 2014-2018 which retrospectively apply the updated DYO calculation method. During 2014-2018, a total of 27 incident donors were identified, eight each for HBV and HIV, and 11 for HCV. In 2018, a total of eight incident infections were detected, two for HBV, and three each for HCV and HIV.

Figure 6 Number of transfusion-transmissible infections detected in blood donations in Australia, in 2018, by infection



	HBV	HCV	HIV	HTLV	Active/potentially infectious syphilis
Positive donations 2018	79	53	7	3	9

Data on the demographic characteristics (sex, age group, state/territory and year of donation) for all blood donors was analysed (see Methodological Notes for details) to determine any association between demographic factors and presence of any TTI among Australian blood donors in 2018, and the five-year period, 2014-2018, separately.

Standardised national data on reported putative risk factors associated with donors infected with HBV, HCV, HIV and HTLV are available since 1999. Importantly, assessing the strength of association of disclosed risk factors is complex and this must be borne in mind when interpreting the data. Risk varies based on a number of variables including the timing and location of the risk event. For instance, tattooing performed in some settings (e.g. in Australian prisons or high risk countries) is a recognised risk for HCV transmission, in contrast to tattooing currently performed in Australian commercial tattooing parlours, where the risk is very low.[4]

This report presents risk factor data for the five-year period 2014 to 2018. A total of 761 positive donors with at least one of the TTIs were observed over the period 2014-2018. Among them, 48 donors were positive for active/potentially infectious syphilis, of which 46 have standardised risk factor data available (for 2014 data, information is available for only three out of five donors positive for active/potentially infectious syphilis). The data on the remaining 713 donors who were positive for any of the other TTIs (HBV, HCV, HIV and HTLV) during 2014-2018 were analysed to determine the key characteristics of blood donors with transfusion-transmissible infections, stratified by year of donation, and findings are presented in the respective infection sections.

Table 1 The number and prevalence rate of transfusion-transmissible Infections in Australia, by state/territory, 2009-2018

1A: HBV, HCV and HIV in Australia, by state/territory, 2009-2018

State/Territory of donation	All accepted donations			HBV			HCV			HIV			Total positive donations		
	First time	Repeat	All	First time	Repeat	All	First time	Repeat	All	First time	Repeat	All	First time	Repeat	All
NSW/ACT	372 388	3 721 062	4 093 450	288	45	333	198	71	269	8	5	13	494	121	615
Number *(Number per 100 000 donations)*				*77.34*	*1.21*	*8.13*	*53.17*	*1.91*	*6.57*	*2.15*	*0.13*	*0.32*	*132.66*	*3.25*	*15.02*
NT	7 861	97 634	105 495	9	3	12	7	4	11	0	1	1	16	8	24
Number *(Number per 100 000 donations)*				*114.49*	*3.07*	*11.37*	*89.05*	*4.1*	*10.43*	*0*	*1.02*	*0.95*	*203.54*	*8.19*	*22.75*
QLD	226 310	2 459 665	2 685 975	124	22	146	107	55	162	4	10	14	235	87	322
Number *(Number per 100 000 donations)*				*54.79*	*0.89*	*5.44*	*47.28*	*2.24*	*6.03*	*1.77*	*0.41*	*0.52*	*103.84*	*3.54*	*11.98*
SA	76 786	1 192 558	1 269 344	42	12	54	41	17	58	0	2	2	83	31	114
Number *(Number per 100 000 donations)*				*54.7*	*1.01*	*4.25*	*53.4*	*1.43*	*4.57*	*0*	*0.17*	*0.16*	*108.09*	*2.6*	*8.98*
TAS	31 516	461 579	493 095	8	3	11	15	8	23	0	0	0	23	11	34
Number *(Number per 100 000 donations)*				*25.38*	*0.65*	*2.23*	*47.59*	*1.73*	*4.66*	*0*	*0*	*0*	*72.98*	*2.38*	*6.89*
VIC	264 443	2 966 520	3 230 963	266	42	308	114	40	154	7	7	14	387	89	476
Number *(Number per 100 000 donations)*				*100.59*	*1.42*	*9.53*	*43.11*	*1.35*	*4.77*	*2.65*	*0.24*	*0.43*	*146.35*	*3*	*14.73*
WA	95 805	1 213 807	1 309 612	93	22	115	36	16	52	1	1	2	130	39	169
Number *(Number per 100 000 donations)*				*97.07*	*1.81*	*8.78*	*37.58*	*1.32*	*3.97*	*1.04*	*0.08*	*0.15*	*135.69*	*3.21*	*12.9*
National	1 075 109	12 112 825	13 187 934	830	149	979	518	211	729	20	26	46	1368	386	1754
Number *(Number per 100 000 donations)*				*77.2*	*1.23*	*7.42*	*48.18*	*1.74*	*5.53*	*1.86*	*0.21*	*0.35*	*127.24*	*3.19*	*13.3*

1B: HTLV and active/potentially infectious syphilis in Australia, by state/territory, 2009-2018

State/Territory of donation	All accepted donations			HTLV			Active/Potentially infectious syphilis			Total positive donations		
	First time	Repeat	All	First time	Repeat	All	First time	Repeat	All	First time	Repeat	All
NSW/ACT	372 388	3 375 332	3 747 720	10	1	11	4	18	22	14	19	33
Number *(Number per 100 000 donations)*				*2.69*	*0.03*	*0.29*	*1.07*	*0.53*	*0.59*	*3.76*	*0.56*	*0.88*
NT	7 861	83 838	91 699	0	0	0	3	3	6	3	3	6
Number *(Number per 100 000 donations)*				*0*	*0*	*0*	*38.16*	*3.58*	*6.54*	*38.16*	*3.58*	*6.54*
QLD	226 310	2 199 072	2 425 382	5	0	5	9	7	16	14	7	21
Number *(Number per 100 000 donations)*				*2.21*	*0*	*0.21*	*3.98*	*0.32*	*0.66*	*6.19*	*0.32*	*0.87*
SA	76 786	1 054 611	1 131 397	2	1	3	5	0	5	7	1	8
Number *(Number per 100 000 donations)*				*2.6*	*0.09*	*0.27*	*6.51*	*0*	*0.44*	*9.12*	*0.095*	*0.71*
TAS	31 516	400 938	432 454	2	0	2	0	0	0	2	0	2
Number *(Number per 100 000 donations)*				*6.35*	*0*	*0.46*	*0*	*0*	*0*	*6.35*	*0*	*0.46*
VIC	264 443	2 642 547	2 906 990	15	0	15	10	11	21	25	11	36
Number *(Number per 100 000 donations)*				*5.67*	*0*	*0.52*	*3.78*	*0.42*	*0.72*	*9.45*	*0.42*	*1.24*
WA	95 805	1 056 346	1 152 151	3	0	3	8	4	12	11	4	15
Number *(Number per 100 000 donations)*				*3.13*	*0*	*0.26*	*8.35*	*0.38*	*1.04*	*11.48*	*0.38*	*1.3*
National	1 075 109	10 812 684	11 887 793	37	2	39	39	43	82	76	45	121
Number *(Number per 100 000 donations)*				*3.44*	*0.02*	*0.33*	*3.63*	*0.4*	*0.69*	*7.07*	*0.42*	*1.02*

This page intentionally left blank

Hepatitis B Virus (HBV)

Epidemiology of HBV in Australia

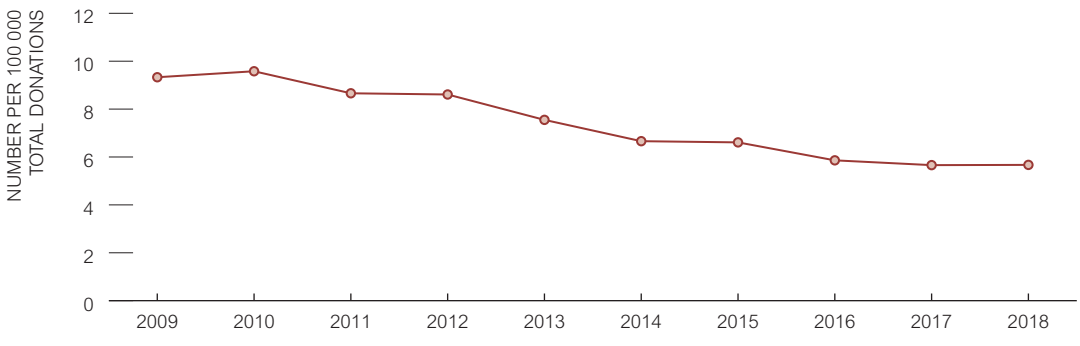
At the end of 2017, an estimated 248 536 people were living with chronic HBV infection in Australia, of whom an estimated 61% were diagnosed with chronic hepatitis B, 21% and 17% were born in the Northeast and Southeast Asia, respectively, and 11% were among Aboriginal and Torres Strait Islander peoples. In total, there were 6 102 notifications of newly diagnosed HBV infection in Australia in 2017; of these, over half (53%) were males, and 90% were people aged 25 years and above. Australia has a concentrated hepatitis B epidemic among key populations: migrants from high prevalence countries, particularly Southeast Asia; men who have sex with men; Aboriginal and Torres Strait Islander peoples; and people who inject drugs. Over the past ten years, 2008-2017, the population rate of diagnosis of HBV infection in Australia has declined in younger age groups: 25 – 29 years (from 69 to 45 per 100 000); 20 – 24 years (from 48 to 22 per 100 000); and 15 – 19 years (from 19 to 8 per 100 000). This decline could be attributable to the successful implementation of immunisation programs for HBV and high levels of vaccine coverage in the younger age groups. In addition, there has been a decline in the rate of newly acquired HBV cases (acquired in the past 2 years) in the past ten years by 50% from 1.2 per 100 000 in 2008 to 0.6 per 100 000 in 2017. The estimated prevalence of chronic HBV infection among people living in Australia is 0.9%, which is higher than for people living in the United Kingdom (<0.5%) but lower than many other countries in South East Asia and the Pacific.[1]

Trends in prevalence

All donations:

In the past ten years, 2009-2018, a total of 979 HBV positive donors have been detected (830 first-time donors & 149 repeat donors) (Table 1A). During this period, the prevalence of HBV infection among all donations has declined significantly (IRR 0.93; 95% CI: 0.91-0.95). There has been an overall reduction of 39% from 2009 to 2018, from 9.3 to 5.6 per 100 000 total donations (Figure 7). This significant decline does not appear to be explained by a declining first-time donor prevalence or a decline in incident donors. Predominantly, it reflects the incremental identification and deferral of repeat donors (n=105) with occult HBV infection (OBI) since HBV NAT commenced in 2010 (see OBI section below). Donors with OBI characteristically have very low HBV viral loads (<200 IU/mL) which are often close to the limit of detection of the most sensitive HBV DNA tests.[5] For detail on the number and prevalence rate of HBV infections among all donations for 2018, see Supplementary Table 2.

Figure 7 Prevalence of HBV infection in all blood donations in Australia, 2009-2018

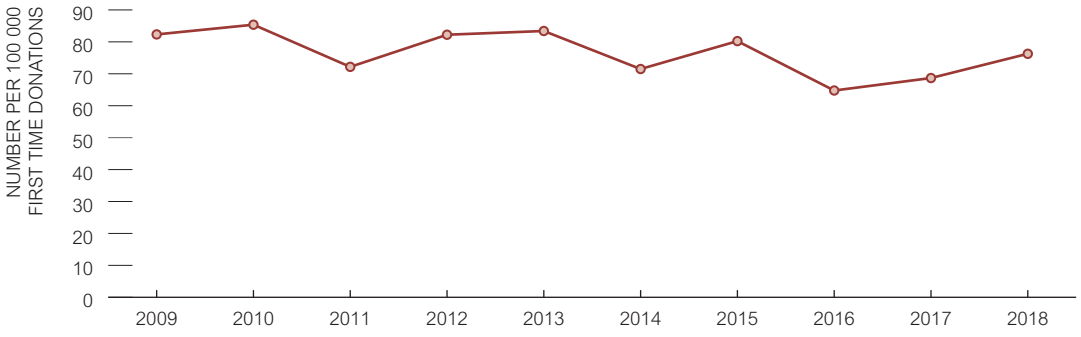


	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018
Prevalence in all donations	9.33	9.58	8.66	8.61	7.55	6.66	6.61	5.86	5.66	5.67

First-time donors:

Over the ten-year period 2009-2018, no significant annual trend was observed in the prevalence of HBV infection among first-time donors (Figure 8) (IRR: 0.98; 95% CI: 0.95-1.00). However, the average rate dropped to 77.2 per 100 000 donations (0.08% of the total first-time donations) for the period 2009-2018 (Table 1A), as compared to 81.6, 80.4 and 77.9 per 100 000 first-time donations for periods 2006-2015, 2007-2016 and 2008-2017, respectively. Similarly, this trend is reflected in the Australian general population with the notification rate showing a slight downward trend in the past ten years, at 30 per 100 000 in 2008, 29 per 100 000 in 2011, and 25 per 100 000 in 2017.[1]

Figure 8 Prevalence of HBV infection in first time blood donors in Australia, 2009-2018

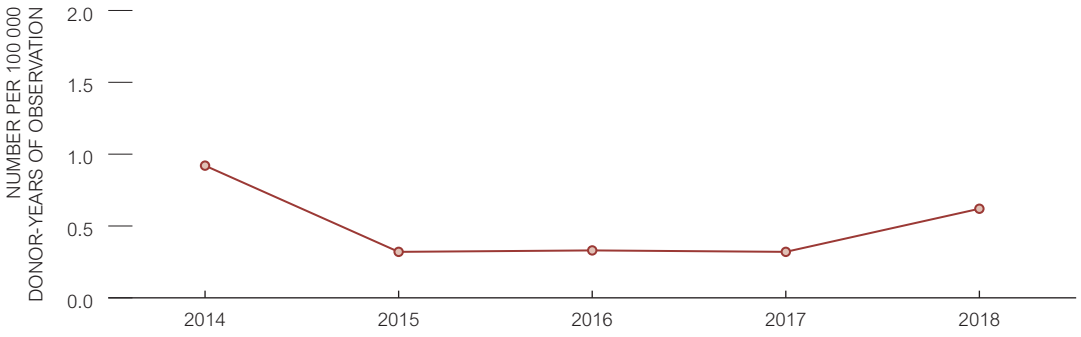


	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018
Prevalence in first-time donors	82.33	85.37	72.17	82.23	83.40	71.49	80.23	64.76	68.67	76.26

Trends in incidence

Due to change in the methodology for calculating incidence, updated data are presented for a five-year period, 2014-2018 (see Methodological Notes for detail). For the five-year period 2014-2018, there were a total of eight incident donors detected for HBV infection with no statistically significant trend observed for incidence rates (between 0.3 and 0.9 per 100 000 donor-years of observation; (IRR: 0.88; 95% CI: 0.54-1.44) (Figure 9). In 2018, only two incident infections were detected for HBV.

Figure 9 Incidence of HBV in repeat blood donors in Australia, 2014-2018



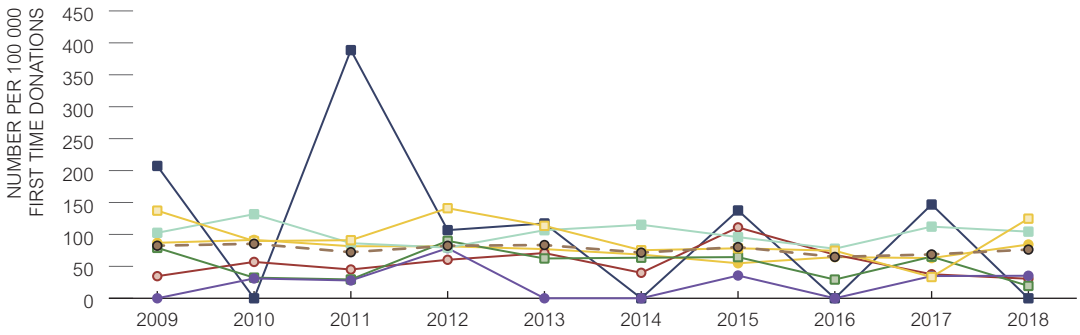
	2014	2015	2016	2017	2018
Incidence	0.92	0.32	0.33	0.32	0.62

No transfusion-transmitted HBV infections were reported in 2018. Three probable cases were reported in the 2008-2014 period, two in 2009 associated with the same donor and one further case in 2011. For details on these cases, see Transfusion-transmissible infections in Australia, 2017 Surveillance Report.

Trends in HBV infection by state/territory

Consistent with previous TTI-surveillance reports, the prevalence of HBV infection among first-time donors varied by jurisdiction in 2018. While the national prevalence was 76.2 per 100 000 donations, this ranged from 0.0 to 124.6 per 100 000 donations across jurisdictions (Figure 10). In 2018, Western Australia recorded the highest prevalence of HBV infection among first-time donors as compared to the other states (124.6 per 100 000 donations). For the ten-year period 2009-2018, the highest average prevalence rate of HBV infection among first-time donors was observed in the Northern Territory at 110.4 per 100 000 donations, followed by Victoria at 101.1 per 100 000 donations; however, no significant trend was observed during this period in the Northern Territory or Victoria, and given the small number of positive donors for the Northern Territory, which ranged between 0-3 per year, this should be interpreted with caution. Unlike last year where a significant declining annual prevalence trend was observed in New South Wales for a ten-year period, 2008-2017, no significant annual trend was observed in the prevalence of HBV infection among first-time donors for a ten-year period 2009-2018 for any state.

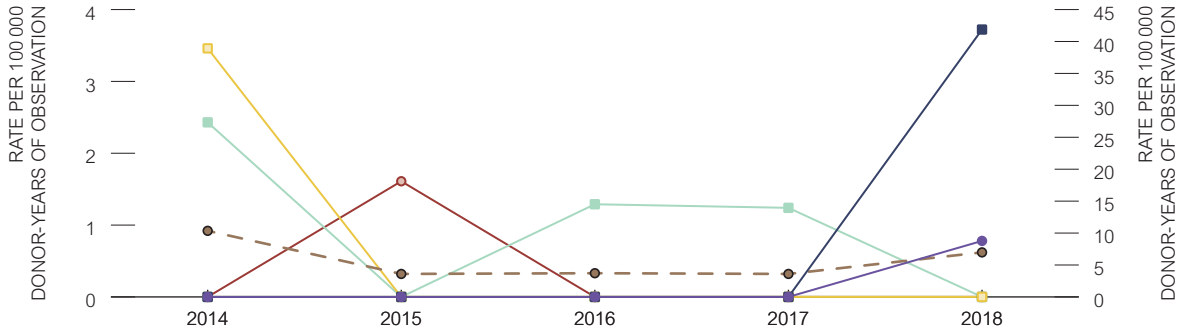
Figure 10 Prevalence of HBV infection among first time donors by state/territory and year of donation, 2009-2018



	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018
NSW/ACT	86.84	91.42	81.51	81.38	77.01	68.41	54.83	64.44	62.97	84.23
NT	207.25	0.00	388.60	106.72	117.23	0.00	137.55	0.00	146.84	0.00
QLD	34.62	56.95	45.08	60.29	70.82	39.91	111.03	68.25	37.63	30.58
SA	78.95	32.31	29.52	89.89	62.33	63.53	64.50	29.31	65.15	19.38
TAS	0.00	31.04	27.88	78.47	0.00	0.00	35.63	0.00	34.79	35.29
VIC	102.54	131.68	86.30	79.37	106.58	115.15	95.79	77.63	112.18	104.37
WA	137.24	89.69	90.98	141.06	113.44	75.26	78.28	74.48	33.31	124.69
National	82.33	85.37	72.17	82.23	83.40	71.49	80.23	64.76	68.67	76.26

Incident HBV infection continues to be rare with only two incident donors recorded nationally in 2018, one each from the Northern Territory and Tasmania. Overall, there was no obvious trend in HBV incidence in any state/territory during the five-year study period 2014-2018 (Figure 11). Among donors in New South Wales and South Australia, HBV incidence has been zero since 2014.

Figure 11 Trend in incidence of HBV infection among repeat donors by state/territory and year of donation, 2014-2018



	2014	2015	2016	2017	2018
NSW/ACT	0.00	0.00	0.00	0.00	0.00
NT	0.00	0.00	0.00	0.00	41.87
QLD	0.00	1.61	0.00	0.00	0.00
SA	0.00	0.00	0.00	0.00	0.00
TAS	0.00	0.00	0.00	0.00	8.77
VIC	2.43	0.00	1.29	1.24	0.00
WA	3.46	0.00	0.00	0.00	0.00
National	0.92	0.32	0.33	0.32	0.62

Occult HBV infection

As noted, the implementation of HBV DNA testing for all Australian donors from 2010 has facilitated the identification of OBI among the donor population.[5] To the end of 2018, 143 donors with OBI have been detected, counselled and referred for external clinical assessment reducing the residual risk of HBV infection. In 2018, twenty-four of the 79 (30%) HBV positive donors detected were classified as OBI, the highest recorded proportion so far. To some degree this may reflect an improved lower limit of detection of the HBV DNA assay used externally to confirm OBI among referred donors. Specifically, the proportion of referred samples with any HBV DNA reactivity at Lifeblood subsequently confirmed as HBV DNA positive has increased. Most (19/24) OBIs were males and over half (13/24) were repeat donors, with an average age of 51 years. The majority of donors with OBI in 2018 were born in Asia (South-East/North East Asia – 11, Southern and Central Asia – 3).

Comparison of prevalence of HBV infection among blood donors and the general population

This section presents a comparison of prevalence of HBV infections among first-time blood donors and the general population. As noted, general population data for 2018 were not available for HBV at the time of report preparation. Therefore, general population data are presented for a combined period of 2008-2017 and 2017, separately. Following this, a discussion is presented on the prevalence reduction in first-time donors as compared to the general population.

The prevalence of HBV is much higher in the general population than in blood donors (Table 2), which is consistent with a previous Lifeblood study for the period 2000-2006[6] and expected, based on effective donor selection/education. Prevalence of HBV infection is substantially lower in blood donors than the estimated prevalence in the general population, with a 12 times lower prevalence in first-time donors during the period

2007/8-2017/18, and 13 times lower prevalence for the year 2017/18. Given blood donors are drawn from the general population, the lower prevalence observed in first-time donors is interpreted to predominantly reflect the combined effectiveness of donor education and donor selection policies.

Table 2 Comparison of prevalence of HBV infection in blood donors with population prevalence

Infection	Estimated population prevalence* (per 100 000 people)		Prevalence in first time blood donors (per 100 000 donations)		Comparison of HBV prevalence in first time blood donors with population prevalence	
	2008-2017	2017	2009-2018	2018	2008/9-2017/18	2017/18
HBV	926	1010	77.20	76.26	12 times lower	13 times lower

* The 2017 HBV prevalence in the general population was calculated by taking the estimated number of people living with chronic HBV[1], and dividing it by the estimated mid-year resident Australian population in 2017 as reported by the Australian Bureau of Statistics. For the period 2008-2017, an average of the ten years' prevalence rates was calculated.

Demographic factors associated with HBV infections in blood donors

Data on the demographic characteristics (sex, age group, state/territory and year of donation) for all blood donors were analysed (see Methodological Notes for details) to determine any association between demographic factors and presence of HBV infections among Australian blood donors in 2018, and the five-year period, 2014-2018, separately (Supplementary Tables 4 and 5). Male donors, donors aged between 20-29 years and donors from New South Wales were used as reference groups for comparison of positivity rate by sex, age group and state/territory of donation.

In 2018, female donors were 74% less likely to be HBV positive, and donors from Queensland and South Australia were 78 and 73% less likely to be HBV positive as compared to the reference groups. In 2018, donors between 30-39 years of age were two times more likely to be HBV positive as compared to the reference age group (Supplementary Table 4).

In the five-year period, 2014-2018, female donors and donors from Tasmania and South Australia were significantly less likely to be HBV positive as compared to the reference groups described above. Donors from Victoria had a significantly greater rate for HBV positivity (1.4 times, see Supplementary Table 5). In comparison, during 2008-2017, the notification rates of HBV infections in Australia have been consistently higher in males than females, have declined in younger age groups (aged under 30 years), with little or no variation in those aged 30+ years, and has consistently been highest in the Northern Territory (88 per 100 000 in 2008 to 41 per 100 000 in 2017). In most other jurisdictions the rate of HBV diagnosis has fluctuated over the last ten years, with a small decline observed in recent years in New South Wales (33 in 2008 to 30 in 2017), Victoria (37 in 2008 to 28 in 2017), and Western Australia (30 in 2008 to 25 in 2017).[1]

Risk factors associated with HBV infected donors

Of the 398 HBV positive donors during 2014-2018, 81% were first-time donors, 70% were male, and the mean age was 40 years (Table 3). Most (87%) of the HBV positive donors were born overseas, which reflects the epidemiology of hepatitis B in the general population. Ethnicity or country of birth (91%) was the most frequent risk factor for HBV positivity, with 48% born in North & South-East Asia in 2018 (Figure 12). There were only 8 incident hepatitis B blood donors in the last five years, consistent with a low incidence rate.

Table 3 Characteristics of donors positive for HBV infection by year of donation, 2014-2018

Characteristics	2014	2015	2016	2017	2018	2014-2018
Number of positive donors	84	84	76	75	79	398
Number of positive first-time donors (%)	65 (77%)	71 (85%)	62 (82%)	63 (84%)	62 (78%)	323 (81%)
% male	55 (65%)	58 (69%)	60 (79%)	47 (63%)	60 (76%)	280 (70%)
Mean age (range) in years	42 (16-69)	37 (16-67)	40 (16-68)	41 (17-78)	41 (19-71)	40 (16-78)
Number of incident donors	3	1	1	1	2	8
% born in Australia	15 (18%)	8 (10%)	5 (7%)	14 (19%)	8 (10%)	50 (13%)
Main reported risk factor	Ethnicity/COB[1] 77%	Ethnicity/COB[1] 93%	Ethnicity/COB[1] 97%*	Ethnicity/COB[1] 87%*	Ethnicity/COB[1] 91%*	Ethnicity/COB[1] 89%
Second reported risk factor	PRP[3] 8%	PRP[3], Other 2% each	Other, Unknown 1% each	FH/HC[2], PRP[3], OR[4] EHS[5] 3% each	Undetermined 3%	PRP[3] 3%

1 COB= Country of birth
2 FH/HC= Family history/Household contact
3 PRP= Partner with known risk/known to be positive
4 OR=Occupational risk
5 EHS=Exposure in health setting
* 4 out of 5, 7 out of 14 and 3 out of 8 donors born in Australia had ethnicity as their major risk factor in 2016, 2017 and 2018, respectively.

Figure 12 Donors with HBV infection by country/region of birth, 2018 (n=79)

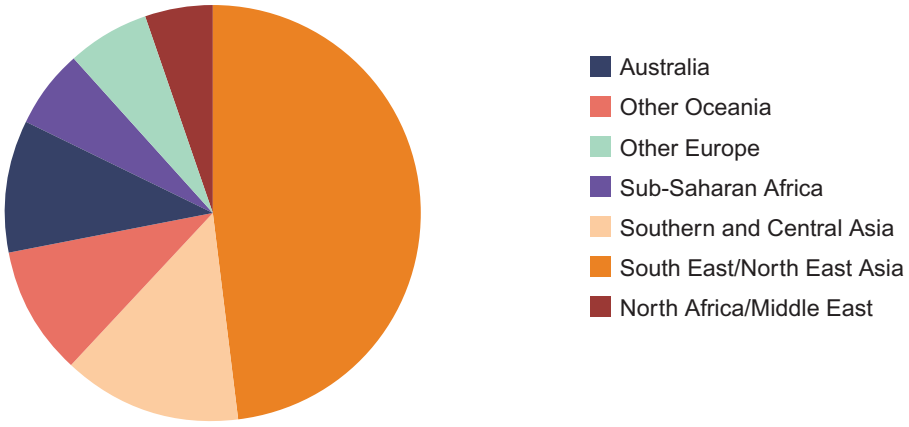
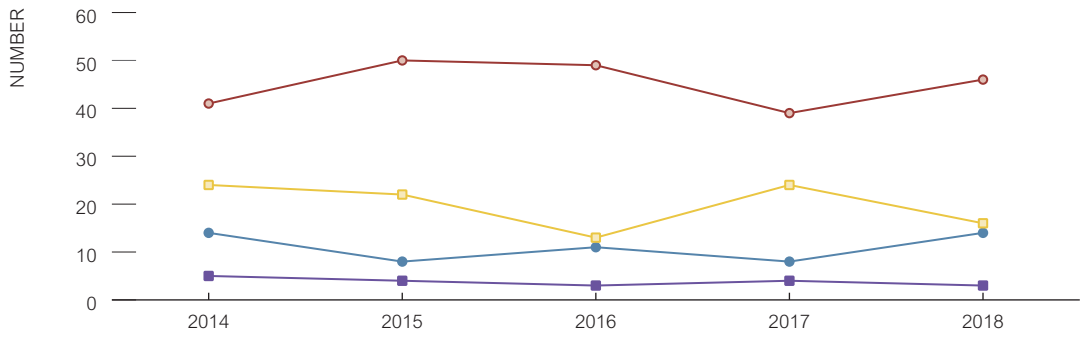


Figure 13 Donors with hepatitis B infection by sex and donor status, 2014-2018



	2014	2015	2016	2017	2018
Male (first-time)	41	50	49	39	46
Male (repeat)	14	8	11	8	14
Female (first-time)	24	22	13	24	16
Female (repeat)	5	4	3	4	3

Since 2014, no trend has been observed in male and female HBV positive first-time donors. The number of HBV positive repeat donors remained relatively stable in both sexes during the same period of time, with no discernible trend observed (Figure 13). In comparison, there have been small declines in HBV notification rates in males and females in the past ten years, 2008-2017 from 33 to 27 per 100 000 population and 27 to 23 per 100 000 population in males and females, respectively.[1] Of note, caution must be applied in comparing the trends by sex between blood donors and general population as they are numbers in the former versus rates in the latter.

For more information on the number and percentage of donors with HBV infection by sex, age group, donor status, country of birth and exposure category for the year 2018 and the period 2014-2018, see Supplementary Tables 6-12.

HBV - Comparison of major exposure categories between blood donors and the general population

A comparison of major exposure categories between blood donors positive for HBV infection and the general population was conducted to determine if any unique source of infection exists for Australian donors (Table 4). The comparison should be interpreted with caution as blood donors are asked about multiple potential sources of infection. In the absence of another declared risk factor, e.g. if the blood donor reports they had an operation, then this will be listed as a potential health care exposure risk despite the fact that this may be a very unlikely route of infection. This classification system likely accounts for the much lower proportion of blood donors who have an undetermined risk factor.

Consistent with previous years, the most frequent risk factor for HBV infection in donors was ethnicity or country of birth which accounted for 91.1% of the HBV positive donors in 2018. This finding also parallels the general population data that shows that country of birth is the strongest risk factor for chronic HBV infection in Australia.[7-9]

Nationally, enhanced information on potential risk categories is collected for the newly acquired infections only (defined as newly diagnosed HBV infection with evidence of acquisition in the 24 months prior to diagnosis - laboratory or clinical evidence). For the newly acquired HBV infections in the general population, 8.8% had country of birth as a major risk factor; importantly, for 37.4% of the newly acquired HBV infections in the general population the risk category was undetermined[1] (Table 4). Caution should be used in comparing the exposure risk categories in blood donors with the general population using newly acquired HBV notification data as the vast majority of HBV positive cases in blood donors have chronic HBV infection as opposed to acute infection.

Table 4 Comparison between HBV positive blood donors (2018) and general population (2017) in Australia by infection and major potential risk categories

		HBV[1]
Major risk category	**General population (2017) (%)**	**Blood donors (2018) (%)**
Intravenous drug use	26.4	1.3
Country of birth/Ethnicity[2]	8.8	91.1
Sexual contact[3]	6.6	1.3
Blood or tissue recipient	0.0	0.0
Tattoo or body piercing	6.6	1.3
Exposure in health care setting	7.7	0.0
Household contact	2.2	0.0
Other blood to blood contact	1.1	0.0
Other/undetermined/unknown	37.4	3.8
Imprisonment	2.2	1.3
Occupational risk	0.0	0.0
No risk factor identified	1.1	0.0

1 Includes exposure categories for newly acquired HBV infections only in general population
2 includes 3 out of 8 hepatitis B positive donors born in Australia that had Ethnicity as their major risk factor
3 Includes three sub-groups: Male-to-male sexual contact, Partner with known risk or known to be positive and Engaged in sex work
Of note, in general population, risk factors are not reported for newly acquired HBV cases from QLD

Conclusion

- The prevalence of HBV infection in first time blood donors has shown no significant trend since 2009 and is substantially lower (12 times) than in the general population estimates for the period 2007/8-2017/18.
- The incidence of newly acquired HBV infection is much lower than estimates from specific at-risk populations in Australia. This supports the general effectiveness of the donor questionnaire and specifically that repeat donors understand what constitutes 'risk behaviour' for acquiring transfusion-transmissible infections.
- Screening for HBV DNA continues to identify donors with occult HBV (24 of the 79 HBV infections in 2018). The proportion of samples with any HBV DNA reactivity at Lifeblood that subsequently confirm as HBV DNA positive externally has increased. To some extent this reflects improved detection of the confirmatory HBV DNA test.
- Putative risk factors identified in blood donors with HBV infection closely parallel those for the general population with no 'unique' risk factors identified to date among blood donors.

Hepatitis C Virus (HCV)

Epidemiology of HCV in Australia

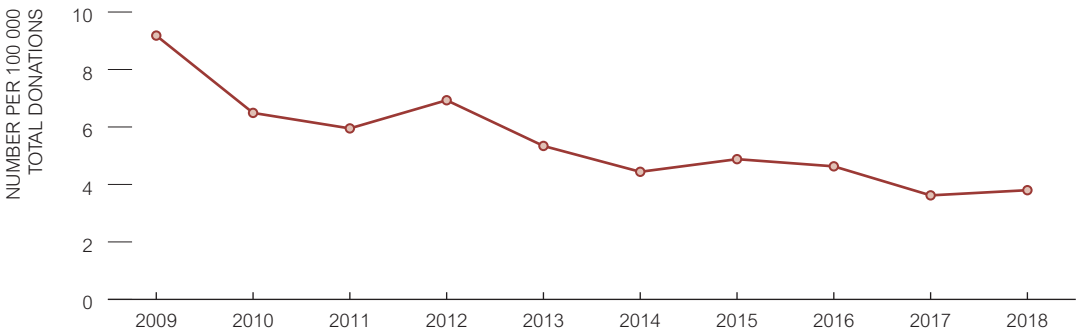
To the end of 2017, an estimated 182 283 (128 981 – 193 119) people were living with chronic hepatitis C in Australia, of which an estimated 80% or 145 838 (114 314 – 181 735) were diagnosed with chronic hepatitis C. Australia has a concentrated chronic hepatitis C epidemic among key populations; people who inject drugs, prisoners, and people from high prevalence countries and HIV positive men who have sex with men. The rate of diagnosis of HCV infection in 2017 was 43 per 100 000 which indicates a decrease from 2016. However, between 2012-2016 the rate increased by 10% from 44 per 100 000 to 47 per 100 000 in 2016. This increase in notification rates may reflect a higher number of people coming forward for testing because of the availability of new treatment options. In general, there has been a 18% decline in the rate of notification of hepatitis C over the ten-year period, 2008-2017, from 53 per 100 000 to 43 per 100 000. The rate of diagnosis in those aged less than 25 years has declined by 30% in the past ten years, 2008-2017. In contrast, the rate of hepatitis C notification in the Aboriginal and Torres Strait Islander population increased by 15% in the five past years, from 146 per 100 000 in 2013 to 168 per 100 000 in 2017. The 2017 rate is 4 times greater than in the non-Indigenous population (38 per 100 000). Most cases (69%) of newly diagnosed HCV infection were in males and 77% were in people aged 30 years and above.[1, 10]

Trends in prevalence

All donations:

In the past ten years, 2009-2018, a total of 729 HCV positive donors have been detected (518 first-time donors & 211 repeat donors) (Table 1A). During the last ten years, the prevalence of HCV infection among all donations has declined significantly (IRR: 0.91; 95% CI: 0.88-0.93). There has been an overall reduction of 59% from 2009 to 2018, from 9.1 per 100 000 donations to 3.8 per 100 000 donations (Figure 14). For detail on number and prevalence rate of HCV infections among all donations for 2018, see Supplementary Table 2.

Figure 14 Prevalence of HCV infection in all blood donations in Australia, 2009-2018, by year of donation

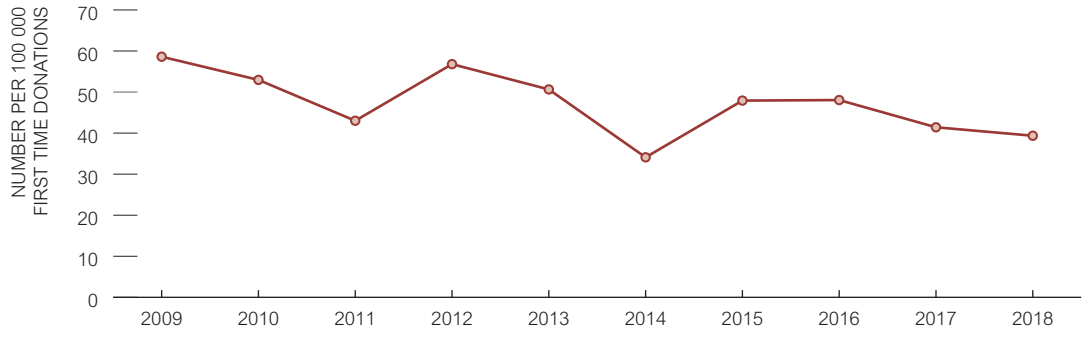


	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018
Prevalence in all donations	9.18	6.49	5.95	6.93	5.34	4.44	4.88	4.63	3.62	3.80

First-time donors:

During 2009-2018, there has been a significant decrease in HCV prevalence in first-time donors in Australia (IRR: 0.96; 95% CI: 0.93-0.99); from 58.6 per 100 000 donations in 2009, to 50.6 per 100 000 donations in 2013 and 39.3 per 100 000 donations in 2018 (Figure 15). This translates to a decrease from 0.06% of the total first-time donations in 2009 to 0.04% in 2018. This trend is consistent with the rate of diagnosis of HCV infection reported through the Australian National Notifiable Disease Surveillance System, which declined from 53 per 100 000 in 2008 to 43 per 100 000 in 2017.[1] In addition, there has also been a decrease in prevalence of hepatitis C antibody among people seen at needle and syringe programs from 62% in 2008 to 49% in 2017, whilst the rates of receptive needle and syringe sharing in the same period remained stable at an average of 16%, highlighting the importance of sustaining and enhancing harm reduction services.[1]

Figure 15 Prevalence of HCV infection in first time blood donors in Australia, 2009-2018, by year of donation

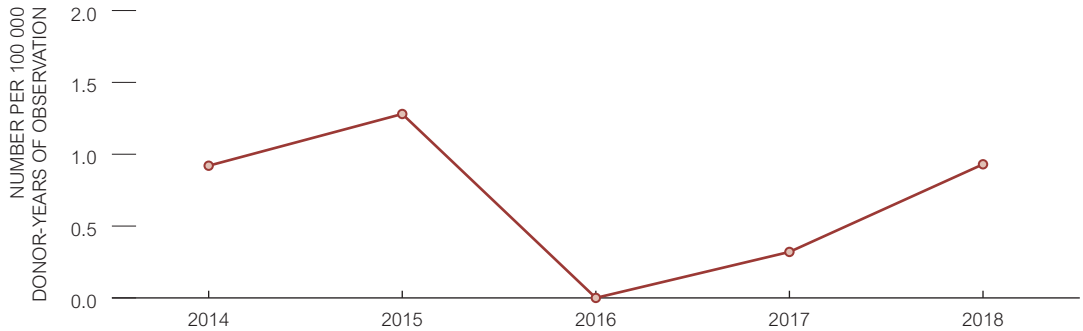


	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018
Prevalence in first-time donors	58.61	52.96	43.01	56.80	50.64	34.10	47.92	48.05	41.42	39.36

Trends in incidence

Due to a change in the methodology for calculating incidence, updated data are presented for a five-year period (see Methodological Notes for detail). Over the five-year period 2014-2018, a total of 11 incident HCV infections in donors were detected with no statistically significant trend observed for incidence rates (between 0.0 and 1.2 per 100 000 donor-years of observation; IRR: 0.87; 95% CI: 0.57-1.33) (Figure 16). Three HCV incident donors were identified in 2018, equating to an incidence rate of 0.9 per 100 000 donor-years of observation (Figure 16), a threefold increase on the 0.3 per 100 000 donor years of observations recorded in 2017. Similarly, no significant annual trend was observed for incidence of HCV infection over a five-year study period (2013-2017) among people who inject drugs attending the Kirketon Road Centre, a primary care clinic in central Sydney. The incidence fluctuated between 2.6 and 15.8 per 100 person-years, with lowest in 2016 at 2.6.[1]

Figure 16 Incidence of HCV in repeat blood donors in Australia, 2014-2018



	2014	2015	2016	2017	2018
Incidence	0.92	1.28	0.00	0.32	0.93

No transfusion-transmitted HCV infections were reported in Australia during 2014-2018.

HCV RNA detection rate in donors

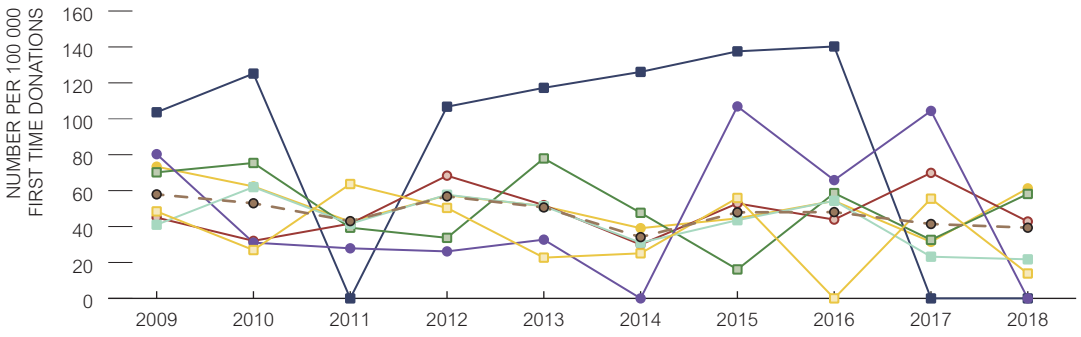
It is generally considered that blood components sourced from HCV antibody positive donors without detectable HCV RNA pose a negligible risk of transfusion-transmission. These donors are presumed to have past resolved infection, however as they meet the public health HCV notification criteria, Lifeblood continues to counsel and refer them for medical follow-up. Notably, for the five-year study period 2014-2018, there has been a steady decline in the proportion of HCV RNA positive (infectious) donors, with a relative reduction of over 30% since 2014, from 46% to 32% in 2018. This proportion has incrementally reduced from 68% in 2008 and around 75% when HCV RNA donation testing was introduced in 2000.

Examining 2008 and 2018 data, the decline is significantly associated with a decrease in the rate of RNA positive donors among first-time donors (or those not previously HCV tested), from 60 per 100 000 in 2008 to 16 per 100 000 new donations in 2018. This mirrors the falling HCV incidence (peak seroconversion in 1999)[11] and falling prevalence in the general population. Assuming a continuing incidence decline in the general population (consistent with the Australian Government aim of treating HCV infected individuals with direct acting anti-viral medications as outlined in the Fourth National Hepatitis C strategy[12]), then a continuing decline in HCV prevalence among first-time donors is predicted, as well as a declining proportion of RNA positive donors.

Trends in HCV infection by state/territory

Similar to patterns in previous years' TTI surveillance reports, the prevalence of HCV infection among first-time donors varied by jurisdiction in 2018, ranging from 0.0 to 61.2 per 100 000 donations. Nationally, the prevalence of HCV infection in first-time donors has shown a significant declining trend throughout the ten-year period 2009-2018. However, unlike last year where a significant decrease was observed in the annual trend in the prevalence of HCV infection among first-time donors in New South Wales/Australian Capital Territory, no significant trend was observed for any jurisdiction in 2018. In 2018, New South Wales/Australian Capital Territory recorded the highest prevalence of HCV infection among first-time donors as compared to other states at 61.2 per 100 000 donations (Figure 17). On the other hand, in 2018, the Northern Territory and Tasmania observed the lowest rate of 0.0 per 100 000 donations each. The fluctuating trend in the prevalence of HCV infection in first-time donors in the Northern Territory and Tasmania over the past ten years should be interpreted with caution due to small number of positive donors, ranging between zero and one, and zero and three, respectively. National notifications data indicate the notification rate of hepatitis C infection in Australia in 2017 was highest in the Northern Territory (57 per 100 000) and Queensland (49 per 100 000).[1]

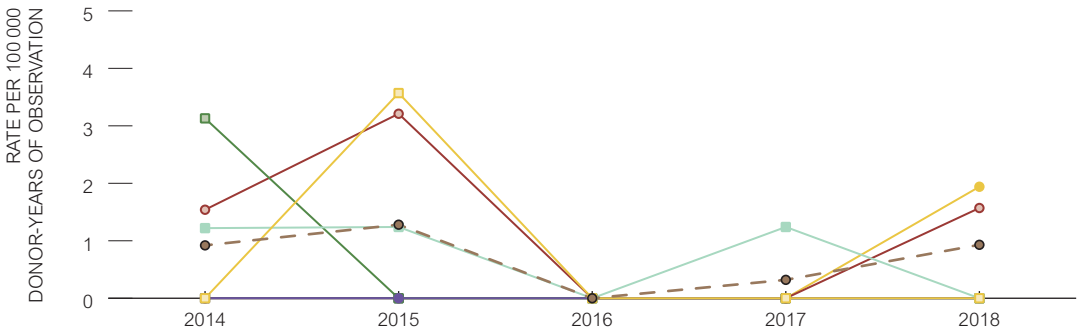
Figure 17 Prevalence of HCV infection among first time donors by state/territory and year of donation, 2009-2018



	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018
NSW/ACT	73.33	62.33	42.70	57.44	51.34	39.09	44.55	54.26	31.48	61.26
NT	103.63	125.16	0.00	106.72	117.23	126.10	137.55	140.25	0.00	0.00
QLD	45.00	32.03	41.61	68.33	51.93	29.94	52.87	43.87	69.88	42.81
SA	70.18	75.40	39.35	33.71	77.92	47.65	16.12	58.62	32.57	58.15
TAS	80.30	31.04	27.88	26.16	32.70	0.00	106.88	65.85	104.38	0.00
VIC	41.02	61.97	41.55	57.72	51.32	31.00	43.54	54.34	23.21	21.74
WA	48.44	26.91	63.68	50.38	22.69	25.09	55.92	0.00	55.51	13.85
National	57.91	52.96	43.01	56.80	50.64	34.10	47.92	48.05	41.42	39.36

There was no significant annual trend observed for the HCV incidence in repeat donors nationally during the 2014-2018 study period (IRR: 0.87; 95% CI: 0.57-1.33). Generally, the incidence of HCV infection in repeat donors has remained very low across all Australian jurisdictions during the past five years (Figure 18); however, no significant decrease was observed for any state or territory. Notably, in Tasmania and Northern Territory, HCV incidence has remained zero since 2014.

Figure 18 Incidence of HCV infection among repeat donors by state/territory and year of donation, 2014-2018



	2014	2015	2016	2017	2018
NSW/ACT	0.00	0.00	0.00	0.00	1.94
NT	0.00	0.00	0.00	0.00	0.00
QLD	1.54	3.21	0.00	0.00	1.57
SA	3.13	0.00	0.00	0.00	0.00
TAS	0.00	0.00	0.00	0.00	0.00
VIC	1.22	1.24	0.00	1.24	0.00
WA	0.00	3.57	0.00	0.00	0.00
National	0.92	1.28	0.00	0.32	0.93

Comparison of prevalence of HCV infection among blood donors and the general population

This section presents a comparison of prevalence of HCV infections among first-time blood donors and the general population. As noted, general population data for 2018 were not available for HCV at the time of report preparation. Therefore, general population data are presented for a combined period of 2008-2017 and 2017, separately. Subsequently, a discussion is presented on the prevalence reduction in first-time donors as compared to the general population.

The prevalence of HCV infection is much higher in the general population than in blood donors, which is consistent with a previous Lifeblood study for the period 2000-2006.[6] There was a 21 and 19 times lower prevalence in first-time donors for the period 2008/09-2017/18, and for year 2017/18, respectively, as compared to the prevalence in general population (Table 5). Given blood donors are drawn from the general population, the prevalence reduction observed in first-time donors is interpreted to reflect the combined effectiveness of donor education and donor selection policies.

Table 5 Comparison of prevalence of HCV infection in blood donors with population prevalence by infection

Infection	Estimated population prevalence* (per 100 000 people)		Prevalence in first time blood donors (per 100 000 donations)		Comparison of HCV prevalence in first time blood donors with population prevalence	
	2008-2017	2017	2009-2018	2018	2008/09-2017/18	2017/18
HCV	1026	741	48.18	39.36	21 times lower	19 times lower

* The 2017 HCV prevalence in the general population was calculated by taking the estimated number of people living with chronic HCV[1], and dividing it by the estimated mid-year resident Australian population in 2017 reported by the Australian Bureau of Statistics. For the period 2008-2017, an average of ten years' prevalence rates was calculated.

Demographic factors associated with HCV infections in blood donors

Data on the demographic characteristics (sex, age group, state/territory and year of donation) for all blood donors were analysed (see Methodological Notes for details) to determine the association between demographic factors and presence of HCV infection among Australian blood donors in 2018, and the five-year period, 2014-2018, separately (Supplementary Tables 4 and 5). Male donors, donors aged between 20-29 years and donors from New South Wales were used as reference groups for comparison of positivity rate by sex, age group and state/territory of donation.

In 2018, unlike HBV, there was no significant association between sex and HCV infection status. Donors over 50 years of age were three times more likely to be HCV positive compared to the reference group (Supplementary Table 4). In 2018, donors from Victoria were 63% less likely to be HCV positive as compared to the reference group.

During the five-year period, 2014-2018, female donors were significantly less likely to be HCV positive (42%) compared to male donors. There was a significantly greater risk of HCV infection among donors aged 40 years or above, and among donors from the Northern Territory as compared to the reference groups noted above (Supplementary Table 5).

Risk factors associated with HCV infected donors

Of the 279 HCV positive donors during 2014-2018, 68% were first-time donors and 64% were male. Over the last five years, the mean age was 47 years with a wide range (16-71) (Table 6). Unlike HBV where birth overseas predominated, the majority (73%) of HCV positive donors during 2014-2018 were born in Australia, and 75% in 2018 (Figure 19). Of note, in 2018 the percentage of repeat donors has gone up, to 40%, which is higher as compared to 2015-2017 period. Also important to note is the increase of female donors to nearly 50%, which is the highest proportion recorded in the study period, 2014-2018. Overall, the main reported putative risk factor for HCV positivity during 2014-2018 was intravenous drug use (25%), followed by tattoo or body piercing (22%). It should be noted that there is no significant evidence that tattooing and body piercing performed in licensed premises is associated with an increased risk of acquiring HCV.[4] In contrast, tattooing performed in prison

settings, or in some overseas countries is associated with an increased risk of HCV. Given the increasing rate of tattooing among Australians, the 22% of HCV positive donors reporting tattooing or body piercing should be interpreted with caution and this may reflect association rather than causation, and/or non-disclosure of another risk factor. A joint Lifeblood and Kirby Institute study has recently been conducted to further investigate the risk of tattooing in the context of blood donation,[13] noting that blood donors with recent tattoos are currently temporarily deferred from donation. The total modeled risk if donors with a tattoo were allowed to donate without restriction was estimated at 1 in 34 million. The authors concluded that deferral for donors post-tattoo in Australia is not required for blood safety. Highlighting the continuing relative importance of HCV to blood safety, there were 11 incident HCV infections in blood donors in the last five years, the highest among all TTIs.

Table 6 Characteristics of donors positive for HCV infection by year of donation, 2014-2018

Characteristics	2014	2015	2016	2017	2018	2014-2018
Number of positive donors	56	62	60	48	53	279
Number of positive first-time donors (%)	31 (55%)	43 (69%)	46 (77%)	38 (79%)	32 (60%)	197 (71%)
% male	37 (66%)	39 (63%)	40 (67%)	35 (73%)	27 (51%)	178 (64%)
Mean age (range) in years	48 (18 to 71)	44.27 (16-67)	48 (22-67)	48 (23-67)	45 (18-67)	47 (16 to71)
Number of incident donors	3	4	0	1	3	11
% born in Australia	44 (79%)	43 (69%)	40 (67%)	37 (77%)	40 (75%)	204 (73%)
Main reported risk factor	IDU[2]	TBP[1]	IDU[2]	TBP[1]; IDU[2]	TBP[1]	IDU[2]
	30%	29%	27%	23% each	26%	25%
Second reported risk factor	TBP[1], BTR[3] each	IDU[2]	TBP[1]	Other	IDU[2]	TBP[1]
	13%	23%	20%	10%	21%	22%

1 TBP= Tattoo/Body piercing
2 IDU= Intravenous drug use
3 BTR= Blood/tissue recipient

Figure 19 Donors with HCV infection by country/region of birth, 2018 (n=53)

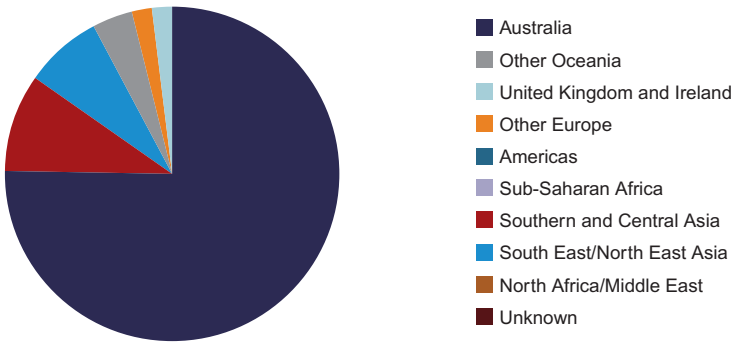
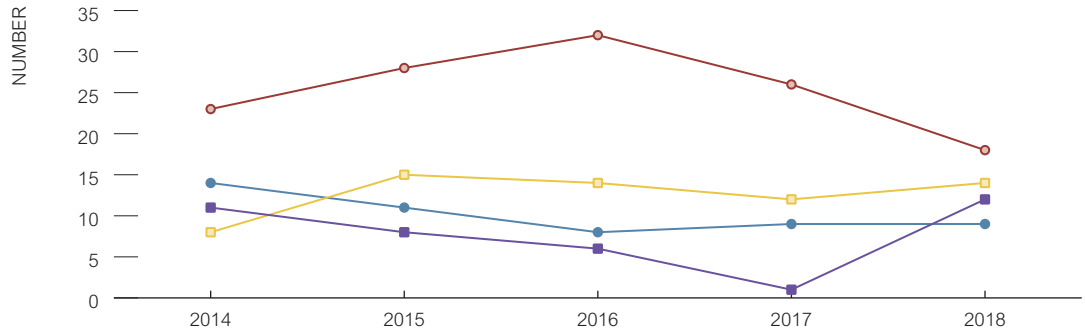


Figure 20 Donors with HCV infection by sex and donor status, 2014-2018



	2014	2015	2016	2017	2018
Male (first-time)	23	28	32	26	18
Male (repeat)	14	11	8	9	9
Female (first-time)	8	15	14	12	14
Female (repeat)	11	8	6	1	12

Over the past five years, 2014-2018, there has been a downward trend in the number of HCV positive first-time and repeat male donors, and a slight upward trend in the number of HCV positive first-time and repeat female donors. In 2018, there were 12 repeat female donors, which is the highest recorded in the past five years (Figure 20). For more information on the number and percentage of donors with HCV infection by sex, age group, donor status, country of birth and exposure category for the year 2018 and the period 2014-2018, see Supplementary Tables 6-12. Of note, caution must be applied in comparing the trends by sex between blood donors and general population as they are numbers in the former versus rates in the latter.

HCV - Comparison of major exposure categories between blood donors and the general population, 2018

A comparison of major exposure categories between blood donors positive for HCV infection and the general population was conducted to determine if any unique source of infection exists for Australian donors (Table 7). As mentioned above in the HBV section, the comparison should be interpreted with caution as blood donors are asked about multiple potential sources of infection and are generally asked about ever being exposed. This classification system likely accounts for the much lower proportion of blood donors who have an undetermined risk factor. When donors give blood they must sign a declaration that informs them there are penalties including imprisonment for anyone providing false or misleading information. Therefore, compared to other surveillance data sources in Australia, donors may be less likely to declare relevant risk factors such as intravenous drug use (IDU) in a post donation interview. In addition, because blood donor infections are generally prevalent infections, the risk factor exposure is not time limited and therefore common events in the population (tattoos, medical procedures) are more likely to be noted when compared to the newly acquired general population data which only relates to exposures since the last negative test. Therefore, the utility of the comparison between the two is acknowledged as limited.

The most frequent risk factor reported for HCV infection in blood donors in 2018 was tattoo or body piercing (26%). In comparison, intravenous drug use was the most common risk factor for newly acquired HCV infection in the general population in 2017 (82.7%) (newly acquired HCV is defined as newly diagnosed hepatitis C infection with laboratory or clinical evidence of acquisition in the 24 months prior to diagnosis).[1]

Table 7 Comparison between HCV positive blood donors (2018) and general population (2017) in Australia by major potential risk categories

		HCV[1]
Major risk category	**General population (2017) (%)**	**Blood donors (2018) (%)**
Intravenous drug use	82.7	20.8
Country of birth/Ethnicity	2.4	1.9
Sexual contact[2]	2.0	5.7
Blood or tissue recipient	0.4	3.8
Tattoo or body piercing	1.2	26.4
Exposure in health care setting	1.6	9.4
Household contact	0.4	1.9
Other blood to blood contact	2.4	3.8
Other/undetermined/unknown	5.5	22.6
Imprisonment	1.2	3.8
No risk factor Identified	0.4	0

1 Includes exposure categories for newly acquired HCV infections only in the general population
2 Includes three sub-groups: Male-to-male sexual contact, Partner with known risk or known to be positive and Engaged in sex work
Of note, in general population, risk factors are not reported for newly acquired HCV cases from QLD

Conclusion

- Supporting the effectiveness of the donor questionnaire, donor education and selection, the prevalence of HCV infection among first-time donors has shown a significant declining trend since 2009 and was 19 and 21 times lower among first-time blood donors than the general population estimate in 2017/18, and for the period 2008/09-2017/18, respectively.
- The incidence of HCV has not shown a significant trend in the five-year study period 2014-2018. However, it is much lower than incidence estimates from specific at-risk populations in Australia. This supports the general effectiveness of the donor questionnaire and specifically that repeat donors understand what constitutes 'risk behaviour' for acquiring transfusion-transmissible infections.
- There is a declining trend in the proportion of HCV positive first-time donors (or previously untested) with detectable RNA and this reflects declining incidence in the general population.
- Putative risk factors identified in blood donors with HCV infection in 2018 likely parallels those for the general population with no 'unique' risk factors identified to date among blood donors.

Human Immunodeficiency Virus (HIV)

Epidemiology of HIV in Australia

During 2018, an estimated 28 180 (24 610 – 31 840) people were living with HIV and an estimated majority (90%) or 25 490 were diagnosed (22 500 – 28 510)[2]. Transmission of HIV in Australia continues to occur primarily through sexual contact between men, with 83% of newly acquired cases of HIV infection in Australia in the period 2009 to 2018 involving men who reported sexual contact with men. The annual number of new HIV diagnoses has decreased by 12% over the past 10 years, from 945 diagnoses in 2009 to 833 in 2018. Of these newly diagnosed HIV infections in 2018, 90% were in males, 62% occurred among men who have sex with men, 7% due to male-to-male sex and injecting drug use, 23% were attributed to heterosexual sex, and 3% to injecting drug use. At 0.1%, the prevalence or overall proportion of people in Australia who have HIV is lower than other comparable high income countries, and countries in the region.[2]

Trends in prevalence

All donations:

In the past ten years, 2009-2018, a total of 46 HIV positive donors have been detected (20 first-time donors & 26 repeat donors) (Table 1A). Unlike last year where the prevalence of HIV infection among all donations showed a statistically significant downward trend, no significant trend was observed this year (IRR: 0.98; 95% CI: 0.89-1.08). Overall, the rate has fluctuated in the past ten years, 2009-2018, between 0.2-0.5 per 100 000 donations (Figure 21). For detail on the number and prevalence rate of HIV infections among all donations for year 2018, see Supplementary Table 2.

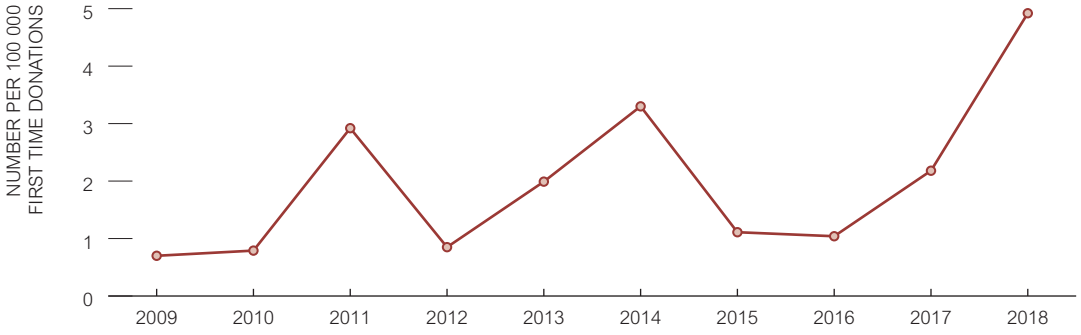
Figure 21 Prevalence of HIV infection in all blood donations in Australia, 2009-2018, by year of donation

First-time donors:

The overall HIV prevalence in first-time donors remained very low at 1.8 per 100 000 over the ten-year period 2009-2018 (Table 1A); it was very low at 0.7 per 100 000 donations in 2009, followed by a fluctuating rate between years 2010 to 2017 before peaking at 4.9 per 100 000 donations in 2018 (Figure 22). The rate of nearly 5 per 100 000 donations observed in first-time donors in 2018 is the highest ever recorded during the 2000-2018 period. The 2018 figure needs to be interpreted with caution given it may reflect a single year variation. Overall, no significant trends were observed in the prevalence of HIV infection among first-time donors in the past ten years (IRR: 1.18; 95% CI: 0.96-1.31).

In comparison, the number of newly diagnosed HIV infections in the general Australian population decreased in the past decade by 12%, from 945 diagnoses in 2009 to 833 cases of newly diagnosed HIV infection in Australia in 2018.[2]

Figure 22 Prevalence of HIV infection in first-time blood donors in Australia, 2009-2018, by year of donation

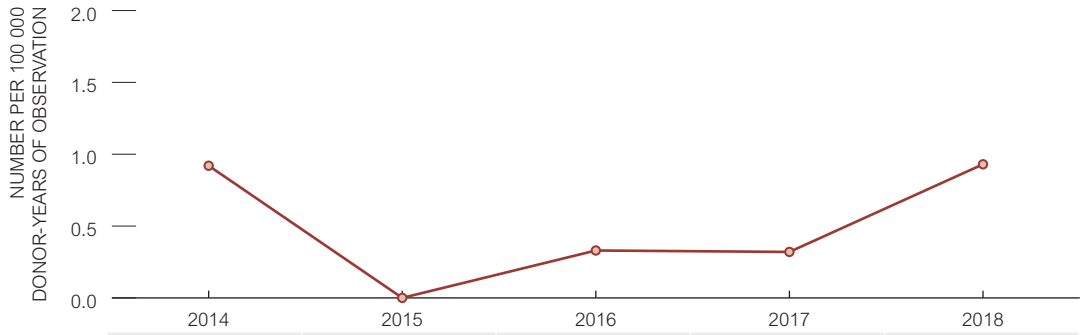


	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018
Prevalence in first-time donors	0.70	0.79	2.92	0.85	1.99	3.30	1.11	1.04	2.18	4.92

Trends in incidence

Due to a change in the methodology for calculating incidence, updated data are presented for a five-year period (see Methodological Notes for detail). In 2018, three incident infections were detected for HIV, equating to an incidence rate of 0.9 per 100 000 donor-years of observation, which is the highest rate observed in the past five years, 2014-2018 (Figure 23). For the five-year period 2014-2018, there were a total of eight incident donors identified for HIV, and no significant trend was observed for incidence rates for HIV infection during this time (IRR: 1.0; 95% CI: 0.65-1.73) (ranged between 0.0 and 0.9 per 100 000 donor-years of observation) (Figure 23). Likewise, no significant trend was observed for the incidence of HIV in a five-year study period (2012-2016) among gay and bisexual men attending sexual health services; the incidence remained less than 0.1 per 100 persons years (fluctuating between 0.58 per 100 person-years to 0.85 per 100 person-years).[14]

Figure 23 Incidence of HIV in repeat blood donors in Australia, 2009-2018, by year of donation



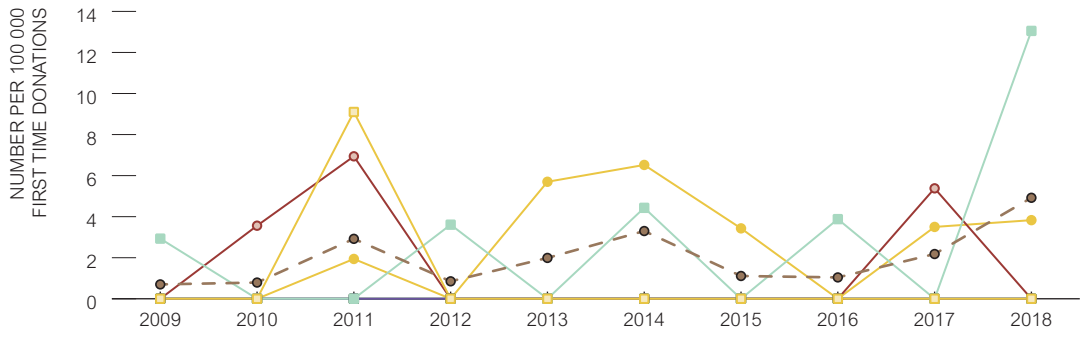
	2014	2015	2016	2017	2018
Incidence	0.92	0.00	0.33	0.32	0.93

No transfusion-transmitted HIV infections were reported in Australia during 2009-2018.

Trends in HIV infection by state/territory

The prevalence of HIV infection in first-time donors remained substantially lower than for hepatitis B and hepatitis C throughout the 2009-2018 period, with an average national prevalence of 1.8 per 100 000 donations (Table 1A). No significant annual trend was observed during the 2009-2018 period in any jurisdiction (Figure 25). In 2018, Victoria observed the highest HIV prevalence in first-time donors at the rate of 13.0 per 100 000 donations (Figure 24), which is the highest ever recorded for any jurisdiction in the past ten years, 2009-2018. This rate equates to three positive first-time donors, which is also the highest number of HIV positive first-time donors observed for any jurisdiction in the ten-year study period, 2009-2018. Given small numbers, this may reflect random variation and therefore caution should be taken in interpretation. During 2009-2018, HIV prevalence in first-time donors was zero in the Northern Territory, South Australia and Tasmania (Table 1A and Figure 24).

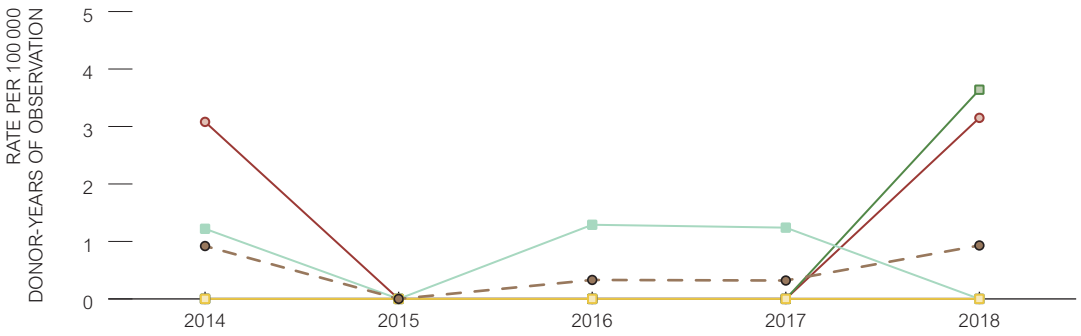
Figure 24 Prevalence of HIV infection among first time donors by state/territory and year of donation, 2009-2018



	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018
NSW/ACT	0.00	0.00	1.94	0.00	5.70	6.52	3.43	0.00	3.50	3.83
NT	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
QLD	0.00	3.56	6.94	0.00	0.00	0.00	0.00	0.00	5.38	0.00
SA	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
TAS	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
VIC	2.93	0.00	0.00	3.61	0.00	4.43	0.00	3.88	0.00	13.05
WA	0.00	0.00	9.10	0.00	0.00	0.00	0.00	0.00	0.00	0.00
National	0.70	0.79	2.92	0.85	1.99	3.30	1.11	1.04	2.18	4.92

In 2018, there were three incident donors (two from Queensland and one from South Australia). No incident HIV donors were recorded in New South Wales/Australian Capital Territory, Tasmania, Western Australia or the Northern Territory in the past five years, 2014-2018 (Figure 25). No significant annual trend was observed in any jurisdiction during 2014-2018.

Figure 25 Incidence of HIV infection among repeat donors by state/territory and year of donation, 2014-2018



	2014	2015	2016	2017	2018
NSW/ACT	0.00	0.00	0.00	0.00	0.00
NT	0.00	0.00	0.00	0.00	0.00
QLD	3.08	0.00	0.00	0.00	3.15
SA	0.00	0.00	0.00	0.00	3.64
TAS	0.00	0.00	0.00	0.00	0.00
VIC	1.22	0.00	1.29	1.24	0.00
WA	0.00	0.00	0.00	0.00	0.00
National	0.92	0.00	0.33	0.32	0.93

Comparison of prevalence of HIV infection among blood donors and the general population

This section presents a comparison of prevalence of HIV infections among first-time blood donors and the general population for a combined period of 2009-2018, and then 2018 separately. Subsequently, a discussion is presented on the prevalence reduction in first-time donors as compared to the general population.

The prevalence of HIV is much higher in the general population than in blood donors, which is consistent with a previous Lifeblood study for the period 2000-2006.[6] There was a 61 times lower prevalence in first-time donors for the period 2009-2018, and a 28 times lower prevalence in 2018 as compared to the general population (Table 8). Given blood donors are drawn from the general population, the prevalence reduction observed in first-time donors is interpreted to reflect the combined effectiveness of donor education and donor selection policies.

Table 8 Comparison of prevalence of HIV infection in blood donors with population prevalence* by infection, 2009-2018

Infection	Estimated population prevalence (per 100 000 people)		Prevalence in first time blood donors (per 100 000 donations)		Comparison of HIV prevalence in first time blood donors with population prevalence	
	2009-2018	2018	2009-2018	2018	2009-2018	2018
HIV	113	139	1.86	4.92	61 times lower	28 times lower

* For population prevalence, the denominator only includes people aged older than 15 years, consistent with the WHO reporting.

Demographic factors associated with HIV infections in blood donors

Data on the demographic characteristics (sex, age group, state/territory and year of donation) for all blood donors were analysed (see Methodological Notes for details) to determine the association between demographic factors and presence of HIV infection among Australian blood donors in 2018, and the five-year period, 2014-2018, separately (Supplementary Tables 4 and 5). Male donors, donors aged between 20-29 years and donors from New South Wales were used as reference groups for comparison of positivity rate by sex, age group and state/territory of donation.

In 2018, there was no significant association between gender, age or state/territory and HIV infection status (Supplementary Table 4). During the five-year period, 2014-2018, there was no association between gender or state/territory and HIV positivity, however, donors over 50 years of age were 70% less likely to be HIV positive for the period 2013-2017 (Supplementary Table 5).

Risk factors associated with HIV infected donors

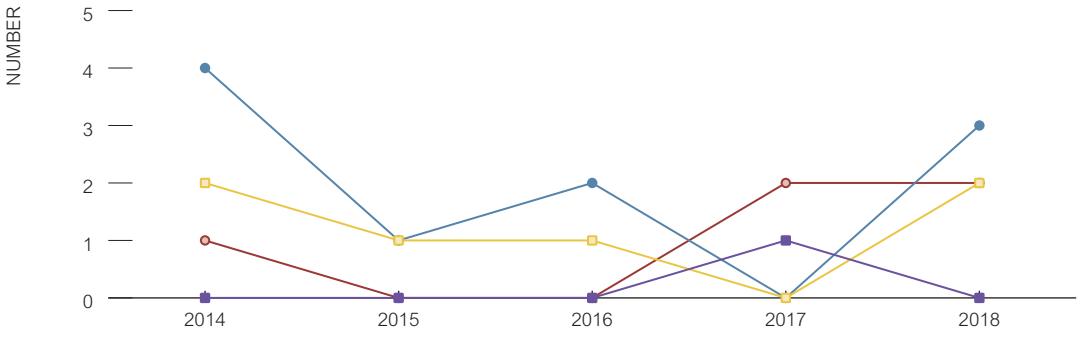
During 2014-2018 there was an equal number of repeat and first-time donors (11 each) (Table 9). Most HIV positive donors were male (68%) and had a mean age of 36 years. Male-to-male sexual contact was the most common reported risk factor for HIV positivity in blood donors during 2014-2018 (32%), followed by having a sexual partner with known risk or known to be positive for HIV infection (23%). Similarly, male-to-male sexual contact and heterosexual contact accounted for 62% and 22% of the new HIV diagnoses in the general population in 2018, respectively.[2] Of 22 HIV positive donors in the five-year period 2014-2018, 8 were incident HIV infections.

Table 9 Characteristics of donors positive for HIV infection by year of donation, 2014-2018

Characteristics	2014	2015	2016	2017	2018	2014-2018
Number of positive donors	7	2	3	3	7	22
Number of positive first-time donors (%)	3 (43%)	1 (50%)	1 (33%)	2 (67%)	4 (57%)	11 (50%)
% male	5 (71%)	1 (50%)	2 (67%)	2 (67%)	5 (71%)	15 (68%)
Mean age (range) in years	36 (26 to 56)	30 (26-33)	46 (30-56)	36 (24-57)	32 (20-66)	36 (20 to 66)
Number of incident donors	3	0	1	1	3	8
% born in Australia	3 (43%)	1 (50%)	2 (67%)	2 (67%)	2 (29%)	10 (45%)
Main reported risk factor	MSM[1] contact	Other, Unknown each	PRP[2], MSM[1] contact, Unknown each	PRP[2]	MSM[1] contact	MSM[1] contact
	43%	50%	33%	100%	43%	32%
Second reported risk factor	PRP[2], BTR[3], Unknown each	…	…	…	PUSR[4], undetermined each	PRP[2]
	14%				29%	23%

1 MSM= Male to male sexual contact
2 PRP= Partner with known risk/known to be positive
3 BTR= Blood/tissue recipient (note: receipt of blood/tissue overseas, so does not indicate transmission through blood products in Australia)
4 PUSR=Partner with unspecified risk

Figure 26 Donors with HIV infection by sex and donor status, 2014-2018



	2014	2015	2016	2017	2018
Male (first-time)	1	0	0	2	2
Male (repeat)	4	1	2	0	3
Female (first-time)	2	1	1	0	2
Female (repeat)	0	0	0	1	0

Over the past five years, 2014-2018, there has been no discernible overall trend in repeat and first-time male and female donors (Figure 26). For more information on the number and percentage of donors with HIV infection by sex, age group, donor status, country of birth and exposure category for period 2014-2018, see Supplementary Tables 6-12.

HIV - Comparison of major exposure categories between blood donors and the general population, 2018

A comparison of major exposure categories between blood donors positive for HIV infection and the general population was conducted to determine if any unique source of infection exists for Australian donors (Table 10). The comparison should be interpreted with caution as blood donors are asked about multiple potential sources of infection. In the absence of another declared risk factor, e.g. if the blood donor reports they had an operation, then this will be listed as a potential health care exposure risk despite the fact that this may be an unlikely route of infection. This classification system likely accounts for the much lower proportion of blood donors who have an undetermined risk factor. In addition, as discussed in the HCV section, the risk factor reporting for blood donors should be interpreted with caution given donors are informed of penalties if they knowingly provide misleading information.

As in previous years, the majority of newly diagnosed HIV infection in the general population was attributed to sexual contact (~80%).[1] This was consistent with the findings among blood donors, where sexual contact was identified as the primary risk factor for the majority (71%) of positive donors.

Table 10 Comparison between HIV positive blood donors and general population in Australia by major potential risk categories, 2018

		HIV[1]
Major risk category	**General population (%)**	**Blood donors (%)**
Intravenous drug use	3.4	0.0
Country of birth/Ethnicity	1.0	0.0
Sexual contact[2]	79.2	71.4
Blood or tissue recipient	0.0	0.0
Tattoo or body piercing	0.0	0.0
Exposure in health care setting	0.0	0.0
Household contact	0.0	0.0
Other blood to blood contact	0.0	0.0
Other/undetermined/unknown	16.4	28.5
Imprisonment	0.0	0.0
Occupational risk	0.0	0.0
No risk factor identified	0.0	0.0

1 Includes exposure categories for new HIV diagnoses only in general population
2 Includes three sub-groups: Male-to-male sexual contact, Partner with known risk or known to be positive and Engaged in sex work

Conclusion

- The prevalence of HIV infection is 28 times lower among first-time blood donors than in the general population in 2018, and 61 times lower for the period 2009-2018.
- The incidence of newly acquired HIV infection measured by the rate of incident donors is also much lower than incidence estimates from specific at-risk populations in Australia.
- There was no unique putative risk factor identified in blood donors with HIV infection in 2018.

This page intentionally left blank

Human T-Lymphotropic Virus (HTLV)

Epidemiology of HTLV in Australia

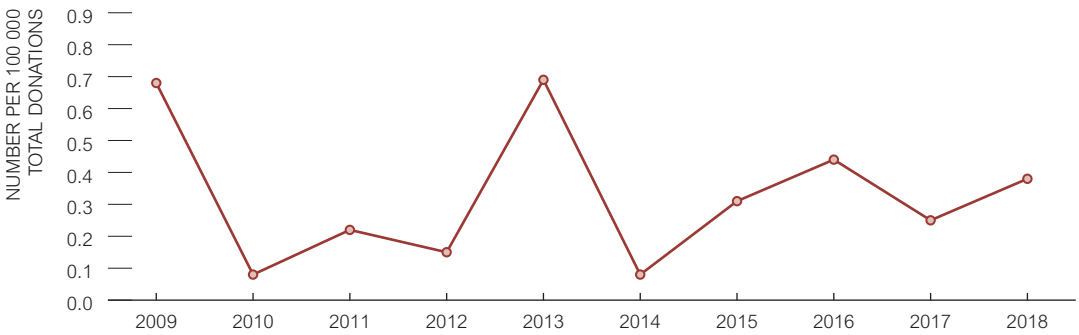
HTLV is not a notifiable infection in Australia except in the Northern Territory. A number of studies have been conducted in Central Australian populations, but few have comprehensively examined the nation-wide epidemiology. The international literature focuses on HTLV-1 as this is more pathogenic than HTLV-2, with disease outcomes including HTLV-1-associated myelopathy and adult T-cell leukaemia/lymphoma.[15, 16] The HTLV-1 prevalence in Australia reported in published studies varies considerably, from 1.7% among Aboriginal and Torres Strait Islander adults in the Northern Territory as a whole to 51.7% among adults in the Anangu Pitjantjatjara Lands of South Australia.[17-19] A recent HTLV-1 seroprevalence study conducted in a remote Indigenous community of Northern Territory reported 31 of 97 (32.0%) participants being anti-HTLV-1 positive, including 30 of 74 (40.5%) adults and 1 of 23 (4.3%) children <15 years.[20]

Trends in prevalence

All donations:

Repeat donors donating plasma for fractionation only, no longer require testing for HTLV resulting in a different test denominator for this TTI, a point that needs due consideration when assessing recent trends. In the past ten years, 2009-2018, a total of 39 HTLV positive donors have been detected (37 first-time donors & two repeat donors) (Table 1B). During the period 2009-2018, the overall prevalence of HTLV infection among all donations was 0.3 per 100 000 donations (Table 1B) and has shown no statistically significant trend (IRR: 0.98; 95% CI: 0.88-1.10) (Figure 27). For detail on the number and prevalence rate of HTLV infections among all donations for year 2018, see Supplementary Table 3.

Figure 27 Prevalence of HTLV infection in all blood donations in Australia, 2009-2018, by year of donation

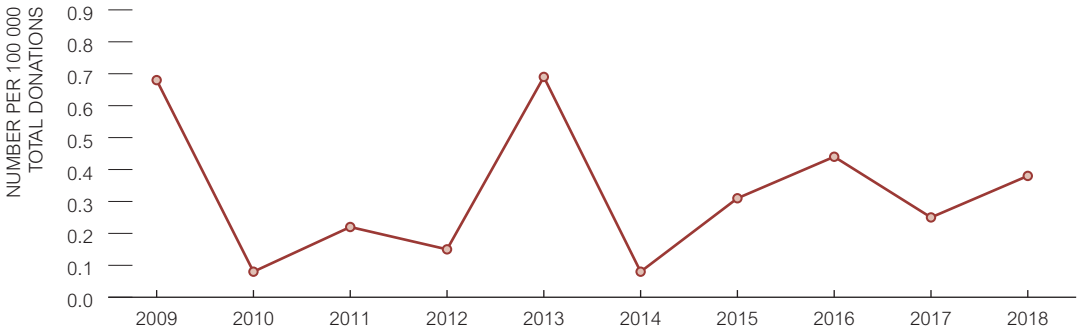


	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018
Prevalence in all donations	0.68	0.08	0.22	0.15	0.69	0.08	0.31	0.44	0.25	0.38

First-time donors:

The prevalence of HTLV infection in first-time donors remained very low over the past ten years, 2009-2018 with an overall rate of 3.4 per 100 000 donations and has shown no significant trend (Table 1B) (IRR: 0.97; 95% CI: 0.87-1.09). The prevalence rate fluctuated between 0.7 and 8.9 per 100 000 donations during this period (Figure 28), which is not unexpected given that low numbers can cause baseline fluctuation (Figure 28).

Figure 28 Prevalence of HTLV infection in first time blood donors in Australia, 2009-2018, by year of donation



	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018
Prevalence in first-time donors	6.28	0.79	2.19	1.70	8.94	1.10	3.34	5.22	2.18	2.46

Trends in incidence

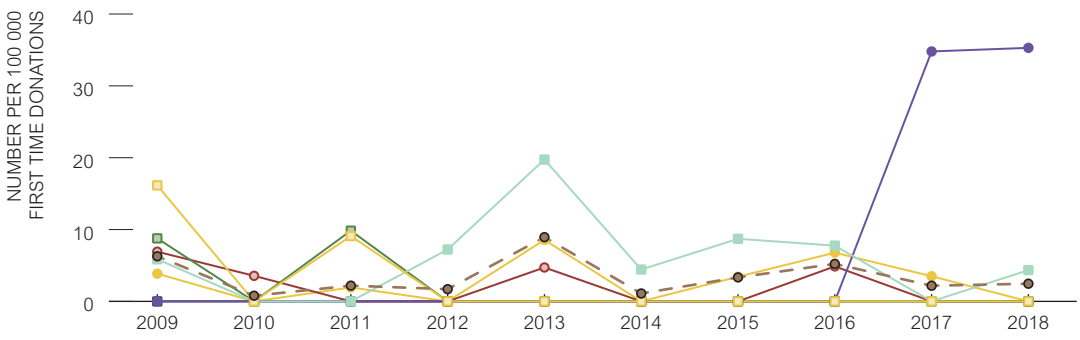
HTLV incidence among repeat Australian donors in 2018 was zero, as it was for the averaged ten-year period 2009-2018. Of note, two lapsed donors from 2007 and 2010 seroconverted in 2015 and 2018, respectively; however, these cases did not meet the definition for an incident donor which is a positive repeat donor whose last donation was within the last 12 months and tested negative for the same TTI. No transfusion-transmitted HTLV infections were reported in Australia during 2009-2018.

Trends in HTLV infection by state/territory

In 2018, HTLV prevalence in first-time donors was zero in most jurisdictions except for Tasmania and Victoria where the prevalence was 35.2 and 4.3 per 100 000 donations, respectively (Figure 30); caution should be taken in interpretation of HTLV prevalence in first-time donors in Tasmania as this rate equates to only one positive donor. No significant trend was observed for prevalence in first-time donors during the period 2009-2018 in any jurisdiction. The prevalence of HTLV infection in first-time donors has remained zero in the Northern Territory during the ten-year study period, 2009-2018 (Figure 29).

No incident HTLV infected donors were reported during 2018 in any jurisdiction, and HTLV incidence has remained zero in the ten-year period 2009-2018 with the last incident donor identified in 2004.

Figure 29 Prevalence of HTLV infection among first time donors by state/territory and year of donation, 2009-2018



	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018
NSW/ACT	3.86	0.00	1.94	0.00	8.56	0.00	3.43	6.78	3.50	0.00
NT	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
QLD	6.92	3.56	0.00	0.00	4.72	0.00	0.00	4.87	0.00	0.00
SA	8.77	0.00	9.84	0.00	0.00	0.00	0.00	0.00	0.00	0.00
TAS	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	34.79	35.29
VIC	5.86	0.00	0.00	7.22	19.74	4.43	8.71	7.76	0.00	4.35
WA	16.15	0.00	9.10	0.00	0.00	0.00	0.00	0.00	0.00	0.00
National	6.28	0.79	2.19	1.70	8.94	1.10	3.34	5.22	2.18	2.46

Comparison of prevalence of HTLV infection among blood donors and the general population

As noted above, prevalence of HTLV infection in first-time donors in 2018, and the ten-year study period 2009-2018 was 2.4 and 3.4 per 100 000 donations, respectively. However, population prevalence for HTLV infection is largely unknown with only the NT requiring formal notification; therefore, it is not possible to compare the prevalence of HTLV infection among Australian blood donors and the general population.

Demographic factors associated with HTLV infections in blood donors

Data on the demographic characteristics (sex, age group, state/territory and year of donation) for all blood donors was analysed (see Methodological Notes for details) to determine the association between demographic factors and presence of HTLV infection among Australian blood donors in 2018, and the five-year period, 2014-2018, separately (Supplementary Tables 4 and 5). Male donors, donors aged between 20-29 years and donors from New South Wales were used as reference groups for comparison of positivity rate by sex, age group and state/territory of donation.

In 2018, there was no significant association between gender, donors' age group or location and HTLV infection status (Supplementary Table 4).

Similarly, during the five-year period, 2014-2018, there was no significant association between gender, age & donor location and HTLV infection status (Supplementary Table 5).

Risk factors associated with HTLV infected donors

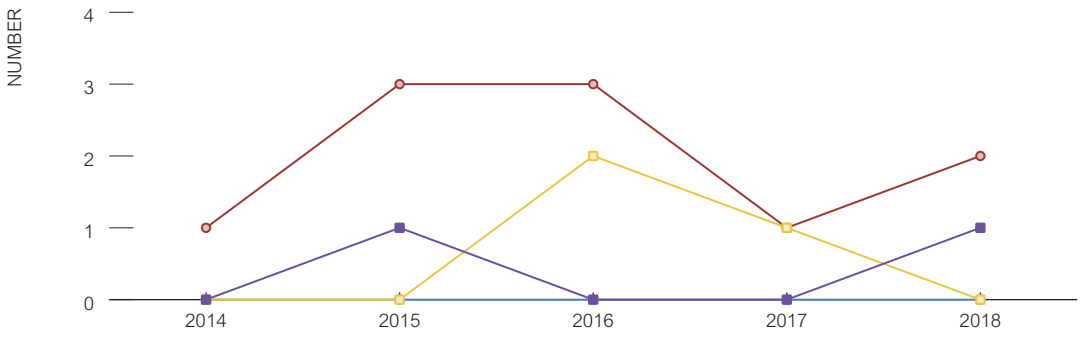
Only 15 donors were positive for HTLV infection during the 2014-2018 period; 13 were first-time donors, two repeat positive donors were identified, one each in 2015 and 2018; 67% were male, and the mean age was 39 years with a wide range (20-68 years) (Table 11). The majority of the HTLV positive donors (80%) were born overseas. Ethnicity or country of birth (73%) was the most common risk factor for HTLV infection in blood donors in Australia during the study period, followed by partner with known risk or known to be positive (27%). As noted, comparison data were not available for risk factors in the general population. There were no incident HTLV infections in donors during the five-year period 2014-2018.

Table 11 Characteristics of donors positive for HTLV infection by year of donation, 2014-2018

Characteristics	2014	2015	2016	2017	2018	2014-2018
Number of positive donors	1	4	5	2	3	15
Number of positive first-time donors (%)	1 (100%)	3 (75%)	5 (100%)	2 (100%)	2 (67%)	13 (87%)
% male	1 (100%)	3 (75%)	3 (60%)	1 (50%)	2 (67%)	10 (67%)
Mean age (range) in years	68	33(30-40)	32 (20-45)	54 (44-64)	38 (26-54)	39 (20-68)
Number of incident donors	0	0	0	0	0	0
% born in Australia	0 (0%)	1(25%)	0 (0%)	1 (50%)	1 (33%)	3 (20%)
Main reported risk factor	Ethnicity/COB[1] 100%	Ethnicity/COB[1] 75%	Ethnicity/COB[1] 80%	Ethnicity/COB[1] 50%	Ethnicity/COB[1] 67%	Ethnicity/COB[1] 73%
Second reported risk factor	25%	PRP[2] 20%	PRP[2] 50%	PRP[2] 33%	PRP[2] 27%	PRP[2] 14%

1 COB= Country of birth
2 PRP= Partner with known risk/known to be positive

Figure 30 Donors with HTLV infection by sex and donor status, 2014-2018



	2014	2015	2016	2017	2018
Male (first-time)	1	3	3	1	2
Male (repeat)	0	0	0	0	0
Female (first-time)	0	0	2	1	0
Female (repeat)	0	1	0	0	1

No discernible overall trend has been observed for first-time male and female donors and repeat female donors. The number of repeat male donors positive for HTLV has remained zero for the study period 2014-2018 (Figure 30). For more information on the number and percentage of donors with HTLV infection by sex, age group, donor status and country of birth for year 2018 and period 2014-2018, see Supplementary Tables 6-12.

HTLV - Comparison of major exposure categories between blood donor and the general population

Due to the scarcity of reliable data on prevalence of key risk factors for HTLV in the Australian population, no meaningful comparison was possible. Nonetheless, Aboriginal and Torres Strait Islander populations in inland Australian regions are known to represent a high HTLV-1-prevalence population.[21] In addition, HTLV-1 is highly endemic in certain geographic regions including Japan, the Caribbean and central Africa and to a lesser extent in Iran, Iraq, southern India and China.[22] This is consistent with the finding that ethnicity or country of birth and a sexual partner with a known risk was the likely infective risk in the two HTLV positive donors in 2018. Notably, a recent UK report has suggested self-flagellation as a novel HTLV transmission route.[23] Similar to Tang et al., Lifeblood has identified self-flagellation as a possible unique risk factor for HTLV-1 infection.[24] Retrospective review identified that a history of self-flagellation was elicited in 7 (28%) of 25 HTLV-1–positive donors identified during January 2012–December 2018. All 7 donors were men 20–37 years of age, of whom 5 were born in Pakistan and 2 in India; 6 had given blood in Victoria. The 18 remaining HTLV-1–positive donors were 29–68 years of age; 10 (56%) were men; 1 was born in India and none in Pakistan; and 7 (39%) gave blood in Victoria. At the time of post-test counseling, no previous HTLV results were available for donors reporting self-flagellation or for their family members. Until the known modes of vertical and sexual transmission have been excluded by such results, the likelihood of self-flagellation as an infective risk factor remains unclear. A noticeable degree of transmission through communal self-flagellation would first require a raised prevalence of infection among the practicing group. Further research is required to clarify the apparent link between self-flagellation and HTLV-1 infection.

Conclusion

- The prevalence of HTLV among first-time donors remained low; however, there are no data to compare prevalence rates in the general population.
- Putative risk factors identified in blood donors with HTLV infection closely parallel those noted in the published literature; however, due to the scarcity of reliable data on prevalence of key risk factors for HTLV in the Australian population, no meaningful comparison was possible.

This page intentionally left blank

Potentially Infectious Syphilis (PIS)

Epidemiology of infectious syphilis in Australia

Population level data are available on notifications of infectious syphilis. PIS is a blood safety definition designed to capture donors that have a theoretical risk of transmitting syphilis by transfusion. To distinguish between PIS and infectious syphilis, the two definitions are presented here: PIS includes repeat donors if they have seroconverted within the last two years (TPHA negative to positive) with a positive confirmatory result, or had a history of syphilis treatment since their last TPHA non-reactive donation, or were previously known to have past treated syphilis and subsequently had possible reinfection (four-fold RPR titre rise). First time donors were included as PIS cases if screening and confirmatory tests for treponemal antibodies were positive, in addition to an RPR titre >8, or clinical evidence (signs of syphilis) or recent contact with a confirmed case. Prior to 2017 the term 'Active syphilis' was used in Lifeblood surveillance reporting. Active syphilis was defined by reactivity on treponemal and non-treponemal syphilis testing +/- clinically apparent infection (i.e. excluding past treated infections and may also exclude latent syphilis[25]). Infectious syphilis, on the other hand, is defined in the national case definition as syphilis infection of less than two years' duration (including primary, secondary and early latent stages[26]). Although the two definitions are slightly different, this section provides information on the epidemiology of infectious syphilis in Australia to provide a context for the report.

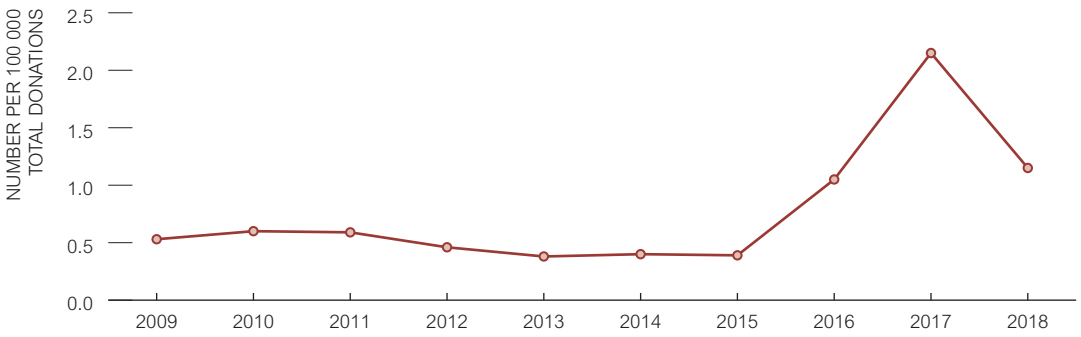
Infectious syphilis in Australia continues to be an infection primarily of men having male to male sex in urban settings, and of heterosexual Aboriginal people in remote and outer regional areas. The number of cases of infectious syphilis (infections of less than 2 years' duration) notified in 2017 was 4 398.[1] The rate of diagnosis of infectious syphilis among men has increased in the past ten years, from 11.0 per 100 000 in 2008 to 31.0 per 100 000 in 2017; similarly the rate among women has increased from 1.4 per 100 000 in 2008 to 5.5 per 100 000 in 2017.[1]

Trends in prevalence

All donations:

According to the revised testing panel for plasma for fractionation in repeat donors, syphilis testing is not required, resulting in fewer donations screened for syphilis, and therefore the impact of this needs due consideration when assessing recent trends. Notwithstanding this, in the past ten years, 2009-2018, a total of 82 donors positive for PIS/active syphilis have been detected (39 first-time donors and 43 repeat donors) (Table 1B). During the period 2009-2018, the overall prevalence of PIS/active syphilis infection among all donations remained very low at 0.6 per 100 000 donations (Table 1B); however, the prevalence in all donations has increased substantially in recent years from 0.3 per 100 000 donations in 2015 to 1.0 per 100 000, 2.1 per 100 000 donations and 1.1 per 100 000 donations in 2016, 2017 and 2018, respectively. As a result, a significant increase in the prevalence of PIS/active syphilis among all donations was observed during 2009-2018 (IRR 1.14; 95% CI: 1.05-1.24) (Figure 31). Although this should be interpreted with caution because of the definition change and impact of the change in syphilis testing profile, there has been a definitive increase in syphilis cases in blood donors. For detail on the number and prevalence rate of potentially infectious syphilis among all donations for the year 2018, see Supplementary Table 3.

Figure 31 Prevalence of PIS/active syphilis in all blood donations in Australia, 2009-2018, by year of donation

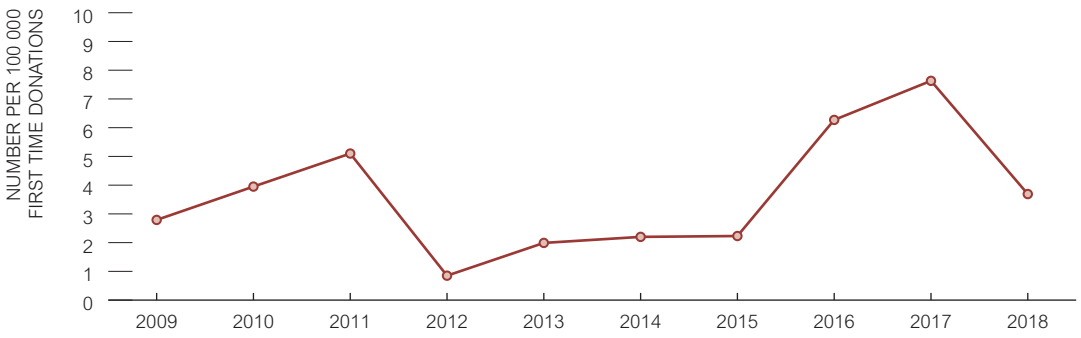


	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018
Prevalence in all donations	0.53	0.6	0.59	0.46	0.38	0.4	0.39	1.05	2.15	1.15

First-time donors:

In the past ten years, 2009-2018, the prevalence of PIS/active syphilis in first-time donors remained low, at 3.6 per 100 000 donations (Table 1B). Overall, the prevalence of PIS/active syphilis in first-time donors showed no significant trend during 2009-2018 (IRR: 1.06; 95% CI: 0.95-1.18); and the rate fluctuated between 0.8 per 100 000 donations and 7.6 per 100 000 donations (Figure 32). Compared to the highest ever recorded rate of 7.6 per 100 000 donations in 2017, the prevalence of PIS/active syphilis in first-time donors has reduced by 52%, to 3.6 per 100 000 donations in 2018 (Figure 32). By comparison, the rate of diagnosis of infectious syphilis reported through the Australian National Notifiable Diseases Surveillance System was 12.7 per 100 000 population in 2008; it remained stable for the next 4 years and fluctuated between 11.0 - 12.7 per 100 000 population. The rate showed a steep increase to 19.8 per 100 000 population in 2015, and 26.4 per 100 000 in 2017 corresponding to the highest recorded number of notifications, with 4 399 diagnoses of infectious syphilis.[1] Caution should be taken in interpretation, as the infectious case definition changed in July 2015, to include more cases of likely recent acquisition.[26]

Figure 32 Prevalence of PIS/active syphilis in first-time blood donors in Australia, 2009-2018, by year of donation

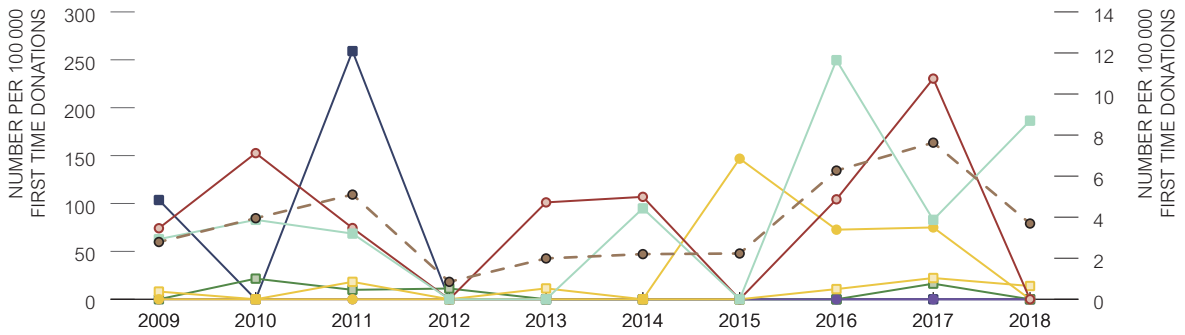


	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018
Prevalence in first-time donors	2.79	3.95	5.1	0.85	1.99	2.2	2.23	6.27	7.63	3.69

Trends in PIS/active syphilis infection by state/territory

In 2018, PIS/active syphilis prevalence in first-time donors was zero in all jurisdictions with the exception of Western Australia and Victoria, where rates were 13.8 per 100 000 donations (equating to only one positive donation in first-time donors) and 8.7 per 100 000 donations (equating to two positive donations in first-time donors), respectively (Figure 33). The prevalence of PIS/active syphilis in first-time donors in Tasmania remained zero over the last ten years. Similarly, in the Northern Territory, the prevalence has remained zero since 2012 after peaking at 259 per 100 000 donations in 2011. There were no discernible trends in most jurisdictions during the ten-year study period, 2009-2018. In comparison, the trend in the general population over the past ten years, 2008-2017, shows an increase in rates of diagnosis of infectious syphilis in all jurisdictions, except Tasmania and the Australian Capital Territory.[1]

Figure 33 Prevalence[1] of PIS/active syphilis among first time donors by state/territory and year of donation, 2009-2018



	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018
NSW/ACT	0.00	0.00	0.00	0.00	0.00	0.00	6.85	3.39	3.50	0.00
NT	103.63	0.00	259.07	0.00	0.00	0.00	0.00	0.00	0.00	0.00
QLD	3.46	7.12	3.47	0.00	4.72	4.99	0.00	4.87	10.75	0.00
SA	0.00	21.54	9.84	11.24	0.00	0.00	0.00	0.00	16.29	0.00
TAS	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
VIC	2.93	3.87	3.20	0.00	0.00	4.43	0.00	11.65	3.87	8.70
WA	8.07	0.00	18.20	0.00	11.34	0.00	0.00	10.64	22.20	13.85
National	2.79	3.95	5.10	0.85	1.99	2.20	2.23	6.27	7.63	3.69

1 Prevalence in QLD, VIC, Tasmania, NSW/ACT and at the National level are provided according to the scale on the secondary axis on the right-hand side

Comparison of prevalence of PIS/active syphilis infection among blood donors and the general population

As noted above, prevalence of PIS/active syphilis in first-time donors in 2018 and the ten-year study period 2009-2018 was 3.69 and 3.63 per 100 000 donations, respectively (Supplementary Table 3 and Table 1B). However, estimates on population prevalence for infectious syphilis are unknown and information is only available on infectious syphilis notifications.[1] It is therefore difficult to compare the prevalence of PIS/active syphilis infection among Australian blood donors and the general population as notifications likely represent only a proportion of the total cases (those for which health care was sought, a test conducted and a diagnosis made, followed by a notification to health authorities).

Demographic factors associated with PIS/active syphilis in blood donors

Standardised national data on demographic factors associated with donors positive with PIS/active syphilis are available on a total of 46 donors (3 from 2014, then all donors thereafter). Data on the demographic characteristics (sex, age group, state/territory and year of donation) for all blood donors was analysed (see Methodological Notes for details) to determine the association between demographic factors and presence of PIS/active syphilis infection among Australian blood donors in 2018, and the five-year period, 2014-2018, separately (Supplementary Tables 4 and 6). Of note, during the five-year period, 2014-2018, there were 48 donors positive for PIS/active syphilis. Male donors, donors aged between 20-29 years and donors from New South Wales were used as reference groups for comparison of positivity rate by sex, age group and state/territory of donation.

In 2018, female donors were significantly less likely (90%) compared to male donors to be positive for PIS (Supplementary Table 4). There was no significant association between donors' age group or location and PIS status. During the five-year period, 2014-2018, female donors were 69% less likely to be to be positive with PIS/active syphilis as compared to male donors. Donors between 40-49 years and 50-years-and-above age groups were 71% and 72% less likely to be positive with PIS/active syphilis, respectively, as compared to the reference group of 20-29 years (Supplementary Table 5). There was no association between state/territory of the donors and PIS/active syphilis infection among Australian blood donors during this period.

Risk factors associated with PIS/active syphilis infected donors

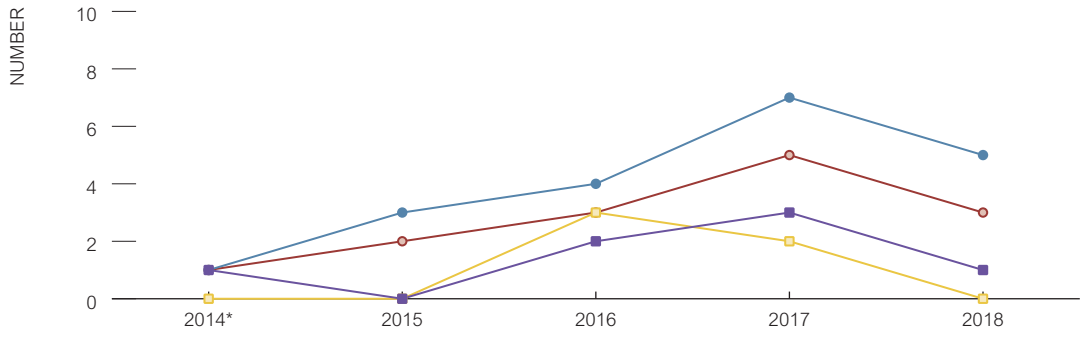
As noted above, during 2014-2018, a total of 48 donors were positive for PIS/active syphilis, of which 46 have standardised risk factor data available. Of the 46 donors (with known standardised risk factor data) positive for PIS/active syphilis during 2014-18, 41% were first-time donors, 74% were male, and 67% were born in Australia (Table 12). The mean age was 35 (range 19-63). Partner with unspecified risk (42%) was the most frequent likely risk factor for PIS/active syphilis positivity. In comparison, in 2017, nationally, 85% of infectious syphilis diagnoses were in males, and 60% were in people aged 20 – 39 years.[1]

Table 12 Characteristics of donors positive for PIS/active syphilis by year of donation, 2014-2018

Characteristics	2014	2015	2016	2017	2018	2014-2018
Number of positive donors	5	5	12	17	9	48
Number of positive first-time donors (%)	1 out of 3* (33%)	2 (40%)	6 (50%)	7 (41%)	3 (33%)	19 (41%)
% male	2 out of 3* (67%)	5 (100%)	7 (58%)	12 (71%)	8 (89%)	34 (74%)
Mean age (range) in years	40 (29-60)	32 (29-60)	37 (24-55)	30 (19-51)	42 (25-63)	35 (19-63)
% born in Australia	1 out of 3* (33%)	2 (40%)	9 (75%)	12 (71%)	7 (78%)	32 (67%)
Main reported risk factor	Partner with unspecified risk	Unknown	Partner with unspecified risk Unknown	Partner with unspecified risk	Partner with unspecified risk	Partner with unspecified risk
	100%	60%	42% each	47%	56%	42%
Second reported risk factor	…	MSM[1] contact & PUSR[2]	PRP[3]	PRP[2]/ Undetermined	MSM[1]/ Undetermined	Unknown
		20% each	17%	18% each	22% each	21%

1 MSM=Men who have sex with men
2 PUSR=Partner with unspecified risk
3 PRP= Partner with known risk/known to be positive
* For 2014 data, information is available for only three out of five donors positive for active syphilis
% calculations are based on 46 donors (that have standardised risk data available) as the denominator.

Figure 34 Donors with PIS/active syphilis infection by sex and donor status, 2014-2018



	2014*	2015	2016	2017	2018
Male (first-time)	1	2	3	5	3
Male (repeat)	1	3	4	7	5
Female (first-time)	0	0	3	2	0
Female (repeat)	1	0	2	3	1

* For 2014 data, information is available for only three out of five positive donors

Over the past five years, 2014-2018, there has been an upward trend in the number of PIS/active syphilis positive first-time and repeat male donors (Figure 34). For more information on the number and percentage of donors with PIS/active syphilis infection by sex, age group, donor status, country of birth and exposure category for year 2018 and period 2014-2018, see Supplementary Tables 6-12.

Conclusion

- Overall, the prevalence of PIS/active syphilis among all blood donations during 2009-2018 has shown a significant upward trend; nonetheless there has been a reduction in 2018 as compared to 2017. Due to definition changes this should be interpreted with caution.
- Comparison between prevalence of PIS/active syphilis in blood donors and general population could not be done as estimates on population prevalence for infectious syphilis are unknown and information is only available on infectious syphilis notifications.

Additional information

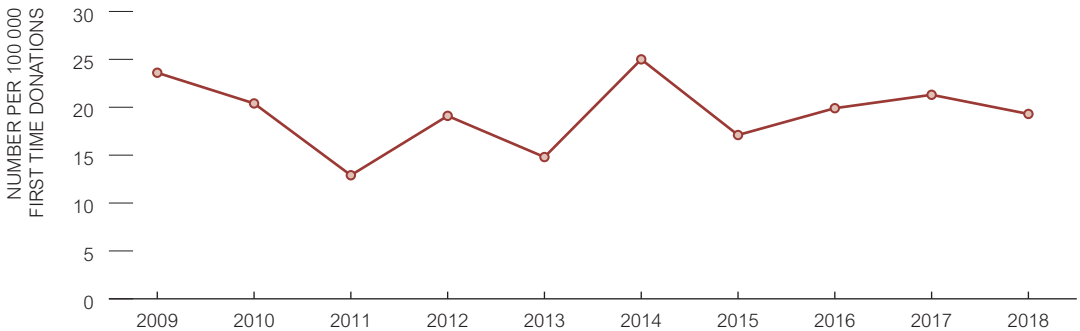
Screening compliance

Every donor is required to self-complete a comprehensive donor questionnaire (Donor Questionnaire – DQ). For whole blood donors, this is a paper document whereas regular plasmapheresis donors at dedicated Lifeblood sites whose plasma is exclusively used for the manufacture of plasma-derived blood products complete an electronic version (the Plasma electronic Donor Questionnaire - PeDQ). The PeDQ omits some of the questions asked of whole blood donors because plasma fractionation has dedicated pathogen inactivation steps which substantially reduce the risk of transmission compared to fresh blood components. For example, there is no travel history question as donors exposed to malaria risk are accepted to donate for plasma for fractionation. All donors, with the exception of regular plasmapheresis donors who have answered 'no' to all the questions in the PeDQ undergo a confidential interview with a Lifeblood staff where the donor's eligibility to donate is determined. All donors have to sign a legal binding declaration before the donor can donate. Lifeblood is therefore highly reliant on donors truthfully answering all questions (i.e. 'compliance').

Not completing the pre-donation questionnaire truthfully is termed 'non-compliance' with donor selection guidelines and Lifeblood remains highly committed to minimising non-compliance by optimising methods for ascertaining donor risk behaviour. A donor who does not appropriately report risk behaviour for a TTI poses a potential risk to the safety of the blood supply for two reasons. Firstly, if they are infected but within the testing window period, they are undetectable by available testing and their blood may be issued for transfusion. Secondly, even when successfully detected by testing there is an extremely remote risk of erroneously issuing this positive unit (i.e. a process failure). Lifeblood takes measures to minimise this latter risk, including the use of computerised release systems. Non-detection and process failure are both avoidable risks if a positive donor appropriately discloses their risk (i.e. complies - leading to deferral) since no donation will be collected.

Over twenty percent (155) of infected donors in 2014-2018 disclosed risk factors during their post-donation interview that would have deferred them from donating had they disclosed their risk behaviour at the pre-donation interview (Table 13). Of these, 67% (104 donors) were first-time donors. The rate of non-compliance in TTI positive donors has been relatively stable for the past decade in the range 13-25%. The average rate observed in a previous Lifeblood study[6] for 2000-2006 was 22%. There was evidence of a declining trend between 2009 and 2011 with the rate incrementally declining to its lowest ever level of 12.9% in 2011 (Figure 35). However, the rate since has fluctuated between 15 and 25%.

Figure 35 Rate of reported non-compliance in transfusion-transmissible-infection positive donors, 2009-2018



	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018
Rate of non-compliance	23.6	20.4	12.9	19.1	14.8	25	17.1	19.9	21.3	19.3

Table 13 Non-compliance category and rate among donors who were positive for any transfusion-transmissible infection, 2014-2018

Non-compliance by year and reason for deferral	2014	2015*	2016**	2017	2018***	2014-2018
Number (%) of non-compliant donors by reasons for deferral						
Intravenous drug use	19 (51.3)	14 (52)	15 (48.3)	9 (29.0%)	9 (31.0%)	66 (42.6%)
Known status/previous positive ^	10 (27)	10 (37)	17 (54.8)	16 (51.6%)	17 (58.6%)	70 (45.1%)
Male-to-male-sexual contact	2 (5.4)	1 (3.7)	1 (3.2)	2 (6.4%)	4 (13.8%)	10 (6.4%)
Partner with known risk or known to be positive	4 (10.8)	1 (3.7)	2 (6.4)	4 (12.9%)	3 (10.3%)	14 (9.0%)
Others	2 (5.4)	7 (26)	0 (0)	0 (0)	1 (3.4%)	10 (6.4%)
Total number (%) of non-compliant donors by year	37 (25)	27 (17)	31 (20%)	31 (21%)	29 (19%)	155 (20.3%)

^ includes people with a history of jaundice
* In 2015, 6 out of 27 non-compliant donors had more than one reason for non-compliance hence the total% is more than 100%
** In 2016, 5 out of 31 non-compliant donors had more than one reason for non-compliance hence the total % is more than 100%
*** In 2018, 8 out of 29 non-compliant donors had more than one reason for non-compliance hence the total% is more than 100%

Unlike 2014 and 2015 where the majority of non-compliant positive donors had a history of injecting drug use, from 2016 onward the most common risk behaviour identified was known status of previously being positive for a virus (including history of jaundice): 54.8% in 2016, 51.6% in 2017, and a record high of 58.6% in 2018. To some extent this might reflect an increasing number of returning/prospective donors with past HCV infection who have successfully undergone treatment with direct acting anti-viral medications. While these donors have undetectable RNA and are 'cured', they have detectable HCV antibodies and therefore are not eligible to donate blood. Overall, during the period of 2014-2018, 45.1% of non-compliance was attributed to known status of previously being positive for a virus followed by injecting drug use (42.5%), having a sexual partner with known risk or known to be positive (9.0%), and 'other' and male-to-male sexual contact within the last 12 months (6.4% each) (Table 13).

Viral residual risk estimates

The rate of incident donors can be used to estimate the risk of collecting a unit of blood from a donor with very early infection (window period) which might test negative. Individuals donating in the window period (incident infections) generally pose the majority of the risk in terms of transmission because they may be missed by testing whereas long standing (prevalent) infections are readily detected by modern screening tests. The exception is HBV where chronically infected donors with occult HBV infection (OBI) may contribute a substantial risk. Highlighting this, a model developed by Lifeblood estimated that in 2012/2013 the majority (55%) of the hepatitis B residual risk in Australia resulted from donors with OBI.[27] More recent estimation indicates an increasing proportion of OBI risk, about 84% and 94% for 2015-16 and 2017-18 period, respectively in the latest estimate (Lifeblood, unpublished).

In 2017, Lifeblood changed the method of estimating the window period risk for HIV and HCV, bringing it in line with the method for HBV adopted in 2016. This addresses the current limitation that existing models are overly conservative, estimating the probability of collecting a window period donation, rather than the more appropriate estimate of the risk of infection in a recipient. The adoption of the method of Weusten *et al*[28] leads generally to lower estimates and standardises the method with HBV. Using viral testing data including the number of incident donors reported for the 2017 and 2018 calendar year periods and applying these to the Lifeblood[28] and Weusten risk models, residual risk estimates[29] (per unit transfused) were derived for the four transfusion-transmissible viral infections subject to mandatory testing (Table 14). Of note, a revised model was applied to HBV which specifically addresses the risk of occult hepatitis B infection (OBI).[30] The risk estimate for active syphilis is not derived by the same method but rather assumed from the lack of reported cases of transfusion-transmission for several decades. The estimates for all fall below the 'negligible' risk threshold of 1 in 1 million used by Lifeblood to contextualise the risks for transfusion recipients. Further information can be obtained at; http://www.transfusion.com.au/adverse_events/risks/estimates.

Table 14 Estimated risk of HBV, HCV, HIV, HTLV and syphilis transmission from Australian blood donations (2017-2018)

	HBV	HCV	HIV	HTLV	PIS/active syphilis
Estimated number of infected units collected (per annum)	<1	<1	<1	<1	<1
Residual risk to recipient - per unit transfused	Less than 1 in 1 million	Less than 1 in 1 million	Less than 1 in 1 million	Less than 1 in 1 million	Less than 1 in 1 million

Based on the estimates and assuming approximately 1.3 million donations collected per annum, less than one transfusion-transmission for the above-mentioned infectious agents (most likely HBV) would be predicted per annum. The lower reported frequency of cases of transfusion-transmission supports that the modelled estimates are conservative with no cases of transfusion-transmitted HCV reported in Australia since 1991, none for HTLV since universal testing commenced in 1993, none for HIV since 1998 and three probable cases of HBV in the 2005-2015 period. It should be noted that no HIV or HCV transfusion-transmissions have been identified since the introduction of NAT testing in 2000.

Testing for malaria

In Australia, donation testing for malaria infection is limited to 'at risk' donors. This includes donors who report at the pre-donation interview travel to or residence in malaria endemic countries, as well as those with a previous history of infection.[31] The availability of malaria antibody testing results in significant recovery of valuable fresh blood components (red blood cells and platelets) as prior to the commencement of testing such donors were restricted to donating plasma for fractionation only, for 1-3 years. Annually, approximately 65 000 red cells and 7 000 platelets are 'recovered' as a result of non-reactive malaria antibody test results. Since malaria antibodies can indicate both recent and past infection, all antibody repeat reactive donors in 2018 were referred to their doctor with a copy of their results.

In 2018, 108 783 donations were tested for malaria antibody of which 1 538 (1.4%) were found to be repeat reactive for malaria antibodies. This rate of antibody detection is comparable to the 1.3% rate recorded in 2017. No cases of transfusion transmitted malaria were reported in Australia in 2018 with the last recorded Australian case in 1991.[32] The residual risk for transfusion transmitted malaria is estimated to be substantially less than 1 in 1 million per unit transfused.

Minimising bacterial contamination of blood components

Transfusion with platelets or red cells carries the highest risk of bacterial transmission, with international data indicating that the risk of a clinically-apparent reaction is at least 1 in 75 000 for platelets[33] and 1 in 500 000 for red cells.[34] Contamination may be due to bacteraemia at the time of blood donation (presumably asymptomatic), contamination with commensal skin bacteria during collection or introduction during processing (e.g. when pooling buffy coats).

Platelets are stored at room temperature which provides a more favourable growth environment for most pathogenic bacteria than the storage conditions used for red cells (refrigeration) or plasma (freezing). This increases the risk that even small initial numbers of contaminating bacteria in a platelet pack may replicate to levels sufficient to result in a transfusion reaction.[35]

Lifeblood reduces this risk using a combination of strategies:

1. **Pre-donation health screening**
   Specific questions in the Donor Questionnaire aim to detect donors at risk of bacteraemia or with potentially compromised skin at the phlebotomy site, e.g. recent dental procedures, gastrointestinal symptoms and various dermatological lesions.

2. **Donor site skin disinfection**
   Prior to phlebotomy, the donor's skin is carefully disinfected using a standardised, validated technique with chlorhexidine and alcohol. This reduces the bacterial load and risk of contamination at the time of collection.

3. **Flow diversion**
   The first 30mL (minimum) of blood collected is diverted away from the collection bag. Introduced in Australia in 2006,[3] this procedure had been previously shown to reduce the bacterial contamination of platelet concentrates by more than 70%.[36]

4. **Process control**
   Optimal process control is achieved by adherence to the Code of Good Manufacturing Practice (cGMP), which includes the employment of competent, trained staff who follow documented standard operating procedures for donor assessment, aseptic collection of donations into sterile, closed collection systems, and appropriate subsequent handling and storage.

5. **Pre-release bacterial contamination screening (BCS)**
   Since 2008, all platelets produced by Lifeblood have been screened for bacterial contamination using the automated BacT/ALERT 3D system.[37] This system is scheduled to be replaced nationally in late 2019 by the BacT/ALERT VIRTUO, which is expected to improve sensitivity and reduce the time-to-detection of bacterial contaminants.

6. **Patient Blood Management (PBM)**
   The risk of many adverse transfusion outcomes, including bacterial transmission, is dose-dependent. PBM is a suite of strategies including optimised erythropoiesis, reduction of surgery-related blood loss and appreciation of the degree of physiological tolerance for anaemia in the individual patient, which together optimise the use of blood products.[38]

In combination, these strategies substantially reduce (but cannot wholly eliminate) the residual risk related to transfusion-transmissible bacterial infections.

7. **Other strategies**
   Pathogen reduction/inactivation technologies (PI/PRT) could potentially further mitigate the risk of bacterial transmission, and have been implemented by some overseas providers.[39] Methods are available for platelets and plasma and are in late stage clinical trials for red cells, however there are currently no licensed technologies in Australia. Platelet components in Australia already carry low residual risk which, together with the low cost-effectiveness and potential adverse impacts on product quality associated with PI/PRT, makes implementation of this technology undesirable at this time.

During 2018 there were a number of changes to the skin decontamination protocol. ChloraPrep (chlorhexidine and alcohol) was used for skin decontamination from January to May 2018. Between May and July 2018, ChloraPrep was replaced in most donor centres by SoluPrep swabs, which contained the same active ingredients. Due to an excessive number of apparent hypersensitivity reactions in donors, SoluPrep swabs were replaced by SoluPrep wipes in December 2018. The reason for the reactions is under investigation by the manufacturer. Since December 2018, the rate of localised reactions has returned to the previous baseline.

Bacterial prerelease testing for platelets

Platelet concentrates are manufactured directly by apheresis or by pooling the buffy coats from four whole blood donations into a single platelet unit. Apheresis-derived donations may produce one or two platelet units. In the latter case, BCS sampling is performed on the combined platelet volume prior to splitting. Figures in the tables below refer to the number of pre-split apheresis samples. At least 24 hours after collection, a minimum of 15 mL is removed from the platelet pack and used to inoculate a set of specialised anaerobic (BPN) and aerobic (BPA) culture bottles. In 2018 these were monitored for bacterial growth by the automated BacT/ALERT 3D system.

Due to the short 5-day shelf life of platelet concentrates, platelet packs are released for use immediately after BCS sampling. From 1 January 2018 to 9 September 2018, culture bottles were incubated for 7 days. From 10 September 2018, the incubation period was reduced to match platelet expiry (5 days in the BacT/ALERT). An internal post-implementation review showed little impact on the relative proportions of organisms, or in the overall contamination rate in the pre- vs. post-implementation periods.

If possible bacterial growth is detected, all unused platelet packs and associated components are immediately recalled or quarantined. If any components have already been transfused, the treating clinician is notified and updated regularly as further information becomes available. Positive BCS bottles are investigated at external reference laboratories (ERL) by Gram staining, subculture to agar media, bacterial identification and antimicrobial susceptibility testing (where appropriate). False positive BCS triggers discard of all associated components, unless the ERL is licenced by the Therapeutic Goods Administration (TGA) as conforming to the Code of Good Manufacturing Process (cGMP), in which case non-platelet components may be released for clinical use.

In 2018 a total of 124 399 platelet units were screened for bacterial contamination.

Of 97 216 pooled platelets, 386 (0.4%) were flagged by the BacT/ALERT as potentially positive. Of the total platelets tested, 118 (0.12%) were designated “confirmed positive”, 114 (0.12%) were “indeterminate” and the remaining 154 (0.16%) were considered to be “false positive”.

Of 27 183 apheresis platelets, 118 (0.43%) were flagged by the BacT/ALERT as potentially positive. Of the total platelets tested, 9 (0.03%) were designated “confirmed positive”, 16 (0.06%) were “indeterminate” and the remaining 93 (0.34%) were considered to be “false positive” (Table 15).

Table 15 Summary of bacterial testing of platelets by BacT/ALERT 3D, 2018

Platelet type	No. components screened	No. initial positive (%) i	No. confirmed positive (%) ii	No. indeterminate (%) iii	No. false positive (%) iv
Pooled platelets	97 216	386 (0.40)	118 (0.12)	114 (0.12)	154 (0.16)
Apheresis platelets	27 183	118 (0.43)	9 (0.03)	16 (0.06)	93 (0.34)
Total	124 399	504 (0.41)	127 (0.10)	130 (0.10)	247 (0.20)

i. One or both culture bottles reported as positive by the BacT/ALERT system
ii. Includes the following:
- Platelet pack is available for retesting and the same organism is re-isolated
- The same organism is isolated from both the platelets and another associated blood component

iii. An organism is isolated from the original platelet sample, however follow-up testing is inconclusive because:
- the original platelet pack is not available for resampling AND
- the associated components are either all culture-negative, or some are unavailable for testing (e.g. leaked, discarded or transfused)

iv. Includes the following:
- The BacT/ALERT system signals a positive bottle, but no organisms are found by the reference laboratory (negative Gram/other stain and no growth on subcultures)
- An organism identified in the initial sample is not re-isolated when the original platelet pack is re-sampled

In addition to the figures above, 62 BCS samples were lost due to failure of a BacT/ALERT incubator at one processing centre. Forty-two were from pooled platelets and 20 were from apheresis platelets. These samples were all culture negative and are not included in the statistics presented here, although for administrative convenience these were recorded internally as false positives.

Of 127 confirmed positives, the most frequently isolated genera were *Cutibacterium* and *Propionibacterium,* which accounted for 109 (85.8%) of the total. A further 10 isolates (7.9%) were coagulase-negative staphylococci (CoNS). CoNS are unlikely to represent donor bacteraemia in the absence of artificial intravascular materials such as prosthetic heart valves, cardiac pacemaker leads, central intravenous lines or vascular grafts. Both the propionibacteria and CoNS were most likely to be skin contaminants which contaminated the blood at the time of collection (Table 16).

The remaining 8 (6.3%) confirmed positives grew potentially pathogenic species.

- *Enterococcus faecalis* (2 isolates):
  - Isolate 1: all components were quarantined, and no other components grew the organism. The source was not determined.
  - Isolate 2: all components were quarantined, and the same species was isolated from the red cell component of one donor in the pool. The source was suspected to be an asymptomatic urinary tract infection.
- *Lactococcus garvieae*: all associated components were quarantined, and no other components grew the organism. The source was not determined.
- *Serratia marcescens* (2 isolates): all associated components were quarantined, and no other components grew the organism. Both isolates originated from the same processing centre. The possibility of intermittent contamination during processing was considered, however it was thought that environmental screening would be unlikely to reveal a source when only two contamination events had occurred. There were no further detections of this species in 2018.
- *Streptococcus dysgalactiae*: all components were quarantined or recalled. The same organism grew from plasma component of one donor in the pool, who remained well. The source was suspected to be asymptomatic colonisation of the donor's skin.
- *Streptococcus pneumoniae* (2 isolates):
  - Isolate 1: all components were quarantined, and no other components grew the organism. The source was not determined.
  - Isolate 2: all components were quarantined and no other components grew the organism. The source was not determined.

There has been debate in the literature about the utility of including anaerobic culture media for BCS. Proposed benefits of including both aerobic and anaerobic culture media include:

- Larger total sample volume with consequent greater sensitivity for detection of facultative contaminants
- Detection of strictly anaerobic bacteria, particularly the spores of *Clostridium* species which may persist within the aerobic platelet environment and cause sepsis in the recipient[40]

In 2018 there were 3 indeterminate isolates of strictly anaerobic organisms, namely *Fusobacterium* sp., *Bacteroides uniformis* and *Colinsella aerofaciens.* It is suspected that these organisms were real contaminants but died during storage in the aerobic platelet bag, since they were unrecoverable at the time of re-sampling. The clinical significance of non-spore forming strict anaerobes is questionable, since these would seem to be incapable of replicating to levels which could cause a septic transfusion reaction in a platelet recipient. Detection of contamination with anaerobes is nonetheless important as part of process control and for donor safety (detection of asymptomatic bacteraemia).

There were no platelet-associated septic transfusion events in 2018.

Red cell components are not universally screened for bacterial contamination due to the lower storage temperature (4°C) and overall lower observed risk of transfusion-transmitted sepsis compared to platelets. Furthermore, a large proportion of red cells (approximately half) are screened by proxy when their associated buffy coats are used to produce pooled platelets.

In 2018 there was one case of transfusion-transmitted sepsis involving a red cell component contaminated with the bacterium *Yersinia enterocolitica*. The donor was asymptomatic both prior to and following donation. During the transfusion the recipient developed symptoms consistent with sepsis. The recipient recovered fully with treatment. *Y. enterocolitica* was isolated from both the recipient's blood and the implicated red cell unit, which were both found to be biotype 4 and serogroup O:3. The associated platelet pool was BCS negative but was discarded without being transfused. *Y. enterocolitica* is associated clinically with gastroenteritis and may be invasive, particularly in patients with iron overload syndromes. The organism is able to replicate to clinically significant levels at 4°C and is a classic agent of transfusion-related sepsis.

Septic transfusion reactions are rare. In the 7.7 years following the introduction of universal platelet bacterial contamination screening, the rate of transfusion-transmitted bacterial infection (TTBI) was 0.4 per 100 000 platelet units transfused.[3] This compares favourably with US data indicating a rate of 0.9 per 100 000 platelet units.[41] For red cells, the Lifeblood rate was similarly low at 0.04 per 100 000 transfused units.[3]

Table 16 Summary of confirmed positive contaminants from platelets, 2018 (n=127)

Confirmed positives: organism isolated	Number
Cutibacterium and *Propionibacterium* species	109
Coagulase-negative staphylococci	10
Enterococcus faecalis	2
Lactococcus garvieae	1
Serratia marcescens	2
Streptococcus dysgalactiae	1
Streptococcus pneumoniae	2
Total	127

Surveillance for emerging infections

Lifeblood maintains surveillance for emerging infections through close liaison with Australian Government communicable disease control units, CSL Behring, membership of international medical/infectious disease groups and active horizon scanning. Potential threats are regularly reviewed by the Lifeblood Donor and Product Safety Committee (DAPS Committee) and risk assessment performed in the event that an emerging infection is identified as a clear and present threat to the safety of the blood supply. Where appropriate this will be performed in collaboration with CSL Behring (in their capacity as national plasma fractionator) and the Therapeutic Goods Administration (TGA).

2018-2019 Summary:

Dengue outbreaks in Queensland

Dengue virus transmission by fresh blood components has been demonstrated and thus poses a risk to blood safety.[42] To mitigate this risk, supplementary donor selection measures and product restrictions are implemented for travel to/residence in affected areas on the Australian mainland. Donations from these areas are restricted to CSL fractionation/processing until the outbreaks are declared over, a strategy that has been shown to effectively eliminate dengue virus risk. In 2019 to date (13 August 2019) the only reported outbreak of dengue fever was in Rockhampton where 13 locally-acquired cases were reported.[43] This is the first outbreak in Rockhampton in decades.[44]

West Nile virus (WNV)

Outbreaks in Europe and Lifeblood's risk assessment

Transmission of West Nile virus (WNV) by blood, tissue and organ transplantation has been documented.[45] A virulent strain of WNV is endemic in North America and therefore donors visiting USA (including Hawaii) and Canada are restricted to donating plasma for fractionation for 28 days after their return. A number of European Union and neighbouring countries experience annual WNV transmission seasons. The 2018 transmission season (June to November) was notable due to the earlier than usual start and a record number of reported WNV infections compared to previous years. The total number of reported autochthonous WNV confirmed/probable infections was 2 083 with the highest number of cases reported in Serbia (580), Italy (576), Greece (311), Romania (277), Hungary (215) and Israel (128). Compared to the previous 5 years, in 2017 there were 288 confirmed/probable cases, 492 in 2016, 369 in 2015, 210 in 2014 and 785 in 2013. Lifeblood monitored these outbreaks based on regular updates of WNV cases provided by the European Centre for Disease Prevention and Control (ECDC). Lifeblood performed weekly risk modelling to estimate the risk of a donor returning from these countries and donating while infectious (i.e. viraemic). This modelling indicated that the additional level of risk to the Australian blood supply associated with donors returning from these countries during the 2018 WNV transmission seasons did not exceed the threshold (established for local dengue outbreaks) that requires cessation of fresh blood component manufacture.[46, 47]

Hendra virus

Human Hendra virus (HeV) infection is an emerging Australian zoonotic disease associated with high mortality.[48] Since 1994 there have been 4 human deaths from HeV infection from a total of 7 confirmed human infections, the last case reported in 2008. To date all seven recorded cases of HeV transmission to humans have been due to contact with horses infected by *Pteropus* bats (flying foxes). There was 1 reported case of equine HeV infection in 2018 (NSW) and one in 2019 (to 13 August), also in NSW.[49] On 1 November 2012, the world's first commercially available HeV vaccine for horses, Equivac® HeV, was launched in Australia. The Equivac® HeV vaccine is seen as an important step towards breaking the transmission cycle of HeV and reducing its impact on the horse-owning community. The Australian Veterinarian Association (AVA) encourages all horse owners to consider using this vaccine, but use is not mandatory. It is predicted that the risk of human infection would progressively decline as the number of susceptible horses diminishes due to vaccination. However, the continued reporting of equine cases indicates a need for wider uptake of the vaccine. The primary mode of human exposure to HeV is thought to be from the respiratory secretions and/or blood of infected horses. HeV has been isolated from the nasopharyngeal secretions, saliva, urine, foetal material and organs of horses.[48] Transfusion-transmission has not been reported but is theoretically possible and as a precautionary measure Lifeblood permanently excludes donors with HeV infection. In addition, contacts of infected horses are notified that they should not donate blood for a period of at least 6 weeks and thereafter are required to provide documented evidence of lack of anti-HeV seroconversion before being accepted to donate.

Middle East respiratory syndrome coronavirus (MERS-CoV)

Human cases of infection with Middle East respiratory syndrome coronavirus (MERS-CoV) were first reported by WHO in September 2012 and the first known cases were retrospectively recognised as occurring in March of that year. MERS-CoV has been classified as a member of the *Betacoronavirus* genus, which also includes the severe acute respiratory syndrome-related coronavirus (SARS-CoV). This raised initial concerns that the new virus may result in a pandemic similar to that of SARS in 2003-04. The clinical presentation of MERS-CoV infection ranges from asymptomatic to very severe pneumonia with acute respiratory distress syndrome (ARDS), septic shock and multi-organ failure resulting in death. The origin of human MERS-CoV has not yet been established. However, current evidence suggests a bat origin by which the virus was introduced to dromedary camels with subsequent overflow from camels to humans. Although it is likely that zoonotic transmission is the starting point of most clusters, human-to-human transmission is the most common mode of transmission for MERS-CoV.[50] While human-to-human transmission has been observed to a limited extent in households, the majority of human cases reported to date have resulted from human-to-human transmission in health care settings. Sustained transmission within communities has not been observed. Since human cases of MERS-CoV were first reported in 2012, the highest number of annually reported cases was in 2014 and 2015 when over 600 cases were reported. In the other years up to 2018, the annual number of reported cases varied between approximately 140 and 250. Approximately 168 cases were reported in the first half of 2019.[51] 83% of human MERS-CoV cases have been reported in Saudi Arabia and only a small number of cases have been reported outside the Middle East. In its August 2018 Global Summary and Risk Assessment, the WHO maintained its assessment that given the lack of evidence of sustained human-to-human transmission in the community, it does not advise special screening at points of entry with regard to this event nor does it currently recommend the application of any travel or trade restrictions.[52] In its most recent risk assessment (August 2018), the European Centre for Disease Prevention and Control (ECDC) concurred with the WHO assessment and noted that the risk of sustained human-to-human transmission in Europe remains very low and there is only a very low risk of a MERS-CoV outbreak in the EU.[53-55] Transfusion transmission of MERS-CoV has not been reported. However, given that infection includes a viraemic phase, the possibility of asymptomatic viraemia and potential transfusion transmission cannot be excluded. The current risk posed by MERS-CoV to blood safety in Australia is considered to be very low. Lifeblood is managing the potential risk from MERS-CoV by ongoing monitoring of reports of laboratory-confirmed cases, the geographical location of case clusters and local human-to-human transmission.

Ebola viruses

There are 5 known species of the *Ebolavirus* genus which belongs to the *Filoviridae* family and are referred to collectively as ebolaviruses. Ebolavirus infection causes severe disease in humans, including internal and external haemorrhaging, with a case fatality rate of about 50%. The first reported outbreak of Ebola virus disease (EVD) was reported in 1976 in Sudan and the Democratic Republic of the Congo. Between 1976 and 2013 there were 20 reported EVD outbreaks, all in equatorial African countries. The largest reported outbreak of EVD occurred in West Africa in 2014–16 with the worst affected countries being Guinea, Liberia and Sierra Leone. A total of 28 616 confirmed, probable and suspected cases were reported, with 11 310 deaths.[56] On 8 May 2018 a new outbreak was reported in Equateur Province, Democratic Republic of the Congo (DRC). The outbreak was declared over in late July 2018 by which time a total of 54 EVD cases (38 confirmed and 16 probable) had been reported, including 33 deaths. Subsequently, a second EVD outbreak was declared in the DRC on 1 August 2018 with the epicentre in North Kivu Province. As at 28 July 2019, the outbreak remains ongoing with 2 577 confirmed (1 790 deaths) and 94 probable (94 deaths) cases.[57] On 17 July 2019, WHO declared the EVD outbreak in the DRC a Public Health Emergency of International Concern (PHEIC).[57, 58] Although transfusion-transmission of ebolaviruses has not been reported, it cannot be excluded as ebolaviruses are typically detectable in the blood for about 1-2 weeks during acute infection. Lifeblood manages the potential risk from ebolaviruses by ongoing monitoring of reports of laboratory-confirmed cases, the geographical location of case clusters and local human-to-human transmission. Donors reporting a current or past ebolavirus infection are permanently deferred. Additionally, donors who have travelled to countries defined as risk areas for ebolavirus, or have had contact with someone who has a current infection or had a past infection, are deferred from donating for 8 weeks after leaving the risk area. In summary, the current risk posed by ebolaviruses to Australia's blood safety is very low.

Zika virus (ZIKV)

ZIKV is a mosquito-borne virus (arbovirus) classified as a member of the *Flaviviridae* family and *Flavivirus* genus. ZIKV was first isolated in 1947 from the blood of a sentinel Rhesus monkey in the Zika forest, near Lake Victoria in Uganda. The first reported case of ZIKV isolated from a human was in Nigeria in 1954. Phylogenetic analyses have indicated that ZIKV emerged in Uganda between 1892 and 1943, most probably around 1920. There are 2 main ZIKV lineages—an Asian and African lineage which has 2 genotypes.[59] Until a ZIKV outbreak on Yap Island in 2007, no major outbreaks and only 14 cases of human ZIKV-associated illness had been reported. However, since 2007 there have been 3 major ZIKV outbreaks: Yap island in 2007, Western Pacific region in 2013-15 and the Americas in 2015–16, the largest ever reported ZIKV outbreak.[60] During the outbreak in the Americas approximately 406 000 suspected and 107 888 confirmed ZIKV cases were reported.[60] Countries with the highest number of reported suspected/confirmed cases were Brazil (174 003/78 421), Colombia (92 842/8 826), Venezuela (54 551/1 632), Martinique (34 310/12), Honduras (29 896/191) and Guadeloupe (26 520/379).[61]

The annual numbers of confirmed ZIKV cases reported in Australia for the period 2012 to 2015 were 1, 1, 13 and 9, respectively. In 2016 the number of reported cases increased to 102. Country of origin was reported for 101 of these cases – 54 (53.4%) were acquired in the Asia/Pacific region and 47 (46.6%) in the Americas. The number of reported cases declined to 9 in 2017 and 4 in 2018 and no cases were reported in 2019 to 23 March.[62] Approximately 80% of ZIKV infections are asymptomatic and most symptomatic infections are accompanied by mild symptoms including rash and fever.[59, 63] However, there is now a general consensus that ZIKV is a causative agent of neurological disease in some infected individuals. In particular, ZIKV infection is associated with microcephaly in newborns and Guillain-Barre syndrome (GBS).[64] ZIKV is considered to be transfusion-transmissible as infection includes an asymptomatic viraemic phase and at least four cases of probable transfusion-transmitted ZIKV infection were reported during the outbreak in the Americas.[65, 66]

In response to the potential risk of ZIKV to blood safety in Australia, Lifeblood has implemented a number of donor restrictions. All countries that reported autochthonous cases of ZIKV transmission in the recent outbreaks in the Western Pacific and Americas were already subject to donor travel restrictions related to either malaria (120 days), DENV or CHIKV (4 weeks). Lifeblood has also implemented a 4-month deferral from date of recovery for donors with a current ZIKV infection and a four-week deferral from date of last contact for donors who have had sexual contact with someone infected with ZIKV. With the geographical spread of ZIKV it is possible that local transmission may be reported in countries without current donor travel deferrals. Therefore, Lifeblood has also implemented a 4-week restriction for donors who may have travelled to countries where ZIKV transmission has been reported but do not have travel deferrals relating to other EIDs. Given these donor restrictions, the low number of imported ZIKV infections reported in Australia, the absence of reported local transmission, the limited distribution of mosquito vectors and rarity of reported transfusion-transmission cases worldwide,[67, 68] ZIKV represents a low risk to blood safety in Australia.

Listeria monocytogenes

Listeria monocytogenes is a gram-positive bacterium that causes listeriosis. Although *L. monocytogenes* is found widely in nature including in soil, decaying vegetation, water and faeces of many mammals, it is an uncommon cause of human illness. The primary route of transmission to humans is believed to be through the consumption of contaminated food. In early 2017 the largest ever reported outbreak of listeriosis began in South Africa and was not brought under control until March 2018. Genome sequencing of isolates indicated that most belonged to the same strain which was identified in a widely consumed ready-to-eat processed meat product. Between 1 Jan 2017 through to 24 Apr 2018, 1024 laboratory-confirmed listeriosis cases were reported. The outcome of illness is known for 700 patients, of whom 200 (28.6 percent) died; this case fatality rate is comparable to other recorded listeriosis outbreaks worldwide. Most of the cases are persons who have higher risks for a severe disease outcome, such as neonates, pregnant women, the elderly and immunocompromised persons. During this outbreak, 42 percent of cases were neonates who were infected during pregnancy or delivery.[69]

Only a single case of transfusion transmission of *Listeria monocytogenes* has been reported worldwide and typically <100 cases of listeriosis are reported annually in Australia. In 2019 (to the end of May), there has been one Australian food-based outbreak associated with *Listeria monocytogenes* contamination risk. The outbreak occurred in a private hospital in Victoria and was linked to an external catering company.[70] The risk to the blood supply from *Listeria* outbreaks is extremely low and does not justify any additional risk mitigation strategies over and above routine practice. The latter includes; health screening questions in the donor questionnaire which would exclude symptomatic individuals presenting to donate and bacterial screening of all platelets and a proportion of red blood cells, which would detect *Listeria monocytogenes*.

Japanese encephalitis virus (JEV)

JEV is a mosquito-borne flavivirus. Similar to WNF, most cases of JEV are asymptomatic with <1% of infections resulting in a severe encephalitis. In July 2017 the Hong Kong Centre for Health Protection reported the first identified cases of transfusion-transmission which were subsequently published in January 2018. An asymptomatic viraemic donor transmitted JEV to 2 immunocompromised recipients.[71] In Australia, the risk JEV poses to blood safety is extremely low. There has not been a reported locally acquired case of JEV in Australia since 1998 (Torres Strait).[72] Reported overseas-acquired cases of JEV in Australia are rarely reported in Australia and countries where the vast majority of cases of JE occur are covered by existing malarial or dengue restrictions that prevent donations being used for fresh component manufacture. Although Hong Kong is not subject to donor travel restrictions, reported cases of JE in Hong Kong are rare and risk modelling has demonstrated that the risk to blood safety is negligible.

Parvovirus B19

Parvovirus B19 (B19V) is a common community-acquired respiratory-transmitted infection which causes erythema infectiosum in children and has now been linked to a spectrum of outcomes including asymptomatic infection, non-specific flu like symptoms, arthropathy and transient red cell aplasia. B19V is a known transfusion-transmissible agent and three probable cases of transfusion-transmission have occurred in recent years in Australia.[73] Despite this, world-wide case reports of transfusion-transmission are rare. A risk assessment of B19V in Australia has been completed.[73] The risk to general recipients was negligible and less than 1 in 1 million. However, a small group of transfusion recipients were at increased risk of complications including patients who are immunosuppressed or have hereditary haemolytic anaemias. For all transfusion recipients the risk from community exposure was far greater than the risk of transfusion and equivalent to receiving 17 to 68 transfusions per year, dependent on the age of the recipient. Consistent with most other blood services, given community risk far outweighs blood transfusion risk, blood donor testing for B19V is not performed. Therefore, it is important that clinicians are aware of the possibility of B19V transfusion-transmission, in addition to community acquired B19V infection, especially in patients that are at higher risk of complications. Clinician awareness will enable informed consent and timely investigation, diagnosis and treatment. Clinicians should consider B19V in patients with unexplained hypoplastic anaemia (anaemia with a low reticulocyte count). In addition, it is important that cases of suspected transfusion-transmission of B19V are reported to Lifeblood for further evaluation. Lifeblood continues to monitor the risk of B19V in Australia and international developments.

Hepatitis E Virus (HEV)

HEV can lead to chronic infection in immunosuppressed patients such as transplant recipients. HEV is a known transfusion-transmissible agent and HEV infection has increased in prevalence in many developed nations. A high proportion of HEV infections in donors are asymptomatic and therefore the exclusion of unwell donors has only limited effectiveness in preventing transfusion-transmitted HEV (TT-HEV). Because of this, and the high prevalence in donors in Europe, European countries such as the UK and the Netherlands have implemented HEV blood donor screening to protect transfusion recipients. However, there is treatment for chronic infection that will result in cure in the vast majority of infected patients.

Lifeblood has recently published the results of a study of HEV RNA prevalence in Australian donors. During 2016 we collected and tested 74 131 whole blood samples for HEV and only one sample was confirmed to be positive.[74] This is the lowest reported prevalence in blood donors world-wide, and taking into account transmission factors and symptoms, we estimated that the risk of an adverse outcome in Australia is approximately 1 in 3.5 million components transfused.[74] Therefore, the risk of TT-HEV in Australia is negligible. As a result of the low prevalence of HEV in Australia donors, it is expected that complications due to TT-HEV would be exceedingly rare. Based on feedback from clinician and government stakeholders, Lifeblood concluded that HEV blood donor screening is not currently warranted in Australia. The vast majority of confirmed HEV infections in Australia are acquired through overseas travel, especially to developing countries. Blood donors are generally ineligible to donate fresh components on return from these countries because of deferrals related to the risk of malaria. All reports of suspected TT-HEV should be reported to Lifeblood for further evaluation. Lifeblood will continue to monitor the risk of HEV in Australia and will review our assessment if required. National surveillance data documents that the number of HEV cases diagnosed in Australia has remained stable.[72]

Conclusion

- The non-compliance rate during the ten-year study period has fluctuated between 13%-25%. The rate highlights the importance of promoting donor education to ensure that the potential donors understand the importance of appropriate 'self-deferral' to reduce the risk of collecting blood from a potentially infected donor whose infection may not be detected by testing.
- While non-compliance among positive donors has been routinely monitored since 2000, the rate among TTI test-negative donors is more difficult to track. Results from a large national survey conducted in 2012-2013 showed a comparatively low rate of non-compliance (in the range 0.05 to 0.29%) among TTI test-negative donors for several sexual activity-based donor deferrals.
- The estimated residual risk of transmission for HIV, HCV, HBV, HTLV and syphilis are all less than 1 in 1 million per unit transfused, which is considered a 'negligible' risk.
- In 2018, 127 (0.10%) of a total 124 399 screened platelet units had confirmed bacterial contamination. The majority of organisms identified were slow-growing anaerobic skin flora not usually associated with post-transfusion septic reactions. However, a minority of platelets grew clinically-significant organisms which were likely to have been due to transient or occult bacteraemia in the donor and could have led to potentially serious septic transfusion reactions in the recipient. During 2018 there was one case of transfusion-transmitted sepsis involving a red cell component contaminated with bacterium *Yersinia enterocolitica*; the recipient fully recovered post treatment.
- In addition to established transfusion-transmissible infections, emerging infectious diseases continue to demand vigilant surveillance and risk assessment. Along with the ongoing risk from local dengue outbreaks and seasonal WNV outbreaks in Europe, large outbreaks of Ebola virus and Zika virus have also been monitored during 2018-2019. The risk to the blood supply posed by donors returning from Ebola virus and Zika virus outbreak areas has been managed by deferring donation (or restricting to plasma for fractionation) for an appropriate period. Lifeblood continues to monitor HEV and parvovirus B19 in Australia and a significant change in the risk profile has not occurred since the risk assessments were performed.

Supplementary Tables

Supplementary Table 1 Screening tests for transfusion transmissible infections

Transfusion-transmissible infection	Mandatory screening tests	Test target	Year of introduction	Median window period estimate	Estimated risk of window period donation (per million transfusion)
Syphilis	*Treponema pallidum* Haemagglutination Assay (TPHA)	Antibodies to *Treponema pallidum*	~1949	30 days	<1 in 1 million[75]
	HBsAg[1]	Hepatitis B surface antigen (HBsAg)	1970	38 days	---
HBV	Nucleic Acid Test for HBV	HBV DNA	2010	16 days	<1 in 1 million
	anti-HIV 1[1] anti-HIV 2[1]	Antibody to both HIV 1 and HIV 2 (anti-HIV-1/2)	1985 (HIV-1) 1993 (HIV-1/HIV-2)	22 days	---
HIV	Nucleic Acid Test for HIV 1[2]	HIV 1 RNA	2000	6 days	<1 in 1 million
	anti-HCV	Antibody to HCV	1990	66 days	---
HCV	Nucleic Acid Test for HCV[2]	HCV RNA	2000	3 days	<1 in 1 million
HTLV	anti-HTLV 1[1] anti-HTLV 2[1]	Antibody to both HTLV 1 and HTLV 2	1993	51 days	<1 in 1 million

1 Currently Abbott PRISM (Abbott Diagnostics, Wiesbaden-Delkenheim, Germany) Chemiluminescent Immunoassay system.
2 Chiron Procleix HIV-1/HCV (Multiplex) Assay, and the HIV-1 and HCV Discriminatory Assays (Chiron Blood Testing, Emeryville, California) from June 2000 until July 2010. Subsequently replaced in 2010 by Novartis HIV-1/HCV/HBV Procleix Ultrio assay using a fully automated testing system (Procleix Tigris). Ultrio assay replaced by Grifols/Hologic HIV-1/HCV/HBV Procleix Ultrio Plus assay in August 2013.

Supplementary Table 2 The number and prevalence rate of transfusion transmissible infections (HBV, HCV and HIV) in Australia, by state/territory, 2018

State/Territory of donation	All accepted donations			HBV			HCV			HIV			Total positive donations		
	First time	Repeat	All	First time	Repeat	All	First time	Repeat	All	First time	Repeat	All	First time	Repeat	All
NSW/ACT	26 120	402 876	428 996	22	7	29	16	8	24	1	0	1	39	15	54
Number *(Number per 100 000 donations)*				*84.23*	*1.74*	*6.76*	*61.26*	*1.99*	*5.59*	*3.83*	*0*	*0.23*	*149.31*	*3.72*	*12.59*
NT	621	9 909	10 530	0	1	1	0	0	0	0	0	0	0	1	1
Number *(Number per 100 000 donations)*				*0*	*10.09*	*9.5*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*10.09*	*9.5*
QLD	16 351	263 267	279 618	5	1	6	7	4	11	0	2	2	12	7	19
Number *(Number per 100 000 donations)*				*30.58*	*0.38*	*2.15*	*42.81*	*1.52*	*3.93*	*0*	*0.76*	*0.72*	*73.39*	*2.66*	*6.79*
SA	5 159	114 051	119 210	1	2	3	3	0	3	0	1	1	4	3	7
Number *(Number per 100 000 donations)*				*19.38*	*1.75*	*2.52*	*58.15*	*0*	*2.52*	*0*	*0.88*	*0.84*	*77.53*	*2.63*	*5.87*
TAS	2 834	52 708	55 542	1	1	2	0	0	0	0	0	0	1	1	2
Number *(Number per 100 000 donations)*				*35.29*	*1.9*	*3.6*	*0*	*0*	*0*	*0*	*0*	*0*	*35.29*	*1.9*	*3.6*
VIC	22 995	339 162	362 157	24	5	29	5	6	11	3	0	3	32	11	43
Number *(Number per 100 000 donations)*				*104.37*	*1.47*	*8.01*	*21.74*	*1.77*	*3.04*	*13.05*	*0*	*0.83*	*139.16*	*3.24*	*11.87*
WA	7 218	131 168	138 386	9	0	9	1	3	4	0	0	0	10	3	9
Number *(Number per 100 000 donations)*				*124.69*	*0*	*6.5*	*13.85*	*2.29*	*2.89*	*0*	*0*	*0*	*138.54*	*2.29*	*9.39*
National	81 298	1 313 141	1 394 439	62	17	79	32	21	53	4	3	7	98	41	139
Number *(Number per 100 000 donations)*				*76.26*	*1.29*	*5.67*	*39.36*	*1.6*	*3.8*	*4.92*	*0.23*	*0.5*	*120.54*	*3.12*	*9.97*

Supplementary Table 3 The number and prevalence rate of transfusion transmissible infections (HTLV and potentially infectious syphilis) in Australia, by state/territory, 2018

State/Territory of donation	All accepted donations			HTLV			Potentially infectious syphilis			Total positive donations		
	First time	Repeat	All	First time	Repeat	All	First time	Repeat	All	First time	Repeat	All
NSW/ACT	26 120	237 395	263 515	0	0	0	0	2	2	0	2	2
Number *(Number per 100 000 donations)*				*0*	*0*	*0*	*0*	*0.84*	*0.76*	*0*	*0.84*	*0.76*
NT	621	3 504	4 125	0	0	0	0	0	0	0	0	0
Number *(Number per 100 000 donations)*				*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*
QLD	16 351	142 698	159 049	0	0	0	0	1	1	0	1	1
Number *(Number per 100 000 donations)*				*0*	*0*	*0*	*0*	*0.7*	*0.63*	*0*	*0.7*	*0.63*
SA	5 159	51 187	56 346	0	1	1	0	0	0	0	1	1
Number *(Number per 100 000 donations)*				*0*	*1.95*	*1.77*	*0*	*0*	*0*	*0*	*1.95*	*1.77*
TAS	2 834	24 513	27 347	1	0	1	0	0	0	1	0	1
Number *(Number per 100 000 donations)*				*35.29*	*0*	*3.66*	*0*	*0*	*0*	*35.29*	*0*	*3.66*
VIC	22 995	186 383	209 378	1	0	1	2	2	4	3	2	5
Number *(Number per 100 000 donations)*				*4.35*	*0*	*0.48*	*8.7*	*1.07*	*1.91*	*13.05*	*1.07*	*2.39*
WA	7 218	58 168	65 386	0	0	0	1	1	2	1	1	2
Number *(Number per 100 000 donations)*				*0*	*0*	*0*	*13.85*	*1.72*	*3.06*	*13.85*	*1.72*	*3.06*
National	81 298	703 848	785 146	2	1	3	3	6	9	5	7	12
Number *(Number per 100 000 donations)*				*2.46*	*0.14*	*0.38*	*3.69*	*0.85*	*1.15*	*6.15*	*0.99*	*1.53*

Supplementary Table 4 Association of demographic characteristics with presence of transfusion-transmissible infections among blood donors in Australia, 2018

		HBV			HCV		
	Number of donors	Number of positive donors *(Number per 100 000 donors)*	IRR and their 95% CI (Multivariate adjusted)	p-value	Number of positive donors *(Number per 100 000 donors)*	IRR and their 95% CI (Multivariate adjusted)	p-value
Sex							
Male	*227 041*	*60 (26.43)*	*1 (ref)*	*…*	*27 (11.89)*	*1 (ref)*	*…*
Female	*236 508*	*19 (8.03)*	*0.26 (0.15-0.45)*	*0.00*	*26 (10.99)*	*0.74 (0.42-1.29)*	*0.29*
Age group (years)							
20-29	*114 951*	*13 (11.31)*	*1 (ref)*	*…*	*8 (6.96)*	*1 (ref)*	*…*
Less than 20	*19 129*	*2 (10.46)*	*1.00 (0.22-4.45)*	*0.99*	*2 (10.46)*	*1.49 (0.31-7.05)*	*0.61*
30-39	*96 989*	*25 (25.78)*	*2.02 (1.03-3.95)*	*0.04*	*9 (9.28)*	*1.30 (0.50-3.38)*	*0.58*
40-49	*81 171*	*16 (19.71)*	*1.58 (0.76-3.30)*	*0.21*	*11 (13.55)*	*1.90 (0.76-4.73)*	*0.16*
50 and above	*151 309*	*23 (15.2)*	*1.75 (0.87-3.50)*	*0.11*	*23 (15.2)*	*3.00 (1.33-6.76)*	*0.00*
State/Territory							
NSW	*135 322*	*28 (20.69)*	*1 (ref)*	*…*	*23 (17)*	*1 (ref)*	*…*
ACT	*14 225*	*1 (7.03)*	*0.24(0.33-1.80)*	*0.16*	*1 (7.03)*	*0.30 (0.41-2.30)*	*0.25*
NT	*3 319*	*1 (30.13)*	*1.08 (0.14-7.97)*	*0.93*	*0 (0)*	*…*	*0.99*
QLD	*90 683*	*6 (6.62)*	*0.22 (0.09-0.55)*	*0.00*	*11 (12.13)*	*0.49 (0.23-1.04)*	*0.06*
SA	*37 522*	*3 (8)*	*0.27 (0.08-0.91)*	*0.03*	*3 (8)*	*0.31 (0.09-1.05)*	*0.06*
TAS	*15 643*	*2 (12.79)*	*0.45 (0.10-1.93)*	*0.28*	*0 (0)*	*…*	*0.99*
VIC	*125 239*	*29 (23.16)*	*0.80 (0.47-1.37)*	*0.42*	*11 (8.78)*	*0.37 (0.17-0.77*	*0.00*
WA	*41 592*	*9 (21.64)*	*0.73 (0.34-1.58)*	*0.43*	*4 (9.62)*	*0.40 (0.13-1.17)*	*0.09*
Total	463 549	79 (17.04)			53 (11.43)		

		HIV			HTLV		
	Number of donors	Number of positive donors *(Number per 100 000 donors)*	IRR and their 95% CI (Multivariate adjusted)	p-value	Number of positive donors *(Number per 100 000 donors)*	IRR and their 95% CI (Multivariate adjusted)	p-value
Sex							
Male	*227 041*	*5 (2.2)*	*1 (ref)*	*…*	*2 (0.88)*	*1 (ref)*	*…*
Female	*236 508*	*2 (0.85)*	*0.31 (0.06-1.62)*	*0.16*	*1 (0.42)*	*0.44 (0.03-4.95)*	*0.50*
Age group (years)							
20-29	*114 951*	*5 (4.35)*	*1 (ref)*	*…*	*1 (0.87)*	*1 (ref)*	*…*
Less than 20	*19 129*	*0 (0)*	*…*	*0.99*	*0 (0)*	*…*	*0.99*
30-39	*96 989*	*1 (1.03)*	*0.21 (0.02-1.85)*	*0.16*	*1 (1.03)*	*1.07 (0.06-17.22)*	*0.05*
40-49	*81 171*	*0 (0)*	*..*	*0.99*	*0 (0)*	*…*	*0.99*
50 and above	*151 309*	*1 (0.66)*	*0.14 (0.01-1.27)*	*0.08*	*1 (0.66)*	*0.56 (0.03-9.23)*	*0.68*
State/Territory							
NSW	*135 322*	*1 (0.74)*	*1 (ref)*	*…*	*0 (0)*	*1 (ref)*	*…*
ACT	*14 225*	*0 (0)*	*..*	*0.99*	*0 (0)*	*…*	*1.00*
NT	*3 319*	*0 (0)*	*..*	*0.99*	*0 (0)*	*…*	*1.00*
QLD	*90 683*	*2 (2.21)*	*2.66 (0.23-29.71)*	*0.42*	*0 (0)*	*…*	*1.00*
SA	*37 522*	*1 (2.67)*	*3.55 (0.21-58.02)*	*0.37*	*1 (2.67)*	*…*	*0.99*
TAS	*15 643*	*0 (0)*	*..*	*0.99*	*1 (6.39)*	*…*	*0.99*
VIC	*125 239*	*3 (2.4)*	*2.79 (0.28-27.12)*	*0.37*	*1 (0.8)*	*…*	*0.99*
WA	*41 592*	*0 (0)*	*..*	*0.99*	*0 (0)*	*...*	*1.00*
Total	463 549	7 (1.51)			3 (0.65)		

	Number of donors	Potentially infectious syphilis		
		Number of positive donors *(Number per 100 000 donors)*	IRR and their 95% CI (Multivariate adjusted)	p-value
Sex				
Male	*227 041*	*8 (3.52)*	*1 (ref)*	*…*
Female	*236 508*	*1 (0.42)*	*0.10 (0.01-0.83)*	*0.03*
Age group (years)				
20-29	*114 951*	*3 (2.61)*	*1 (ref)*	*…*
Less than 20	*19 129*	*0 (0)*	*…*	*0.99*
30-39	*96 989*	*1 (1.03)*	*0.33 (0.03-3.18)*	*0.33*
40-49	*81 171*	*1 (1.23)*	*0.41 (0.04-3.96)*	*0.44*
50 and above	*151 309*	*4 (2.64)*	*1.19 (0.25-5.67)*	*0.82*
State/Territory				
NSW	*135 322*	*2 (1.48)*	*1 (ref)*	*…*
ACT	*14 225*	*0 (0)*	*…*	*0.99*
NT	*3 319*	*0 (0)*	*…*	*0.99*
QLD	*90 683*	*1 (1.1)*	*0.40 (0.03-4.73)*	*0.46*
SA	*37 522*	*0 (0)*	*…*	*0.99*
TAS	*15 643*	*0 (0)*	*…*	*0.99*
VIC	*125 239*	*4 (3.19)*	*1.20 (0.20-7.11)*	*0.83*
WA	*41 592*	*2 (4.81)*	*1.79 (0.23-13.74)*	*0.57*
Total	463 549	9 (1.94)		

Supplementary Table 5 Association of demographic characteristics with presence of transfusion-transmissible infections among blood donors* in Australia, 2014-2018

		HBV			HCV		
	Number of donors	Number of positive donors *(Number per 100 000 donors)*	IRR and their 95% CI (Multivariate adjusted)	p-value	Number of positive donors *(Number per 100 000 donors)*	IRR and their 95% CI (Multivariate adjusted)	p-value
Sex							
Male	*1 154 057*	*280 (24.26)*	*1 (ref)*	*…*	*178 (15.42)*	*1 (ref)*	*…*
Female	*1 167 095*	*118 (10.11)*	*0.41 (0.33-0.51)*	*0.00*	*101 (8.65)*	*0.58 (0.45-0.74)*	*0.00*
Age group (years)							
20-29	*542 448*	*83 (15.3)*	*1 (ref)*	*…*	*35 (6.45)*	*1 (ref)*	*…*
Less than 20	*155 473*	*22 (14.15)*	*0.97 (0.60-1.56)*	*0.91*	*7 (4.5)*	*1.17 (0.59-2.32)*	*0.64*
30-39	*428 302*	*104 (24.28)*	*1.47 (1.10-1.96)*	*0.00*	*38 (8.87)*	*1.40 (0.87-2.23)*	*0.15*
40-49	*397 529*	*73 (18.36)*	*1.14 (0.83-1.56)*	*0.41*	*52 (13.08)*	*2.06 (1.33-3.18)*	*0.00*
50 and above	*797 400*	*116 (14.55)*	*0.92 (0.69-1.22)*	*0.57*	*145 (18.18)*	*2.93 (2.00-4.28)*	*0.00*
State/Territory							
NSW	*684 924*	*112 (16.35)*	*1 (ref)*	*…*	*82 (11.97)*	*1 (ref)*	*…*
ACT	*62 112*	*7 (11.27)*	*0.65 (0.30-1.39)*	*0.26*	*9 (14.49)*	*1.17 (0.59-2.34)*	*0.63*
NT	*16 744*	*4 (23.89)*	*1.38 (0.50-3.74)*	*0.52*	*6 (35.83)*	*2.99 (1.30-6.85)*	*0.01*
QLD	*460 302*	*62 (13.47)*	*0.79 (0.58-1.08)*	*0.15*	*69 (14.99)*	*1.16 (0.84-1.59)*	*0.36*
SA	*202 035*	*20 (9.9)*	*0.59 (0.36-0.95)*	*0.03*	*21 (10.39)*	*0.77 (0.47-1.24)*	*0.29*
TAS	*77 284*	*5 (6.47)*	*0.39 (0.16-0.97)*	*0.04*	*11 (14.23)*	*1.06 (0.56-2.00)*	*0.83*
VIC	*607 671*	*149 (24.52)*	*1.44 (1.12-1.84)*	*0.00*	*63 (10.37)*	*0.82 (0.59-1.14)*	*0.24*
WA	*210 075*	*39 (18.56)*	*1.07 (0.74-1.55)*	*0.68*	*18 (8.57)*	*0.67 (0.40-1.12)*	*0.13*
Total	2 321 152	398 (17.15)			279 (12.02)		

		HIV			HTLV		
	Number of donors	Number of positive donors *(Number per 100 000 donors)*	IRR and their 95% CI (Multivariate adjusted)	p-value	Number of positive donors *(Number per 100 000 donors)*	IRR and their 95% CI (Multivariate adjusted)	p-value
Sex							
Male	*1 154 057*	*15 (1.3)*	*1 (ref)*	*…*	*10 (0.87)*	*1 (ref)*	*…*
Female	*1 167 095*	*7 (0.6)*	*0.42 (0.17-1.03)*	*0.05*	*5 (0.43)*	*0.48 (0.16-1.43)*	*0.19*
Age group (years)							
20-29	*542 448*	*11 (2.03)*	*1 (ref)*	*…*	*3 (0.55)*	*1 (ref)*	*…*
Less than 20	*155 473*	*0 (0)*	*…*	*0.99*	*0 (0)*	*…*	*0.99*
30-39	*428 302*	*4 (0.93)*	*0.43 (0.13-1.35)*	*0.15*	*6 (1.4)*	*2.36 (0.58-9.46)*	*0.22*
40-49	*397 529*	*2 (0.5)*	*0.23 (0.05-1.06)*	*0.06*	*3 (0.75)*	*1.26 (0.25-6.30)*	*0.77*
50 and above	*797 400*	*5 (0.63)*	*0.30 (0.10-0.86)*	*0.02*	*3 (0.38)*	*0.64 (0.12-3.21)*	*0.59*
State/Territory							
NSW	*684 924*	*5 (0.73)*	*1 (ref)*	*…*	*4 (0.58)*	*1 (ref)*	*…*
ACT	*62 112*	*1 (1.61)*	*2.00 (0.23-17.13)*	*0.52*	*1 (1.61)*	*2.48 (0.27-22.22)*	*0.41*
NT	*16 744*	*0 (0)*	*…*	*0.99*	*0 (0)*	*…*	*0.99*
QLD	*460 302*	*5 (1.09)*	*1.43 (0.41-4.94)*	*0.57*	*1 (0.22)*	*0.36 (0.04-3.26)*	*0.36*
SA	*202 035*	*1 (0.49)*	*0.68 (0.07-5.86)*	*0.73*	*1 (0.49)*	*0.85 (0.09-7.65)*	*0.88*
TAS	*77 284*	*0 (0)*	*…*	*0.99*	*2 (2.59)*	*4.60 (0.83-25.21)*	*0.07*
VIC	*607 671*	*9 (1.48)*	*1.88 (0.63-5.62)*	*0.25*	*6 (0.99)*	*1.58 (0.44-5.62)*	*0.47*
WA	*210 075*	*1 (0.48)*	*0.60 (0.07-5.16)*	*0.64*	*0 (0)*	*…*	*0.99*
Total	2 321 152	22 (0.95)			15 (0.65)		

	Number of donors	Potentially infectious syphilis		
		Number of positive donors *(Number per 100 000 donors)*	IRR and their 95% CI (Multivariate adjusted)	p-value
Sex				
Male	*1 154 057*	*34 (2.95)*	*1 (ref)*	…
Female	*1 167 095*	*12 (1.03)*	*0.31 (0.16-0.60)*	*0.00*
Age group (years)				
20-29	*542 448*	*22 (4.06)*	*1 (ref)*	…
Less than 20	*155 473*	*1 (0.64)*	*0.18 (0.02-1.38)*	*0.10*
30-39	*428 302*	*9 (2.1)*	*0.46 (0.21-1.00)*	*0.05*
40-49	*397 529*	*5 (1.26)*	*0.29 (0.11-0.77)*	*0.01*
50 and above	*797 400*	*9 (1.13)*	*0.28 (0.13-0.61)*	*0.00*
State/Territory				
NSW	*684 924*	*15 (2.19)*	*1 (ref)*	…
ACT	*62 112*	*1 (1.61)*	*0.63 (0.08-4.82)*	*0.66*
NT	*16 744*	*1 (5.97)*	*2.36 (0.31-17.88)*	*0.40*
QLD	*460 302*	*8 (1.74)*	*0.75 (0.31-1.78)*	*0.52*
SA	*202 035*	*1 (0.49)*	*0.22 (0.03-1.74)*	*0.15*
TAS	*77 284*	*0 (0)*	…	*0.99*
VIC	*607 671*	*15 (2.47)*	*1.02 (0.50-2.10)*	*0.93*
WA	*210 075*	*5 (2.38)*	*0.99 (0.36-2.74)*	*0.99*
Total	2 321 152	46 (1.98)		

* The total of 2.3 million donors over a five-year period, 2014-2018, are not unique donors, although they are unique for any given year. The reason being that many donors are double counted from year to year (repeat donors)

Supplementary Table 6 Number and percentage of donors positive with transfusion-transmissible infections, by sex and age group, 2018

	HBV (2018)				HCV (2018)				HIV (2018)				HTLV (2018)				Potentially infectious syphilis (2018)			
Donor status	M	F	Total	%	M	F	Total	%	M	F	Total	%	M	F	Total	%	M	F	Total	%
First time donors																				
<20 years	1	1	2	2.5	0	1	1	1.9	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0
20-29 years	10	2	12	15.2	2	1	3	5.7	2	1	3	42.9	1	0	1	33.3	2	0	2	22.2
30-39 years	14	7	21	26.6	5	3	8	15.1	0	1	1	14.3	1	0	1	33.3	0	0	0	0.0
40-49 years	10	3	13	16.5	2	3	5	9.4	0	0	0	0.0	0	0	0	0.00	1	0	1	11.1
50-59 years	7	3	10	12.7	8	4	12	22.6	0	0	0	0.0	0	0	0	0.00	0	0	0	0.0
60 years and above	4	0	4	5.1	1	2	3	5.7	0	0	0	0.0	0	0	0	0.00	0	0	0	0.0
Repeat donors																				
<20 years	0	0	0	0.0	1	0	1	1.9	0	0	0	0.0	0	0	0	0.00	0	0	0	0.00
20-29 years	1	0	1	1.3	1	4	5	9.4	2	0	2	28.6	0	0	0	0.00	1	0	1	11.1
30-39 years	4	0	4	5.1	0	1	1	1.9	0	0	0	0.00	0	0	0	0.00	1	0	1	11.1
40-49 years	2	1	3	3.8	2	4	6	11.3	0	0	0	0.00	0	0	0	0.00	0	0	0	0.0
50-59 years	3	2	5	6.3	3	3	6	11.3	0	0	0	0.00	0	1	1	33.3	1	1	2	22.2
60 years and above	4	0	4	5.1	2	0	2	3.8	1	0	1	14.3	0	0	0	0.00	2	0	2	22.2
Total	60	19	79	100	27	26	53	100	5	2	7	100	2	1	3	100	8	1	9	100

Note: Percentages may not add to exactly 100% due to rounding.

Supplementary Table 7 Number and percentage of donors positive with transfusion-transmissible infections, by sex and age group, 2014-2018

	HBV (2014-2018)				HCV (2014-2018)				HIV (2014-2018)				HTLV (2014-2018)				PIS/active syphilis (2014-2018)*			
Donor status	M	F	Total	%	M	F	Total	%	M	F	Total	%	M	F	Total	%	M	F	Total	%
First time donors																				
<20 years	12	9	21	5.3	3	5	8	2.9	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0
20-29 years	53	26	79	19.8	14	9	23	8.2	4	2	6	27.3	3	0	3	20.0	10	4	14	30.4
30-39 years	72	21	93	23.4	22	8	30	10.8	0	2	2	9.1	4	1	5	33.3	1	1	2	4.3
40-49 years	39	22	61	15.3	19	13	32	11.5	0	1	1	4.5	2	1	3	20.0	3	0	3	6.5
50-59 years	30	13	43	10.8	47	24	71	25.4	1	1	2	9.1	0	0	0	0.0	0	0	0	0.0
60 years and above	19	8	27	6.8	22	4	26	9.3	0	0	0	0.0	1	1	2	13.3	0	0	0	0.0
Repeat donors																				
<20 years	0	1	1	0.3	1	0	1	0.4	0	0	0	0.0	0	0	0	0.0	1	0	1	2.2
20-29 years	3	1	4	1.0	4	8	12	4.3	4	1	5	22.7	0	0	0	0.0	4	4	8	17.4
30-39 years	11	0	11	2.8	3	5	8	2.9	2	0	2	9.1	0	1	1	6.7	6	1	7	15.2
40-49 years	9	3	12	3.0	10	10	20	7.2	1	0	1	4.5	0	0	0	0.0	1	1	2	4.3
50-59 years	19	7	26	6.5	22	11	33	11.8	2	0	2	9.1	0	1	1	6.7	5	1	6	13.0
60 years and above	13	7	20	5.0	11	4	15	5.4	1	0	1	4.5	0	0	0	0.0	3	0	3	6.5
Total	280	118	398	100	178	101	279	100	15	7	22	100	10	5	15	100	34	12	46	100

* Of note, during the five-year period, 2014-2018, there were 48 donors positive for PIS/active syphilis; however, information is available for only three out of five donors positive for active syphilis in 2014, therefore the total comes to 46.

Note: Percentages may not add to exactly 100% due to rounding

Supplementary Table 8 Number and percentage of donors with transfusion-transmissible infections, by country/region of birth^, 2014-2018

	HBV (2014-2018)		HCV (2014-2018)		HIV (2014-2018)		HTLV (2014-2018)		PIS/active syphilis (2014-2018)*	
Region of birth	Number	%	Number	%	Number	%	Number	%	Number	%
Australia	50	12.6	204	73.1	10	45.5	3	20.0	32	69.6
Overseas born										
Other Oceania	43	10.8	11	3.9	2	9.1	0	0.0	2	4.3
United Kingdom and Ireland	1	0.3	11	3.9	0	0.0	0	0.0	0	0.0
Other Europe	36	9.0	6	2.2	3	13.6	0	0.0	1	2.2
Middle East/North Africa	20	5.0	3	1.1	0	0.0	4	26.7	0	0.0
Sub-Saharan Africa	16	4.0	2	0.7	1	4.5	0	0.0	2	4.3
South & North East Asia	156	39.2	13	4.7	2	9.1	2	13.3	2	4.3
Southern and Central Asia	76	19.1	20	7.2	3	13.6	6	40.0	2	4.3
North America	0	0.0	1	0.4	0	0.0	0	0.0	0	0.0
South/Central America and the Caribbean	0	0.0	0	0.0	1	4.5	0	0.0	0	0.0
Total with a reported country of birth	398	100.0	271	97.1	22	100.0	15	100.0	41	89.1
Not reported	0.00	0.0	8.00	3.0	0.00	0.0	0.00	0.0	5.00	11.0
Total	398	100	279	100	22	100	15	100	46	100

^ Region of birth from the Australian Bureau of Statistics

* Of note, during the five-year period, 2014-2018, there were 48 donors positive for PIS/active syphilis; however, information is available for only three out of five donors positive for active syphilis in 2014, therefore the total comes to 46.

Note: Percentages may not add to exactly 100% due to rounding

Supplementary Table 9 Number and percentage of transfusion-transmissible infections among first time donors, by potential reported exposure category and sex, 2018

	HBV (2018)				HCV (2018)				HIV (2018)				HTLV (2018)				Potentially infectious syphilis (2018)			
Exposure categories	M	F	Total	%	M	F	Total	%	M	F	Total	%	M	F	Total	%	M	F	Total	%
Ethnicity/Country of birth	44	16	60	96.8	0	0	0	0.0	0	0	0	0.0	2	0	2	100.0	0	0	0	0.0
Intravenous drug user	0	0	0	0.0	6	3	9	28.1	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0
Tattoo/Piercing	1	0	1	1.6	5	4	9	28.1	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0
Partners with any risks or known to be positive	0	0	0	0.0	0	1	1	3.1	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0
Partner with unspecified risks	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0	3	0	3	100.0
Male-to-male sexual contact	0	0	0	0.0	0	0	0	0.0	1	0	1	25.0	0	0	0	0.0	0	0	0	0.0
Exposure in health care setting	0	0	0	0.0	0	2	2	6.3	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0
Engaged in sex work	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0
Blood or tissue recipient	0	0	0	0.0	1	0	1	3.1	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0
Household contact	0	0	0	0.0	0	1	1	3.1	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0
Other blood to blood contact	0	0	0	0.0	2	0	2	6.3	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0
Other	0	0	0	0.0	2	1	3	9.4	0	2	2	50.0	0	0	0	0.0	0	0	0	0.0
No risk factors identified/Unknown	1	0	1	1.6	2	2	4	12.5	1	0	1	25.0	0	0	0	0.0	0	0	0	0.0
Not reported	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0
Total	46	16	62	100	18	14	32	100	2	2	4	100	2	0	2	100	3	0	3	100

Note: Percentages may not add to exactly 100% due to rounding

Supplementary Table 10 Number and percentage of transfusion-transmissible infections among first time donors, by potential reported exposure category and sex, 2014-2018

	HBV (2014-2018)				HCV (2014-2018)				HIV (2014-2018)				HTLV (2014-2018)				PIS/active syphilis (2014-2018)*			
Exposure categories	M	F	Total	%	M	F	Total	%	M	F	Total	%	M	F	Total	%	M	F	Total	%
Ethnicity/Country of birth	213	88	301	92.9	5	1	6	3.2	0	1	1	9.1	10	1	11	84.6	0	0	0	0.0
Intravenous drug user	0	0	0	0.0	35	9	44	23.2	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0
Tattoo/Piercing	2	2	4	1.2	31	21	52	27.4	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0
Partners with any risks or known to be positive	4	2	6	1.9	3	4	7	3.7	2	1	3	27.3	0	2	2	15.4	0	1	1	5.3
Partners with unspecified risks	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0	8	4	12	63.2
Male-to-male sexual contact	0	0	0	0.0	0	0	0	0.0	2	0	2	18.2	0	0	0	0.0	3	0	3	15.8
Exposure in health care setting	1	2	3	0.9	7	7	14	7.4	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0
Engaged in sex work	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0
Blood or tissue recipient	0	0	0	0.0	7	7	14	7.4	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0
Household contact	2	3	5	1.5	5	3	8	4.2	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0
Other blood to blood contact	0	0	0	0.0	4	0	4	2.1	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0
Other	1	1	2	0.6	14	5	19	10.0	0	3	3	27.3	0	0	0	0.0	0	0	0	0.0
No risk factors identified/Unknown	2	1	3	0.9	13	6	19	10.0	1	0	1	9.1	0	0	0	0.0	3	0	3	15.8
Not reported	0	0	0	0.0	3	0	3	1.6	0	1	1	9.1	0	0	0	0.0	0	0	0	0.0
Total	225	99	324	100.0	127	63	190	100	5	6	11	100	10	3	13	100	14	5	19	100

* Of note, during the five-year period, 2014-2017, there were 20 first-time donors positive for PIS/active syphilis; however, information is available for only one out of two first-time donors positive for active syphilis in 2014, therefore the total comes to 19.

Note: Percentages may not add to exactly 100% due to rounding

Supplementary Table 11 Number and percentage of transfusion-transmissible infections among repeat donors, by potential reported exposure category and sex, 2018

	HBV (2018)				HCV (2018)				HIV (2018)				HTLV (2018)				Active Syphilis (2018)			
Exposure categories	M	F	Total	%	M	F	Total	%	M	F	Total	%	M	F	Total	%	M	F	Total	%
Ethnicity/Country of birth	9	3	12	70.6	0	1	1	4.8	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0
Intravenous drug user	1	0	1	5.9	2	0	2	9.5	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0
Tattoo/Piercing	0	0	0	0.0	2	3	5	23.8	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0
Partners with any risks or known to be positive	1	0	1	5.9	0	2	2	9.5	0	0	0	0.0	0	1	1	100.0	0	0	0	0.0
Partner with unspecified risks	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0	2	0	2	33.3
Male-to-male sexual contact	0	0	0	0.0	0	0	0	0.0	2	0	2	66.7	0	0	0	0.0	2	0	2	33.3
Exposure in health care setting	0	0	0	0.0	1	2	3	14.3	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0
Engaged in sex work	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0
Blood or tissue recipient	0	0	0	0.0	0	1	1	4.8	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0
Household contact	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0
Other blood to blood contact	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0
Other	1	0	1	5.9	0	1	1	4.8	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0
																	0	0		
No risk factors identified/Unknown	2	0	2	11.8	4	2	6	28.6	1	0	1	33.3	0	0	0	0.0	1	1	2	33.3
Not reported	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0
Total	14	3	17	100	9	12	21	100	3	0	3	100	0	1	1	100	5	1	6	100

Note: Percentages may not add to exactly 100% due to rounding

Supplementary Table 12 Number and percentage of transfusion-transmissible infections among repeat donors, by potential reported exposure category and sex, 2014-2018

	HBV (2014-2018)				HCV (2014-2018)				HIV (2014-2018)				HTLV (2014-2018)				PIS/Active Syphilis (2014-2018)*			
Exposure categories	M	F	Total	%	M	F	Total	%	M	F	Total	%	M	F	Total	%	M	F	Total	%
Ethnicity/Country of birth	39	14	53	71.6	0	1	1	1.1	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0
Intravenous drug user	2	0	2	2.7	22	3	25	28.1	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0
Tattoo/Piercing	1	0	1	1.4	6	8	14	15.7	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0
Partners with any risks or known to be positive	6	0	6	8.1	1	7	8	9.0	1	1	2	18.2	0	2	2	100.0	3	2	5	18.5
Partners with unspecified risks	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0	6	3	9	33.3
Male-to-male sexual contact	0	0	0	0.0	0	0	0	0.0	5	0	5	45.5	0	0	0	0.0	2	0	2	7.4
Exposure in health care setting	2	2	4	5.4	4	4	8	9.0	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0
Engaged in sex work	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0
Blood or tissue recipient	0	0	0	0.0	3	4	7	7.9	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0
Household contact	0	0	0	0.0	3	1	4	4.5	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0
Other blood to blood contact	0	0	0	0.0	1	0	1	1.1	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0
Other	2	2	4	5.4	3	3	6	6.7	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0
No risk factors identified/Unknown	3	1	4	5.4	7	7	14	15.7	4	0	4	36.4	0	0	0	0.0	9	2	11	40.7
Not reported	0	0	0	0.0	1	0	1	1.1	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0
Total	55	19	74	100	51	38	89	100	10	1	11	100	0	2	2	100	20	7	27	100

* Of note, during the five-year period, 2014-2018, there were 28 repeat donors positive for PIS/active syphilis; however, information is available for only two out of three repeat donors positive for active syphilis in 2014, therefore the total comes to 27.
Note: Percentages may not add to exactly 100% due to rounding

This page intentionally left blank

Supporting information for transfusion-transmissible infections surveillance report

Blood donation: from volunteer to recipient

In Australia, blood donations from each state and territory are processed and tested at one of the four Lifeblood processing centres. Each of the states (excepting Tasmania and South Australia) has a processing centre in their capital city. Blood donations collected during the period of the report in South Australia and Tasmania were sent to Melbourne for testing while those collected in the Australian Capital Territory and Northern Territory were sent to Sydney for testing and further processing.

Australian volunteer blood donors may be aged 16 to 80 years of age. Each donor is required to self-complete a comprehensive donor questionnaire every time they donate. A slightly different process is used for regular plasmapheresis donors (see Additional Information for more detail). The questionnaire is reviewed to determine eligibility and a legally binding Declaration Form is signed in the presence of a Lifeblood staff member prior to donation. There are penalties including fines and imprisonment for anyone providing false or misleading information. The questionnaire asks about various medical conditions, travel history and behaviours related to increased risk of a blood-borne infection. Lifeblood is highly reliant on the donor's complete and truthful answers to all interview questions (i.e. 'compliance'). This is particularly important for questions relating to risk behaviour for transfusion-transmissible infection given the existence of the testing window period (see below). Should a donor in the window period fail to truthfully answer a question that would normally result in their deferral from donation, they will place recipients at risk because a potentially infectious unit of blood will be collected that testing will not identify.

Subsequent to satisfactorily completing the above assessment process the donor proceeds to donate. Every first-time donation is processed and undergoes mandatory tests for specific transfusion-transmissible infections (TTIs) including HBV, HCV, HIV, HTLV and syphilis. From September 2016, repeat donors donating plasma for fractionation only no longer require testing for syphilis and HTLV resulting in a different test denominator for these TTIs. Additional testing for other transfusion-transmissible infections (e.g. malaria) as well as testing for bacteria is performed on selected donations. Donations positive for mandatory screening tests are quarantined and subsequently discarded. Confirmatory testing is conducted to determine the infectious status of the donor and if positive, they are recalled for follow-up testing and counselling.

An overview of current donor selection criteria can be accessed from the Lifeblood website www.lifeblood.com.au

The 'tiered' safety approach

Internationally, blood services undertake a number of processes to minimise the risk of TTIs. Because no single process can completely eliminate the risk, scientific evidence demonstrates that a combination approach is most effective for minimising risk. In accordance with this, Lifeblood employs a four-tier approach to safety:

1. Through pre-donation public education using the www.lifeblood.com.au website, Lifeblood Community Relations staff, the media and Lifeblood National Contact Centre as well as brochures and handouts in collection facilities, donors are informed of eligibility criteria for blood donation and common reasons for deferral from donation.

2. Individuals whose behaviours or actions result in them having an increased risk of transmitting blood-borne infection are excluded by specific responses to questions asked prior to donation.

3. State-of-the-art tests are undertaken on donated blood to identify prospective donors with pre-existing infection and newly acquired infections in repeat donors.

4. Where available, physical and/or chemical measures are applied to inactivate viruses and other infectious agents (pathogen inactivation or PI). Presently PI is used for manufactured plasma products but is not routinely available in Australia for fresh blood components.

Each donation used for the manufacture of fresh blood components is tested for HBV, HCV, HIV, HTLV and syphilis. Testing of selected donors at risk for malaria (e.g. travellers to/residents of endemic countries) has also been performed since 2005. Despite incremental improvements, testing is not 100% effective in identifying infected donors. The primary limitation relates to the existence of a 'window period' (WP), defined as the period immediately after infection but before the agent is first detectable in the bloodstream. The window period varies in duration from several days (for HIV) to several weeks (for HBV) depending on the transfusion-transmissible infectious agent and the specific test used.

The addition of nucleic acid tests (NAT) to existing serological assays for HIV and HCV in June 2000 substantially reduced the WP from approximately 22 days and 66 days to approximately 9 days for HIV-1 and 5 days for HCV.[76] During 2010, Lifeblood implemented NAT for HBV DNA as a mandatory screen for all blood donations in addition to the existing HBV test (HBsAg), which reduced the HBV window period from approximately 38 to 24 days.[77] An updated NAT triplex (HIV-1/HCV/HBV) test was implemented during 2013 reducing the HBV window period to approximately 16 days. These advances incrementally lowered the risk of not detecting a recently infected donor but importantly the WP is not eliminated. Thus, despite state-of-the-art donation testing there remains a small but nonzero risk of transmission from donors with very recently acquired infection, who may test negative if they donate during the window period.

Using donation testing results, Lifeblood monitors for trends in both prevalence (i.e. the frequency of infection in first-time donors) and incidence (i.e. the rate of newly acquired infection in repeat donors). In addition, all viral positive donors are invited to participate in confidential interviews to establish likely routes of infection. Lifeblood also estimates the risk of transmission (termed 'residual risk') per unit transfused for each TTI and publishes annual updates.

Lifeblood has collected and periodically presented data about detected infections in Australian blood donors since its establishment in 1996. In 2011, a review of available data pertaining to TTIs in Australia was jointly produced by Lifeblood and the Surveillance and Evaluation Program for Public Health at the Kirby Institute. This was the first of what have now been established as annual reports that summarise data and trends for detected infections among Australian blood donors. The 2011 report included data for the period of 2005-2010 and demonstrated an overall reduction in prevalence of TTIs by almost 30% over the six years. Subsequently eight annual surveillance reports have now been published. While these focus on data from the current year they also assess for trends against the previously published data. Data on malaria testing and surveillance activity for emerging infections were also included from the 2011 report. Consistent with previous years, both the prevalence and incidence of TTIs in Australian blood donors generally remained low in 2018, with a steady or declining trend for all infections. Infected first-time donors in 2018 mostly had undiagnosed prevalent infections but a small number of recently acquired (incident) infections among repeat donors continued to be identified.

This is the ninth annual surveillance report that analyses data from the national surveillance system for blood donors maintained electronically by Lifeblood. The analysis of the previous report is extended to accommodate the most recent available data pertaining to the presence of TTIs among Australian blood donors. The report aims to inform further revision and evaluation of donor education/selection guidelines and donation testing algorithms in Australia. Finally, the residual risk estimates provide an important tool particularly for clinical stakeholders involved in patient consent for transfusion.

Objective

The main objectives of the report are to:

1. Monitor trends over time in the incidence and prevalence of TTIs in blood donors in Australia, in particular, for HCV, HBV, HIV, HTLV and syphilis, and to compare the findings from the most recent analysis with that reported for the 2009-2018 period.
2. Compare the level of TTIs in first-time and in previously negative repeat blood donors with the general population.
3. Identify and analyse the risk factors that are associated with TTIs in blood donors and compare them to the risk factors in the general population.
4. Provide estimates of the residual risk of infection in the blood supply for HCV, HBV, HIV, HTLV and syphilis.
5. Summarise the data from bacterial testing of platelets and assess the risk of transfusion-associated sepsis.
6. Estimate the rate of 'non-compliance' with TTI specific deferral questions.
7. Summarise major surveillance activity for emerging infectious disease and the Lifeblood response.

Data

This report incorporates national donation testing data on Australian blood donors for the period 2009 to 2018. Anonymous donor data for all donors who donated blood between January 2009 and December 2018 were extracted from Lifeblood's national donor database. Trends in TTIs among first-time and previously negative repeat donors were analysed for donations in the years from 2009-2018. Demographic factors associated with TTIs in blood donors were analysed for donations made in 2018 and were compared with the findings from 2014-2018. Likely routes of exposure (termed 'putative risk factors') for each TTI in blood donors were also identified and analysed. Data from the 2017 and 2018 calendar years were combined, and risk modelling conducted to derive estimates of the risk of transmission for HIV, HCV, and HTLV in Australia. As there were no incident HBV donors donating fresh blood components in the 2017-2018 period, the 2015-2018 period was used instead. Additional modelling was performed to account for the risk associated with blood components from donors with occult HBV infection (OBI). This modelling used data from January to December 2018.

Methodological notes

Age-specific rate

Age-specific rate is defined as the proportion of blood donors in a particular age group who have the infection, usually expressed per 100 000 donors in the specified age group. Age-specific rate was calculated as follows:

$$\text{Age-specific rate of HBV infection among donors aged 20-29 years} = \left(\frac{\text{Number of donors with HBV infection aged 20-29 years}}{\text{Total number of donors aged 20-29 years}} \right) \times 100\,000$$

Donor-years of observation

Data on interval between each donation by all donors who donated at least twice in 2018 were available from the Lifeblood database. For all donors with negative tests for transfusion-transmissible viral infections, donor-years of observation were calculated as the sum of all inter-donation intervals. For positive donors, donor-years of observation were calculated as the sum of all inter-donation intervals between the first negative and the positive donation.

Exposure categories

A single most important risk factor for each positive donor was identified using the primary risk factor data from the Lifeblood risk factor database. The key exposure categories for positive donors were classified as follows:

1. Intravenous drug use (IDU)
2. Country of birth (COB)/Ethnicity
3. Partners with any risks or known to be positive
4. Engaged in sex work
5. Male-to-male sexual contact
6. Blood or tissue recipient
7. Tattoo or body piercing
8. Exposure in health care setting (both occupational and non-occupational)
9. Household contact
10. Other blood to blood contact
11. Others
12. No risk factors identified
13. Not reported

For a consistent comparison of the prevalence of major exposure categories between blood donors and the general population, *Partners with any risks or known to be positive*, *Engaged in sex work* and *Male-to-male sexual contact* were combined to create a broader risk category named *Sexual contact*. Thus, from the above thirteen key categories, the following exposure groups were established to match the main exposure groups in general population for each of the transfusion-transmissible infections.

The key exposure categories modified for comparison with general population were as follows:

1. Intravenous drug use (IDU)
2. Country of birth (COB)/Ethnicity
3. Sexual contact
    a. Partners with any risks or known to be positive
    b. Engaged in sex work
    c. Male-to-male sexual contact
4. Blood or tissue recipient
5. Tattoo or body piercing
6. Exposure in health care setting
7. Household contact
8. Other blood to blood contact
9. Others
10. No risk factors identified
11. Not reported

Incidence

Incidence of TTI is defined as a rate per 100 000 donor-years of observation. It was calculated as follows:

$$\text{Incidence per 100 000 donor-years of observation} = \left(\frac{\text{Number of incident donors}}{\text{Total donor-years of observation}} \right) \times 100\,000$$

Incidence rate of any TTI over the five-year period, 2014-2018, was calculated as follows:

$$\text{Incidence per 100 000 donor-years of observation} = \left(\frac{\text{Total number of incident donors in 2014-2018}}{\text{Average of 2014-2018 total donor-years of observation}} \right) \times 100\,000$$

Of note, the methodology for calculating incidence was modified in last year's report due to a change in methodology to calculate the donor-years of observation (DYO) and includes the inter-donation intervals from the current year only. Previous reports used two years of inter-donation interval data. For this reason, updated data were used for a five-year period, 2014-2018, and retrospectively applied the updated DYO calculation method, that is, changing the inter-donation intervals from two years to one year for each year.

Newly acquired infection

Newly acquired infection was defined as newly diagnosed infection with evidence of a previous negative or indeterminate test result.

Newly diagnosed infection

Newly diagnosed infection was defined as the first occasion of diagnosis in Australia.

Prevalence

Prevalence is defined as the number of positive donations per 100 000 donations. It was calculated as follows:

$$\text{Prevalence in first-time donors} = \left(\frac{\text{Number of positive first time donations}}{\text{Total number of first-time donations}} \right) \times 100\,000$$

$$\text{Prevalence in all donors} = \left(\frac{\text{Number of donations (both first time and repeat) positive for a TTI marker}}{\text{Total number of accepted donations (both first time and repeat)}} \right) \times 100\,000$$

Residual risk estimates

Lifeblood routinely applies published models to derive risk estimates based on viral testing data from rolling two calendar year periods. In 2017, Lifeblood changed the method of estimating the WP risk for HIV and HCV, bringing it in line with the method for HBV adopted in 2016. This addresses the current limitation that existing models are overly conservative, estimating the probability of collecting a WP donation, rather than the more appropriate estimate of the risk of infection in a recipient. The adoption of the method of Weusten et al[28] leads generally to lower estimates and standardises the method with HBV. For HBV, there is a separate estimation of the risk associated with chronic OBI, defined as HBcAb negative or positive, HBsAg negative and HBV DNA positive outside the acute phase of infection. This risk is summed with the HBsAg WP risk to derive an overall HBV residual risk. The method is based on assessing the probability of 'non-detection' by HBV NAT and the average probability of HBV transmission from NAT non-reactive donations. NAT non detection is derived by examining HBV NAT data and assessing the frequency of prior NAT non-detectable donations from donors identified as OBI by NAT. The transmission function is based on investigation of the outcome of transfusions from blood components (termed lookback) sourced from donors with OBI.

For HTLV, there were no incident infections for the period which necessitated estimation based on the Model C method for first time and repeat donors based on the method from Seed et al.[78]

Further information is available at http://www.transfusion.com.au/adverse_events/risks/estimates.

Statistical tests to analyse trends in transfusion-transmissible infections

Trends in prevalence and incidence of transfusion-transmissible infections were examined for the ten-year period, 2009-2018, and the five-year period, 2014-2018, respectively. Poisson regression analysis was used to calculate incidence rate ratios (IRRs) and their 95% confidence intervals. A p-value of less than 0.05 was considered as statistically significant.

The trend in the total number of donations for the period 2009-2018 was examined by linear regression analysis. A p-value of less than 0.05 was considered as statistically significant.

Tabulated count data on the demographic characteristics (sex, age group, state/territory and year of donation) for all blood donors (both positive and negative donors) were retrieved for the year 2018, and five-year period, 2014-2018 (for HBV, HCV, HIV, HTLV and PIS/active syphilis). The association between demographic factors and presence of any transfusion-transmissible infections (HBV, HCV, HIV, HTLV and PIS/active syphilis) among Australian blood donors were assessed using multivariate Poisson regression model for each infection separately. The predictor variables were analysed simultaneously thus adjusting for all variables in the model. A p-value of less than 0.05 was considered as statistically significant.

References

1. The Kirby Institute. HIV, viral hepatitis and sexually transmissible infections in Australia Annual Surveillance Report 2018. The Kirby Institute, UNSW, Sydney; 2018.
2. Kirby Institute. HIV: What's new in 2018? Available at: https://data.kirby.unsw.edu.au/hiv Access date: 08 October, 2019.
3. Thyer J, Perkowska-Guse Z, Ismay S, et al. Bacterial testing of platelets–has it prevented transfusion-transmitted bacterial infections in Australia? *Vox sanguinis* 2018; 113: 13-20.
4. Tohme RA and Holmberg SD. Transmission of hepatitis C virus infection through tattooing and piercing: a critical review. *Clinical infectious diseases* 2012; 54: 1167-1178.
5. Kiely P, Margaritis AR, Seed CR, et al. Hepatitis B virus nucleic acid amplification testing of Australian blood donors highlights the complexity of confirming occult hepatitis B virus infection. *Transfusion* 2014; 54: 2084-2091. DOI: 10.1111/trf.12556.
6. Polizzotto MN, Wood EM, Ingham H, et al. Reducing the risk of transfusion-transmissible viral infection through blood donor selection: the Australian experience 2000 through 2006. *Transfusion* 2008; 48: 55-63.
7. Nguyen VTT, Razali K, Amin J, et al. Estimates and projections of hepatitis B-related hepatocellular carcinoma in Australia among people born in Asia-Pacific countries. *Journal of gastroenterology and hepatology* 2008; 23: 922-929.
8. O'Sullivan BG, Gidding HF, Law M, et al. Estimates of chronic hepatitis B virus infection in Australia, 2000. *Australian and New Zealand journal of public health* 2004; 28: 212-216.
9. Williams S, Vally H, Fielding J, et al. Hepatitis B prevention in Victoria, Australia: the potential to protect. *Euro Surveill* 2011; 16: 19879.
10. The Kirby Institute. Bloodborne viral and sexually transmitted infections in Aboriginal and Torres Strait Islander people: Annual Surveillance Report 2018 (in press). The Kirby Institute, UNSW Sydney; 2018. 2018.
11. Razali K, Amin J, Dore G, et al. Modelling and calibration of the hepatitis C epidemic in Australia. *Statistical Methods in Medical Research* 2009; 18: 253-270.
12. Communicable Diseases Network of Australia. National Bloodborne Viruses and Sexually Transmissible Infections Surveillance and Monitoring Plan 2014 – 2017. In: (AHPPC) AHPPC, editor. Canberra, Australia 2015.
13. Hoad VC, Guy RJ, Seed CR, Harley R. Tattoos, blood-borne viruses and blood donors: a blood donor cohort and risk assessment. Vox Sang. 2019 Aug 8. PubMed PMID: 31396975.
14. Kirby Institute. HIV, viral hepatitis and sexually transmissible infections in Australia: annual surveillance report 2017. Sydney: Kirby Institute, UNSW Sydney; 2017.
15. Gallo RC. History of the discoveries of the first human retroviruses: HTLV-1 and HTLV-2. *Oncogene* 2005; 24: 5926-5930.
16. Feuer G and Green PL. Comparative biology of human T-cell lymphotropic virus type 1 (HTLV-1) and HTLV-2. *Oncogene* 2005; 24: 5996-6004.
17. Bastian I, Hinuma Y and Doherty RR. HTLV-I among Northern Territory aborigines. *The Medical journal of Australia* 1993; 159: 12-16.
18. Einsiedel L, Spelman T, Goeman E, et al. Clinical associations of Human T-lymphotropic Virus type 1 infection in an indigenous Australian population. *PLoS Negl Trop Dis* 2014; 8: e2643.
19. Davies J, Jabbar Z, Gagan F, et al. Blood-borne viruses in the haemodialysis-dependent population attending Top End Northern Territory facilities 2000–2009. *Nephrology* 2012; 17: 501-507.

20. Einsiedel LJ, Pham H, Woodman RJ, et al. The prevalence and clinical associations of HTLV-1 infection in a remote Indigenous community. *The Medical journal of Australia* 2016; 205: 305.

21. May J, Stent G and Schnagl R. Antibody to human T-cell lymphotropic virus type I in Australian aborigines. *The Medical journal of Australia* 1988; 149: 104-104.

22. Verdonck K, González E, Van Dooren S, et al. Human T-lymphotropic virus 1: recent knowledge about an ancient infection. *The Lancet infectious diseases* 2007; 7: 266-281.

23. Tang AR, Taylor GP, Dhasmana D. Self-Flagellation as Possible Route of Human T-Cell Lymphotropic Virus Type-1 Transmission. Emerging Infectious Diseases. 2019;25(4):811.

24. Styles CE, Hoad VC, Denham-Ricks P, Brown D, Seed CR. Self-Flagellation as Possible Route of Human T-Cell Lymphotropic Virus Type 1 Transmission. 2019;25(10):1996-7.

25. Ratnam S. The laboratory diagnosis of syphilis. *Canadian Journal of Infectious Diseases and Medical Microbiology* 2005; 16: 45-51.

26. Australian Government Department of Health. Syphilis - infectious (primary, secondary and early latent), less than 2 years duration case definition, 2015. Available at: http://www.health.gov.au/internet/main/publishing.nsf/Content/cda-surveil-nndss-casedefs-cd_syphl2.htm Access date: 12 September, 2016.

27. Seed C and Kiely P. A method for estimating the residual risk of transfusion-transmitted HBV infection associated with occult hepatitis B virus infection in a donor population without universal anti-HBc screening. *Vox sanguinis* 2013; 105: 290-298.

28. Weusten J, Vermeulen M, van Drimmelen H, et al. Refinement of a viral transmission risk model for blood donations in seroconversion window phase screened by nucleic acid testing in different pool sizes and repeat test algorithms. *Transfusion* 2011; 51: 203-215.

29. Seed C, Kiely P and Keller A. Residual risk of transfusion transmitted human immunodeficiency virus, hepatitis B virus, hepatitis C virus and human T lymphotrophic virus. *Internal medicine journal* 2005; 35: 592-598.

30. Seed C, Kiely P, Hoad V, et al. Refining the risk estimate for transfusion-transmission of occult hepatitis B virus. *Vox Sanguinis* 2017; 112: 3-8.

31. Seed C, Kee G, Wong T, et al. Assessing the safety and efficacy of a test-based, targeted donor screening strategy to minimize transfusion transmitted malaria. *Vox sanguinis* 2010; 98: e182-e192.

32. Stickland J, Roberts A and Williams V. Transfusion-induced malaria in Victoria. *The Medical journal of Australia* 1992; 157: 499-500.

33. Eder AF, Kennedy JM, Dy BA, et al. Bacterial screening of apheresis platelets and the residual risk of septic transfusion reactions: the American Red Cross experience (2004-2006). *Transfusion* 2007; 47: 1134-1142.

34. Kuehnert MJ, Roth VR, Haley NR, et al. Transfusion-transmitted bacterial infectionin the United States, 1998 through 2000. *Transfusion* 2001; 41: 1493-1499.

35. Wood E. Prevention of bacterial contamination, including initial flow diversion. *ISBT Science Series* 2009; 4: 221-229.

36. Satake M, Mitani T, Oikawa S, et al. Frequency of bacterial contamination of platelet concentrates before and after introduction of diversion method in Japan. *Transfusion* 2009; 49: 2152-2157.

37. Borosak M and Wood E. Bacterial pre-release testing of platelets–the Australian Red Cross Blood Service clinical experience. *Transfusion Medicine and Hemotherapy* 2011; 38: 239-241.

38. Thomson A, Farmer S, Hofmann A, et al. Patient blood management–a new paradigm for transfusion medicine? *ISBT Science Series* 2009; 4: 423-435.

39. Busch MP, Bloch EM and Kleinman S. Prevention of transfusion-transmitted infections. *Blood* 2019; 133: 1854-1864.

40. Horth RZ, Jones JM, Kim JJ, et al. Fatal Sepsis Associated with Bacterial Contamination of Platelets - Utah and California, August 2017. *MMWR Morbidity and mortality weekly report* 2018; 67: 718-722. DOI: 10.15585/mmwr.mm6725a4.

41. Benjamin R, Dy B, Perez J, et al. Bacterial culture of apheresis platelets: a mathematical model of the residual rate of contamination based on unconfirmed positive results. *Vox sanguinis* 2014; 106: 23-30.

42. Lanteri MC and Busch MP. Dengue in the context of "safe blood" and global epidemiology: to screen or not to screen? *Transfusion* 2012; 52: 1634-1639.

43. Queensland Government Queensland Health. Dengue outbreaks. Available at: https://www.health.qld.gov.au/clinical-practice/guidelines-procedures/diseases-infection/diseases/mosquito-borne/dengue/dengue-outbreaks Access date: 13 August, 2019.

44. Queesnland Government Queensland Health. Dengue fever update: Rockhampton. Available at: https://www.health.qld.gov.au/cq/about/news/articles/dengue-fever-update-rockhampton Access date: 5 August, 2019.

45. Marka A, Diamantidis A, Papa A, et al. West Nile virus state of the art report of MALWEST Project. *International journal of environmental research and public health* 2013; 10: 6534-6610.

46. European Centre for Disease Prevention and Control. Historical data by year - West Nile fever seasonal surveillance. Available at: https://ecdc.europa.eu/en/west-nile-fever/surveillance-and-disease-data/historical Access date: 28 June, 2019.

47. Kiely P, Gosbell IB, Hoad VC, et al. Modelling the Transfusion-Transmission Risk of West Nile Virus in Australia Associated with Travelling Donors. In: *Transfusion* 2018, pp.203A-204A.

48. Young JR, Selvey CE and Symons R. Hendra virus. *The Medical journal of Australia* 2011; 195: 250.

49. Queensland Government. Queensland Business. Summary of Hendra virus incidents in horses. Available at: https://www.business.qld.gov.au/industries/service-industries-professionals/service-industries/veterinary-surgeons/guidelines-hendra/incident-summary Access date: 13 August, 2019.

50. Mohd HA, Al-Tawfiq JA and Memish ZA. Middle East Respiratory Syndrome Coronavirus (MERS-CoV) origin and animal reservoir. *Virology journal* 2016; 13: 1.

51. World Health Organization. MERS Situation Update. Available at: http://applications.emro.who.int/docs/EMROPub_MERS_June_2019_EN_23811.pdf?ua=1 Access date: 13 August, 2019. 2019.

52. World Health Organization. WHO MERS Global Summary and Assessment of Risk. August 2018. Available at: https://www.who.int/csr/disease/coronavirus_infections/risk-assessment-august-2018.pdf?ua=1&ua=1 Access date: 28 June, 2019.

53. World Health Organization. Middle East respiratory syndrome coronavirus (MERS-CoV) – The Kingdom of Saudi Arabia - Disease Outbreak News: Update 17 May 2019. Avaliable at: https://www.who.int/csr/don/17-may-2019-mers-saudi-arabia/en/ Access date: 28 June, 2019

54. FluTrackers.com. Case List of MoH/WHO Novel Coronavirus MERS Announced Cases. Available at: https://flutrackers.com/forum/forum/novel-coronavirus-ncov-mers-2012-2014/146270-case-list-of-moh-who-novel-coronavirus-mers-announced-cases?t=205075 Access date: 28 June, 2019.

55. European Centre for Disease Prevention and Control. Severe respiratory disease associated with Middle East respiratory syndrome coronavirus (MERS-CoV). 22nd update, 29 August 2018. Available at: https://ecdc.europa.eu/sites/portal/files/documents/RRA-Severe-respiratory-disease-associated-MERS-CoV-22nd%20update-29-aug-2018.pdf Access date: 28 June, 2019.

56. World Health Organization. Ebola outbreak 2014-2015. Available at: https://www.who.int/csr/disease/ebola/en/ Access date: 6 August, 2018.

57. World Health Organization. Ebola situation reports: Democratic Republic of the Congo. Updated 25 May 2019. Available at: https://www.who.int/ebola/situation-reports/drc-2018/en/ Access date: 13 August, 2019.

58. World Health Organization. Ebola outbreak in the Democratic Republic of the Congo declared a Public Health Emergency of International Concern. Available at: https://www.who.int/news-room/detail/17-07-2019-ebola-outbreak-in-the-democratic-republic-of-the-congo-declared-a-public-health-emergency-of-international-concern Access date: 5 August, 2019.

59. Musso D and Gubler DJ. Zika virus. *Clinical microbiology reviews* 2016; 29: 487-524.

60. Chang C, Ortiz K, Ansari A, et al. The Zika outbreak of the 21st century. *Journal of autoimmunity* 2016; 68: 1-13.

61. Pan American Health Organization / World Health Organization. Zika suspected and confirmed cases reported by countries and territories in the Americas Cumulative cases, 2015-2016. Updated as of 18 August 2016. Washington, D.C.: PAHO/WHO; 2016; Pan American Health Organization. www.paho.org. © PAHO/WHO, 2016.

62. Australian Government, Department of Health. Summary information about overseas-acquired vectorborne disease notifications in Australia. Overseas - acquired vectorborne disease notifications in Australia - Fortnight ending 23 March 2019. Available at: https://www.health.gov.au/internet/main/publishing.nsf/Content/ohp-vectorborne-overseas-acquired.htm Access date: 28 May, 2019.

63. Plourde A and Bloch E. A Literature Review of Zika Virus. *Emerging infectious diseases* 2016; 22.

64. Baud D, Gubler DJ, Schaub B, et al. An update on Zika virus infection. *The Lancet* 2017 Nov 4;390(10107):2099-2109.

65. Barjas-Castro ML, Angerami RN, Cunha MS, et al. Probable transfusion-transmitted Zika virus in Brazil. *Transfusion* 2016; 56: 1684-1688.

66. Motta IJ, Spencer BR, Cordeiro da Silva SG, et al. Evidence for transmission of Zika virus by platelet transfusion. *New England Journal of Medicine* 2016; 375: 1101-1103.

67. Hall-Mendelin S, Pyke AT, Moore PR, et al. Assessment of Local Mosquito Species Incriminates Aedes aegypti as the Potential Vector of Zika Virus in Australia. *PLoS Negl Trop Dis* 2016; 10: e0004959.

68. Baggoley C, Knope K, Colwell A, et al. Zika preparedness in Australia. *The Medical journal of Australia* 2016; 204: 249.

69. World Health Organization. Disease outbreak news, 2 May 2018. Listeriosis – South Africa. Available at: http://www.who.int/csr/don/02-may-2018-listeriosis-south-africa/en/ Access date: 2 July, 2018.

70. Food Safety News. Listeriosis death prompts investigation, closure of hospital catering company. 23 February 2019. Available at: https://www.foodsafetynews.com/2019/02/listeriosis-death-prompts-investigation-closure-of-hospital-catering-company/ Access date: 28 May, 2019.

71. Cheng VC, Sridhar S, Wong S-C, et al. Japanese encephalitis virus transmitted via blood transfusion, Hong Kong, China. *Emerging infectious diseases* 2018; 24: 49.

72. Australian Government, Department of Health. National notifiable diseases surveillance system, 2018. Available at: http://www9.health.gov.au/cda/source/cda-index.cfm Access date: 5 August, 2019.

73. Styles CE, Hoad VC, Gorman E, et al. Modeling the parvovirus B19 blood safety risk in Australia. *Transfusion* 2019; 59: 295-302.

74. Hoad V, Seed C, Fryk J, et al. Hepatitis E virus RNA in Australian blood donors: prevalence and risk assessment. *Vox sanguinis* 2017; 112: 614-621.

75. Jayawardena T, Hoad V, Styles C, et al. Modelling the risk of transfusion-transmitted syphilis: a reconsideration of blood donation testing strategies. *Vox sanguinis* 2019; 114: 107-116.

76. Busch MP, Glynn SA, Stramer SL, et al. A new strategy for estimating risks of transfusion-transmitted viral infections based on rates of detection of recently infected donors. *Transfusion* 2005; 45: 254-264.

77. Kleinman SH and Busch MP. Assessing the impact of HBV NAT on window period reduction and residual risk. *Journal of clinical virology* 2006; 36: S23-S29.

78. Seed CR, Kiely P and Keller AJ. Residual risk of transfusion transmitted human immunodeficiency virus, hepatitis B virus, hepatitis C virus and human T lymphotrophic virus. *Intern Med J* 2005; 35: 592-598.

This page intentionally left blank

Design: **Il Razzo** Telephone: **0407 210 388** E- mail: **admin@ilrazzo.com.au**