Transfusion-transmissible infections in Australia

2020

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: 2020 Surveillance Report. Kirby Institute, UNSW Sydney, and Australian Red Cross Lifeblood; 2020

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ISSN 2203-0751 (Online)

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Acknowledgements

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

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

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

Foreword

This report is jointly produced by 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 report 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 low in 2019 (n=194). Of these, 85% 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 2019 continues to be substantially (8-37 times) lower than the estimated national population prevalence for 2018/19. Six (3.1%) of all infections in 2019 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, 2015-2019.

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 2019, ~18% had risk factors identified in their post-donation interview which were not disclosed in their initial donation interview (termed 'noncompliance'). 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.[1] Accordingly, Lifeblood implemented an electronic donor questionnaire across almost all blood collection sites in December 2019.

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.

Injecting drug use
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 'Seroreversion' definition on page 7).

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 donor 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 tested positive to the relevant transfusion-transmissible infection consistent with national case definitions.

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 2010-2019, there were over 13 million blood donations in Australia with an average of 1.3 million donations per year. Over the past ten years, 2010-2019, there has been no significant change in the total number of donations (see Methodological Notes for details). Total blood donations in 2019 increased by 7% (representing 98 652 more donations) compared to 2018, most of which were plasma donations.
2. Of the 'age-eligible' Australian population (aged between 18-80 years), 2.6% donated blood during 2019.
3. On average, first-time and repeat donors comprised 14.2% and 85.8% of all blood donors in Australia over the period 2010-2019, respectively. Although the ratio of first-time donors declined gradually over the past ten years, from 15.6% in 2010 to 13.2% in 2014 and 11.9% in 2018, there was an increase in 2019, to 14.5%. Male donors constituted 48.9% of all donors in 2019, which aligns with 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 2019, a total of 191 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 2019, three donors were infected by more than one TTI (two with HBV and HCV, and one with HCV and HTLV, co-infections), making a total of 194 TTIs detected. In the ten-year period 2010-2019 a total of 1 803 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 2019, 84.5% were positive for either HBV or HCV, a slight decrease from 87.4% in 2018.
3. Overall HTLV was the least common infection among all donors in 2019, with just five donors testing positive. In the ten-year period 2010-2019, HTLV was the least common infection among all donors (35 positive donors); and HIV was the least common infection in the first-time donors (23 positive donors).
4. Although representing only 14.5% of the donor population, first-time blood donors contributed to 79% of TTIs in Australia in 2019, as compared to the 68% in 2018. This proportion has remained relatively stable since 2010 (67%-80%).
5. No transfusion-transmitted HIV, HCV, HTLV or syphilis infections were reported in Australia during 2010-2019.
6. Consistent with previous years, in 2019, the prevalence of TTIs was substantially lower among first-time blood donors (8 to 37 times) compared with national prevalence estimates for 2018.

* see 'Potentially infectious syphilis' definition in the Glossary section

HBV infection among Australian blood donors

1. There were 90 HBV infections detected among all donations in 2019 (71 in first-time donors and 19 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 2019 decreased by 11% as compared to that observed in 2018, 67.7 versus 76.2 per 100 000 donations, respectively. This equates to 0.07% of the total first-time donations in 2019, which is 13 times lower than the estimated 0.9% prevalence reported in national HBV surveillance data for 2018.[2]
4. Among the 90 HBV infections, 29 (12 first-time and 17 repeat donors) were classified as occult HBV (OBI) based on the detection of HBV DNA without HBsAg. Most donors (25) were Asian-born (72%) men with an average age of 49.2 years.
5. Incident HBV donors continue to be rare with only two recorded nationally in 2019, giving an incidence rate of 0.6 per 100 000 donor-years of observation, similar to that observed in 2018. There was no significant temporal trend in HBV donor incidence nationally or in any state/territory during the five-year study period 2015-2019.
6. In 2019, HBV positive donors were slightly younger as compared to all donors (40 years versus the mean age 43 years), more likely to be male (81% in hepatitis B positive donors versus 49% in all donors) and more likely to be born in the Northeast/Southeast Asia (44%). 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, 2015-2019, was ethnicity/country of birth (92%). In Australia, an estimated 43% of people living with hepatitis B were born in the Northeast/Southeast Asia at the end of 2018.[3]
8. No transfusion-transmitted HBV infections were recorded in 2019. One probable case (in 2011) was reported in the 2010-2019 period (see Transfusion-transmissible infections in Australia 2017 Surveillance Report for details).

HCV infection among Australian blood donors

1. There were 74 HCV infections detected among all donors in 2019 (67 in first-time donors and 7 in repeat donors). In 2019, the proportion of HCV RNA positive (potentially infectious) donors was 47%, a marked increase as compared to 32% in 2018. Nonetheless, 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 2010-2019, no significant trend was observed in HCV prevalence in first-time donors in Australia. However, HCV prevalence in first-time donors increased to 63.9 per 100 000 donations in 2019 as compared to 39.36 per 100 000 observed in 2018. This increase is likely to be a result of two factors. Firstly, there was an increase in the number of prospective donors with 'resolved' HCV (HCV antibody positive/RNA negative) presenting to donate subsequent to successful treatment. Secondly, a change to the blood donation deferral for IDU, from indefinite to a five-year deferral from last injection, could have led to an increase in newly eligible donors with undiagnosed HCV. The 0.06% first-time donor prevalence in 2019 is eight times lower than the estimated 0.5% reported for HCV national surveillance data for 2018. This decreasing donor HCV prevalence trend is consistent with national HCV new-diagnoses notification rate (from 50 per 100 000 in 2009 to 38 per 100 000 in 2018).[2]
4. In 2019, there were seven repeat donors who tested positive but only one met the incidence definition. The average incidence rate of HCV among previously negative repeat donors during 2015-2019 was very low at 0.57 per 100 000 donor-years of observation (see Methodological Notes for details). HCV incidence has shown no significant trend during the study period, 2015-2019.
5. In 2019, the mean age of HCV positive donors was 47 years compared to 43 years for all donors. The HCV positive donors were more likely to be male (59% versus 49% in all donors), and the majority (64%) were born in Australia.
6. The most common putative risk factor reported by donors with HCV infection during 2015-2019 was injecting drug use and tattoo/piercing (24% each). Note this reporting does not confirm causation and background tattoo prevalence likely accounts for this reporting. In comparison, for the newly acquired HCV infections in the general population, 18% had injecting drug use as their route of exposure in 2018.[3, 4]
7. No transfusion-transmitted HCV infections were reported in Australia during 2010-2019.

HIV infection among Australian blood donors

1. There were eight HIV infections detected among all donations in 2019 (four first-time and four repeat donors).
2. The prevalence of HIV infection among first-time donors during 2010-2019 remained very low at 2.2 per 100 000 donations (or 0.002% of the total first-time donations) and comparatively much lower than hepatitis B (75.5 per 100 000 donations) and hepatitis C (48.3 per 100 000 donations). No significant HIV prevalence trend was observed during 2010-2019. The 0.002% HIV prevalence in first-time donors is 37 times lower than the 0.1% prevalence reported for HIV national surveillance data in 2019.[5]
3. The incidence of HIV in 2019 was 0.9 per 100 000 donor-years of observation, similar to 2018. The increase seen in 2018 and 2019 is nearly three-fold as compared to 0.3 per 100 000 donor-years of observation in 2017. However, there is no statistically significant change to the incidence trend in the 2015-2019 period.
4. In 2019, the mean age of HIV positive donors (n=8) was 37 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 (75% vs 49%). Unlike 2018 where the majority (71%) were born overseas, in 2019 half of the HIV positive donors were born in Australia.
5. The most common reported routes of exposure for donors with HIV infection during 2015-2019 were male-to-male sex (26%) and partners with a known risk or known to be positive (26%). This compares to the new HIV diagnoses notification data in Australia where men who have sex with men accounted for 59% of new HIV diagnoses in Australia in 2019, followed by heterosexual sex (23%).[5]
6. No transfusion-transmitted HIV infections were reported in Australia during 2010-2019.

HTLV infection among Australian blood donors

1. There were five HTLV infections detected among all donations in 2019 (all in first-time donors).
2. The prevalence of HTLV infection among first-time donors during 2010-2019 has remained low at 3.18 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 2019 was zero as it was for the five-year period 2015-2019.
4. In 2019, the mean age of the five donors with HTLV infection was 44 years; the majority (60%) were male and born overseas (60%).
5. The most common putative risk factor for donors with HTLV infection during 2015-2019 was ethnicity or country of birth (63%). There are no data to compare risk factors in the general population.
6. No transfusion-transmitted HTLV infections were reported in Australia during 2010-2019.

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

1. There were 17 potentially infectious syphilis infections (7 first-time and 10 repeat donors) detected in 2019.
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, 2010-2019, or in the past five years, 2015-2019.
3. The mean age of potentially infectious syphilis positive donors in 2019 was 30 years (compared to 43 years for all donors); and they were more likely to be male as compared to all donors (82% versus 49%).
4. The most common reported route of exposure by donors with active/potentially infectious syphilis during 2015-2019 period was having a partner with an unspecified risk (37%).

Donor compliance

1. Of the TTI-positive donors in 2015-2019, 19% (152 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 accounted for 71% (108 donors) of 'non-compliant' donors.
2. The detected non-compliance rate of all TTI-positive donors has fluctuated in the past decade between 12.9 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 2019, 122 910 donations were tested for malaria antibody of which 2 373 (1.9%) were repeatedly reactive for malaria antibodies.
2. There were no reported cases of transfusion-transmitted malaria during 2019, with the last reported Australian case occurring in 1991.

Bacterial pre-release testing for platelets

1. In 2019, 115 (0.10%) of a total 120 591 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. The next most common group was coagulase-negative staphylococci, which along with propionibacteria are usually considered skin contaminants.
3. Confirmed positive pathogens included *Serratia marcescens* (2 isolates), *Bacillus cereus, Finegoldia magna, Parvimonas micra, Staphylococcus aureus, Streptococcus dysgalactiae, Streptococcus agalactiae, Streptococcus pyogenes* and *Streptococcus* species (Lancefield Group C) (1 isolate each).
4. In 2019, there were two confirmed cases of transfusion-transmitted bacterial infections.

Emerging infections

1. The ongoing risk from SARS-CoV-2, local dengue outbreaks, seasonal West Nile virus (WNV) outbreaks in Europe, outbreaks of hepatitis A virus and Zika virus have been closely monitored during 2019-2020.
2. Lifeblood implemented a number of strategies for mitigating the risk associated with overseas- and locally-acquired infections (SARS-CoV-2) or restricting donations to plasma sent for fractionation for an appropriate period (Zika).

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Abbreviations

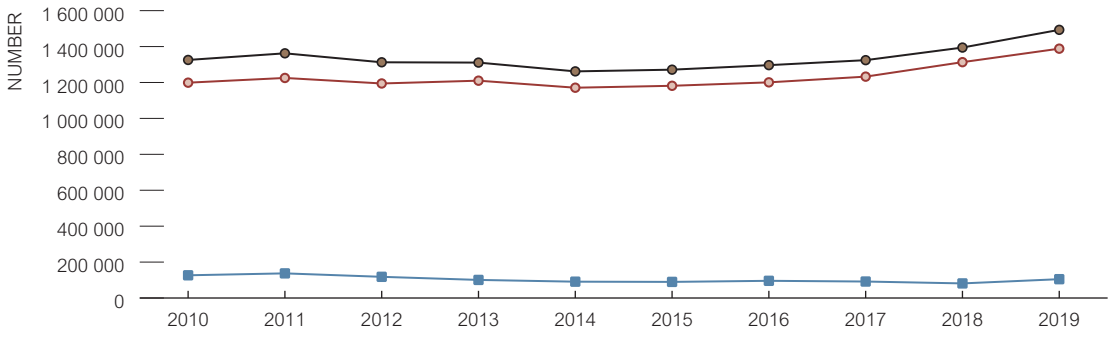
Anti-HAV	Antibody to hepatitis A
anti-HBc	antibody to hepatitis B core antigen
anti-HBe	antibody to hepatitis B e antigen
anti-HBs	antibody to hepatitis B surface antigen
anti-HeV	antibody to Hendra virus
A(H7N9)	avian influenza H7N9 virus
B19V	Parvovirus
CJD	Creutzfeldt-Jakob disease
DQ	donor questionnaire
HBeAg	hepatitis B e antigen
HBsAg	hepatitis B surface antigen
HAV	hepatitis A virus
HBV	hepatitis B virus
HCV	hepatitis C virus
HEV	hepatitis E virus
HIV	human immunodeficiency virus
HTLV	human T-lymphotropic virus
IDU	injecting drug use
Lifeblood	Australian Red Cross Lifeblood
MERS-CoV	Middle East respiratory syndrome coronavirus
NAT	nucleic acid testing
OBI	occult hepatitis B virus infection
PIS	Potentially infectious syphilis
RRV	Ross River virus
SARS-CoV	severe acute respiratory syndrome-related coronavirus
STIs	sexually-transmissible infections
TTIs	transfusion-transmissible infections
WNV	West Nile virus
WP	window period
ZIKV	Zika virus

Main Findings

Blood donors in Australia

Over 13 million donations were tested for TTIs in Australia during the ten-year period 2010-2019, with an average of 1.3 million donations per year. In 2019, the number of donations was nearly 1.5 million, an increase of 7% compared to 2018. The majority of this increase reflects an expansion in plasma collections to meet increasing demand for fractionated plasma products. Over the entire ten-year period there was no significant trend in the number of donations (Figure 1) (see Methodological Notes for details). All donations undergo mandatory testing for specific TTIs including HBV, HCV, HIV, HTLV and syphilis, however from 2016 onwards repeat donors donating plasma for fractionation only no longer require testing for syphilis and HTLV resulting in a different denominator. Therefore, a total of 1.49 million donations were tested for HBV, HCV and HIV in 2019, as compared to 0.81 million donations for HTLV and syphilis.

Figure 1 Number of blood donations in Australia by year of donation, 2010-2019



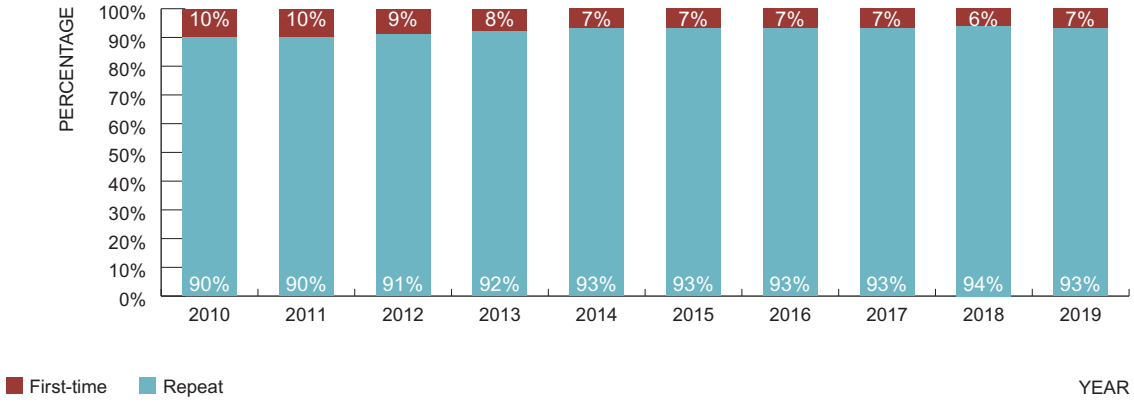
	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019
Total	1.33 M	1.36 M	1.31 M	1.31 M	1.26 M	1.27 M	1.30 M	1.32 M	1.39 M	1.49 M
First-time	0.13 M	0.14 M	0.12 M	0.10 M	0.09 M	0.09 M	0.10 M	0.09 M	0.08 M	0.10 M
Repeat	1.20 M	1.23 M	1.19 M	1.21 M	1.17 M	1.18 M	1.20 M	1.23 M	1.31 M	1.39 M

In 2019, 2.6% of the general population who were aged between 18-80 years (age-eligible to donate) donated blood in Australia. Together, New South Wales, Queensland and Victoria accounted for 76% of all blood donations. The jurisdiction where the greatest proportion of the age-eligible local population donated blood in 2019 was the Australian Capital Territory (4.9%), followed by Tasmania at 4.1% (Figure 2).

Figure 2 Percentage of age eligible general population who donated blood in 2019, by state/territory

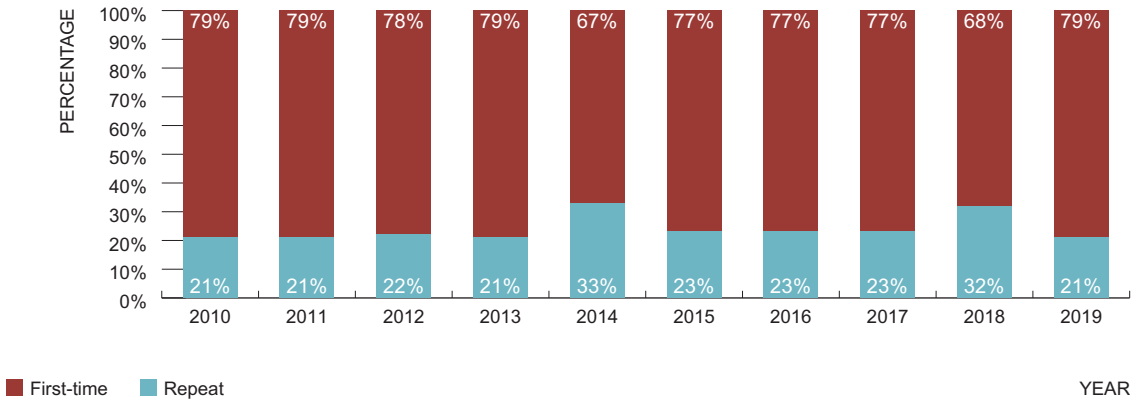
As in previous years, more than 90% of all donations in 2019 were from repeat donors (Figure 3). In the past ten years, 2010-2019, there has been a gradual decrease in the percentage of donations by first-time donors, from 10% in 2010 to 7% in 2019. While first-time blood donors represented only ~15% of the donor population, and 7% of the total donations, they contributed the majority (79%) of TTIs in Australian blood donors in 2019, 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, 2010-2019



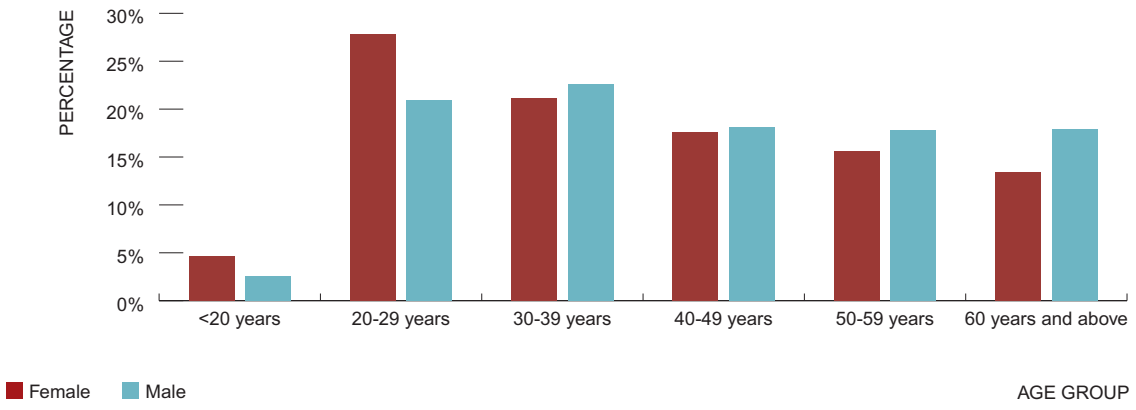
Overall, in the past ten years, the proportion of repeat donors among all TTI-positive blood donations in Australia fluctuated between 21-23% with an exception of the years 2014 and 2018, where the proportions increased to 33% and 32%, respectively (Figure 4). The increase in 2014 (33%) is explained by an anomaly in the rate of returning 'lapsed' donors, who had made their last donation prior to 1990 (when HCV testing was implemented), thus undergoing HCV testing for the first time. The substantial increase in 2018 in the proportion of repeat donors with a TTI 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. Importantly, the proportional increase in TTI-positive repeat donors in these two years was 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, 2010-2019



Among all blood donors who donated in 2019, 51.0% were female and 49.0% were male. There was a higher proportion of women among younger age groups (less than 30 years), and a higher proportion of men in donors 30 years and above (Figure 5). Over 32% 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, 2019



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, 2010-2019, overall in Australia, and trends observed in state/territory jurisdictions. In addition, the association of demographic characteristics with the presence of TTIs for the year 2019 and the five-year period 2015-2019 will be discussed. Putative risk factors associated with positive blood donors in Australia are also reported for the five-year period, 2015-2019. 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 2018, trends in the last ten years, notifications of newly diagnosed TTIs in Australia, and risk exposure categories associated with respective infections. Of note, the 2019 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 2018 data. The information is drawn from the National update on HIV, viral hepatitis and sexually transmissible infections – a summary report 2009-2018, The Kirby Institute data website, and the National Notifiable Diseases Surveillance System (NNDSS).[2-5]

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 2015-19 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.

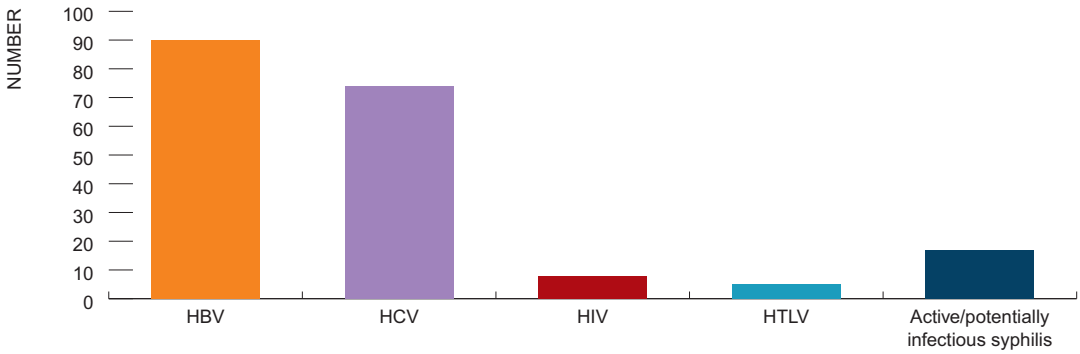
Lifeblood assesses the incidence rate of newly acquired infection in donors, since this correlates directly with the risk of transmission in the window period. Incident donors (formerly 'seroconverters') are defined as 'positive repeat donors whose last donation tested negative for the same TTI within 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.

In the ten-year period 2010-2019, a total of 1 803 donations (1 381 first-time and 422 repeat donations) were positive for at least one of the TTIs subject to mandatory donation testing. Of these, 1 676 were positive for HBV, HCV and HIV (12.5 per 100 000 donations), and 127 (1.1 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 2010-2019, (13.3 million donations for HBV, HCV and HIV, as opposed to 11.4 million donations tested for HTLV and syphilis), these data are presented separately (Table 1A and 1B). Of the positive donations, 90.1% were positive for either HBV or HCV.

In 2019, a total of 191 donors were found positive for at least one of the TTIs subject to mandatory donation testing; two donors were positive for dual HBV and HCV infections, and one donor was positive for dual HCV and HTLV infections, making a total of 194 TTIs detected in 2019. Overall, HBV and HCV were the two most frequent TTIs identified in Australian blood donors in 2019, together contributing to 84.5% of all infections (Figure 6). This proportion has decreased by a relative 9.1% as compared to 93.0% in 2009, suggesting a declining trend in the prevalence of HBV and HCV in all donors, where prevalence in all donations decreased from 9.5 in 2010 to 6.0 in 2019 for HBV and 6.4 in 2010 to 4.9 in 2019 for HCV. In 2019, HBV and HCV were the most frequent TTIs in first-time donors while HBV and active/potentially infectious syphilis were the most frequent TTIs in repeat donors.

As outlined in previous reports, 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. Prior to 2018, 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, 2015-2019 which retrospectively apply the updated DYO calculation method. During 2015-2019, a total of 24 incident donors were identified, seven for HBV, nine for HCV and eight for HIV. In 2019, a total of six incident infections were detected, two for HBV, one for HCV and three for HIV (Figure 6).

Figure 6 Number of transfusion-transmissible infections detected in blood donations in Australia, in 2019, by infection



	HBV	HCV	HIV	HTLV	Active/potentially infectious syphilis
Positive donations 2019	90	74	8	5	17

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)[1] to determine any association between demographic factors and presence of any TTI among Australian blood donors in 2019, and the five-year period, 2015-2019, 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 the more commonly reported 'risk events', these represent the background population prevalence of the event and little inference on causation should be interpreted. 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.[6] Lifeblood undertook a risk assessment which determined that the HCV incidence rate in donors returning after a tattoo was negligible.[7] Lifeblood subsequently sought, and was granted regulatory approval to amend the existing four-month donation deferral. As of September 27, 2020, where tattoos are received at an Australian licenced/registered tattoo parlour or cosmetic clinic, the donor is eligible to donate plasma for fractionation during the four months period without restriction.

This report presents risk factor data for the five-year period 2015 to 2019. A total of 799 positive donors with at least one of the TTIs were observed over the period 2015-2019. The data on these donors were analysed for the period 2015-2019 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, 2010-2019

1A HBV, HCV and HIV in Australia, by state/territory, 2010-2019

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	354 312	3 780 612	4 134 924	266	50	316	176	60	236	9	8	17	451	118	569
Number *(Number per 100 000 donations)*				*75.08*	*1.32*	*7.64*	*49.67*	*1.59*	*5.71*	*2.54*	*0.21*	*0.41*	*127.29*	*3.12*	*13.761*
NT	7 602	96 845	104 447	7	3	10	6	4	10	0	1	1	13	8	21
Number *(Number per 100 000 donations)*				*92.08*	*3.1*	*9.57*	*78.93*	*4.13*	*9.57*	*0*	*1.03*	*0.96*	*171.01*	*8.26*	*20.106*
QLD	217 878	2 497 490	2 715 368	123	22	145	108	48	156	4	8	12	235	78	313
Number *(Number per 100 000 donations)*				*56.45*	*0.88*	*5.34*	*49.57*	*1.92*	*5.75*	*1.84*	*0.32*	*0.44*	*107.86*	*3.12*	*11.527*
SA	72 676	1 184 655	1 257 331	36	14	50	35	15	50	0	2	2	71	31	102
Number *(Number per 100 000 donations)*				*49.53*	*1.18*	*3.98*	*48.16*	*1.27*	*3.98*	*0*	*0.17*	*0.16*	*97.69*	*2.62*	*8.1124*
TAS	30 969	478 223	509 192	10	3	13	16	6	22	0	0	0	26	9	35
Number *(Number per 100 000 donations)*				*32.29*	*0.63*	*2.55*	*51.66*	*1.25*	*4.32*	*0*	*0*	*0*	*83.95*	*1.88*	*6.8736*
VIC	259 909	3 044 711	3 304 620	263	49	312	127	33	160	7	8	15	397	90	487
Number *(Number per 100 000 donations)*				*101.19*	*1.61*	*9.44*	*48.86*	*1.08*	*4.84*	*2.69*	*0.26*	*0.45*	*152.75*	*2.96*	*14.737*
WA	93 260	1 233 296	1 326 556	78	21	99	33	13	46	3	1	4	114	35	149
Number *(Number per 100 000 donations)*				*83.64*	*1.7*	*7.46*	*35.38*	*1.05*	*3.47*	*3.22*	*0.08*	*0.3*	*122.24*	*2.84*	*11.232*
National	1 036 606	12 315 832	13 352 438	783	162	945	501	179	680	23	28	51	1 307	369	1 676
Number *(Number per 100 000 donations)*				*75.53*	*1.32*	*7.08*	*48.33*	*1.45*	*5.09*	*2.22*	*0.23*	*0.38*	*126.08*	*3*	*12.55*

1B HTLV and active/potentially infectious syphilis in Australia, by state/territory, 2010-2019

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	354 312	3 244 462	3 598 774	11	1	12	8	22	30	19	23	42
Number (Number per 100 000 donations)				*3.10*	*0.03*	*0.33*	*2.26*	*0.68*	*0.83*	*5.36*	*0.71*	*1.17*
NT	7 602	76 187	83 789	0	0	0	2	2	4	2	2	4
Number (Number per 100 000 donations)				*0.00*	*0.00*	*0.00*	*26.31*	*2.63*	*4.77*	*26.31*	*2.63*	*4.77*
QLD	217 878	2 098 090	2 315 968	3	0	3	8	10	18	11	10	21
Number *(Number per 100 000 donations)*				*1.38*	*0.00*	*0.13*	*3.67*	*0.48*	*0.78*	*5.05*	*0.48*	*0.91*
SA	72 676	977 460	1 050 136	1	1	2	5	0	5	6	1	7
Number *(Number per 100 000 donations)*				*1.38*	*0.10*	*0.19*	*6.88*	*0.00*	*0.48*	*8.26*	*0.10*	*0.67*
TAS	30 969	386 924	417 893	3	0	3	0	0	0	3	0	3
Number *(Number per 100 000 donations)*				*9.69*	*0.00*	*0.72*	*0.00*	*0.00*	*0.00*	*9.69*	*0.00*	*0.72*
VIC	259 909	2 552 503	2 812 412	14	0	14	12	13	25	26	13	39
Number *(Number per 100 000 donations)*				*5.39*	*0.00*	*0.50*	*4.62*	*0.51*	*0.89*	*10.00*	*0.51*	*1.39*
WA	93 260	996 581	1 089 841	1	0	1	7	3	10	8	3	11
Number *(Number per 100 000 donations)*				*1.07*	*0.00*	*0.09*	*7.51*	*0.30*	*0.92*	*8.58*	*0.30*	*1.01*
National	1 036 606	10 332 207	11 368 813	33	2	35	42	50	92	75	52	127
Number *(Number per 100 000 donations)*				*3.18*	*0.02*	*0.31*	*4.05*	*0.48*	*0.81*	*7.24*	*0.50*	*1.12*

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Hepatitis B Virus (HBV)

Epidemiology of HBV in Australia

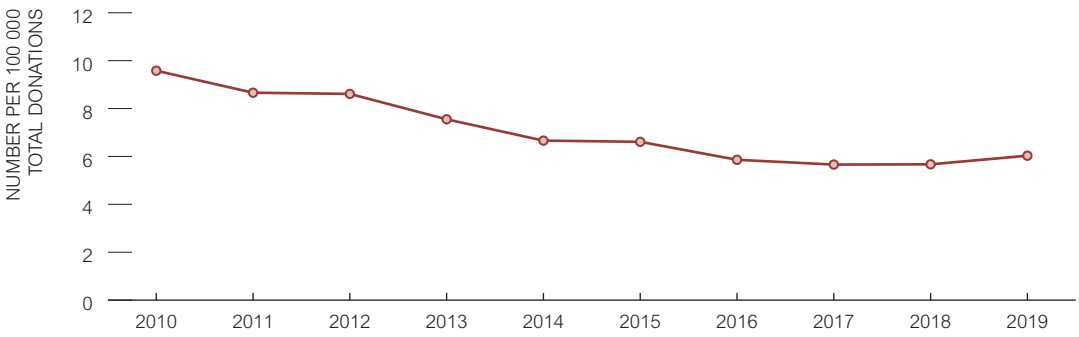
At the end of 2018, an estimated 226 566 people were living with chronic HBV infection in Australia, of whom an estimated 68% were diagnosed with chronic hepatitis B, 23% and 20% were born in the Northeast and Southeast Asia, respectively, and 7% were among Aboriginal and Torres Strait Islander peoples. In total, there were 6 045 notifications of newly diagnosed HBV infection in Australia in 2018; of these, over half (54%) were male, and 91% 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, 2009-2018, the population rate of diagnosis of HBV infection in Australia has declined in younger age groups: 25 – 29 years (from 73 to 42 per 100 000); 20 – 24 years (from 50 to 21 per 100 000); and 15 – 19 years (from 22 to 7 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 2009 to 0.6 per 100 000 in 2018. 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.[2-4]

Trends in prevalence

All donations:

In the past ten years, 2010-2019, a total of 945 HBV positive donors have been detected (783 first-time donors & 162 repeat donors) (Table 1A). During this period, the prevalence of HBV infection among all donations has declined significantly (IRR 0.94; 95% CI: 0.91-0.96). There has been an overall reduction of 37% from 2010 to 2019, from 9.6 to 6.0 per 100 000 total donations (Figure 7). This significant decline does not appear to be explained by declining first-time donor prevalence or a decline in incident donors. Predominantly, it reflects the incremental identification and deferral of repeat donors (n=121) 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.[8] For detail on the number and prevalence rate of HBV infections among all donations for 2019, see Supplementary Table 2.

Figure 7 Prevalence of HBV infection in all blood donations in Australia, 2010-2019

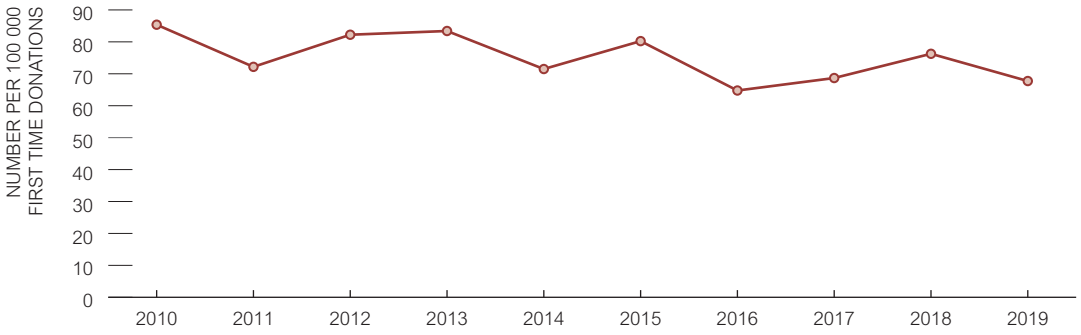


	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019
Prevalence in all donations	9.58	8.66	8.61	7.55	6.66	6.61	5.86	5.66	5.67	6.03

First-time donors:

Over the ten-year period 2010-2019, no significant annual trend is apparent in the prevalence of HBV infection among first-time donors (Figure 8) (IRR: 0.98; 95% CI: 0.95-1.00). However, the average prevalence rate shows a declining trend dropping to 75.5 per 100 000 donations (0.08% of the total first-time donations) for the period 2010-2019 (Table 1A), as compared to 80.4, 77.9 and 77.2 per 100 000 first-time donations for periods 2007-2016, 2008-2017, 2009-2018, 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 33 per 100 000 in 2009, 28 per 100 000 in 2014, and 24 per 100 000 in 2018.[2]

Figure 8 Prevalence of HBV infection in first time blood donors in Australia, 2010-2019

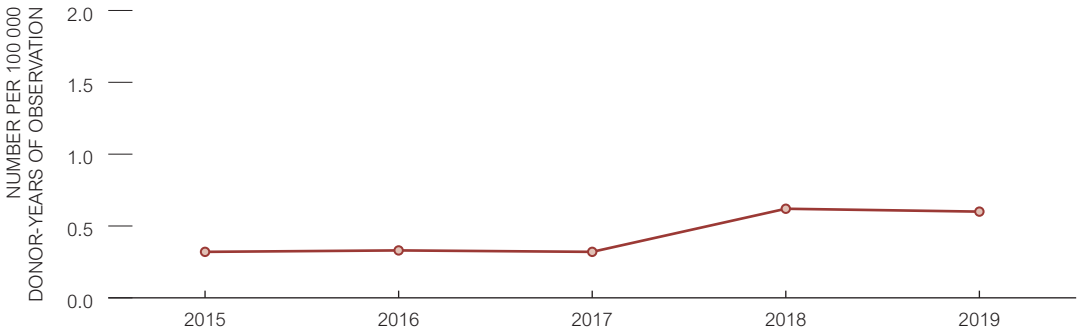


	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019
Prevalence in first-time donors	85.37	72.17	82.23	83.40	71.49	80.23	64.76	68.67	76.26	67.73

Trends in incidence

Due to a change in the methodology for calculating incidence, updated data are presented for a five-year period, 2015-2019 (see Methodological Notes for detail). For the five-year period 2015-2019, there were a total of seven incident donors detected for HBV infection with no statistically significant trend observed for incidence rates (between 0.3 and 0.6 per 100 000 donor-years of observation; (IRR: 1.21; 95% CI: 0.71-2.08) (Figure 9). In 2019, only two incident infections were detected for HBV.

Figure 9 Incidence of HBV in repeat blood donors in Australia, 2015-2019



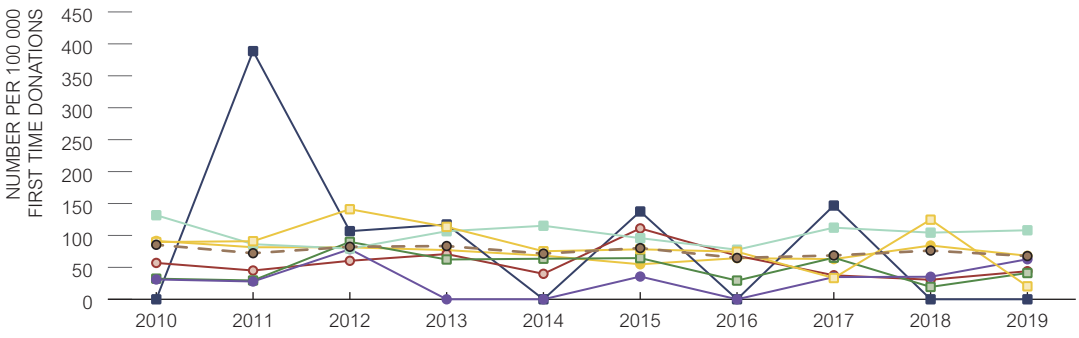
	2015	2016	2017	2018	2019
Incidence	0.32	0.33	0.32	0.62	0.60

No transfusion-transmitted HBV infections were reported in 2019. One probable case (in 2011) was reported in the 2010-2019 period. For details on this case, 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 markedly by jurisdiction in 2019. While the national prevalence was 67.7 per 100 000 donations, this ranged from 0.0 to 108.1 per 100 000 donations across jurisdictions (Figure 10). In 2019, Victoria recorded the highest prevalence of HBV infection among first-time donors (108.1 per 100 000 donations) as compared to the other states. For the ten-year period 2010-2019, the highest average prevalence rate of HBV infection among first-time donors was observed in Victoria, at 101.7 per 100 000 donations, followed by the Northern Territory at 89.7 per 100 000 donations. However, no significant trend was observed during this period in the Northern Territory and 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. The only declining annual prevalence trend was observed in Western Australia for the ten-year period, 2010-2019 (IRR: 0.92; 95% CI: 0.85-0.99). In comparison, Northern Territory had the highest rate of diagnosis of HBV infection reported in the 2018 national surveillance data (33 per 100 000 population), followed by New South Wales (30 per 100 000 population) and Victoria (27 per 100 000 population).[2]

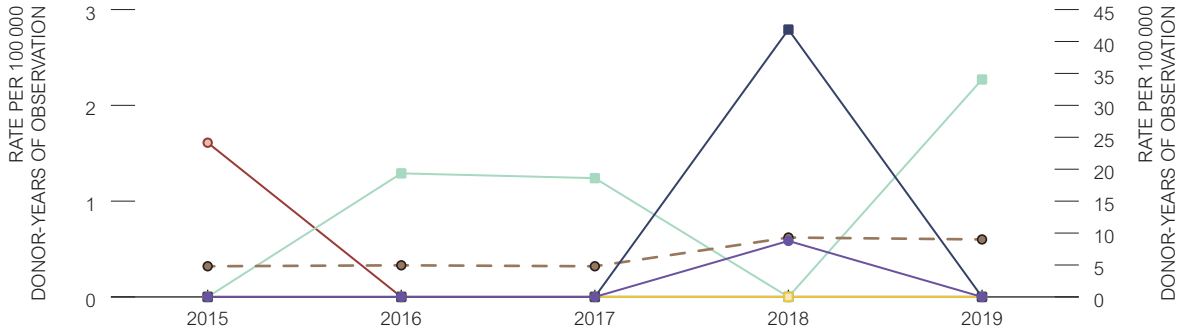
Figure 10 Prevalence of HBV infection among first time donors by state/territory and year of donation, 2010-2019



	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019
NSW/ACT	91.42	81.51	81.38	77.01	68.41	54.83	64.44	62.97	84.23	68.16
NT	0.00	388.6	106.72	117.23	0.00	137.55	0.00	146.84	0.00	0.00
QLD	56.95	45.08	60.29	70.82	39.91	111.03	68.25	37.63	30.58	43.99
SA	32.31	29.52	89.89	62.33	63.53	64.5	29.31	65.15	19.38	41.15
TAS	31.04	27.88	78.47	0.00	0.00	35.63	0.00	34.79	35.29	62.72
VIC	131.68	86.3	79.37	106.58	115.15	95.79	77.63	112.18	104.37	108.11
WA	89.69	90.98	141.06	113.44	75.26	78.28	74.48	33.31	124.69	20.32
National	85.37	72.17	82.23	83.4	71.49	80.23	64.76	68.67	76.26	67.73

Incident HBV infection continues to be rare with only two incident donors recorded nationally in 2019, both from Victoria. Overall, there was no obvious trend in HBV incidence in any state/territory during the five-year study period 2015-2019 (Figure 11). Among donors in New South Wales, South Australia and Western Australia, HBV incidence has been zero since 2015.

Figure 11 Trend in incidence of HBV infection among repeat donors by state/territory and year of donation, 2015-2019[1]



	2015	2016	2017	2018	2019
NSW/ACT	0.00	0.00	0.00	0.00	0.00
NT	0.00	0.00	0.00	41.87	0.00
QLD	1.61	0.00	0.00	0.00	0.00
SA	0.00	0.00	0.00	0.00	0.00
TAS	0.00	0.00	0.00	8.77	0.00
VIC	0.00	1.29	1.24	0.00	2.27
WA	0.00	0.00	0.00	0.00	0.00
National	0.32	0.33	0.32	0.62	0.60

1 Incidence in NT and TAS are provided according to the scale on the secondary axis on the right-hand side

Occult HBV infection

As noted, the implementation of HBV DNA testing for all donations from 2010 has facilitated the identification of OBI among the donor population.[8] To the end of 2019, 172 donors with OBI have been detected, counselled and referred for external clinical assessment which both reduces the residual risk of HBV infection and contributes to the identification of undiagnosed HBV in Australia. In 2019, 29 of the 90 (32%) 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. Most (25/29) OBIs in 2019 were men and over half (17/29) were repeat donors, with an average age of 49 years. The majority of donors with OBI in 2019 were born in Asia (South-East/North East Asia – 11, Southern and Central Asia/Middle East – 10).

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 above, general population data for 2019 were not available at the time of report preparation, therefore although blood donor data are presented for 2010-2019 and 2019, comparison with the general population was made with a combined period of 2009-2018 and 2018, 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 previous Lifeblood studies[9,10] 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 12 times lower prevalence in first-time donors during the period 2009/10-2018/19, and 13 times lower prevalence for the year 2018/19. 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, 2009/10-2018/19

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	
	2009-2018	2018	2010-2019	2019	2009/10-2018/19	2018/19
HBV	929	893	75.5	67.7	12 times lower	13 times lower

* The 2018 HBV prevalence in the general population was calculated by taking the estimated number of people living with chronic HBV,[2] and dividing it by the estimated mid-year resident Australian population in 2018 as reported by the Australian Bureau of Statistics. For the period 2009-2018, 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)[2] to determine any association between demographic factors and presence of HBV infections among Australian blood donors in 2019, and the five-year period, 2015-2019, 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 2019, female donors were 78% less likely to be HBV positive compared to male donors. In 2019, donors between 30-39 years of age and donors from Victoria were almost three and two times more likely to be HBV positive as compared to the reference groups, respectively (Supplementary Table 4).

In the five-year period, 2015-2019, female donors were significantly less likely to be HBV positive as compared to male donors. Donors aged between 30-39 years and donors from Victoria had a significantly greater rate for HBV positivity as compared to the reference groups (1.8 and 1.5 times, respectively, see Supplementary Table 5). In comparison, during 2009-2018, the notification rates of HBV infections in Australia have been consistently higher in male than female persons, 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 (72 per 100 000 in 2009 to 33 per 100 000 in 2018). 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 (40 in 2009 to 30 in 2018), Victoria (36 in 2009 to 27 in 2017), and Western Australia (29 in 2009 to 20 in 2018).[2-4]

Risk factors associated with HBV infected donors

Of the 404 HBV positive donors during 2015-2019, 81% were first-time donors, 74% were male, and the mean age was 40 years (Table 3). Most (89%) of the HBV positive donors were born overseas, which reflects the epidemiology of hepatitis B in the general population. Ethnicity or country of birth (90%) was the most frequent risk factor for HBV positivity, with 44% born in North & South-East Asia in 2019 (Figure 12). There were only seven 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, 2015-2019

Characteristics	2015	2016	2017	2018	2019	2015-2019
Number of positive donors	84	76	75	79	90	404
Number of positive first-time donors (%)	71 (85%)	62 (82%)	63 (84%)	62 (78%)	71 (79%)	329 (81%)
% male	58 (69%)	60 (79%)	47 (63%)	60 (76%)	73 (81%)	298 (74%)
Mean age (range) in years	37 (16-67)	40 (16-68)	41 (17-78)	41 (19-71)	40 (19-73)	40 (16-78)
Number of incident donors	1	1	1	2	2	7
% born in Australia	8 (10%)	5 (7%)	14 (19%)	8 (10%)	11 (15%)	46 (11%)
Main reported risk factor	Ethnicity/COB[1] 93%	Ethnicity/COB[1] 97%*	Ethnicity/COB[1] 87%*	Ethnicity/COB[1] 91%*	Ethnicity/COB[1] 90%*	Ethnicity/COB[1] 92%
Second reported risk factor	PRP[3], Other each 2%	Other, Unknown each 1%	FH/HC[2], PRP[3], OR[4] EHS[5] each 3%	Undetermined 3%	PUSR[6] 3%	PRP[3], FH/HC[2] 1%

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
6 PUSR=Partner with unspecified risk
* 4 out of 5, 7 out 14, 3 out of 8 and 4 out of 11 donors born in Australia had Ethnicity as their major risk factor in 2016, 2017, 2018, 2019 respectively

Figure 12 Donors with HBV infection by country/region of birth, 2019 (n=90)

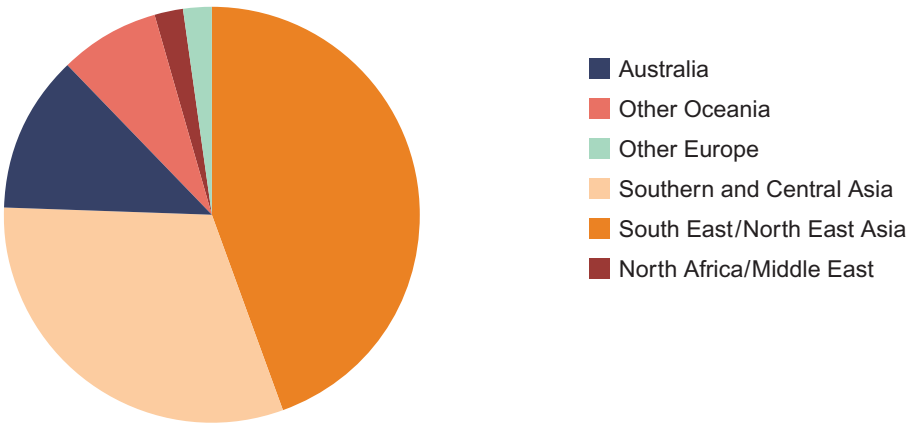
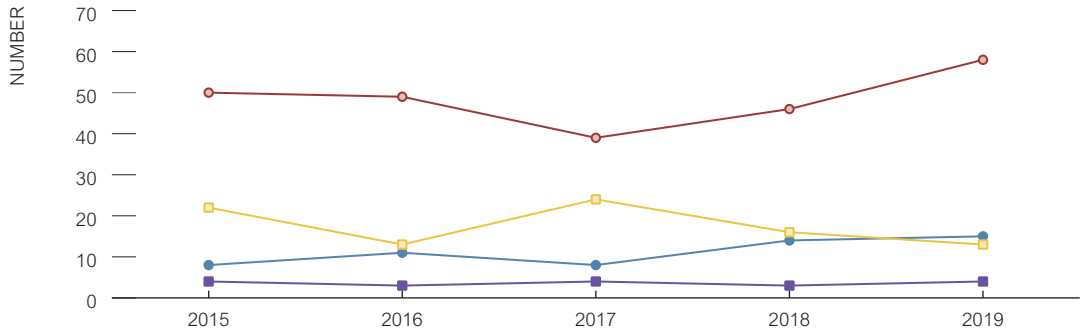


Figure 13 Donors with hepatitis B infection by sex and donor status, 2015-2019



	2015	2016	2017	2018	2019
Male (first-time)	50	49	39	46	58
Male (repeat)	8	11	8	14	15
Female (first-time)	22	13	24	16	13
Female (repeat)	4	3	4	3	4

Since 2015, no trend has been observed in male and female HBV positive first-time donors. The number of HBV positive repeat donors remained relatively stable for women and saw a slight increase in men, during the same period of time (Figure 13). In comparison, there have been small declines in HBV notification rates by sex in the past ten years, 2009-2018 from 36 to 27 per 100 000 male population and 30 to 22 per 100 000 female population.[3,4] 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 2019 and the period 2015-2019, 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 90.0% of the HBV positive donors in 2019. 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.[11-13]

Nationally, enhanced information on potential risk categories is collected for the newly acquired infections only (defined as newly diagnosed HBV infection with laboratory or clinical evidence of acquisition in the 24 months prior to diagnosis). In 2018, for newly acquired HBV infection in the general population, 8.0% had country of birth as a major risk factor; importantly, for 40.1% of newly acquired HBV infections in the general population, the risk category was undetermined[3,4] (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 and general population in Australia by infection and major potential risk categories, 2019

		HBV[1]
Major risk category	**General population (2018) (%)**	**Blood donors (2019) (%)**
Intravenous drug use	21.2	1.1
Country of birth/Ethnicity[2]	8.0	90.0
Sexual contact[3]	10.2	4.4
Blood or tissue recipient	3.6	0.0
Tattoo or body piercing	7.3	1.1
Exposure in health care setting	5.8	0.0
Household contact/Family history	0.7	2.2
Other blood to blood contact	0.7	0.0
Other/undetermined/unknown/not reported	40.1	1.1
Imprisonment	0.0	0.0
Occupational risk	0.0	0.0
No risk factor identified	2.2	0.0

1 Includes exposure categories for newly acquired HBV infections only in general population
2 Includes 4 out of 11 hepatitis B positive donors born in Australia that had Ethnicity as their major risk factor
3 Includes four sub-groups: Male-to-male sexual contact, Partner with known risk or known to be positive, Partners with unspecified risks and Engaged in sex work
Of note, in the 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 2010 and is substantially lower (12 times) than the general population estimates for the period 2009-2018.
- 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 (29 of the 90 HBV infections in 2019).
- 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

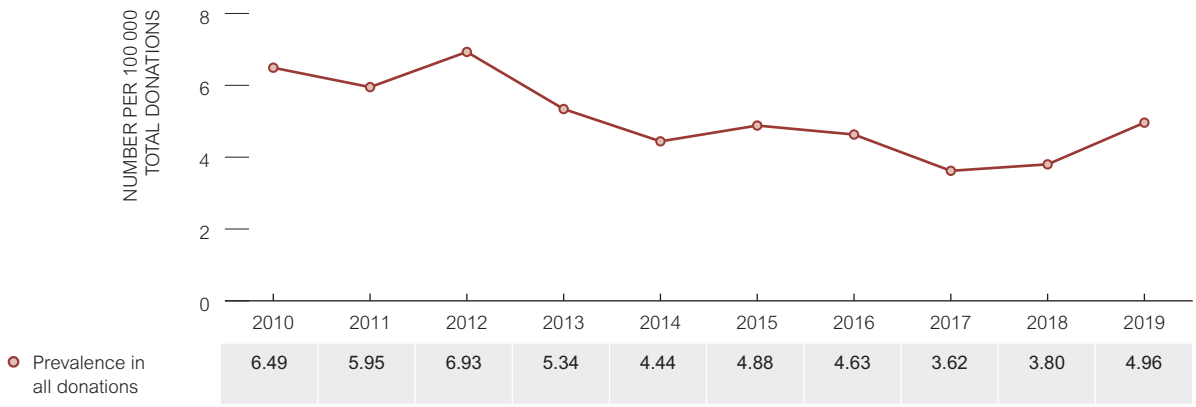
To the end of 2018, an estimated 128 530 people were living with chronic hepatitis C in Australia, of which an estimated 79% or 101 480 were diagnosed with chronic hepatitis C. Australia has a concentrated chronic hepatitis C epidemic among key populations: people who inject drugs, prisoners, people from high prevalence countries and HIV positive men who have sex with men. The rate of diagnosis of HCV infection in 2018 was 38 per 100 000 which indicates a decrease from 2017. However, in the period 2012-2016 the rate increased by over 20% from 44 per 100 000 to 53 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 24% decline in the rate of notification of hepatitis C over the ten-year period, 2009-2018, from 50 per 100 000 to 38 per 100 000. The rate of diagnosis in those aged less than 25 years has declined by 29% in the past ten years, 2009-2018. Similarly, between 2015 and 2018, the rate of diagnosis in the Aboriginal and Torres Strait Islander population under 25 years has declined by 25%. Nonetheless, in 2018, the diagnosis rate of HCV was nearly five times higher in the Aboriginal and Torres Strait Islander population (164 per 100 000) than that of the non-indigenous population (33 per 100 000). In 2018, most cases (68%) of newly diagnosed HCV infection were in male persons and 78% were in people aged 30 years and above.[2-4]

Trends in prevalence

All donations:

In the past ten years, 2010-2019, 680 HCV positive donors have been detected (501 first-time donors & 179 repeat donors) (Table 1A). This is the lowest ten-year total so far. During the last ten years, the prevalence of HCV infection among all donations has declined significantly (IRR: 0.94; 95% CI: 0.92-0.97). There has been an overall reduction of 24% over the period, from 6.4 per 100 000 donations in 2010 to 4.9 per 100 000 donations in 2019 (Figure 14). For detail on the number and prevalence rate of HCV infections among all donations for 2019, see Supplementary Table 2.

Figure 14 Prevalence of HCV infection in all blood donations in Australia, 2010-2019, by year of donation

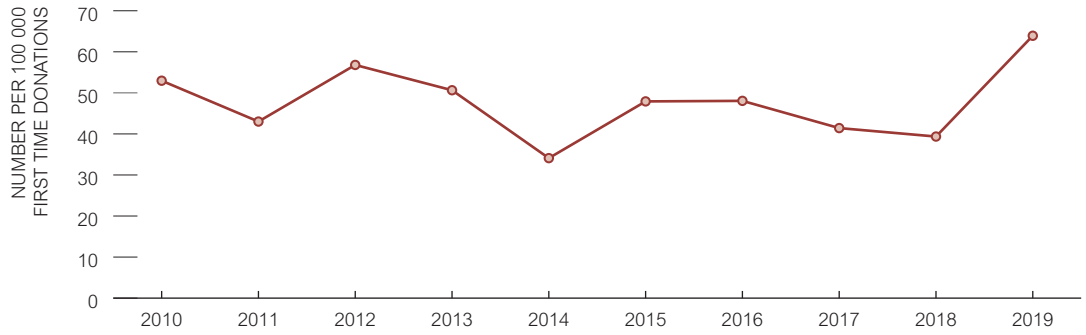


First-time donors:

No significant trend was observed in HCV prevalence in first-time donors in the 2010-2019 period (IRR: 1.00; 95% CI: 0.97-1.03); from 52.9 per 100 000 donations in 2010, to 34.1 per 100 000 donations in 2014 and 63.9 per 100 000 donations in 2019 (Figure 15), as compared to a significant downward trend in the 2009-2018 period. This change reflects an increase in HCV prevalence in first-time donors in 2019 at 63.9 as compared to 39.36 observed in 2018. The increase observed in 2019 is likely to be the result of two factors. Firstly, there was an increase in the number of prospective donors attending with a past history of HCV. Lifeblood attributes this to an increased propensity for individuals with resolved HCV (HCV antibody positive / RNA negative) to consider they are now eligible to donate. Secondly, in September 2018, Lifeblood implemented the TGA approved change from an indefinite blood donation deferral relating to injecting drug use to a 5-year deferral from last injection. There was an expectation that there may be an increase in HCV positive donors subsequent to the change because some of the newly eligible donors (i.e. those with last injection >5 years ago who were previously ineligible and / or already deferred) may donate with undiagnosed HCV.

In comparison, the rate of diagnosis of HCV infection reported through the Australian National Notifiable Disease Surveillance System declined from 50 per 100 000 in 2009 to 38 per 100 000 in 2018.[2] In addition, there has also been a decrease in the prevalence of hepatitis C antibody among people seen at needle and syringe programs, from 53% in 2010 to 45% in 2019, whilst the rates of receptive needle and syringe sharing in the same period remained stable at an average of 18%, highlighting the importance of sustaining and enhancing harm reduction services.[14]

Figure 15 Prevalence of HCV infection in first time blood donors in Australia, 2010-2019, by year of donation

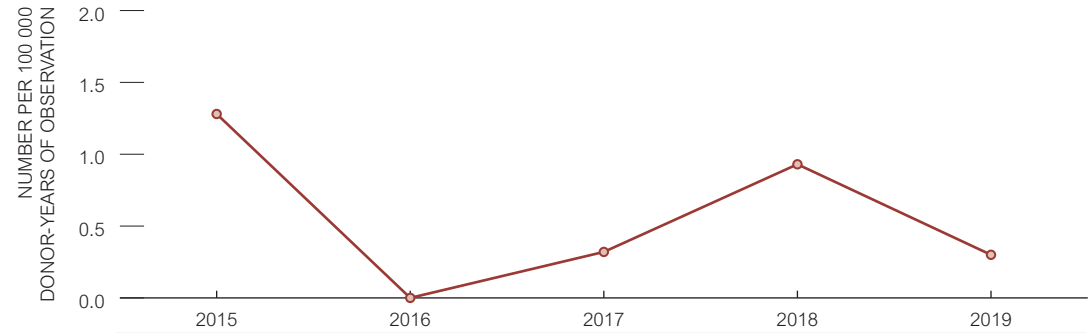


	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019
Prevalence in first-time donors	52.96	43.01	56.8	50.64	34.10	47.92	48.05	41.42	39.36	63.91

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 2015-2019, a total of nine 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: 0.83; 95% CI: 0.52-1.32) (Figure 16). Only one HCV incident donor was identified in 2019, equating to an incidence rate of 0.3 per 100 000 donor-years of observation (Figure 16), a threefold decrease on the 0.9 per 100 000 donor years of observations recorded in 2018. Similarly, no significant annual trend was observed for incidence of HCV infection over a five-year study period (2014-2018) among people who inject drugs attending the Kirketon Road Centre, a primary care clinic in central Sydney. The incidence fluctuated between 2.0 and 13.2 per 100 persons-years, with lowest in 2016 at 2.0.[3] No transfusion-transmitted HCV infections were reported in Australia during 2015-2019.

Figure 16 Incidence of HCV in repeat blood donors in Australia, 2015-2019



	2015	2016	2017	2018	2019
Incidence	1.28	0.00	0.32	0.93	0.30

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. There had been a steady decline in the proportion of HCV RNA positive (infectious) donors during the 2010-2018. However, a marked increase was observed in both this proportion and the overall HCV prevalence rate in 2019. The RNA positive proportion increase to 47.3% from 32.1% in 2018 might be in part, or completely explained by the change to the blood donation deferral relating to injecting drug use, as mentioned above.

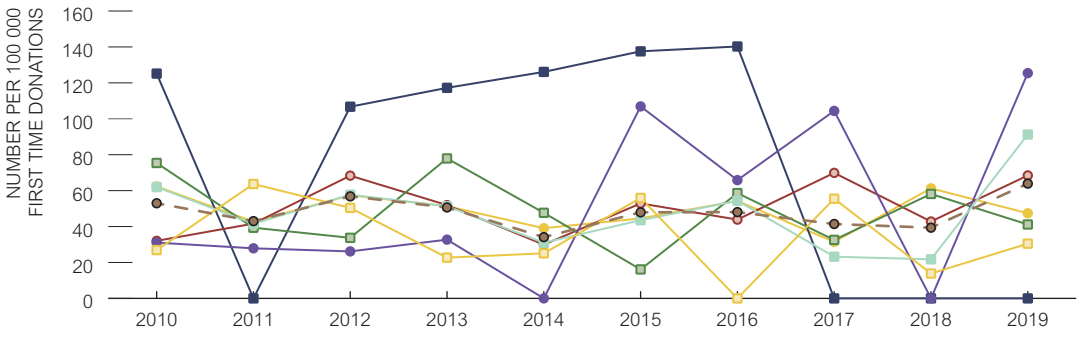
Examining 2010 and 2018 data, the decline is significantly associated with a decrease in the rate of RNA positive donors among first-time donors (or those not previously HCV tested), from 39.5 per 100 000 in 2010 to 16 per 100 000 new donations in 2018 (IRR: 0.90; 95% CI: 0.85-0.95). However, the majority (91.4%) of the HCV RNA positive donors in 2019 were first-time donors, equating to a rate of RNA positive donors among first-time donors at 30.5 per 100 000 new donations. Nonetheless, this decline is also significant for the 2010-2019 data (IRR: 0.94; 95% CI: 0.90-0.98).

As highlighted above, this increase could, at least in part be explained by the change to the blood donation deferral relating to injecting drug use. Importantly, the increase in first-time HCV positive donors does not correlate directly with an increase in the HCV residual transmission risk. This is because the increase is among prevalent (long-standing) infections, readily detectable by Lifeblood's dual NAT/Ab testing strategy. The transmission risk for transfused blood components correlates with window period (WP) infections which, in repeat donors Lifeblood estimates from 'incident' donors (i.e. a confirmed HCV positive donor with negative HCV testing in the prior 12 months). That is why for all infectious diseases the deferral strategy is not based on every donor having a risk, but an adequate deferral period from blood donation to cover a window period. Importantly, the number of HCV incident donors identified by Lifeblood declined from 3 in 2018, to 1 in 2019. Lifeblood does not measure incidence directly among first time donors. However, the best available incidence proxy is the number of HCV 'yield' donors (i.e. HCV RNA positive/anti-HCV negative), which Lifeblood routinely includes in the incident donor count, even if they are first-time donors as they are in the process of seroconverting and represent new infections. The last first-time donor HCV 'yield' occurred in 2015, arguing against any substantial recent increase in first-time donor incidence.

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 markedly by jurisdiction in 2019, ranging from 0.0 to 125.4 per 100 000 donations. During the past ten years, 2010-2019, no significant trend was observed for any jurisdiction. In 2019, Tasmania recorded the highest prevalence of HCV infection among first-time donors as compared to other states, at 125.4 per 100 000 donations (Figure 17). On the other hand, in 2019, the Northern Territory observed the lowest rate of 0.0 per 100 000 donations. 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 four, respectively. National notifications data indicate the notification rate of hepatitis C infection in Australia in 2018 was highest in the Northern Territory (58 per 100 000) and Queensland (45 per 100 000).[2]

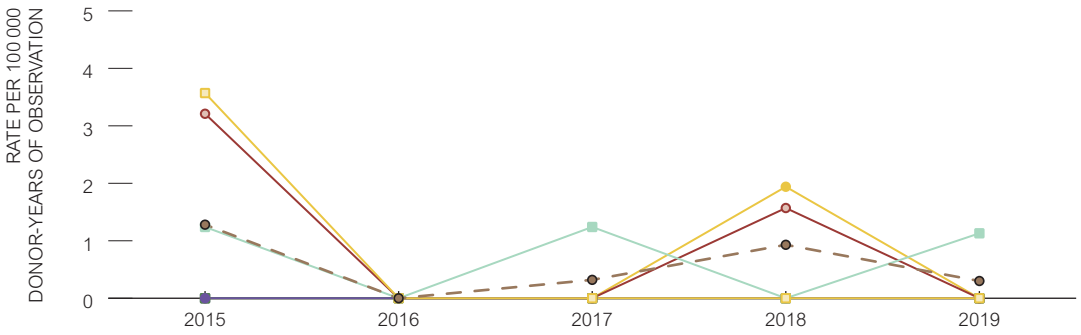
Figure 17 Prevalence of HCV infection among first time donors by state/territory and year of donation, 2010-2019



	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019
NSW/ACT	62.33	42.70	57.44	51.34	39.09	44.55	54.26	31.48	61.26	47.41
NT	125.16	0.00	106.72	117.23	126.10	137.55	140.25	0.00	0.00	0.00
QLD	32.03	41.61	68.33	51.93	29.94	52.87	43.87	69.88	42.81	68.44
SA	75.40	39.35	33.71	77.92	47.65	16.12	58.62	32.57	58.15	41.15
TAS	31.04	27.88	26.16	32.70	0.00	106.88	65.85	104.38	0.00	125.43
VIC	61.97	41.55	57.72	51.32	31.00	43.54	54.34	23.21	21.74	91.22
WA	26.91	63.68	50.38	22.69	25.09	55.92	0.00	55.51	13.85	30.48
National	52.96	43.01	56.80	50.64	34.10	47.92	48.05	41.42	39.36	63.91

There was no significant annual trend observed for HCV incidence in repeat donors nationally during the 2015-2019 study period (IRR: 0.83; 95% CI: 0.52-1.32). 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 the Northern Territory, South Australia and Tasmania, HCV incidence has remained zero since 2015.

Figure 18 Incidence of HCV infection among repeat donors by state/territory and year of donation, 2015-2019



	2015	2016	2017	2018	2019
NSW/ACT	0.00	0.00	0.00	1.94	0.00
NT	0.00	0.00	0.00	0.00	0.00
QLD	3.21	0.00	0.00	1.57	0.00
SA	0.00	0.00	0.00	0.00	0.00
TAS	0.00	0.00	0.00	0.00	0.00
VIC	1.24	0.00	1.24	0.00	1.13
WA	3.57	0.00	0.00	0.00	0.00
National	1.28	0.00	0.32	0.93	0.30

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 above, general population data for 2019 were not available at the time of report preparation, therefore, although blood donor data are presented for 2010-2019 and 2019, separately, comparison with the general population was made with 2009-2018 and 2018. 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 studies for the period.[9,10] The prevalence in first-time donors was 22 and 8 times lower than the prevalence in the general population for the period 2009/10-2018/19, and the year 2018/19, respectively (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, 2009/10-2018/19

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	
	2009-2018	**2018**	**2010-2019**	**2019**	**2009/10-2018/19**	**2018/19**
HCV	1 063	507	48. 3	63.9	22 times lower	8 times lower

* The 2018 HCV prevalence in the general population was calculated by taking the estimated number of people living with chronic HCV,[2] and dividing it by the estimated mid-year resident Australian population in 2018 reported by the Australian Bureau of Statistics. For the period 2009-2018, an average of the 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)[3] to determine the association between demographic factors and presence of HCV infection among Australian blood donors in 2019, and the five-year period, 2015-2019, 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 2019, unlike HBV, there was no significant association between sex and HCV infection status. Donors between 40-49 and over 50 years of age were 2.5 and 3.1 times more likely to be HCV positive compared to the reference group (Supplementary Table 4). In 2019, there was no significant association between state/territory and HCV infection status.

During the five-year period, 2015-2019, female donors were significantly less likely to be HCV positive (39%) compared to male donors. There was a significantly greater risk of HCV infection among donors aged 30 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 297 HCV positive donors during 2015-2019, 76% were first-time donors and 62% were male. Over the last five years, the mean age was 46 years with a wide range (16-70) (Table 6). Unlike HBV where birth overseas predominated, the majority (70%) of HCV positive donors during 2015-2019 were born in Australia, and 64% in 2019 (Figure 19). Of note, in 2019 the percentage of repeat donors has decreased, to 9%, which is lowest percentage for a single year within the five-year period 2015-2019, and lower than the overall total for the 2015-2019 period. The proportion of female donors declined from nearly 50% in 2018 to 41% in 2019.

Overall, the main reported putative risk factors for HCV positivity during 2015-2019 were injecting drug use and tattoo or body piercing (24%, each). As noted previously, there is no significant evidence that tattooing and body piercing performed in licensed premises is associated with an increased risk of acquiring HCV.[6] 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 24% of HCV positive donors reporting tattooing or body piercing should be interpreted with caution and this reflects 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,[7] noting that at the time, blood donors with recent tattoos were temporarily deferred from donation. The total modelled 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. This study supported a submission to the blood regulator (TGA) seeking to reduce the deferral period to 1 week. However, TGA approved the proposal for plasma for fractionation donations only, where a deferral does not apply effective September 2020. 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, 2015-2019

Characteristics	2015	2016	2017	2018	2019	2015-2019
Number of positive donors	62	60	48	53	74	297
Number of positive first-time donors (%)	43 (69%)	46 (77%)	38 (79%)	32 (60%)	67 (91%)	226 (76%)
% male	39 (63%)	40 (67%)	35 (73%)	27 (51%)	44 (59%)	185 (62%)
Mean age (range) in years	44 (16-67)	48 (22-67)	48 (23-67)	45 (18-67)	47 (18-70)	46 (16 to70)
Number of incident donors	4	0	1	3	1	9
% born in Australia	43 (69%)	40 (67%)	37 (77%)	40 (75%)	47 (64%)	207 (70%)
Main reported risk factor	TBP[1]	IDU[2]	TBP[1]; IDU[2]	TBP[1]	IDU[2]	TBP[1], IDU[2]
	29%	27%	23% each	26%	26%	24% each
Second reported risk factor	IDU[2]	TBP[1]	Other	IDU[2]	TBP[1]	BTR[3], EHS[4], Unknown
	23%	20%	10%	21%	23%	7%

1 TBP= Tattoo/Body piercing
2 IDU= Injecting drug use
3 BTR= Blood/tissue recipient
4 EHS= Exposure in a healthcare setting

Figure 19 Donors with HCV infection by country/region of birth, 2019 (n=74)

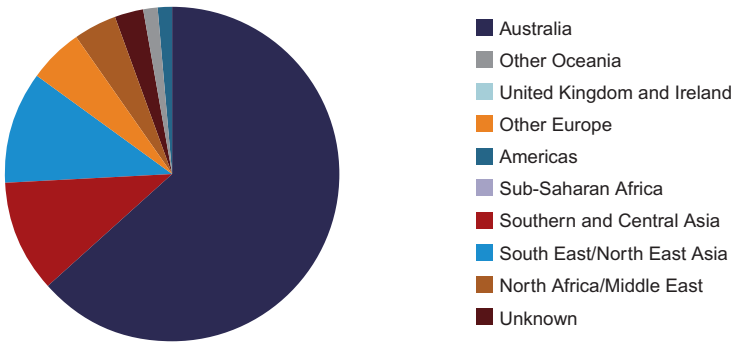
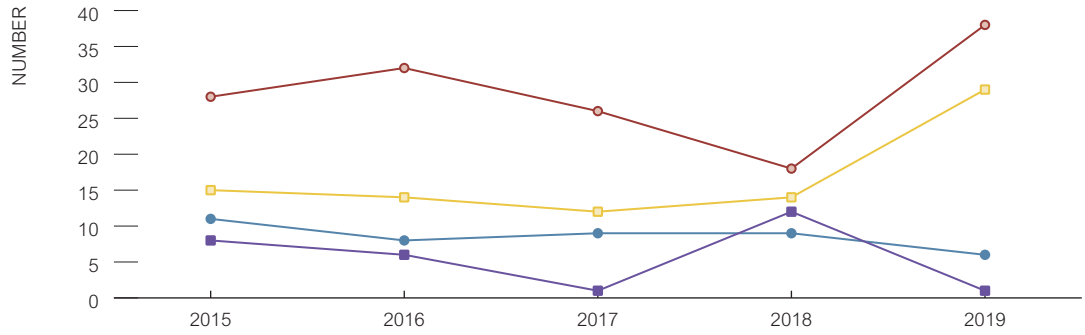


Figure 20 Donors with HCV infection by sex and donor status, 2015-2019



	2015	2016	2017	2018	2019
Male (first-time)	28	32	26	18	38
Male (repeat)	11	8	9	9	6
Female (first-time)	15	14	12	14	29
Female (repeat)	8	6	1	12	1

Over the five-year period, 2015-2019, there has been a downward trend in the number of HCV positive repeat male and female donors. No trend was seen in the number of HCV positive first-time male and female donors, however a sharp increase in 2019 was observed in both sex groups of the first-time donors (discussed previously). In comparison to 2018, where there were 12 repeat female donors (the highest recorded since 2014), in 2019 there was only one repeat female donor (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 2019 and the period 2015-2019, 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, 2019

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 injecting 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 2019 was IDU (25.7%), followed by tattoo or body piercing (23%). In comparison, for the newly acquired HCV infections in Australia, ~18% had IDU as their major risk factor in the general population. Importantly, for 52.3% of the newly acquired HCV infection in the general population, no risk factor was identified, followed by 26.4% that were undetermined or not reported (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).[3,4]

Table 7 Comparison between HCV positive blood donors (2019) and general population (2018) in Australia by major potential risk categories

		HCV[1]
Major risk category	**General population (2018) (%)**	**Blood donors (2019) (%)**
Intravenous drug use	17.8	25.7
Country of birth/Ethnicity	0.2	9.5
Sexual contact[2]	1.3	10.8
Blood or tissue recipient	0.0	9.5
Tattoo or body piercing	0.8	23.0
Exposure in health care setting	0.0	2.7
Household contact/Family history	0.5	5.4
Other blood to blood contact	0.7	0.0
Other/undetermined/unknown/not reported	26.4	10.8
Imprisonment	0.2	1.4
Occupational risk	0.0	1.4
No risk factor Identified	52.3	0.0

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

Conclusion

- The prevalence of HCV infection among first-time donors in 2019 and for the period 2010-2019 was 8 and 22 times lower among first-time blood donors than the general population estimates in 2018, and for the period 2009-2018, respectively.
- The incidence of HCV has not shown a significant trend in the five-year study period 2015-2019. 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 2019 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

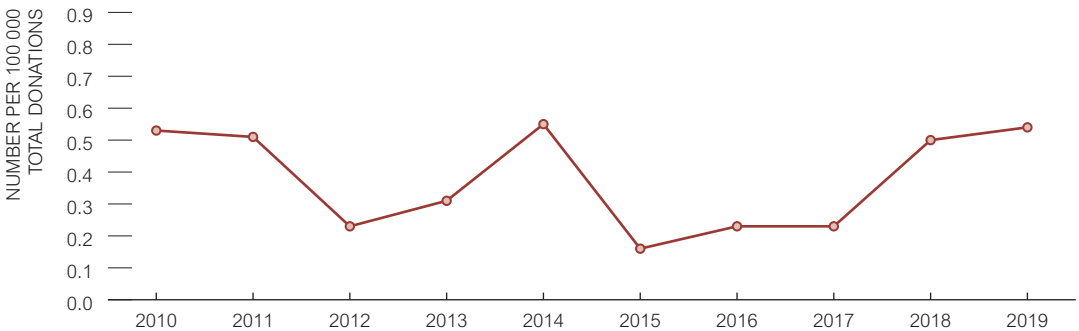
During 2019, an estimated 29 045 people were living with HIV and an estimated majority (90%) or 26 025 were diagnosed. Transmission of HIV in Australia continues to occur primarily through sexual contact between men, with 71% of newly acquired cases of HIV infection in Australia in the period 2010 to 2019 involving men who reported sexual contact with men. The annual number of new HIV diagnoses has decreased by 12% over the past five years, from 1 028 diagnoses in 2015 to 903 in 2019. Of these newly diagnosed HIV infections in 2019, 89% were in men, 66% 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.[5]

Trends in prevalence

All donations:

In the past ten years, 2010-2019, a total of 51 HIV positive donors have been detected (23 first-time donors & 28 repeat donors) (Table 1A). No significant trend was observed in the prevalence of HIV infection among all donations in 2019 (IRR: 0.99; 95% CI: 0.90-1.09). Overall, the rate has fluctuated in the past ten years, 2010-2019, between 0.1-0.5 per 100 000 donations (Figure 21). For detail on the number and prevalence rate of HIV infections among all donations for 2019, see Supplementary Table 2.

Figure 21 Prevalence of HIV infection in all blood donations in Australia, 2010-2019, by year of donation



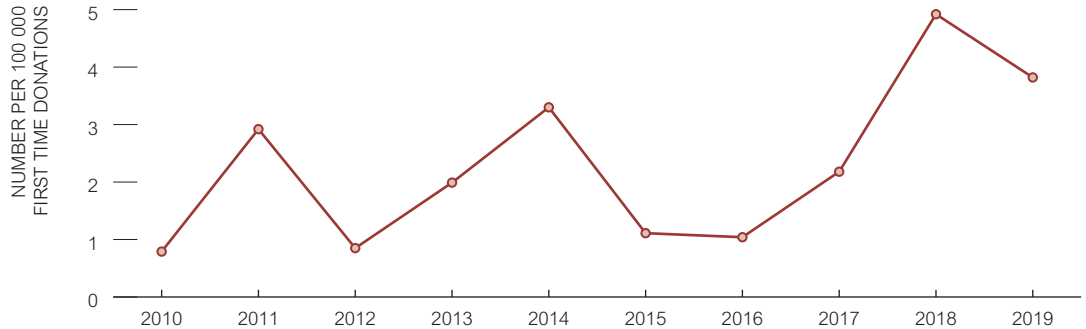
	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019
Prevalence in all donations	0.53	0.51	0.23	0.31	0.55	0.16	0.23	0.23	0.50	0.54

First-time donors:

The overall HIV prevalence in first-time donors remained very low at 2.2 per 100 000 over the ten-year period 2010-2019 (Table 1A); it was lowest in 2010 at 0.8 per 100 000 donations, followed by a fluctuating rate between the years 2011 to 2017 before peaking at 4.9 per 100 000 donations in 2018 and slightly reducing to 3.8 in 2019 (Figure 22). Overall, no significant trends were observed in the prevalence of HIV infection among first-time donors in the past ten years (IRR: 1.11; 95% CI: 0.96-1.27).

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.[15]

Figure 22 Prevalence of HIV infection in first-time blood donors in Australia, 2010-2019, by year of donation

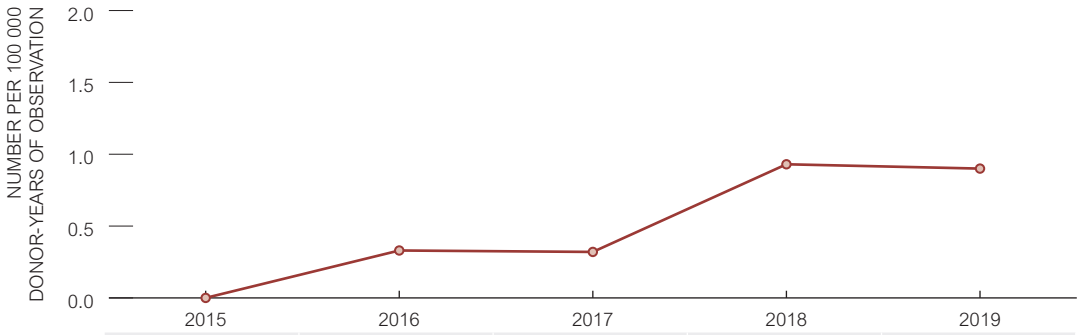


	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019
Prevalence in first-time donors	0.79	2.92	0.85	1.99	3.30	1.11	1.04	2.18	4.92	3.82

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 2019, three incident infections were detected for HIV, equating to an incidence rate of 0.9 per 100 000 donor-years of observation, making it the second highest rate observed in the five-year period, 2015-2019 (Figure 23). For the five years 2015-2019, 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: 1.7; 95% CI: 0.95-3.09). 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).[16]

Figure 23 Incidence of HIV in repeat blood donors in Australia, 2010-2019, by year of donation



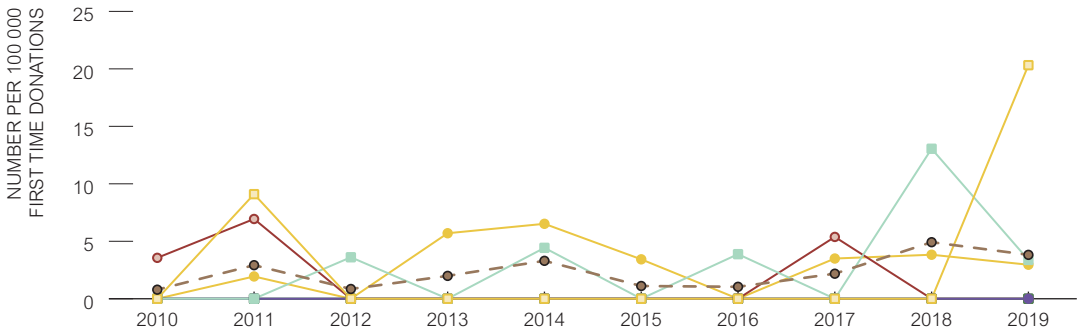
	2015	2016	2017	2018	2019
Incidence	0.00	0.33	0.32	0.93	0.90

No transfusion-transmitted HIV infections were reported in Australia during 2010-2019.

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 2010-2019 period, with an average national prevalence of 2.2 per 100 000 donations (Table 1A). No significant annual trend was observed during the 2010-2019 period in any jurisdiction (Figure 25). In 2019, Western Australia observed the highest HIV prevalence in first-time donors at the rate of 20.3 per 100 000 donations (Figure 24), which is the highest recorded for any jurisdiction in the past ten years, 2010-2019. This rate equates to two positive first-time donors. Given small numbers, this likely reflects random variation and therefore caution should be taken in interpretation. During 2010-2019, HIV prevalence in first-time donors was zero in the Northern Territory, South Australia and Tasmania (Table 1A and Figure 24).

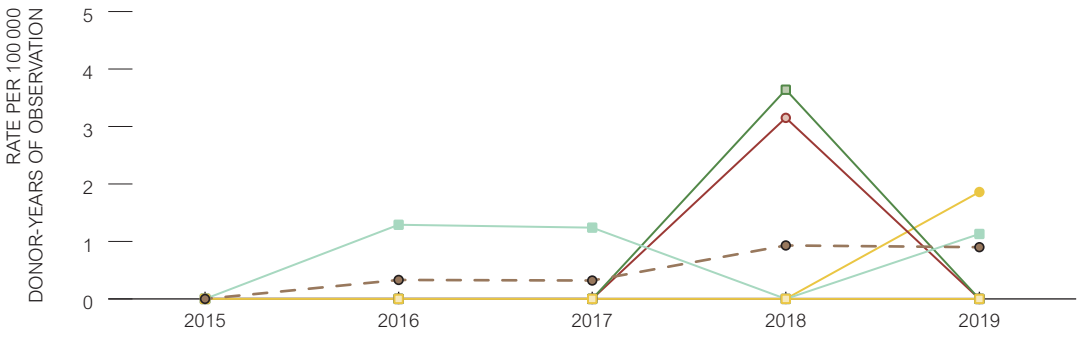
Figure 24 Prevalence of HIV infection among first time donors by state/territory and year of donation, 2010-2019



	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019
NSW/ACT	0.00	1.94	0.00	5.70	6.52	3.43	0.00	3.50	3.83	2.96
NT	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
QLD	3.56	6.94	0.00	0.00	0.00	0.00	0.00	5.38	0.00	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	0.00	0.00	3.61	0.00	4.43	0.00	3.88	0.00	13.05	3.38
WA	0.00	9.10	0.00	0.00	0.00	0.00	0.00	0.00	0.00	20.32
National	0.79	2.92	0.85	1.99	3.30	1.11	1.04	2.18	4.92	3.82

In 2019, there were three incident donors (two from New South Wales / Australian Capital Territory and one from Victoria). No incident HIV donors were recorded in Tasmania, Western Australia or the Northern Territory in the past five years, 2015-2019 (Figure 25). No significant annual trend was observed in any jurisdiction during 2015-2019.

Figure 25 Incidence of HIV infection among repeat donors by state/territory and year of donation, 2015-2019



	2015	2016	2017	2018	2019
NSW/ACT	0.00	0.00	0.00	0.00	1.86
NT	0.00	0.00	0.00	0.00	0.00
QLD	0.00	0.00	0.00	3.15	0.00
SA	0.00	0.00	0.00	3.64	0.00
TAS	0.00	0.00	0.00	0.00	0.00
VIC	0.00	1.29	1.24	0.00	1.13
WA	0.00	0.00	0.00	0.00	0.00
National	0.00	0.33	0.32	0.93	0.90

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 2010-2019, and then 2019 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 previous Lifeblood studies.[9,10] The prevalence in first-time donors was 52 times lower for the period 2010-2019, and 37 times lower in 2019 alone 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, 2010-2019

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	
	2010-2019	2019	2010-2019	2019	2010-2019	2019
HIV	116	141	2.22	3.82	52 times lower	37 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)[4] to determine the association between demographic factors and presence of HIV infection among Australian blood donors in 2019, and the five-year period, 2015-2019, 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 2019, there was no significant association between gender, age or state/territory and HIV infection status (Supplementary Table 4). During the five-year period, 2015-2019, female donors, and donors between 40-49 age group were significantly less likely to be HIV positive, compared to the reference groups. There was no association between state/territory and HIV positivity (Supplementary Table 5).

Risk factors associated with HIV infected donors

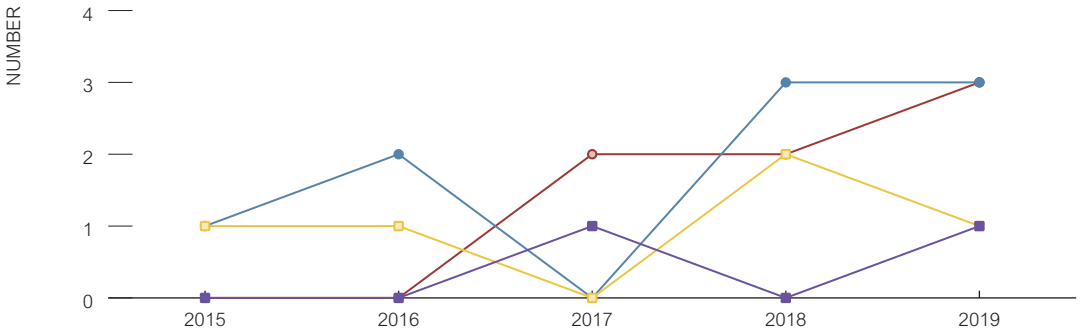
During 2015-2019, over 50% of the 23 positive donors were first-time donors (Table 9). Most HIV positive donors were male (70%) and had a mean age of 36 years. Of 23 HIV positive donors in the five-year period 2015-2019, eight were incident HIV infections. Male-to-male sexual contact and having a sexual partner with a known risk, or known to be positive for HIV infection were the most common reported risk factors for HIV positivity in blood donors during 2015-2019 (26%, each), followed by underdetermined risk factor and having a sexual partner with unspecified risk (17%, each). In comparison, 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.

Table 9 Characteristics of donors positive for HIV infection by year of donation, 2015-2019

Characteristics	2015	2016	2017	2018	2019	2015-2019
Number of positive donors	2	3	3	7	8	23
Number of positive first-time donors (%)	1 (50%)	1 (33%)	2 (67%)	4 (57%)	4 (50%)	12 (52%)
% male	1 (50%)	2 (67%)	2 (67%)	5 (71%)	6 (75%)	16 (70%)
Mean age (range) in years	30 (26-33)	46 (30-56)	36 (24-57)	32 (20-66)	37 (21-70)	36 (20 to 70)
Number of incident donors	0	1	1	3	3	8
% born in Australia	1 (50%)	2 (67%)	2 (67%)	2 (29%)	4 (50%)	11 (48%)
Main reported risk factor	Other, Unknown each	PRP[2], MSM[1] contact, Unknown each	PRP[2]	MSM[1] contact	MSM[1], PRP[2], PUSR[4], undetermined each	MSM[1], PRP[2] each
	50%	33%	100%	43%	25%	26%
Second reported risk factor	…	…	…	PUSR[4], undetermined each	…	PUSR[4], Undetermined each
				29%		17%

1 MSM= Male to male 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, 2015-2019



	2015	2016	2017	2018	2019
Male (first-time)	0	0	2	2	3
Male (repeat)	1	2	0	3	3
Female (first-time)	1	1	0	2	1
Female (repeat)	0	0	1	0	1

Over the past five years, 2015-2019, there was an upward trend in the numbers of HIV positive first-time and repeat male donors. No discernible overall trend was seen in first-time and repeat 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 2015-2019, see Supplementary Tables 6-12.

HIV - Comparison of major exposure categories between blood donors and the general population, 2019

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 (82%).[5] This is consistent with the findings among blood donors, where sexual contact was identified as the primary risk factor for the majority (50%) of positive donors.

Table 10 Comparison between HIV positive blood donors and general population in Australia by major potential risk categories, 2019

		HIV[1]
Major risk category	**General population (%)**	**Blood donors (%)**
Injecting drug use[2]	9.7	0.0
Country of birth/Ethnicity	0.0	25.0
Sexual contact[3]	82.2	50.0
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/Family history	0.0	0.0
Other blood to blood contact	0.0	0.0
Other/undetermined/unknown	8.1	25.0
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 For general population, it includes injecting drug use and MSM that are IDUs
3 Includes four sub-groups: Male-to-male sexual contact, Partner with known risk or known to be positive, Partner with unspecified risk and Engaged in sex work

Conclusion

- Despite marginally higher prevalence among first-time donors in the past two years, prevalence of HIV infection is 37 times lower among first-time blood donors than in the general population in 2019, and 52 times lower for the period 2010-2019.
- 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 2019.

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Human T-Lymphotropic Virus (HTLV)

Epidemiology of HTLV in Australia

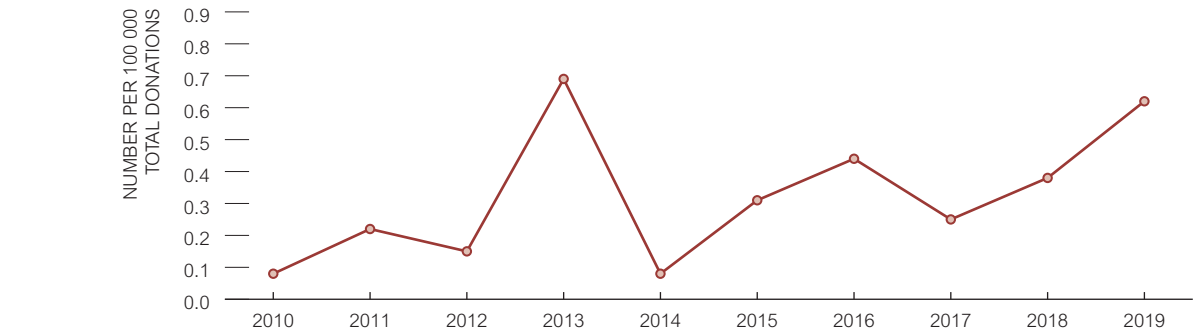
HTLV is not a notifiable infection in Australia except in the Northern Territory. Several studies have been conducted in Central Australian populations, but few have comprehensively examined the nationwide epidemiology. The international literature focuses on HTLV-1 as this is more pathogenic than HTLV-2, with disease outcomes including HTLV-1-associated myelopathy and adult T-cell leukaemia/lymphoma.[17,18]
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.[19-21] 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.[22]

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, 2010-2019, a total of 35 HTLV positive donors have been detected (33 first-time donors & two repeat donors) (Table 1B). During the period 2010-2019, 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: 1.12; 95% CI: 0.99-1.26) (Figure 27). For detail on the number and prevalence rate of HTLV infections among all donations for 2019, see Supplementary Table 3.

Figure 27 Prevalence of HTLV infection in all blood donations in Australia, 2010-2019, by year of donation

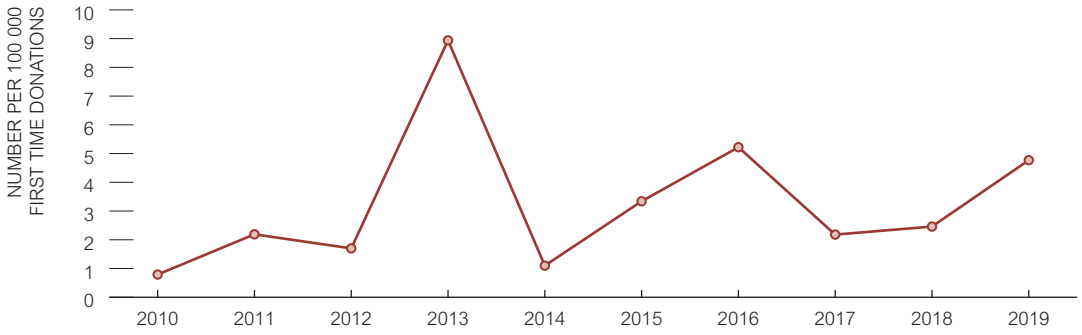


	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019
Prevalence in all donations	0.08	0.22	0.15	0.69	0.08	0.31	0.44	0.25	0.38	0.62

First-time donors:

The prevalence of HTLV infection in first-time donors remained very low over the past ten years, 2010-2019 with an overall rate of 3.2 per 100 000 donations and has shown no significant trend (Table 1B) (IRR: 1.07; 95% CI: 0.95-1.20). 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, 2010-2019, by year of donation



	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019
Prevalence in first-time donors	0.79	2.19	1.70	8.94	1.10	3.34	5.22	2.18	2.46	4.77

Trends in incidence

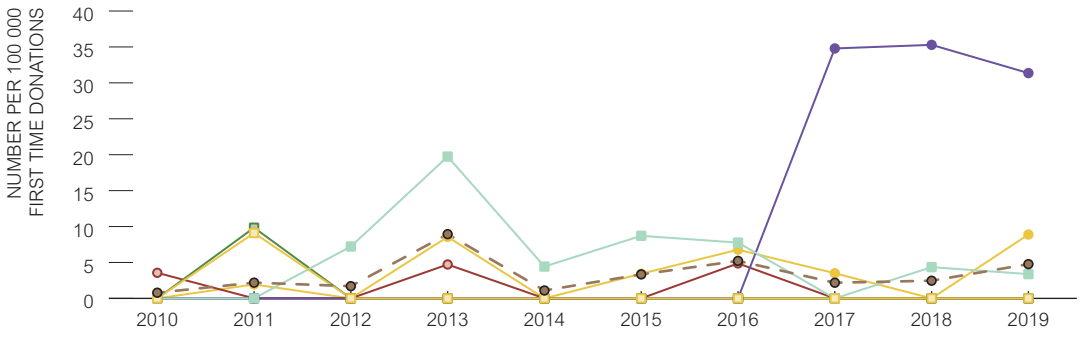
HTLV incidence among repeat Australian donors in 2019 was zero, as it was for the averaged ten-year period 2010-2019. Of note, two lapsed donors from 2007 and 2010 seroconverted in 2015 and 2018, respectively; however, these cases did not meet the definition for an incident donor, which is a positive 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 2010-2019.

Trends in HTLV infection by state/territory

In 2019, HTLV prevalence in first-time donors was zero in most jurisdictions except for New South Wales / Australian Capital Territory, Tasmania and Victoria where the prevalence was 8.9, 31.4 and 3.4 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 2010-2019 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, 2010-2019 (Figure 29).

No incident HTLV infected donors were reported during 2019 in any jurisdiction, and HTLV incidence has remained zero in the ten-year period 2010-2019 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, 2010-2019



	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019
NSW/ACT	0.00	1.94	0.00	8.56	0.00	3.43	6.78	3.50	0.00	8.89
NT	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
QLD	3.56	0.00	0.00	4.72	0.00	0.00	4.87	0.00	0.00	0.00
SA	0.00	9.84	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	34.79	35.29	31.36
VIC	0.00	0.00	7.22	19.74	4.43	8.71	7.76	0.00	4.35	3.38
WA	0.00	9.10	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
National	0.79	2.19	1.70	8.94	1.10	3.34	5.22	2.18	2.46	4.77

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

Population prevalence for HTLV infection is largely unknown with only the Northern Territory 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 were analysed (see Methodological Notes for details)[5] to determine the association between demographic factors and presence of HTLV infection among Australian blood donors in 2019, and the five-year period, 2015-2019, 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 2019, there was no significant association between gender or donors' age group and HTLV infection status, however donors from the Australian Capital Territory are more likely to be HTLV positive than the reference group, however, caution must be applied to interpret this result due to small numbers and a wide confidence interval (Supplementary Table 4).

Similarly, during the five-year period, 2015-2019, there was no significant association between gender or age and HTLV infection status, although donors from the Australian Capital Territory and Tasmania are nearly six times more likely to be HTLV positive than the reference group (Supplementary Table 5).

Risk factors associated with HTLV infected donors

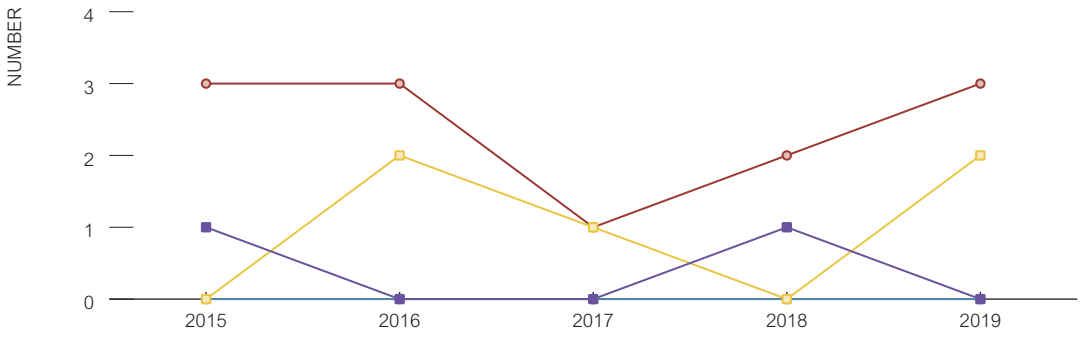
Only 19 donors were positive for HTLV infection during the 2015-2019 period; 17 were first-time donors, two repeat positive donors were identified (neither meeting the incident donor criterion), one each in 2015 and 2018; 63% were male, and the mean age was 39 years with a wide range (20-64 years) (Table 11). The majority of the HTLV positive donors (74%) were born overseas. Ethnicity or country of birth (63%) 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 for any TTI (26%). 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 2015-2019. Of note, literature also identifies self-flagellation as a possible unique risk factor for HTLV infection.[23] This was also noted in the Australian setting where 28% (7 of 25) of the HTLV positive donors had a history of self-flagellation during the 2012-2018 period.[24]

Table 11 Characteristics of donors positive for HTLV infection by year of donation, 2015-2019

Characteristics	2015	2016	2017	2018	2019	2015-2019
Number of positive donors	4	5	2	3	5	19
Number of positive first-time donors (%)	3 (75%)	5 (100%)	2 (100%)	2 (67%)	5 (100%)	17 (89%)
% male	3 (75%)	3 (60%)	1 (50%)	2 (67%)	3 (60%)	12 (63%)
Mean age (range) in years	33(30-40)	32 (20-45)	54 (44-64)	38 (26-54)	44 (32-60)	39 (20-64)
Number of incident donors	0	0	0	0	0	0
% born in Australia	1(25%)	0 (0%)	1 (50%)	1 (33%)	2 (40%)	5 (26%)
Main reported risk factor	Ethnicity/COB[1] 75%	Ethnicity/COB[1] 80%	Ethnicity/COB[1] 50%	Ethnicity/COB[1] 67%	Ethnicity/COB[1] 40%	Ethnicity/COB[1] 63%
Second reported risk factor	PRP[2] 25%	PRP[2] 20%	PRP[2] 50%	PRP[2] 33%	PRP[2], PUSR[3], Other each 20%	PRP[2] 26%

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

Figure 30 Donors with HTLV infection by sex and donor status, 2015-2019



	2015	2016	2017	2018	2019
Male (first-time)	3	3	1	2	3
Male (repeat)	0	0	0	0	0
Female (first-time)	0	2	1	0	2
Female (repeat)	1	0	0	1	0

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 2015-2019 (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 2019 and period 2015-2019, see Supplementary Tables 6-12.

HTLV - Comparison of major exposure categories between blood donors 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 is possible. Nonetheless, Aboriginal and Torres Strait Islander populations in inland Australian regions are known to represent a high HTLV-1-prevalence population.[25] 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.[26] 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 three out of five HTLV positive donors in 2019.

Conclusion

- The prevalence of HTLV among first-time donors remained low; however, there are no data to compare to 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.

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Potentially Infectious Syphilis (PIS)

Epidemiology of infectious syphilis in Australia

Potentially infectious syphilis (PIS) is a blood safety definition designed to capture donors that have a theoretical risk of transmitting syphilis by transfusion. Importantly, the risk of syphilis transfusion-transmission is quite distinct from the viral TTIs. Storage of blood products reduces the transmission risk (red cell storage at <20°C for >120 hours inactivates *T.pallidum* spirochaetes (the causative agent),[27] plasma stored at -20°C for 48 hours was shown to be non-infectious in an animal model,[28] and oxygen flow levels in platelet storage bags are believed to be toxic to *T.paliidum*.[29] Hence, the infectivity of transfused products is expected to be low even without syphilis testing. A published Lifeblood analysis concluded that the residual risk of syphilis transmission is currently negligible (1 in 49.5 million per unit transfused).[30] Since blood bags and cold storage were implemented in Australia during the 1970's, the risk of syphilis transmission can be considered 'theoretical', given the absence of cases of transfusion transmission.

Population level data are available on notifications of infectious syphilis. 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 are included as PIS cases if screening and confirmatory tests for treponemal antibodies are 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[31]). 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[32]). 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.

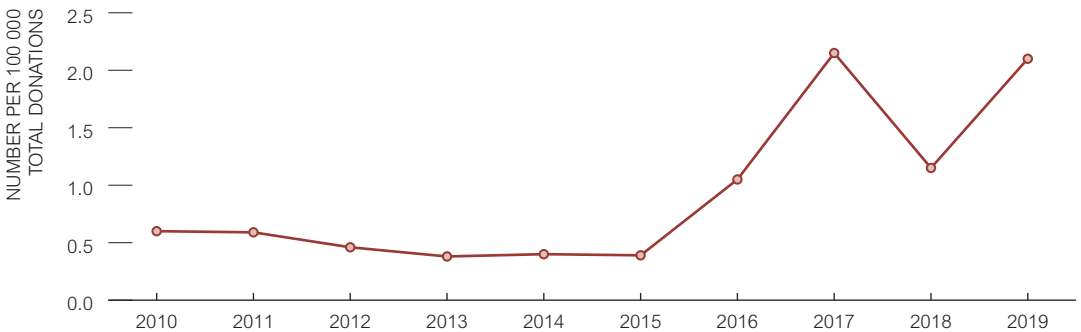
Infectious syphilis in Australia continues to be an infection primarily of men having male to male sex in urban settings, and of heterosexual Aboriginal people in remote and outer regional areas. The number of cases of infectious syphilis (infections of less than 2 years' duration) notified in 2018 was 5 078.[2] The rate of diagnosis of infectious syphilis among men has increased in the past ten years, from 11 per 100 000 in 2009 to 36 per 100 000 in 2018; similarly the rate among women has increased from 1 per 100 000 in 2009 to 6 per 100 000 in 2018.[3,4]

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, 2010-2019, a total of 92 donors positive for PIS/active syphilis have been detected (42 first-time donors and 50 repeat donors) (Table 1B). During the period 2010-2019, the overall prevalence of PIS/active syphilis infection among all donations remained very low at 0.8 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 2.1, 1.1 and 2.1 per 100 000 donations in 2017, 2018 and 2019, respectively. As a result, a significant increase in the prevalence of PIS/active syphilis among all donations was observed during 2010-2019 (IRR 1.20; 95% CI: 1.11-1.29) (Figure 31). Although this should be interpreted with caution because of the definition change and impact of the change in the syphilis testing profile, there has been a definitive increase in syphilis cases in blood donors, which reflects the increasing trend in the general population. For detail on the number and prevalence rate of potentially infectious syphilis among all donations for the year 2019, see Supplementary Table 3.

Figure 31 Prevalence of PIS/active syphilis in all blood donations in Australia, 2010-2019, by year of donation

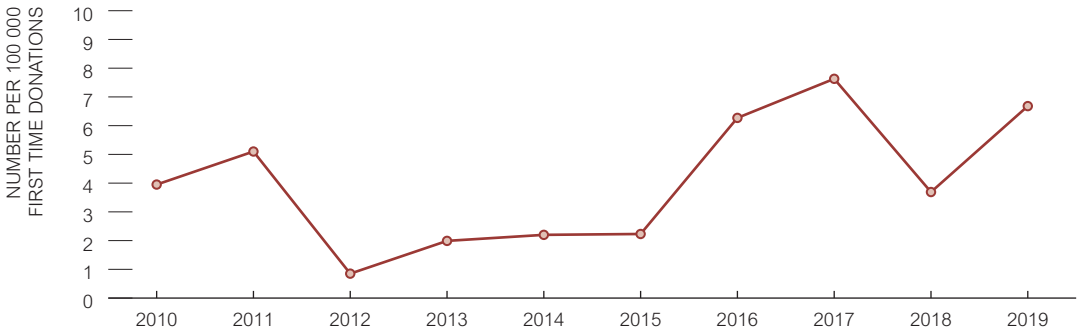


	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019
Prevalence in all donations	0.60	0.59	0.46	0.38	0.40	0.39	1.05	2.15	1.15	2.10

First-time donors:

In the past ten years, 2010-2019, the prevalence of PIS/active syphilis in first-time donors remained low, at 4.1 per 100 000 donations (Table 1B). Overall, the prevalence of PIS/active syphilis in first-time donors showed no significant trend during 2010-2019 (IRR: 1.08; 95% CI: 0.98-1.20); and the rate fluctuated between 0.8 per 100 000 donations and 7.6 per 100 000 donations (Figure 32). By comparison, the rate of diagnoses of infectious syphilis reported through the Australian National Notifiable Diseases Surveillance System was 6.0 per 100 000 population in 2009; it remained stable for the next 4 years and fluctuated between 6.0-7.8 per 100 000 population. The rate showed a steep increase to 12.0 per 100 000 population in 2015, and 20.8 per 100 000 in 2018 corresponding to the highest recorded number of notifications, with 5 078 diagnoses of infectious syphilis.[2] Caution should be taken in interpretation, as the infectious case definition changed in July 2015, to include more cases of likely recent acquisition.[32]

Figure 32 Prevalence of PIS/active syphilis in first-time blood donors in Australia, 2010-2019, by year of donation

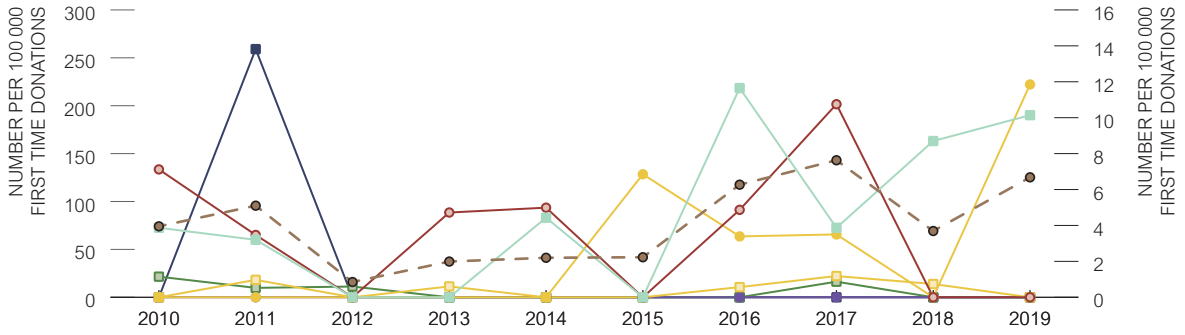


	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019
Prevalence in first-time donors	3.95	5.10	0.85	1.99	2.20	2.23	6.27	7.63	3.69	6.68

Trends in PIS/active syphilis infection by state/territory

In 2019, PIS/active syphilis prevalence in first-time donors was zero in all jurisdictions with the exception of New South Wales / the Australian Capital Territory and Victoria, where rates were 11.9 per 100 000 donations (equating to four positive donations in first-time donors) and 10.1 per 100 000 donations (equating to three 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 significant trends observed in most jurisdictions during the ten-year study period, 2010-2019, except for New South Wales / the Australian Capital Territory, where PIS/active syphilis prevalence in first-time donors showed a significant upward trend (IRR: 1.59; 95% CI: 1.14-2.24). In comparison, the trend in the general population over during the period 2009-2018, showed an increase in rates of diagnosis of infectious syphilis in all jurisdictions, except Tasmania.[2]

Figure 33 Prevalence[1] of PIS/active syphilis among first time donors by state/territory and year of donation, 2010-2019



	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019
NSW/ACT	0.00	0.00	0.00	0.00	0.00	6.85	3.39	3.50	0.00	11.85
NT	0.00	259.07	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
QLD	7.12	3.47	0.00	4.72	4.99	0.00	4.87	10.75	0.00	0.00
SA	21.54	9.84	11.24	0.00	0.00	0.00	0.00	16.29	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	3.87	3.20	0.00	0.00	4.43	0.00	11.65	3.87	8.70	10.14
WA	0.00	18.20	0.00	11.34	0.00	0.00	10.64	22.20	13.85	0.00
National	3.95	5.10	0.85	1.99	2.20	2.23	6.27	7.63	3.69	6.68

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 2019 and the ten-year study period 2010-2019 was 6.68 and 4.05 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.[2] 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

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)[6] to determine the association between demographic factors and presence of PIS/active syphilis infection among Australian blood donors in 2019, and the five-year period, 2015-2019, separately (Supplementary Tables 4 and 6). 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 2019, female donors were significantly less likely (82%) 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, 2015-2019, female donors were 74% less likely to be to be positive with PIS/active syphilis as compared to male donors. Donors between 30-39 years, 40-49 years and 50-years-and-above age groups were 50%, 71% and 82% 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

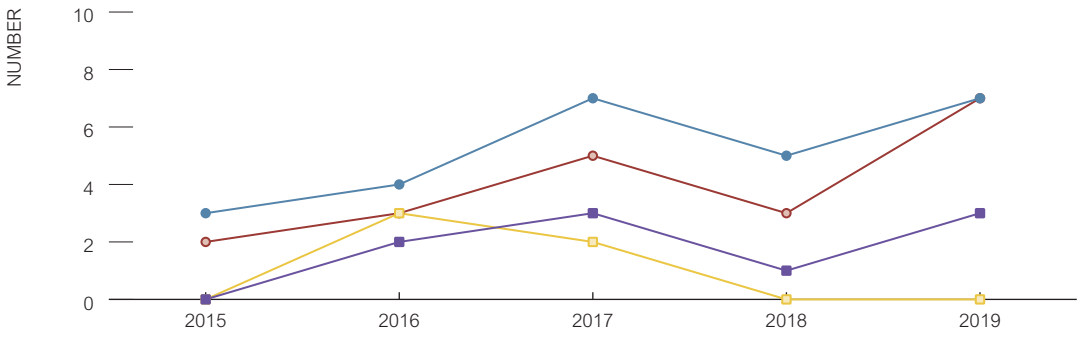
During 2015-2019, a total of 60 donors were positive for PIS/active syphilis, 42% were first-time donors, 77% were male, and 67% were born in Australia (Table 12). The mean age was 33 (range 19-63). Partner with unspecified risk (37%) was the most frequent likely risk factor for PIS/active syphilis positivity. In comparison, in 2017, nationally, 85% of infectious syphilis diagnoses were in males, and 60% were in people aged 20 – 39 years.[33]

Table 12 Characteristics of donors positive for PIS/active syphilis by year of donation, 2015-2019

Characteristics	2015	2016	2017	2018	2019	2015-2019
Number of positive donors	5	12	17	9	17	60
Number of positive first-time donors (%)	2 (40%)	6 (50%)	7 (41%)	3 (33%)	7 (41%)	25 (42%)
% male	5 (100%)	7 (58%)	12 (71%)	8 (89%)	14 (82%)	46 (77%)
Mean age (range) in years	32 (29-60)	37 (24-55)	30 (19-51)	42 (25-63)	30 (21-42)	33 (19-63)
% born in Australia	2 (40%)	9 (75%)	12 (71%)	7 (78%)	10 (59%)	40 (67%)
Main reported risk factor	Unknown	PUSR[2] Unknown - each	PUSR[2]	PUSR[2]	MSM[1]	PUSR[2]
	60%	42%	47%	56%	41%	37%
Second reported risk factor	MSM[1] contact & PUSR[2] each	PRP[3]	PRP[2]/ Undetermined each	MSM[1]/ Undetermined each	PUSR[2]	Unknown
	20%	17%	18%	22%	24%	20%

1 MSM= Men who have sex with men
2 PUSR=Partner with unspecified risk
3 PRP= Partner with known risk/known to be positive

Figure 34 Donors with PIS/active syphilis infection by sex and donor status, 2015-2019



	2015	2016	2017	2018	2019
Male (first-time)	2	3	5	3	7
Male (repeat)	3	4	7	5	7
Female (first-time)	0	3	2	0	0
Female (repeat)	0	2	3	1	3

Over the past five years, 2015-2019, there has been an upward trend in the number of PIS/active syphilis positive first-time / repeat male and repeat female 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 2019 and period 2015-2019, see Supplementary Tables 6-12.

Conclusion

- Overall, the prevalence of PIS/active syphilis among all blood donations during 2010-2019 has shown a significant upward trend.
- A comparison between the prevalence of PIS/active syphilis in blood donors and the 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

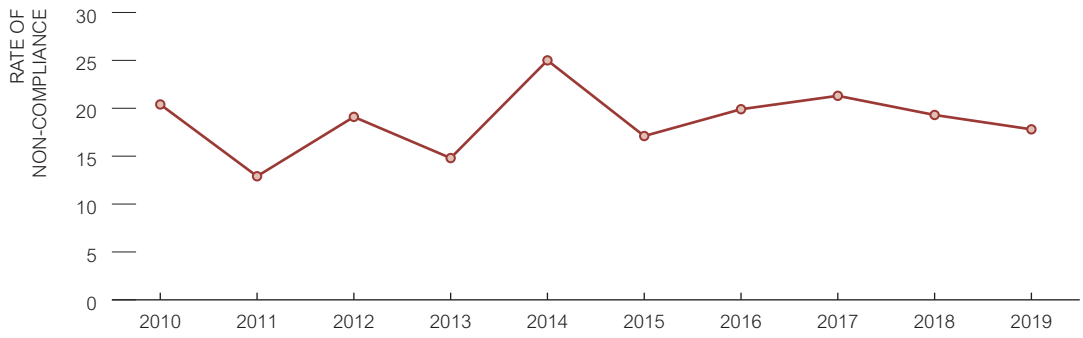
Screening compliance

Every donor is required to self-complete a comprehensive Donor Questionnaire (DQ) prior to each donation. The DQ for a plasma for fractionation donation omits some of the questions asked. Once the donor has completed the DQ, a Lifeblood staff member assesses the donor's eligibility to donate. 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 DQ 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.

Nineteen percent (152) of infected donors in 2015-2019 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, 71% (108 donors) were first-time donors. The rate of reported non-compliance in TTI positive donors has been relatively stable for the past five years (ranging between 17-21%) after peaking at 25% in 2014 (Figure 35). The average rate observed in a previous Lifeblood study[9] for 2000-2006 was 22%.

Figure 35 Rate of reported non-compliance in transfusion-transmissible-infection positive donors, 2010-2019



	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019
Rate of non-compliance	20.4	12.9	19.1	14.8	25.0	17.1	19.9	21.3	19.3	17.8

Table 13 Non-compliance category and rate among donors who were positive for any transfusion-transmissible infection, 2015-2019

Non-compliance by year and reason for deferral	2015[a]	2016[b]	2017	2018[c]	2019[d]	2015-2019
Number (%) of non-compliant donors by reasons for deferral						
Intravenous drug use	14 (52%)	15 (48.3%)	9 (29.0%)	9 (31.0%)	7 (20.6%)	54 (35.53%)
Known status/previous positive^	10 (37%)	17 (54.8%)	16 (51.6%)	17 (58.6%)	17 (50.0%)	77 (50.66%)
Male-to-male-sexual contact	1 (3.7%)	1 (3.2%)	2 (6.4%)	4 (13.8%)	5 (14.7%)	13 (8.55%)
Partner with known risk or known to be positive	1 (3.7%)	2 (6.4%)	4 (12.9%)	3 (10.3%)	6 (17.6%)	16 (10.53%)
Others	7 (26%)	0 (0%)	0 (0%)	1 (3.4%)	2 (5.9%)	10 (6.58%)
Total number (%) of non-compliant donors by year	27 (17%)	31 (20%)	31 (21%)	29 (19%)	34 (18%)	152 (19.02%)

^ includes people with a history of jaundice
a In 2015, 6 out of 27 non-compliant donors had more than one reason for non-compliance hence the total% is more than 100%
b In 2016, 5 out of 31 non-compliant donors had more than one reason for non-compliance hence the total % is more than 100%
c In 2018, 8 out of 29 non-compliant donors had more than one reason for non-compliance hence the total% is more than 100%
d In 2019, 3 out of 34 non-complaint donors had more than one reason for non-compliance hence the total % is more than 100%

Unlike 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, 58.6% in 2018 and 50.0% in 2019. 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 considered 'cured', they have detectable HCV antibodies and therefore are not eligible to donate blood. An increase in non-compliant HBV positive donors might be associated with expanding migration from HBV endemic countries. Overall, during the period of 2015-2019, 50.6% of non-compliance was attributed to known status of previously being positive for a virus followed by injecting drug use (35.5%), and having a sexual partner with known risk or known to be positive for any transfusion-transmissible infection (10.5%) (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. Incident infections represent the majority of the risk of potential individuals donating in the window period 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 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.[34] More recent estimation indicates an increasing proportion of OBI risk, about 84% and 94% for 2015-16 and 2017-18 periods, respectively. (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 addressed the existing limitation that the models applied were 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 in 2017 of the method of Weusten *et al*[35] lead generally to lower estimates and standardised the method with HBV. Using viral testing data including the number of incident donors reported for the 2018 and 2019 calendar year periods and applying these to Lifeblood[35] and Weusten risk models, residual risk estimates[36] (per unit transfused) were derived for the four transfusion-transmissible viral infections subject to mandatory testing (Table 14). Of note, the HBV risk estimate includes a separate model specifically addressing the risk of occult hepatitis B infection (OBI).[37] The risk estimate for active syphilis is derived periodically with the most recent estimate being less than 1 in 49 million per unit transfused.[30] The estimates for all fall below the 'negligible' risk threshold of 1 in 1 million per unit transfused used by Lifeblood to contextualise the risks for transfusion recipients. Further information can be obtained from the following website http://www.transfusion.com.au/adverse_events/risks/estimates.

Table 14 Estimated risk of window period donation/risk of not detecting true infection for HBV, HCV, HIV, HTLV and syphilis in Australian blood donations (2018-2019)

	HBV	HCV	HIV	HTLV	PIS/active syphilis
Estimated number of window period 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 1.34 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 2005-2019 period. Notably, 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.[38] 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 2019 were referred to their doctor with a copy of their results.

In 2019, 122 910 donations were tested for malaria antibody of which 2 373 (1.9%) were found to be repeat reactive for malaria antibodies. This rate of antibody detection is comparable to the 1.4% rate recorded in 2018. No cases of transfusion transmitted malaria were reported in Australia in 2019 with the last recorded Australian case in 1991.[39] 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[40] and 1 in 500 000 for red cells[41]. 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.[42]

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,[43] this procedure had been previously shown to reduce the bacterial contamination of platelet concentrates by more than 70%.[44]

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 April 2008, all platelets produced by Lifeblood have been screened for bacterial contamination. Until late November 2019, BCS utilised the automated BacT/ALERT 3D system.[45] The 3D system was replaced by the BacT/ALERT VIRTUO system at Melbourne Processing Centre (MPC) on 27 November 2019, and at Perth Processing Centre (PPC) on 9 December 2019. Brisbane and Sydney Processing Centres (BPC and SPC respectively) upgraded to the VIRTUO system in early 2020.

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.[46]

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

7. **Other strategies**
   Pathogen inactivation/reduction technologies (PI/PRT) could potentially further mitigate the risk of bacterial transmission, and have been implemented by some overseas providers.[47] 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.

Bacterial pre-release testing for platelets

Platelet concentrates are manufactured either directly by apheresis, or by pooling the buffy coats from four whole blood donations into a single platelet unit. Apheresis collections may be split into one, two or three platelet units. BCS samples are collected from the combined platelet volume prior to splitting, and the same absolute sample volume is extracted regardless of the final number of split components. For apheresis platelets, figures in the tables below therefore refer to the number of platelet collections sampled, not the number of split components derived from these.

Between 24 and 48 hours after collection, a minimum sample volume of 15 mL is removed from the pooled platelet pack, or from the combined apheresis platelet collection. The sample is divided roughly equally between a pair of specialised platelet culture bottles, comprising one anaerobic (BPN) and one aerobic (BPA) culture medium. As noted above, until 27 November 2019 these were monitored for bacterial growth by the automated BacT/ALERT 3D system at all processing sites, and by a mix of BacT/ALERT 3D and VIRTUO incubators until the end of 2019.

Due to the short 5-day shelf life of platelet concentrates, platelet packs are released for use immediately after BCS sampling as "culture negative to date".

If possible bacterial growth is detected, the culture bottle is flagged by the automated incubator as "initial machine positive". All unused platelet packs and associated components are immediately recalled or quarantined. If any components have already been transfused, the treating clinician is notified immediately, and then updated regularly as further information becomes available.

Positive BCS bottles are investigated at external reference laboratories (ERL) in each state by Gram staining, subculture to agar media, bacterial identification and antimicrobial susceptibility testing (where appropriate). False positive BCS results trigger discard of all associated components, unless the ERL possesses a licence from the Therapeutic Goods Administration (TGA) for platelet manufacture by conforming to the Code of Good Manufacturing Process (cGMP). In this latter case, non-platelet components may be released for clinical use if the ERL establishes that the initial BCS flag was a "machine false positive", i.e. no organisms were seen on staining and no growth was noted on agar subculture of the BCS medium.

In 2019 a total of 120 591 BCS samples were tested.

Of 95 484 pooled platelet units tested, 276 (0.29%) were flagged by the BacT/ALERT as initial machine positive. Of the total platelet units tested, 100 (0.10%) were designated "confirmed positive", 75 (0.08%) were "indeterminate" and the remaining 101 (0.10%) were considered to be "false positive".

Of 25 107 apheresis collections tested, 121 (0.48%) were flagged by the BacT/ALERT as initial machine positive. Of the total apheresis collections tested, 15 (0.06%) were designated "confirmed positive", 28 (0.11%) were "indeterminate" and the remaining 78 (0.31%) were considered to be "false positive" (Table 15).

Table 15 Summary of bacterial testing of platelets by BacT/ALERT 3D and BacT/ALERT VIRTUO, 2019

Platelet type	No. BCS samples (% of total)	No. initial positive (% of BCS samples)[i]	No. confirmed positive (% of BCS samples)[ii]	No. indeterminate (% of BCS samples)[iii]	No. false positive (% of BCS samples)[iv]
Pooled platelets[v]	95 484 (79.18)	276 (0.29)	100 (0.10)	75 (0.08)	101 (0.11)
Apheresis platelets[v]	25 107 (20.82)	121 (0.48)	15 (0.06)	28 (0.11)	78 (0.31)
Total	120 591 (100)	397 (0.33)	115 (0.10)	103 (0.09)	179 (0.15)

i. At least one culture bottle reported ("flagged") as positive by the BacT/ALERT 3D or BacT/ALERT VIRTUO system
ii. Includes the following:
• Platelet component is available for retesting, and the same organism is re-isolated from it (or from at least one split component, in the case of double- and triple-apheresis platelets)
• Where the platelet component is not available (e.g. transfused), the same organism is isolated from both the original platelet BCS sample and another associated blood component
• Following a septic transfusion reaction, the same organism is cultured from both the patient's blood and an implicated product
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 either of the following:
• The BacT/ALERT 3D or VIRTUO system signals a positive bottle, but no organisms are found by the reference laboratory (negative Gram/other stain and no growth on subcultures), and repeat BCS sampling of the platelet component is similarly negative
• The organism identified in the initial BCS sample is not re-isolated when the original platelet pack and associated components are re-sampled for BCS
v. Apheresis BCS samples are collected from the combined apheresis collection volume, which may ultimately produce only a single platelet unit, or be split into two or three platelet units. There is therefore a near 1-to-1 correlation between the number of apheresis platelet BCS samples and the number of apheresis collections, but not between the number of BCS samples and the total apheresis-derived platelet units manufactured. Conversely, for pooled platelet units there is a nearly 1-to-1 correlation between the number of BCS samples and the number of platelet units manufactured, and a 1-to-4 correlation with the number of associated whole blood collections. Contamination rates in the table are therefore not directly comparable between pooled platelet BCS and apheresis platelet BCS.

Of the 115 confirmed positives, the most frequently isolated genera were *Cutibacterium and Propionibacterium* (hereafter collectively referred to as "propionibacteria"), which were isolated from 98 samples (85.2%). Coagulase-negative staphylococci (CoNS) were isolated from 8 BCS samples (7.0%). These figures include a single sample (0.1%) from which both *Cutibacterium acnes* and *Staphylococcus epidermidis* were isolated.

Propionibacteria and 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 groups of bacteria were most likely skin contaminants which entered the blood at the time of collection.

The remaining 10 (8.7%) confirmed positives were potentially pathogenic species, which are listed in Table 16.

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[48]

Of 115 confirmed positives, there were 2 confirmed isolates of strictly anaerobic pathogenic organisms (1.7%), namely *Finegoldia magna* and *Parvimonas micra*. The clinical significance of non-spore forming strict anaerobes is questionable, since while two isolates were clearly capable of remaining viable for some time in the aerobic platelet environment, they would be unlikely to replicate to levels which would cause a septic transfusion reaction in a recipient. Detection of contamination with anaerobes is nonetheless important for recipient safety (preventing transmission of viable bacteria), process control and even donor safety (detection of asymptomatic bacteraemia).

In 2019, there were 42 cases of suspected transfusion-transmitted bacterial infections referred for investigation. Two cases were confirmed:

- **Case 1** developed sepsis following transfusion of an apheresis platelet unit at day 5 of storage. *Staphylococcus aureus* was isolated by the hospital's microbiology laboratory from both the transfused platelet unit and the patient's blood cultures, with both isolates having identical antibiotic susceptibility profiles. Lifeblood investigation determined the donor remained well, and no quality issues during collection, manufacture, storage or transport were identified. Pre-release BCS testing of the combined volume was negative after 5 days of incubation, as was one recalled platelet unit. The third associated platelet unit was transfused uneventfully before the recall was initiated.

- **Case 2** developed sepsis during transfusion with a pooled platelet unit on day 3 of storage. Bacterial contamination testing was negative. Group G *Streptococcus* was isolated by the hospital laboratory from both the platelet component and the patient's blood cultures. Lifeblood investigation determined the four contributing donors remained well following donation, and no clinical source of this organism was revealed on interview of each donor after this event. No quality issues during collection, manufacture, storage or transport were identified. Culture of the available associated red cells and plasma were negative, and no adverse reactions were observed in the recipients of associated components which had already been transfused.

There were no red cell or plasma-associated septic transfusion events in 2019.

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.

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.[43] This compares favourably with US data indicating a rate of 0.9 per 100 000 platelet units.[49] For red cells, the Australian Red Cross Blood Lifeblood rate was similarly low at 0.04 per 100 000 transfused units.[43]

Table 16 Summary of confirmed positive contaminants from platelets, 2019 (n=115 BCS samples*)

Confirmed positives: organism isolated	Number
Cutibacterium and *Propionibacterium* species*	98
Coagulase-negative staphylococci*	8
Serratia marcescens	2
Bacillus cereus	1
Finegoldia magna	1
Parvimonas micra	1
Staphylococcus aureus	1
Streptococcus agalactiae (Lancefield Group B)	1
Streptococcus dysgalactiae	1
Streptococcus pyogenes (Lancefield Group A)	1
Streptococcus species (Lancefield Group C)	1
Total	116*

* Figures in the table include a single BCS sample from which both *Propionibacterium acnes* and *Staphylococcus epidermidis* was isolated, therefore the total in this table is one greater than the number of contaminated BCS samples.

Surveillance and risk assessment 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's 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). Since March 2020, in response to the COVID-19 pandemic, Lifeblood has deferred all donors returning from overseas for 4 weeks from their return. This general deferral, which is in addition to any existing geographical deferrals, would effectively mitigate the risk to blood safety in Australia associated with overseas outbreaks. The limitation of overseas travel and decrease in arrivals has significantly decreased the risk of potential TTIs imported from overseas.

2019-2020 Summary:

Pathogen	Transfusion-transmission reported	Infectious risk period	Surveillance/Risk assessment	Additional risk management for blood safety
Dengue virus	Yes, albeit rarely	The incubation period for symptomatic infection following DENV infection is between 3 and 14 days (usually 4–7 days). Following infection with DENV, viraemia is detectable 2–3 days prior to febrile symptoms and can persist from 4–14 days.	In 2020 the only reported outbreak of dengue fever was in Townsville where 2 locally-acquired cases occurred.[50] With decreased overseas arrivals and no direct international arrivals permitted in 2020 where there are competent vectors as per government policy, there is currently no significant risk of local outbreaks.	During local outbreaks in Queensland, donations in outbreak areas are restricted to the manufacture of plasma products during outbreak period.
Hepatitis A	Yes, albeit rarely	The incubation period following infection with HAV can vary from 10 to 50 days with an average of 28– 30 days; symptoms usually last <2 months. HAV viraemia occurs 7–21 days after exposure and typically persists for 30–42 days. Anti-HAV IgM is typically detectable when symptoms appear (average of 28 days from exposure).	The majority of hepatitis A infections in Australia prior to COVID-19 were overseas acquired infections. With the reduction in international travel the numbers of hepatitis A infections have decreased. In 2018 there were 434 cases nationally in Australia with 269 in Victoria[51] due to a significant outbreak at the time in men who have sex with men with community spill over. Whilst the Victorian government has a current advisory as of October 2020 for a small outbreak active since July 2019 in people who inject drugs and homeless people, the numbers in this outbreak have not increased significantly in recent months. In 2020, nationwide, there were 85 cases with 77 of those being in January to April. Only 8 cases have been diagnosed in the last 8 months of 2020, nationally.[51] Modelling has previously demonstrated hepatitis A is a negligible risk to blood safety even with previous local outbreaks and returning travellers. In the current context the risk is significantly lower.	Most cases in Australia in the past have been associated with overseas travel and existing restrictions to protect against other diseases such as malaria also protect against hepatitis A. Outbreaks in Australia have occurred in men who have sex with men, people who inject drugs and homeless people who are generally ineligible to donate blood during the at risk period. Lifeblood has deferrals for close contacts of hepatitis A cases.
Hepatitis E (HEV)	Yes, many cases reported in Europe	Most HEV infections (>95%) are subclinical. The incubation period ranges from 2 to 10 weeks (average 40 days). HEV RNA becomes detectable during the incubation period (2-10 weeks after infection). IgM becomes detectable about the time of symptom onset, followed by IgG shortly after. Following infection with HEV, viraemia is transient, typically lasting from 1 to 6 weeks.	Given the low incidence of HEV in the Australian community in general and the donor population in particular, the low estimated TT risk and donor deferrals for most HEV endemic developing countries, HEV currently represents a low risk to blood safety in Australia. However, as a potential threat to blood safety, ongoing enhanced surveillance is required. The risk of HEV transfusion-transmission in a country is directly related to the incidence in the donor population. Whilst countries in Europe move to screening based on their higher prevalence, the risk and cost-benefit in Australia, as documented in our risk assessment stands if the incidence in Australia has not appreciably changed.[52] From 2014 to 2019 the average number of detected HEV infections has remained stable with 41-58 reported infections a year.[51] With travel restrictions the rate of HEV infections in Australia has decreased with 31 in 2020 and only two since March.[51]	Lifeblood has a deferral for HEV infection and close contact with a confirmed case. Developing countries with higher HEV rates are covered by malaria restrictions limiting fresh component donation.

Pathogen	Transfusion-transmission reported	Infectious risk period	Surveillance/Risk assessment	Additional risk management for blood safety
Parvovirus (B19)	Yes, three probable cases of transfusion-transmission have occurred in recent years in Australia.[53]	The majority of B19V infections are either asymptomatic or accompanied by non-specific symptoms that are not recognised as B19V infection. In symptomatic children, the most common symptom, facial erythema, begins about 18 days after infection. In immunocompetent individuals B19V infection is typically cleared within 6 months. Viraemia occurs about 1 week after exposure, usually persisting in high titre for up to 12 weeks where it is potentially transmissible.	A risk assessment of B19V in Australia has been completed.[53] 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	Lifeblood has a B19V contact deferral.
Ross River virus (RRV)	Yes, a single case in Australia has been reported.[54]	The incubation period following RRV infection can vary from 2 to 21 days with an average of 7–9 days. Following infection with RRV, the pre-symptomatic viraemic period has been estimated to be 1 day (range 0.5–2.0). Viraemia typically becomes undetectable around the time of, or shortly after, symptom onset.	Since the case report in 2015 Lifeblood has completed a comprehensive risk assessment of the risk of RRV.[55] During the largest outbreak in Australia to date in 2015 no TT-RRV cases were reported and testing in highest risk areas of 7500 donations by PCR during the high transmission period did not detect a single positive donation. In 2020 there was significant activity in April and May with a peak of 1908 infections in April in Australia. The return of El Niño may result in an increase in RRV activity in some areas (previously noted as an important indicator of activity in the Murray Darling area, but not others) and Lifeblood will perform enhanced surveillance to ensure extra awareness of the importance of post donation illness reporting in areas with significant outbreaks.	Lifeblood has a deferral for RRV. If a donor donates in the pre-symptomatic period they are encouraged to notify us to ensure recall of the potentially at risk donation can occur.
SARS-CoV-2	No, only a small proportion of COVID-19 patients have detectable SARS-CoV-2 RNA in blood (RNAaemia). The RNAaemia period appears to be brief, low level, has not been shown to represent infectious virus and is typically associated with more severe disease symptoms. SARS-CoV-2 antibodies become detectable in blood between approximately 1 to 2 weeks post-symptom onset and as rising antibody titres are associated with a decline in the level of viral RNA. Similar to other human coronaviruses, transfusion transmission of SARS-CoV-2 has not been reported, suggesting that transfusion-transmission of coronaviruses is rare, if it occurs at all.[56]	The associated disease is referred to as coronavirus disease 2019 (COVID-19). The incubation period is 1-14 days. Phylogenetic analysis indicates SARS-CoV-2 is of bat origin and possibly originally transmitted to humans by an intermediate animal host. Human-to-human transmission, predominantly close contact through respiratory droplets, is the primary mode of transmission.	In Australia, 28 574 confirmed COVID-19 cases and 909 COVID-19-related deaths had been reported by 3 January 2021. The highest number of locally-acquired cases had been reported in Victoria with 19 377 confirmed cases followed by NSW with 2 167 confirmed cases. Of these cases 6 226 (21.8%) were overseas acquired while 22 142 (77.5%) were locally-acquired and 206 cases were of unknown origin. Most of Australia's locally-acquired cases have been reported in Victoria, and most of these were reported during a second wave of locally-acquired infections from approximately mid-June until late October.[57]	In addition to existing deferrals for donors who are unwell, Lifeblood has implemented a number of strategies to mitigate the potential risk to blood safety in Australia associated with SARS-CoV-2. To mitigate the risk associated with overseas-acquired infections, since March 2020 Lifeblood has deferred all donors returning from overseas for 4 weeks from their return. This general deferral is in addition to existing geographical deferrals. Strategies to mitigate the risk associated with locally-acquired infections include the deferral of donors with a current infection for 4 weeks from date of recovery, donors with suspected infection waiting test results until accepted and donors reporting close contact with a confirmed case for 4 weeks from date of last contact.

Pathogen	Transfusion-transmission reported	Infectious risk period	Surveillance/Risk assessment	Additional risk management for blood safety
Variant CJD	Four human cases of vCJD associated with transfusion-transmission have now been reported, all in the UK and associated with non-leucodepleted red blood cells transfused between 1996 and 1999	Following infection there is an extended asymptomatic period, which, although not well defined, has been estimated at 16-17 years for primary vCJD (95% CI, 12-23 years). Although based on limited data, infected individuals appear not to be infectious during the entire incubation period and as unwell people cannot donate blood, the risk is greatest when PrPres is in the blood but before the person has symptoms.	Australia has not recorded any cases of BSE ('mad cow disease') or cases of vCJD and the primary epidemic has waned after peaking in 2000, with the last recorded case in the UK occurring in 2016. While a second wave associated with genetic variants with extended incubation periods cannot be excluded, the risk to blood safety in Australia is deemed negligible and decreasing. We are currently in the process of collating the latest medical evidence to inform a review and risk assessment of this blood donation rule in Australia. Any change to this blood donation rule would need to be approved by the Therapeutic Goods Administration.	Lifeblood has an existing indefinite deferral for cumulative residence of 6 months in the UK during this period, which mitigates the risk but leads to deferral of about 5% of donors.
West Nile virus (WNV)	Yes, transmission of West Nile virus (WNV) by blood, tissue and organ transplantation has been documented.[58]	WNV RNA becomes detectable 1-2 days post-infection followed by anti-WNV IgM and IgG approximately 8 and 11 days post-infection, respectively.	Europe is considered a potential risk area for WNV as there is no existing donation restriction, unlike the US and Canada. Lifeblood has monitored outbreaks in Europe 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 season did not exceed the threshold (established for local dengue outbreaks) that requires cessation of fresh blood component manufacture.[59,60] Due to the very low risk to blood safety in Australia associated with WNV outbreaks in EU and neighbouring countries, Lifeblood has implemented a surveillance system whereby risk modelling will only be implemented when the total number of weekly reported WNF cases in all EU and neighbouring countries reaches a specified number or trigger point.[61]	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.
Zika virus	Yes, but clinical harm has not been established. At least four cases of probable but asymptomatic transfusion-transmitted ZIKV infection were reported during the outbreak in the Americas.[62,63]	Approximately 80% of ZIKV infections are asymptomatic and most symptomatic infections are accompanied by mild symptoms including rash and fever.[64,65] Based on limited data, ZIKV RNA may typically become detectable approximately 6 days (range 4–12 days) prior to symptom onset and remains detectable for a brief period (reported mean of 9.9 days) after symptom onset.	Between 2014 to 2016 the largest ever reported Zika virus outbreak was reported in the Americas. However, in the latter part of 2016 and during 2017 and 2018, the number of reported cases reduced dramatically. The number of reported cases declined to 9 in 2017 and 4 in 2018 and no cases were reported in 2019 to 23 March (which is the last available update as at 15 October 2020).[61] All outbreak areas are covered by existing travel deferrals. Risk assessments have demonstrated the risk to blood safety is negligible.	In addition to geographical Lifeblood has a Zika virus case deferral and a sexual contact deferral.

Conclusion

- The reported 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 '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 2019, 115 (0.10%) of a total 120 591 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 2019 there were two cases of transfusion-transmitted sepsis, one involving a pooled platelet unit contaminated with Group G *Streptococcus* and the other related to an apheresis unit contaminated with *Staphylococcus aureus*.
- In addition to established transfusion-transmissible infections, emerging infectious diseases continue to demand vigilant surveillance and risk assessment. The ongoing risk from SARS-CoV-2, local dengue outbreaks, seasonal WNV outbreaks in Europe, outbreaks of hepatitis A virus and Zika virus have been monitored during 2019-2020. The risk to the blood supply posed by donors returning from Zika virus outbreak areas has been managed by deferring donation (or restricting to plasma for fractionation) for an appropriate period. Lifeblood continues to monitor hepatitis A virus, 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[30]
	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, 2019

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	33 745	432 356	466 101	23	5	28	16	4	20	1	3	4	40	12	52
Number *(Number per 100 000 donations)*				*68.16*	*1.16*	*6.01*	*47.41*	*0.93*	*4.29*	*2.96*	*0.69*	*0.86*	*118.54*	*2.78*	*11.16*
NT	706	10 369	11 075	0	0	0	0	0	0	0	0	0	0	0	0
Number *(Number per 100 000 donations)*				*0.00*	*0.00*	*0.00*	*0.00*	*0.00*	*0.00*	*0.00*	*0.00*	*0.00*	*0.00*	*0.00*	*0.00*
QLD	20 457	279 826	300 283	9	2	11	14	1	15	0	0	0	23	3	26
Number *(Number per 100 000 donations)*				*43.99*	*0.71*	*3.66*	*68.44*	*0.36*	*5.00*	*0.00*	*0.00*	*0.00*	*112.43*	*1.07*	*8.66*
SA	7 290	118 952	126 242	3	2	5	3	1	4	0	0	0	6	3	9
Number *(Number per 100 000 donations)*				*41.15*	*1.68*	*3.96*	*41.15*	*0.84*	*3.17*	*0.00*	*0.00*	*0.00*	*82.3*	*2.52*	*7.13*
TAS	3 189	53 918	57 107	2	0	2	4	0	4	0	0	0	6	0	6
Number *(Number per 100 000 donations)*				*62.72*	*0.00*	*3.50*	*125.43*	*0.00*	*7.00*	*0.00*	*0.00*	*0.00*	*188.15*	*0.00*	*10.51*
VIC	29 599	355 026	384 625	32	8	40	27	1	28	1	1	2	60	10	70
Number *(Number per 100 000 donations)*				*108.11*	*2.25*	*10.40*	*91.22*	*0.28*	*7.28*	*3.38*	*0.28*	*0.52*	*202.71*	*2.82*	*18.20*
WA	9 842	137 816	147 658	2	2	4	3	0	3	2	0	2	7	2	9
Number *(Number per 100 000 donations)*				*20.32*	*1.45*	*2.71*	*30.48*	*0.00*	*2.03*	*20.32*	*0.00*	*1.35*	*71.12*	*1.45*	*6.10*
National	104 828	1 388 263	1 493 091	71	19	90	67	7	74	4	4	8	142	30	172
Number *(Number per 100 000 donations)*				*67.73*	*1.37*	*6.03*	*63.91*	*0.50*	*4.96*	*3.82*	*0.29*	*0.54*	*135.46*	*2.16*	*11.52*

Supplementary Table 3 The number and prevalence rate of transfusion transmissible infections (HTLV and potentially infectious syphilis) in Australia, by state/territory, 2019

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	33 745	241 936	275 681	3	0	3	4	4	8	7	4	11
Number *(Number per 100 000 donations)*				*8.89*	*0.00*	*1.09*	*11.85*	*1.65*	*2.90*	*20.74*	*1.65*	*3.99*
NT	706	3 507	4 213	0	0	0	0	0	0	0	0	0
Number *(Number per 100 000 donations)*				*0.00*	*0.00*	*0.00*	*0.00*	*0.00*	*0.00*	*0.00*	*0.00*	*0.00*
QLD	20 457	141 019	161 476	0	0	0	0	4	4	0	4	4
Number *(Number per 100 000 donations)*				*0.00*	*0.00*	*0.00*	*0.00*	*2.84*	*2.48*	*0.00*	*2.84*	*2.48*
SA	7 290	49 704	56 994	0	0	0	0	0	0	0	0	0
Number *(Number per 100 000 donations)*				*0.00*	*0.00*	*0.00*	*0.00*	*0.00*	*0.00*	*0.00*	*0.00*	*0.00*
TAS	3 189	23 260	26 449	1	0	1	0	0	0	1	0	1
Number *(Number per 100 000 donations)*				*31.36*	*0.00*	*3.78*	*0.00*	*0.00*	*0.00*	*31.36*	*0.00*	*3.78*
VIC	29 599	186 791	216 390	1	0	1	3	2	5	4	2	6
Number *(Number per 100 000 donations)*				*3.38*	*0.00*	*0.46*	*10.14*	*1.07*	*2.31*	*13.51*	*1.07*	*2.77*
WA	9 842	58 562	68 404	0	0	0	0	0	0	0	0	0
Number *(Number per 100 000 donations)*				*0.00*	*0.00*	*0.00*	*0.00*	*0.00*	*0.00*	*0.00*	*0.00*	*0.00*
National	104 828	704 779	809 607	5	0	5	7	10	17	12	10	22
Number *(Number per 100 000 donations)*				*4.77*	*0.00*	*0.62*	*6.68*	*1.42*	*2.10*	*11.45*	*1.42*	*2.72*

Supplementary Table 4 Association of demographic characteristics with presence of transfusion-transmissible infections among blood donors in Australia, 2019

		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	*239 015*	*73 (30.54)*	*1 (ref)*	*…*	*44 (18.41)*	*1 (ref)*	*…*
Female	*249 185*	*17 (6.82)*	*0.22 (0.13-0.38)*	*0.00*	*30 (12.04)*	*0.69 (0.43-1.10)*	*0.12*
Age group (years)							
20-29	*119 178*	*15 (12.59)*	*1 (ref)*	*…*	*8 (6.71)*	*1 (ref)*	*…*
Less than 20	*17 689*	*1 (5.65)*	*0.50 (0.06-3.82)*	*0.5*	*3 (16.96)*	*2.61 (0.69-9.87)*	*0.15*
30-39	*106 655*	*39 (36.57)*	*2.59(1.42-4.70)*	*0.00*	*13 (12.19)*	*1.76 (0.73-4.26)*	*0.2*
40-49	*87 093*	*17 (19.52)*	*1.42 (0.70-2.84)*	*0.32*	*15 (17.22)*	*2.50 (1.06-5.91)*	*0.03*
50 and above	*157 585*	*18 (11.42)*	*0.80 (0.40-1.59)*	*0.52*	*35 (22.21)*	*3.17 (1.46-6.85)*	*0*
State/Territory							
NSW	*142 325*	*22 (15.46)*	*1 (ref)*	*…*	*19 (13.35)*	*1 (ref)*	*…*
ACT	*15 466*	*6 (38.79)*	*2.39(0.97-5.91)*	*0.06*	*1 (6.47)*	*0.50 (0.06-3.75)*	*0.50*
NT	*3 387*	*0 (0)*	*…*	*0.99*	*0 (0)*	*…*	*0.99*
QLD	*95 564*	*11 (11.51)*	*0.75 (0.36-1.55)*	*0.44*	*15 (15.7)*	*1.16 (0.59-2.28)*	*0.66*
SA	*39 017*	*5 (12.81)*	*0.86 (0.32-2.29)*	*0.77*	*4 (10.25)*	*0.73 (0.24-2.15)*	*0.57*
TAS	*16 014*	*2 (12.49)*	*0.87 (0.20-3.74)*	*0.86*	*4 (24.98)*	*1.79 (0.61-5.29)*	*0.28*
VIC	*132 075*	*40 (30.29)*	*1.94 (1.15-3.26)*	*0.01*	*28 (21.2)*	*1.60 (0.89-2.87)*	*0.11*
WA	*44 347*	*4 (9.02)*	*0.56 (0.19-1.63)*	*0.29*	*3 (6.76)*	*0.50 (0.14-1.71)*	*0.27*
Total	488 200	90 (18.44)			74 (15.16)		

		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	*239 015*	*6 (2.51)*	*1 (ref)*	*…*	*3 (1.26)*	*1 (ref)*	*…*
Female	*249 185*	*2 (0.8)*	*0.30 (0.06-1.54)*	*0.15*	*2 (0.8)*	*0.72 (0.12-4.35)*	*0.72*
Age group (years)							
20-29	*119 178*	*3 (2.52)*	*1 (ref)*	*…*	*0 (0)*	*1 (ref)*	*…*
Less than 20	*17 689*	*0 (0)*	*..*	*0.99*	*0 (0)*	*…*	*1*
30-39	*106 655*	*2 (1.88)*	*0.65 (0.10-3.96)*	*0.64*	*3 (2.81)*	*…*	*0.99*
40-49	*87 093*	*1 (1.15)*	*0.42 (0.04-4.05)*	*0.45*	*0 (0)*	*…*	*1*
50 and above	*157 585*	*2 (1.27)*	*0.45 (0.07-2.76)*	*0.39*	*2 (1.27)*	*…*	*0.99*
State/Territory							
NSW	*142 325*	*4 (2.81)*	*1 (ref)*	*…*	*1 (0.7)*	*1 (ref)*	*…*
ACT	*15 466*	*0 (0)*	*…*	*0.99*	*2 (12.93)*	*18.7 (1.69-207.83)*	*0.01*
NT	*3 387*	*0 (0)*	*…*	*0.99*	*0 (0)*	*…*	*0.99*
QLD	*95 564*	*0 (0)*	*…*	*0.42*	*0 (0)*	*…*	*0.99*
SA	*39 017*	*0 (0)*	*…*	*0.37*	*0 (0)*	*…*	*0.99*
TAS	*16 014*	*0 (0)*	*…*	*0.99*	*1 (6.24)*	*8.80 (0.54-141.36)*	*0.12*
VIC	*132 075*	*2 (1.51)*	*0.53 (0.09-2.92)*	*0.47*	*1 (0.76)*	*1.05 (0.06-16.93)*	*0.96*
WA	*44 347*	*2 (4.51)*	*1.59 (0.29-8.72)*	*0.58*	*0 (0)*	*...*	*0.99*
Total	488 200	8 (1.64)			5 (1.02)		

	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	*239 015*	*14 (5.86)*	*1 (ref)*	*…*
Female	*249 185*	*3 (1.2)*	*0.18 (0.05-0.62)*	*0.00*
Age group (years)				
20-29	*119 178*	*9 (7.55)*	*1 (ref)*	*…*
Less than 20	*17 689*	*0 (0)*	*…*	*0.99*
30-39	*106 655*	*6 (5.63)*	*0.66 (0.23-1.87)*	*0.44*
40-49	*87 093*	*2 (2.3)*	*0.27 (0.05-1.27)*	*0.44*
50 and above	*157 585*	*0 (0)*	*…*	*0.99*
State/Territory				
NSW	*142 325*	*8 (5.62)*	*1 (ref)*	*…*
ACT	*15 466*	*0 (0)*	*…*	*0.99*
NT	*3 387*	*0 (0)*	*…*	*0.99*
QLD	*95 564*	*4 (4.19)*	*0.77 (0.23-2.55)*	*0.67*
SA	*39 017*	*0 (0)*	*…*	*0.99*
TAS	*16 014*	*0 (0)*	*…*	*0.99*
VIC	*132 075*	*5 (3.79)*	*0.66 (0.21-2.02)*	*0.46*
WA	*44 347*	*0 (0)*	*…*	*0.99*
Total	488 200	17 (3.48)		

Supplementary Table 5 Association of demographic characteristics with presence of transfusion-transmissible infections among blood donors* in Australia, 2015-2019

		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	*1 155 920*	*298 (25.78)*	*1 (ref)*	*…*	*185 (16)*	*1 (ref)*	*…*
Female	*1 178 757*	*106 (8.99)*	*0.34 (0.27-0.43)*	*0.00*	*112 (9.5)*	*0.61 (0.48-0.78)*	*0.00*
Age group (years)							
20-29	*554 791*	*80 (14.42)*	*1 (ref)*	*…*	*37 (6.67)*	*1 (ref)*	*…*
Less than 20	*134 202*	*17 (12.67)*	*0.94 (0.55-1.59)*	*0.83*	*4 (2.98)*	*1.34 (0.68-2.64)*	*0.39*
30-39	*457 402*	*131 (28.64)*	*1.81 (1.37-2.40)*	*0.00*	*47 (10.28)*	*1.56 (1.01-2.42)*	*0.04*
40-49	*403 760*	*72 (17.83)*	*1.15 (0.84-1.59)*	*0.37*	*56 (13.87)*	*2.11 (1.38-3.23)*	*0.00*
50 and above	*784 522*	*104 (13.26)*	*0.87 (0.65-1.17)*	*0.36*	*148 (18.86)*	*2.95 (2.04-4.28)*	*0.00*
State/Territory							
NSW	*682 982*	*108 (15.81)*	*1 (ref)*	*…*	*84 (12.3)*	*1 (ref)*	*…*
ACT	*65 947*	*13 (19.71)*	*1.16 (0.65-2.06)*	*0.60*	*9 (13.65)*	*1.07 (0.54-2.14)*	*0.83*
NT	*16 590*	*3 (18.08)*	*1.07 (0.34-3.38)*	*0.90*	*5 (30.14)*	*2.43 (0.98-6.00)*	*0.05*
QLD	*460 817*	*65 (14.11)*	*0.86 (0.63-1.18)*	*0.36*	*68 (14.76)*	*1.11 (0.80-1.53)*	*0.50*
SA	*197 879*	*20 (10.11)*	*0.63 (0.39-1.02)*	*0.06*	*19 (9.6)*	*0.69 (0.42-1.14)*	*0.15*
TAS	*77 955*	*6 (7.7)*	*0.49 (0.21-1.13)*	*0.09*	*13 (16.68)*	*1.22 (0.68-2.19)*	*0.49*
VIC	*619 819*	*155 (25.01)*	*1.51 (1.18-1.93)*	*0.00*	*80 (12.91)*	*0.99 (0.73-1.35)*	*0.98*
WA	*212 678*	*34 (15.99)*	*0.95 (0.64-1.40)*	*0.81*	*19 (8.93)*	*0.68 (0.41-1.13)*	*0.14*
Total	2 334 677	404 (17.3)			297 (12.72)		

		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	*1 155 920*	*16 (1.38)*	*1 (ref)*	*…*	*12 (1.04)*	*1 (ref)*	*…*
Female	*1 178 757*	*7 (0.59)*	*0.38 (0.15-0.94)*	*0.03*	*7 (0.59)*	*0.57 (0.22-1.47)*	*0.25*
Age group (years)							
20-29	*554 791*	*11 (1.98)*	*1 (ref)*	*…*	*3 (0.54)*	*1 (ref)*	*…*
Less than 20	*134 202*	*0 (0)*	*…*	*0.99*	*0 (0)*	*…*	*0.99*
30-39	*457 402*	*5 (1.09)*	*0.49 (0.17-1.42)*	*0.19*	*9 (1.97)*	*3.46 (0.93-12.81)*	*0.06*
40-49	*403 760*	*1 (0.25)*	*0.11 (0.01-0.91)*	*0.04*	*3 (0.74)*	*1.28 (0.25-6.39)*	*0.75*
50 and above	*784 522*	*6 (0.76)*	*0.38 (0.14-1.05)*	*0.06*	*4 (0.51)*	*0.90 (0.20-4.07)*	*0.89*
State/Territory							
NSW	*682 982*	*8 (1.17)*	*1 (ref)*	*…*	*5 (0.73)*	*1 (ref)*	*…*
ACT	*65 947*	*0 (0)*	*…*	*0.99*	*3 (4.55)*	*5.74 (1.37-24.04)*	*0.01*
NT	*16 590*	*0 (0)*	*…*	*0.99*	*0 (0)*	*…*	*0.99*
QLD	*460 817*	*3 (0.65)*	*0.53 (0.14-2.00)*	*0.35*	*1 (0.22)*	*0.29 (0.03-2.50)*	*0.26*
SA	*197 879*	*1 (0.51)*	*0.43 (0.05-3.48)*	*0.43*	*1 (0.51)*	*0.69 (0.08-5.93)*	*0.73*
TAS	*77 955*	*0 (0)*	*…*	*0.99*	*3 (3.85)*	*5.46 (1.30-22.92)*	*0.02*
VIC	*619 819*	*9 (1.45)*	*1.14 (0.44-2.96)*	*0.78*	*6 (0.97)*	*1.25 (0.38-4.10)*	*0.71*
WA	*212 678*	*2 (0.94)*	*0.75 (0.15-3.54)*	*0.71*	*0 (0)*	*…*	*0.99*
Total	2 334 677	23 (0.99)			19 (0.81)		

	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	*1 155 920*	*46 (3.98)*	*1 (ref)*	…
Female	*1 178 757*	*14 (1.19)*	*0.26 (0.14-0.48)*	*0.00*
Age group (years)				
20-29	*554 791*	*30 (5.41)*	*1 (ref)*	…
Less than 20	*134 202*	*1 (0.75)*	*0.15 (0.02-1.15)*	*0.06*
30-39	*457 402*	*14 (3.06)*	*0.50 (0.26-0.95)*	*0.03*
40-49	*403 760*	*7 (1.73)*	*0.29 (0.12-0.67)*	*0.00*
50 and above	*784 522*	*8 (1.02)*	*0.18 (0.08-0.40)*	*0.00*
State/Territory				
NSW	*682 982*	*23 (3.37)*	*1 (ref)*	…
ACT	*65 947*	*1 (1.52)*	*0.39 (0.05-2.95)*	*0.36*
NT	*16 590*	*1 (6.03)*	*1.59 (0.21-11.79)*	*0.64*
QLD	*460 817*	*10 (2.17)*	*0.63 (0.30-1.33)*	*0.23*
SA	*197 879*	*1 (0.51)*	*0.15 (0.02-1.18)*	*0.07*
TAS	*77 955*	*0 (0)*	…	*0.99*
VIC	*619 819*	*19 (3.07)*	*0.86 (0.46-1.58)*	*0.63*
WA	*212 678*	*5 (2.35)*	*0.66 (0.25-1.74)*	*0.40*
Total	2 334 677	60 (2.57)		

* The total of 2.3 million donors over a five-year period, 2015-2019, 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, 2019

	HBV (2019)				HCV (2019)				HIV (2019)				HTLV (2019)				Potentially infectious syphilis (2019)			
Donor status	M	F	Total	%	M	F	Total	%	M	F	Total	%	M	F	Total	%	M	F	Total	%
First time donors																				
<20 years	1	0	1	1.1	2	1	3	4.1	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0
20-29 years	11	3	14	15.6	5	1	6	8.1	2	0	2	25.0	0	0	0	0.0	4	0	4	23.5
30-39 years	27	8	35	38.9	10	3	13	17.6	0	0	0	0.0	2	1	3	60.0	2	0	2	11.8
40-49 years	11	2	13	14.4	6	9	15	20.3	0	0	0	0.0	0	0	0	0.0	1	0	1	5.9
50-59 years	5	0	5	5.6	7	9	16	21.6	0	1	1	12.5	0	0	0	0.0	0	0	0	0.0
60 years and above	3	0	3	3.3	8	6	14	18.9	1	0	1	12.5	1	1	2	40.0	0	0	0	0.0
Repeat donors																				
<20 years	0	0	0	0	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0
20-29 years	1	0	1	1.1	2	0	2	2.7	1	0	1	12.5	0	0	0	0.0	3	2	5	29.4
30-39 years	2	2	4	4.4	0	0	0	0.0	1	1	2	25.0	0	0	0	0.0	3	1	4	23.5
40-49 years	3	1	4	4.4	0	0	0	0.0	1	0	1	12.5	0	0	0	0.0	1	0	1	5.9
50-59 years	3	0	3	3.3	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0
60 years and above	6	1	7	7.8	4	1	5	6.8	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0
Total	73	17	90	100	44	30	74	100	6	2	8	100	3	2	5	100	14	3	17	100

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

Supplementary Table 7 Number and percentage of donors positive with transfusion-transmissible infections, by sex and age group, 2015-2019

	HBV (2015-2019)				HCV (2015-2019)				HIV (2015-2019)				HTLV (2015-2019)				PIS/active syphilis (2015-2019)			
Donor status	M	F	Total	%	M	F	Total	%	M	F	Total	%	M	F	Total	%	M	F	Total	%
First time donors																				
<20 years	10	7	17	4.2	5	3	8	2.7	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0
20-29 years	55	23	78	19.3	17	10	27	9.1	5	2	7	30.4	3	0	3	15.8	13	4	17	28.3
30-39 years	90	26	116	28.7	29	11	40	13.5	0	1	1	4.3	6	2	8	42.1	3	1	4	6.7
40-49 years	43	17	60	14.9	21	19	40	13.5	0	0	0	0.0	2	1	3	15.8	4	0	4	6.7
50-59 years	26	10	36	8.9	44	32	76	25.6	1	2	3	13.0	0	0	0	0.0	0	0	0	0.0
60 years and above	18	5	23	5.7	26	9	35	11.8	1	0	1	4.3	1	2	3	15.8	0	0	0	0.0
Repeat donors																				
<20 years	0	0	0	0	1	0	1	0.3	0	0	0	0.0	0	0	0	0.0	1	0	1	1.7
20-29 years	2	0	2	0.5	5	5	10	3.4	3	1	4	17.4	0	0	0	0.0	7	6	13	21.7
30-39 years	13	2	15	3.7	3	4	7	2.4	3	1	4	17.4	0	1	1	5.3	9	1	10	16.7
40-49 years	9	3	12	3	8	8	16	5.4	1	0	1	4.3	0	0	0	0.0	2	1	3	5.0
50-59 years	18	5	23	5.7	16	8	24	8.1	1	0	1	4.3	0	1	1	5.3	5	1	6	10.0
60 years and above	14	8	22	5.4	10	3	13	4.4	1	0	1	4.3	0	0	0	0.0	2	0	2	3.3
Total	298	106	404	100	185	112	297	100	16	7	23	100	12	7	19	100	46	14	60	100

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

Supplementary Table 8 Number and percentage of donors with transfusion-transmissible infections, by country/region of birth^, 2015-2019

	HBV (2015-2019)		HCV (2015-2019)		HIV (2015-2019)		HTLV (2015-2019)		PIS/active syphilis (2015-2019)	
Region of birth	Number	%	Number	%	Number	%	Number	%	Number	%
Australia	46	11.4	207	69.7	11	47.8	5	26.3	40	66.7
Overseas born										
Other Oceania	40	9.9	9	3.0	0	0	0	0.0	2	3.3
United Kingdom and Ireland	0	0.0	11	3.7	0	0	0	0.0	0	0.0
Other Europe	22	5.4	7	2.4	3	13	0	0.0	4	6.7
Middle East/North Africa	21	5.2	6	2.0	0	0	3	15.8	1	1.7
Sub-Saharan Africa	13	3.2	1	0.3	0	0	0	0.0	2	3.3
South & North East Asia	170	42.1	19	6.4	4	17.4	3	15.8	4	6.7
Southern and Central Asia	92	22.8	26	8.8	4	17.4	8	42.1	3	5.0
North America	0	0.0	2	0.7	0	0	0	0.0	0	0.0
South/Central America and the Caribbean	0	0.0	0	0.0	1	4.3	0	0.0	0	0.0
Total with a reported country of birth	404	100.0	288	97.0	23	100	19	100.0	56	93.3
Not reported	0	0.0	9	3.0	0	0	0	0.0	4	7.0
Total	404	100	297	100	23	100	19	100	60	100

^ Region of birth from the Australian Bureau of Statistics
Note: Percentages may not add to exact 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, 2019

	HBV (2019)				HCV (2019)				HIV (2019)				HTLV (2019)				Active Syphilis (2019)			
Exposure categories	M	F	Total	%	M	F	Total	%	M	F	Total	%	M	F	Total	%	M	F	Total	%
Ethnicity/Country of birth	54	12	66	93.0	7	0	7	10.40	0	0	0	0.0	2	0	2	40.0	0	0	0	0.0
Injecting drug user	1	0	1	1.4	12	7	19	28.40	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0
Tattoo/Piercing	0	0	0	0.0	5	10	15	22.40	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0
Partners with known risks or known to be positive	0	0	0	0.0	3	3	6	9.00	0	1	1	25.0	0	1	1	20.0	1	0	1	12.5
Partner with unspecified risks	1	0	1	1.4	0	1	1	1.50	0	0	0	0.0	0	1	1	20.0	1	0	1	12.5
Male-to-male sexual contact	1	0	1	1.4	0	0	0	0.00	1	0	1	25.0	0	0	0	0.0	6	0	6	75.0
Exposure in health care setting	0	0	0	0.0	0	0	0	0.00	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	0.00	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	10.40	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0
Household contact/Family history	1	1	2	2.8	2	1	3	4.50	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	0.00	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0
Other	0	0	0	0.0	4	0	4	6.00	0	0	0	0.0	1	0	1	20.0	0	0	0	0.0
No risk factors identified/Unknown	0	0	0	0.0	2	3	5	7.50	2	0	2	50.0	0	0	0	0.0	0	0	0	0.0
Not reported	0	0	0	0.0	0	0	0	0.00	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0
Total	58	13	71	100	38	29	67	100	3	1	4	100	3	2	5	100	7	0	7	100

Note: Percentages may not add to exact 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, 2015-2019

	HBV (2015-2019)				HCV (2015-2019)				HIV (2015-2019)				HTLV (2015-2019)				PIS/active syphilis (2015-2019)			
Exposure categories	M	F	Total	%	M	F	Total	%	M	F	Total	%	M	F	Total	%	M	F	Total	%
Ethnicity/Country of birth	232	81	313	94.8	11	1	12	5.3	0	0	0	0.0	11	1	12	70.6	0	0	0	0.0
Injecting drug user	1	0	1	0.3	37	15	52	23.0	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0
Tattoo/Piercing^	1	0	1	0.3	31	31	62	27.4	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0
Partners with known risks or known to be positive	0	2	2	0.6	6	6	12	5.3	2	2	4	33.3	0	3	3	17.6	1	1	2	8.0
Partners with unspecified risks	1	0	1	0.3	0	1	1	0.4	0	0	0	0.0	0	1	1	5.9	7	4	11	44.0
Male-to-male sexual contact	1	0	1	0.3	0	0	0	0.0	2	0	2	16.7	0	0	0	0.0	9	0	9	36.0
Exposure in health care setting	0	1	1	0.3	7	7	14	6.2	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
Blood or tissue recipient	0	0	0	0	10	9	19	8.4	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0
Household contact/Family history	3	2	5	1.5	7	2	9	4.0	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0
Other blood to blood contact	0	0	0	0	3	0	3	1.3	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0
Other*	1	1	2	0.6	17	4	21	9.3	0	3	3	25.0	1	0	1	5.9	0	0	0	0.0
No risk factors identified/Unknown	2	1	3	0.9	13	8	21	9.3	3	0	3	25.0	0	0	0	0.0	3	0	3	12.0
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
Total	242	88	330	100	142	84	226	100	7	5	12	100	12	5	17	100	20	5	25	100

^ Four out of 10 first-time male donors positive for HCV in 2015 also had imprisonment as a risk factor alongside tattoo/piercing
* One out of 4 first-time donors in 'Others' in 2019 had imprisonment as a risk factor
Note: Percentages may not add to exact 100% due to rounding

Supplementary Table 11 Number and percentage of transfusion-transmissible infections among repeat donors, by potential reported exposure category and sex, 2019

	HBV (2019)				HCV (2019)				HIV (2019)				HTLV (2019)				Active Syphilis (2019)			
Exposure categories	M	F	Total	%	M	F	Total	%	M	F	Total	%	M	F	Total	%	M	F	Total	%
Ethnicity/Country of birth	13	2	15	78.9	0	0	0	0.0	0	0	0	0.0	0	0	0	0	0	0	0	0.0
Injecting drug user	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0	0	0	0	0	0	0	0	0.0
Tattoo/Piercing	1	0	1	5.3	2	0	2	28.6	0	0	0	0.0	0	0	0	0	0	0	0	0.0
Partners with known risks or known to be positive	0	0	0	0.0	0	1	1	14.3	0	1	1	25.0	0	0	0	0	0	1	1	10.0
Partner with unspecified risks	1	1	2	10.5	0	0	0	0.0	2	0	2	50.0	0	0	0	0	3	1	4	40.0
Male-to-male sexual contact	0	0	0	0.0	0	0	0	0.0	1	0	1	25.0	0	0	0	0	1	0	1	10.0
Exposure in health care setting	0	0	0	0.0	2	0	2	28.6	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
Blood or tissue recipient	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0	0	0	0	0	0	0	0	0.0
Household contact/ Family history	0	0	0	0.0	1	0	1	14.3	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
Other	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	0		
No risk factors identified/Unknown	0	1	1	5.3	1	0	1	14.3	0	0	0	0.0	0	0	0	0	3	1	4	40.0
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
Total	15	4	19	100	6	1	7	100	3	1	4	100	0	0	0	0	7	3	10	100

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

Supplementary Table 12 Number and percentage of transfusion-transmissible infections among repeat donors, by potential reported exposure category and sex, 2015-2019

	HBV (2015-2019)				HCV (2015-2019)				HIV (2015-2019)				HTLV (2015-2019)				Active Syphilis (2015-2019)			
Exposure categories	M	F	Total	%	M	F	Total	%	M	F	Total	%	M	F	Total	%	M	F	Total	%
Ethnicity/Country of birth	44	13	57	77.0	0	1	1	1.4	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0
Injecting drug user	1	0	1	1.4	18	1	19	26.8	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0
Tattoo/Piercing	2	0	2	2.7	7	7	14	19.7	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0
Partners with known risks or known to be positive	3	0	3	4.1	1	7	8	11.3	0	2	2	18.2	0	2	2	100.0	3	3	6	17.1
Partners with unspecified risks	1	1	2	2.7	0	0	0	0.0	2	0	2	18.2	0	0	0	0.0	8	3	11	31.4
Male-to-male sexual contact	0	0	0	0.0	0	0	0	0.0	4	0	4	36.4	0	0	0	0.0	3	0	3	8.6
Exposure in health care setting	1	1	2	2.7	4	3	7	9.9	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	1	2	2.8	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0
Household contact/Family history	0	0	0	0.0	2	0	2	2.8	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	2	2	4	5.4	3	2	5	7.0	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0
No risk factors identified/Unknown	2	1	3	4.1	7	6	13	18.3	3	0	3	27.3	0	0	0	0.0	12	3	15	42.9
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	56	18	74	100	43	28	71	100	9	2	11	100	0	2	2	100	26	9	35	100

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

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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 18 to 80 years of age. Each donor is required to self-complete a comprehensive donor questionnaire (DQ) 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 prior to donation. There are penalties including fines and imprisonment for anyone providing false or misleading information. The DQ 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 required 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 Lifeblood website www.donateblood.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.donateblood.com.au website, Lifeblood Community Relations staff, the media and the 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.[66] 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.[67] 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 non-zero 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 the Australian Red Cross 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 nine 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 2019.

There were small increases in the prevalence of HIV, HCV and syphilis infections among first time donors in particular but none were statistically significant. Infected first-time donors in 2019 mostly had undiagnosed prevalent infections but a small number of recently acquired (incident) infections among repeat donors continued to be identified.

This is the tenth 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 2010-2019 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 and HTLV.
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 2010 to 2019. Anonymous donor data for all donors who donated blood between January 2010 and December 2019 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 2010-2019. Demographic factors associated with TTIs in blood donors were analysed for donations made in 2019 and were compared with the findings from 2015-2019. Likely routes of exposure (termed 'putative risk factors') for each TTI in blood donors were also identified and analysed. Data from the 2018 and 2019 calendar years were combined, and risk modelling conducted to derive estimates of the risk of transmission for HIV, HCV, and HTLV in Australia. HIV, HCV and HBV WP risk estimates are based on Lifeblood data from 1 January 2018 to 31 December 2019. HBV OBI risk based on Lifeblood data from 1 January to 31 December 2019. No HTLV incident donors were recorded for the period – therefore the residual risk estimate was derived from single model using first-time and repeat donor calculation and based on Lifeblood data from 1 January 2018 to 31 December 2019.

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 2019 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. Injecting drug use (IDU)
2. Country of birth (COB)/Ethnicity
3. Partners with known risks or known to be positive
4. Partners with unspecified risks
5. Engaged in sex work
6. Male-to-male sexual contact
7. Blood or tissue recipient
8. Tattoo or body piercing
9. Exposure in health care setting (both occupational and non-occupational)
10. Household contact / Family history
11. Other blood to blood contact
12. Others
13. No risk factors identified
14. 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. Injecting 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, 2015-2019, was calculated as follows:

$$\text{Incidence per 100 000 donor-years of observation} = \left(\frac{\text{Total number of incident donors in 2015-2019}}{\text{Average of 2015-2019 total donor-years of observation}} \right) \times 100\,000$$

Of note, the methodology for calculating incidence was modified in 2018 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, 2015-2019, 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 addressed the existing limitation that existing models wereoverly 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*[68] 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*.[69]

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, 2010-2019, and the five-year period, 2015-2019, 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 2010-2019 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 2019, 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.

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