Transfusion-transmissible infections in Australia

2021

Surveillance Report

Australian Red Cross Lifeblood

UNSW SYDNEY

UNSW 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: 2021 Surveillance Report. Kirby Institute, UNSW Sydney, and Australian Red Cross Lifeblood; 2021

Requests for further information should be addressed to:

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

Or,

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

ISSN 2203-0751 (Online)

edited by

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

Australian Red Cross Lifeblood

in collaboration with

The Kirby Institute, UNSW Australia

Acknowledgements

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

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

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

- 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
- Kylie Yarrington, Ann-Marie Porteous and the Manufacturing Testing teams
- Lifeblood Medical Services Lookback committee
- Glen Shuttleworth, Data Analyst, Lifeblood
- Peta Dennington, Medical Specialist, Lifeblood
- Philip Kiely, Anthea Cheng, Anindita Das and the members of the Donor and Product Safety Policy Unit
- Jonathan King, Epidemiologist, Kirby Institute
- Ela Naruka, Research Assistant, 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 are 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.

Given this report is focused on 2020 testing data and the COVID-19 pandemic commenced in March 2020, the potential impacts of the public health response, including physical distancing and lockdowns are considered in the analysis. Unlike many countries where blood donation rates fell substantially and blood shortages ensued, Australia was generally able to meet demand for blood products, even during the period of national lockdown. This is testimony to the commitment of around 500 000 volunteer blood donors who so generously underpin a safe and sufficient blood supply for all Australian patients.

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 to CSL Behring for fractionation (i.e. HIV, HCV and HBV only). Of note, from December 6, 2020, repeat donors are not required to be tested for HTLV, irrespective of donation type. Consistent with previous years, the overall number of TTIs detected remained low in 2020 (n=207). Of these, 84% 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 2020 continues to be substantially (11-62 times) lower than the estimated national population prevalence for 2019. Five (2.4% of all) infections in 2020 were determined to be incident (newly acquired) based on a past negative test within the last twelve months for the same TTI (see incident donor definition). 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, 2016-2020.

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 2020, 15% 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. A recent example was the transition from a paper-based to an electronic donor questionnaire, which has been welcomed by donors as well as reducing procedural errors.

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 OBI (see below), the presence of viral DNA means that a person is possibly infectious and potentially 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.

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).

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

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.

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.

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 (treponemal antibody test negative to positive) with a positive confirmatory result, or had a history of syphilis treatment since their last treponemal antibody test 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.

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.

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

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.

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’).

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

Summary of the main findings

General characteristics of blood donors in Australia

1. Over the ten-year period 2011-2020, there were over 13 million blood donations in Australia with an average of 1.3 million donations per year. Over the past ten years, 2011-2020, there has been a significant increasing trend in the total number of donations (see Methodological Notes for details), from 1.36 to 1.59 million. Total blood donations in 2020 increased by ~7% (representing 101 590 more donations) compared to 2019, most of which were plasma donations.
2. Of the 'age-eligible' Australian population (aged between 18-80 years), 2.6% donated blood during 2020. Male donors constituted 47.8% of all donors in 2020, which aligns with their proportional representation of 49.4% among the Australian general population aged 16-80 years.
3. On average, first-time and repeat donors comprised 21.4% and 78.6% of all blood donors in Australia over the period 2011-2020, respectively. The proportion of first-time donors increased gradually over the past ten years, from 16.5% in 2011 to 20.9% in 2016 and 21.4% in 2020. However, the proportion of total donations made by first time donors (7% in 2020) has been declining and therefore the increase in total donations is driven by an increased donation frequency among repeat donors.

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 2020, a total of 207 blood donors were detected as positive for 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 the ten-year period 2011-2020 a total of 1 781 TTIs were detected.
2. Consistent with the long-term pattern, the most common TTI detected was HBV, followed by HCV. Of all the donations positive for a TTI in 2020, 83.6% were positive for either HBV or HCV, a slight decrease from 84.5% in 2019.
3. Overall HTLV was the least common TTI detected among all donors in 2020, with just four donors testing positive. In the ten-year period 2011-2020, HTLV was also the least common TTI detected among all donors (38 positive donors); and HIV was the least common TTI detected in first-time donors (24 positive donors).
4. Although representing only 21.4% of the donor population, first-time blood donors contributed to 77% of detected TTIs in Australia in 2020. This proportion has remained relatively stable since 2011 (77%-80% range).
5. No transfusion-transmitted HIV, HCV, HTLV or syphilis infections were reported in Australia during 2020.
6. Consistent with previous years, in 2020, the prevalence of TTIs was substantially lower among first-time blood donors (11 to 62 times) compared with national prevalence estimates for 2019.

HBV-positive Australian blood donors

1. There were 108 HBV-positive donors detected among all donations in 2020 (89 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. During 2011-2020, no significant trend was observed in HBV prevalence in first-time donors in Australia. Nonetheless, the prevalence among first-time donors in 2020 has increased by 23% as compared to that observed in 2019, 83.3 versus 67.7 per 100 000 donations, respectively. This equates to 0.08% of the total first-time donations in 2020, which is 11 times lower than the estimated ~0.9% prevalence reported in national HBV surveillance data for 2019.[1]
4. Among the 108 HBV-positive donors, 23 (7 first-time and 16 repeat donors) were classified as occult HBV (OBI) based on the detection of HBV DNA without HBsAg. Most donors (14) were men, Asian-born (65%) and had an average age of 53.3 years.
5. Incident HBV donors continue to be rare with only two recorded nationally in 2020, giving an incidence rate of 0.94 per 100 000 donor-years of observation, which is comparable to that observed in 2019. There was no significant temporal trend in HBV donor incidence nationally or in any state/territory during the five-year study period 2016-2020.
6. In 2020, HBV-positive donors were the same age as compared to all donors (41 years versus the mean age 41 years), more likely to be male (63% in HBV-positive donors versus 48% in all donors) and more likely to be born in the Northeast/Southeast Asia (55%). 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, 2016-2020, was ethnicity/country of birth (86%). In Australia, an estimated 43% of people living with hepatitis B were born in the Northeast/Southeast Asia at the end of 2019.[2]
8. No transfusion-transmitted HBV infections were recorded in 2020. One probable case (in 2011) was reported in the 2010-2019 period (see Transfusion-transmissible infections in Australia 2017 Surveillance Report for details).

HCV-positive Australian blood donors

1. There were 65 HCV-positive donors detected among all donors in 2020 (55 in first-time donors and 10 in repeat donors). In 2020, the proportion of HCV RNA positive (considered infectious) donors was 38.5%, a marked decrease as compared to 47% in 2019. This figure has incrementally declined from around 75% when HCV RNA donation testing was introduced in 2000.
2. HCV was the second most common TTI detected in first-time blood donors after HBV.
3. During 2011-2020, 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 and 51.5 per 100 000 donations in 2019 and 2020, respectively, as compared to 39.3 per 100 000 observed in 2018. This increase is likely be associated with prospective donors with 'resolved' HCV (HCV antibody positive/RNA negative) presenting to donate subsequent to successful treatment. The 0.05% first-time donor prevalence in 2020 is 12 times lower than the estimated 0.6% reported for HCV national surveillance data for 2019.[3]
4. In 2020, there were ten repeat donors who tested positive but only one met the incidence definition. The average incidence rate of HCV among previously negative repeat donors during 2016-2020 was very low at 0.59 per 100 000 donor-years of observation (see Methodological Notes for details). HCV incidence has shown no significant trend during the study period, 2016-2020.
5. In 2020, the mean age of HCV-positive donors was 45 years compared to 41 years for all donors. They were more likely to be male (65% versus 48% in all donors), and the majority (55%) were born in Australia.
6. The most common putative risk factor reported by HCV-positive donors during 2016-2020 was injecting drug use (23%), followed by tattoo/piercing (21%). 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, 21% had injecting drug use as their route of exposure in 2019.[4]
7. No transfusion-transmitted HCV infections were reported in Australia during 2011-2020.

HIV-positive Australian blood donors

1. There were five HIV-positive donors detected among all donations in 2020 (two first-time and three repeat donors).
2. The prevalence of HIV-positive first-time donors during 2011-2020 remained very low at 2.3 per 100 000 donations (or 0.002% of the total first-time donations) and comparatively much lower than hepatitis B (75.1 per 100 000 donations) and hepatitis C (48.1 per 100 000 donations). No significant HIV prevalence trend was observed during 2011-2020. The 0.002% HIV prevalence in first-time donors is 62 times lower than the 0.1% prevalence reported for HIV national surveillance data in 2019.[5]
3. The incidence of HIV in 2020 was 0.9 per 100 000 donor-years of observation, down from 1.4 per 100 000 donor-years of observation in 2019. However, there is no statistically significant incidence trend in the 2016-2020 period.
4. In 2020, the mean age of HIV-positive donors (n=5) was 38 years as compared to 41 years for all donors. Like HBV, HIV-positive donors were more likely to be male as compared to all donors (100% vs 48%). In 2020 40% (2/5) of the HIV-positive donors were born in Australia.
5. The most common reported routes of exposure for HIV-positive donors during 2016-2020 were male-to-male sex (27%) and partners with a known risk or known to be positive (27%). 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 2011-2020.

HTLV-positive Australian blood donors

1. There were four HTLV-positive donors detected among all donations in 2020 (all in first-time donors).
2. The prevalence of HTLV-positive first-time donors during 2011-2020 has remained low at 3.5 per 100 000 donations and has shown no significant trend. Population prevalence for HTLV is unknown; therefore, meaningful comparison of prevalence rates among first-time donors and the general population is not possible.
3. In 2020, the mean age of the four HTLV-positive was 35 years; all were male and the majority were born overseas (75%).
4. The most common putative risk factor for HTLV-positive donors during 2016-2020 was ethnicity or country of birth (68%). There are no data to compare risk factors in the general population.
5. No transfusion-transmitted HTLV infections were reported in Australia during 2011-2020.

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

1. There were 25 potentially infectious syphilis infections (9 first-time and 16 repeat donors) detected in 2020, the highest recorded number to date.
2. The prevalence of active/potentially infectious syphilis in first-time donors has shown a significant increasing trend in the past ten years, 2011-2020. This is reflective of increasing syphilis notifications in the general population.
3. The mean age of donors with potentially infectious syphilis in 2020 was 36 years (compared to 41 years for all donors); and they were more likely to be male as compared to all donors (76% versus 48%).
4. The most common reported route of exposure by donors with active/potentially infectious syphilis during 2016-2020 period was having a partner with an unspecified risk (34%).

Donor compliance

1. Of the 849 TTI-positive donors in 2016-2020, 18.4% (157 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 time. Proportionally, first time donors accounted for 75% (117 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 2020, 132 338 donations were tested for malaria antibody of which 2 052 (1.6%) were repeatedly reactive for malaria antibodies.
2. There were no reported cases of transfusion-transmitted malaria during 2020, with the last reported Australian case occurring in 1991.

Bacterial pre-release testing for platelets

1. In 2020, 136 (0.11%) of a total 119 856 screened platelet units had confirmed bacterial contamination.
2. Consistent with previous years, by far the most common species isolated (119 isolates) 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 (8 isolates), which along with propionibacteria are usually considered skin contaminants.
3. Other confirmed positive pathogens (one isolate each unless stated) included; *Bacillus cereus, Enterococcus faecium, Listeria monocytogenes, Streptococcus gallolyticus Streptococcus dysgalactiae* (2 isolates), *Streptococcus agalactiae* (Lancefield Group B), *Streptococcus pyogenes* (Lancefield Group A) and *Streptococcus* species (Lancefield Group G).
4. In 2020, there were no confirmed cases of transfusion-transmitted bacterial infection.

Emerging infections

1. The landscape for emerging infections that represent a potential risk to blood safety changed considerably in 2020 due to travel restrictions significantly decreasing the risk. Notified case numbers for infections that have been predominately overseas-acquired, such as dengue, hepatitis and malaria, significantly decreased in 2020.
2. Lifeblood implemented a number of strategies for mitigating the risk associated with overseas, and locally-acquired SARS-CoV-2 infections.

List of figures and tables

List of figures

List of tables

List of Supplementary Tables

This page intentionally left blank

Abbreviations

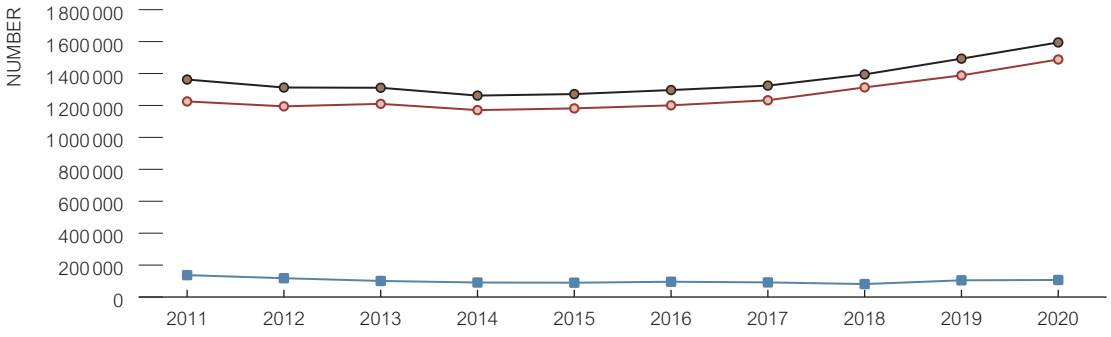
anti-HAV	antibody to hepatitis A
anti-HBc	antibody to hepatitis B core antigen
anti-HBe	antibody to hepatitis B e antigen
anti-HBs	antibody to hepatitis B surface antigen
anti-HeV	antibody to Hendra virus
A(H7N9)	avian influenza H7N9 virus
B19V	parvovirus (human erythrovirus)
CJD	Creutzfeldt-Jakob disease
DQ	donor questionnaire
DENV	dengue virus
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
TPHA	Treponema pallidum Haemagglutination Assay
TTIs	transfusion-transmissible infections
WNV	West Nile virus
WP	window period
ZIKV	Zika virus

Main Findings

Blood donors in Australia

Over 13.5 million donations were tested for TTIs in Australia during the ten-year period 2011-2020, with an average of 1.3 million donations per year. In 2020, the number of donations was nearly 1.6 million, an increase of 6.8% as compared to 2019. The majority of this increase reflects more frequent donation by repeat donors. Over the entire ten-year period there was a significant increasing trend in the number of donations, from 1.36 to 1.59 million (p-value: <0.001) (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 from December 2020, repeat donors no longer require HTLV testing, irrespective of the type of donation (except for donations made into a granulocyte component), resulting in a differing denominators for syphilis and HTLV. Therefore, a total of 1.59 million donations were tested for HBV, HCV and HIV in 2020, as compared to ~0.79 million donations for HTLV and slightly over 0.83 million donations for syphilis.

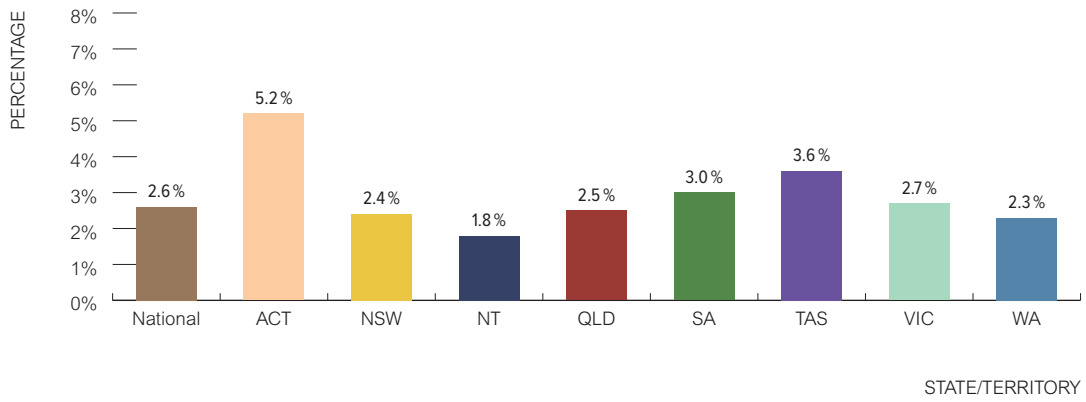
Figure 1 Number of blood donations in Australia by year of donation, 2011-2020



	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020
Total	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	1.59 M
First-time	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	0.11 M
Repeat	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	1.49 M

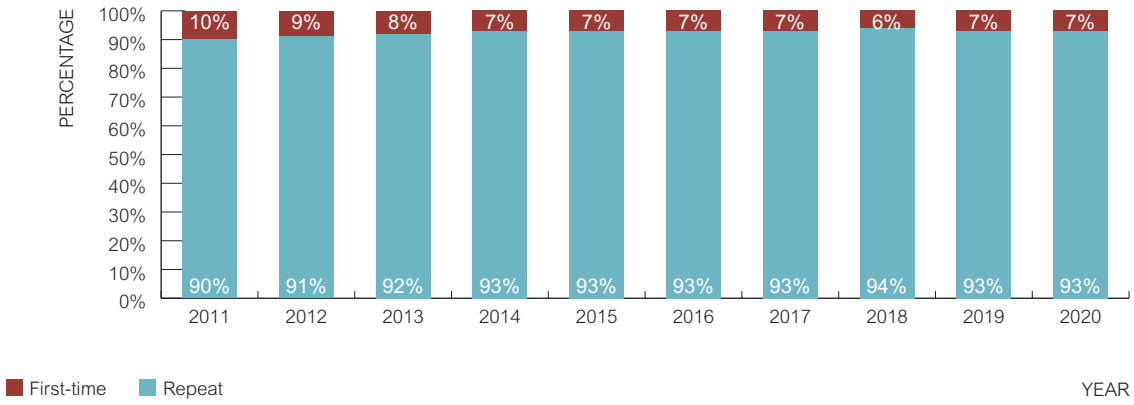
In 2020, 2.6% of the general population aged 18-80 years (age-eligible to donate) donated blood in Australia. Together, New South Wales, Queensland and Victoria accounted for 76% of all blood donations. The jurisdiction where the greatest proportion of the age-eligible local population donated blood in 2020 was the Australian Capital Territory (5.2%), followed by Tasmania at 3.6% (Figure 2).

Figure 2 Percentage of age eligible general population who donated blood in 2020, by state/territory



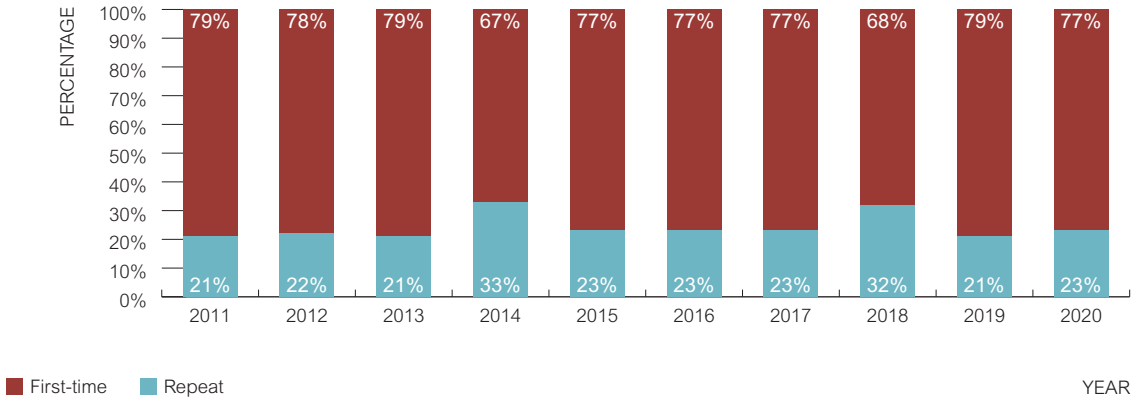
As in previous years, more than 90% of all donations in 2020 were from repeat donors (Figure 3). In the past ten years, 2011-2020, there has been a gradual decrease in the percentage of donations by first-time donors, from 10% in 2011 to 7% in 2020. While first-time blood donors represented only 21% of the donor population, and 7% of the total donations, they contributed the majority (77%) of TTIs in Australian blood donors in 2020, 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, 2011-2020



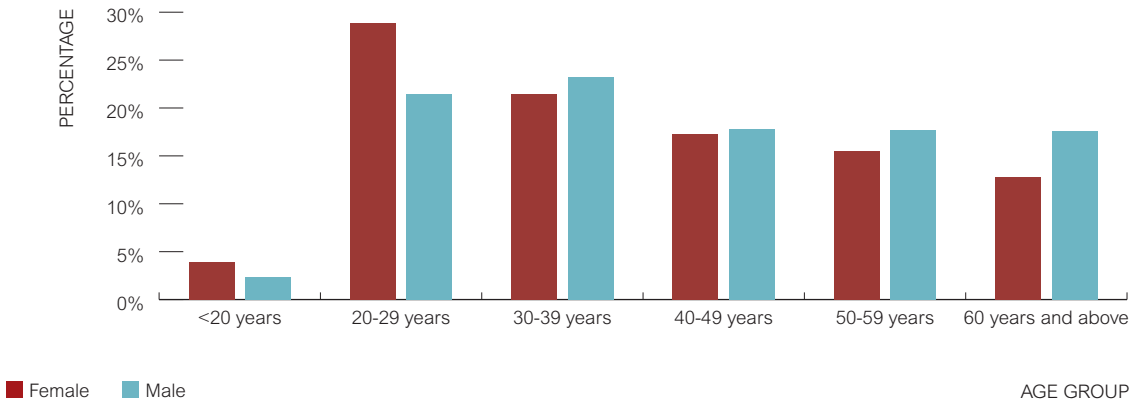
Overall, in the past ten years, the proportion of repeat donors among all TTI-positive blood donations in Australia was stable (21-23%) with the exception of 2014 and 2018, where the proportions increased to 33% and 32%, respectively (Figure 4). For details on the proportional increase in repeat donors among all TTI-positive donations for 2014 and 2018, see Transfusion-transmissible infections in Australia 2020 Surveillance Report.

Figure 4 Percentage of first time and repeat donations among all TTI-positive blood donations in Australia, 2011-2020



Among all blood donors who donated in 2020, 52.2% were female and 47.8% 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). Approximately 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, 2020



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, 2011-2020, 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 2020 and the five-year period 2016-2020 will be discussed. Putative risk factors associated with positive blood donors in Australia are also reported for the five-year period, 2016-2020. 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 2019, trends in the ten-year period, 2010-2019, notifications of newly diagnosed TTIs in Australia, and risk exposure categories associated with respective infections. Of note, the 2020 general population data were not available for HBV, HCV, HIV and infectious syphilis at the time of the report preparation. Therefore, comparisons were made with the 2019 data. The information is drawn from the Kirby Institute data website, and the National Notifiable Diseases Surveillance System (NNDSS).[4-6]

Of note, prevalence is defined as the test-positive rate among all blood donors, and first-time blood donors, separately; whereas incidence is the rate of new test-positive 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 2016-2020 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.

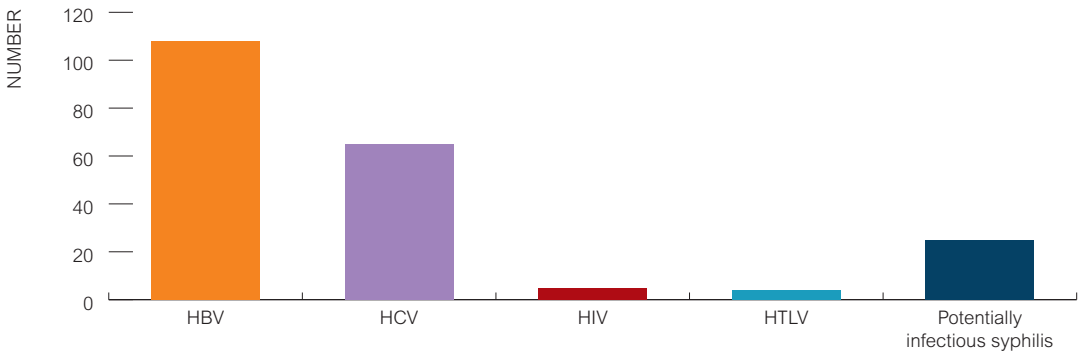
Lifeblood closely monitors donor incidence rates, since this correlates directly with the risk of transmission in the window period. Incident donors are defined as positive repeat donors whose last donation tested negative for the same TTI within the last twelve months (with some exceptions; see glossary). 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 2011-2020, a total of 1 781 donations (1 359 first-time and 422 repeat donations) were positive for at least one of the TTIs subject to mandatory donation testing. Of these, 1 634 were positive for HBV, HCV and HIV (12.0 per 100 000 donations), 109 (1.0 per 100 000 donations) were positive for active/ potentially infectious syphilis and 38 (0.35 per 100 000 donations) were positive for HTLV. As noted above, due to a different total number of donations tested for these infections during the last ten years 2011-2020, (13.6 million donations for HBV, HCV and HIV, as opposed to 10.8 million and ~10.9 donations tested for HTLV and syphilis, respectively), these data are presented separately (Table 1A, 1B and IC). Of the positive donations, 89.0% were positive for either HBV or HCV.

In 2020, a total of 207 donors tested positive for at least one of the TTIs subject to mandatory donation testing. Overall, HBV and HCV were the two most frequent TTIs identified in Australian blood donors in 2020, together contributing to 83.6% of positive donors (Figure 6). This proportion has decreased by a relative 8.8% as compared to 91.7% in 2011, suggesting a declining trend in the prevalence of HBV and HCV in all donors, where prevalence in all donations decreased from 8.6 in 2011 to 6.7 in 2020 for HBV and 5.8 in 2011 to 4.0 in 2020 for HCV. In 2020, 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. In this year's report, the methodology for calculating incidence has been modified again, whereby the DYO were calculated as a sum of inter-donation intervals for unique repeat donors only and were not adjusted for all repeat donations. Therefore, the incidence rates calculated cannot be directly compared to previous reports (see Methodological notes for details). For this reason, updated data are presented for a five-year period, 2016-2020 which retrospectively apply the updated DYO calculation method. During 2016-2020, a total of 24 incident donors were identified, eight for HBV, six for HCV and 10 for HIV. In 2020, a total of five incident infections were detected, two for HBV, one for HCV and two for HIV (Figure 6).

Figure 6 Distribution of test positive blood donations in Australia, in 2020



	HBV	HCV	HIV	HTLV	Potentially infectious syphilis
Positive Donations 2020	108	65	5	4	25

Data on the demographic characteristics (sex, age group, state/territory and year of donation) for all blood donors was analysed (see Methodological Notes for details) to determine any association between demographic factors and presence of any TTI among Australian blood donors in 2020, and the five-year period, 2016-2020, separately.

Standardised national data on reported putative risk factors associated with donors positive for 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.[7] Lifeblood undertook a risk assessment which determined that the HCV incidence rate in donors returning after a tattoo was negligible.[8] 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 2016 to 2020. A total of 849 positive donors with at least one of the TTIs were observed over the period 2016-2020. The data on these donors were analysed for the period 2016-2020 to determine the key characteristics of positive blood donors, stratified by year of donation, and findings are presented in the respective infection sections.

Table 1 Raw number and prevalence of positive donations in Australia, by state/territory, 2011-2020

1A HBV, HCV and HIV, by state/territory, 2011-2020

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	340 636	3 876 325	4 216 961	252	49	301	172	55	227	11	6	17	435	110	545
Number *(Number per 100 000 donations)*				*73.98*	*1.26*	*7.14*	*50.49*	*1.42*	*5.38*	*3.23*	*0.15*	*0.40*	*127.70*	*2.84*	*12.924*
NT	7 427	96 359	103 786	11	2	13	5	4	9	0	1	1	16	7	23
Number *(Number per 100 000 donations)*				*148.11*	*2.08*	*12.53*	*67.32*	*4.15*	*8.67*	*0.00*	*1.04*	*0.96*	*215.43*	*7.26*	*22.161*
QLD	209 509	2 549 907	2 759 416	122	24	146	107	45	152	3	6	9	232	75	307
Number *(Number per 100 000 donations)*				*58.23*	*0.94*	*5.29*	*51.07*	*1.76*	*5.51*	*1.43*	*0.24*	*0.33*	*110.74*	*2.94*	*11.126*
SA	70 255	1 186 170	1 256 425	37	13	50	34	15	49	0	2	2	71	30	101
Number *(Number per 100 000 donations)*				*52.67*	*1.10*	*3.98*	*48.40*	*1.26*	*3.90*	*0.00*	*0.17*	*0.16*	*101.06*	*2.53*	*8.0387*
TAS	30 567	489 033	519 600	13	5	18	18	5	23	0	0	0	31	10	41
Number *(Number per 100 000 donations)*				*42.53*	*1.02*	*3.46*	*58.89*	*1.02*	*4.43*	*0.00*	*0.00*	*0.00*	*101.42*	*2.04*	*7.8907*
VIC	266 031	3 151 459	3 417 490	251	47	298	119	33	152	7	8	15	377	88	465
Number *(Number per 100 000 donations)*				*94.35*	*1.49*	*8.72*	*44.73*	*1.05*	*4.45*	*2.63*	*0.25*	*0.44*	*141.71*	*2.79*	*13.606*
WA	92 474	1 255 531	1 348 005	78	22	100	34	13	47	3	2	5	115	37	152
Number *(Number per 100 000 donations)*				*84.35*	*1.75*	*7.42*	*36.77*	*1.04*	*3.49*	*3.24*	*0.16*	*0.37*	*124.36*	*2.95*	*11.276*
National	1 016 899	12 604 784	13 621 683	764	162	926	489	170	659	24	25	49	1 277	357	1 634
Number *(Number per 100 000 donations)*				*75.13*	*1.29*	*6.80*	*48.09*	*1.35*	*4.84*	*2.36*	*0.20*	*0.36*	*125.58*	*2.83*	*12.00*

1B HTLV, by state/territory, 2011-2020

State/Territory of donation	All accepted donations			HTLV		
	First time	Repeat	All	First time	Repeat	All
NSW/ACT	340 636	3 107 908	3 448 544	12	1	13
Number (Number per 100 000 donations)				*3.52*	*0.03*	*0.38*
NT	7 427	68 715	76 142	0	0	0
Number (Number per 100 000 donations)				*0.00*	*0.00*	*0.00*
QLD	209 509	1 986 926	2 196 435	2	0	2
Number *(Number per 100 000 donations)*				*0.95*	*0.00*	*0.09*
SA	70 255	900 629	970 884	1	1	2
Number *(Number per 100 000 donations)*				*1.42*	*0.11*	*0.21*
TAS	30 567	361 271	391 838	3	0	3
Number *(Number per 100 000 donations)*				*9.81*	*0.00*	*0.77*
VIC	266 031	2 455 035	2 721 066	15	0	15
Number *(Number per 100 000 donations)*				*5.64*	*0.00*	*0.55*
WA	92 474	931 585	1 024 059	3	0	3
Number *(Number per 100 000 donations)*				*3.24*	*0.00*	*0.29*
National	1 016 899	9 812 069	10 828 968	36	2	38
Number *(Number per 100 000 donations)*				*3.54*	*0.02*	*0.35*

1C Active/potentially infectious syphilis, by state/territory, 2011-2020

State/Territory of donation	All accepted donations			PIS/Active Syphilis		
	First time	Repeat	All	First time	Repeat	All
NSW/ACT	340 636	3 125 682	3 466 318	9	24	33
Number (Number per 100 000 donations)				*2.64*	*0.77*	*0.95*
NT	7 427	68 879	76 306	2	1	3
Number (Number per 100 000 donations)				*26.93*	*1.45*	*3.93*
QLD	209 509	1 997 098	2 206 607	9	11	20
Number *(Number per 100 000 donations)*				*4.30*	*0.55*	*0.91*
SA	70 255	903 994	974 249	3	1	4
Number *(Number per 100 000 donations)*				*4.27*	*0.11*	*0.41*
TAS	30 567	362 406	392 973	0	0	0
Number *(Number per 100 000 donations)*				*0.00*	*0.00*	*0.00*
VIC	266 031	2 467 188	2 733 219	15	21	36
Number *(Number per 100 000 donations)*				*5.64*	*0.85*	*1.32*
WA	92 474	935 480	1 027 954	8	5	13
Number *(Number per 100 000 donations)*				*8.65*	*0.53*	*1.26*
National	1 016 899	9 860 727	10 877 626	46	63	109
Number *(Number per 100 000 donations)*				*4.52*	*0.64*	*1.00*

This page intentionally left blank

Hepatitis B Virus (HBV)

Epidemiology of HBV in Australia

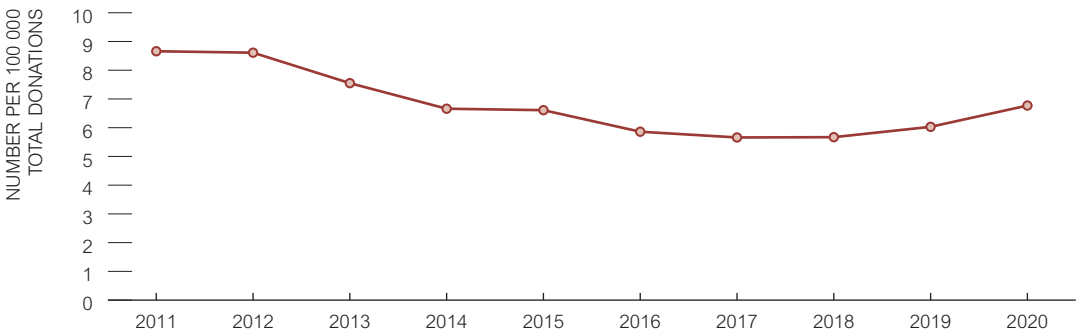
At the end of 2019, an estimated 223 860 people were living with chronic HBV infection in Australia, of whom an estimated 71% were diagnosed with chronic hepatitis B,[1] 23% and 20% were born in the Northeast and Southeast Asia, respectively, and 7% were among Aboriginal and Torres Strait Islander peoples.[2] In total, there were 5 840 notifications of newly diagnosed HBV infection in Australia in 2019; of these, over half (54%) were male, and 92% were people aged 25 years and above.[6] 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 ten-year period, 2010-2019, the population rate of diagnosis of HBV infection in Australia has declined in younger age groups: 25 – 29 years (from 72 to 35 per 100 000); 20 – 24 years (from 43 to 18 per 100 000); and 15 – 19 years (from 19 to 7.5 per 100 000).[6] 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 45% from 1.1 per 100 000 in 2010 to 0.6 per 100 000 in 2019.[6] 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%)[9] but lower than many other countries in South East Asia and the Pacific.

Trends in prevalence

All donations:

In the past ten years, 2011-2020, a total of 926 HBV-positive donors have been detected (764 first-time donors & 162 repeat donors) (Table 1A). During this period, HBV prevalence among all donations has declined significantly (IRR 0.95; 95% CI: 0.93-0.98). There has been an overall reduction of 22% from 2011 to 2020, from 8.7 to 6.8 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=138) 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.[10] For detail on the number and prevalence rate of HBV-positive donors among all donations for 2020, see Supplementary Table 2.

Figure 7 Prevalence of HBV-positive donations among all blood donations in Australia, 2011-2020

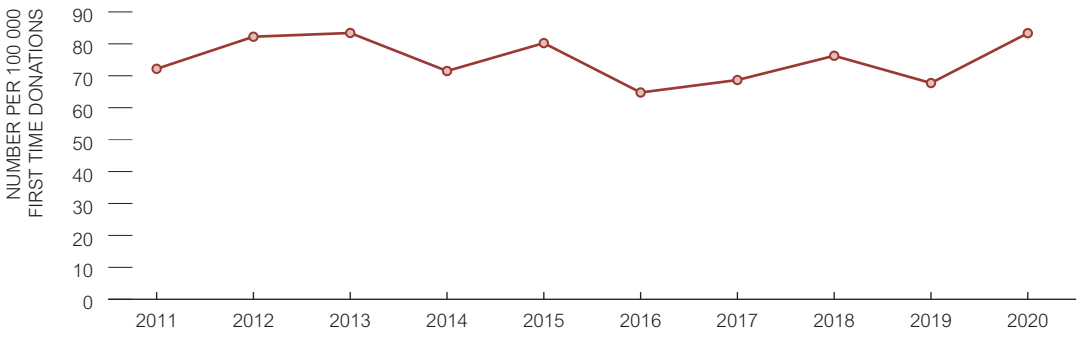


	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020
Prevalence in all donations	8.66	8.61	7.55	6.66	6.61	5.86	5.66	5.67	6.03	6.77

First-time donors:

Although the 2020 HBV prevalence increased marginally compared to 2019, over the ten-year period 2011-2020, no significant annual trend is apparent among first-time donors (Figure 8) (IRR: 0.99; 95% CI: 0.97-1.01). However, the average prevalence shows a declining trend dropping to 75.1 per 100 000 donations (0.08% of the total first-time donations) for the period 2011-2020 (Table 1A). This trend is reflected in the Australian general population with the notification rate showing a slight downward trend in the past ten years, at 31 per 100 000 in 2010, 28 per 100 000 in 2014, and 23 per 100 000 in 2019.[6]

Figure 8 Prevalence of HBV-positive donations among first time blood donors in Australia, 2011-2020

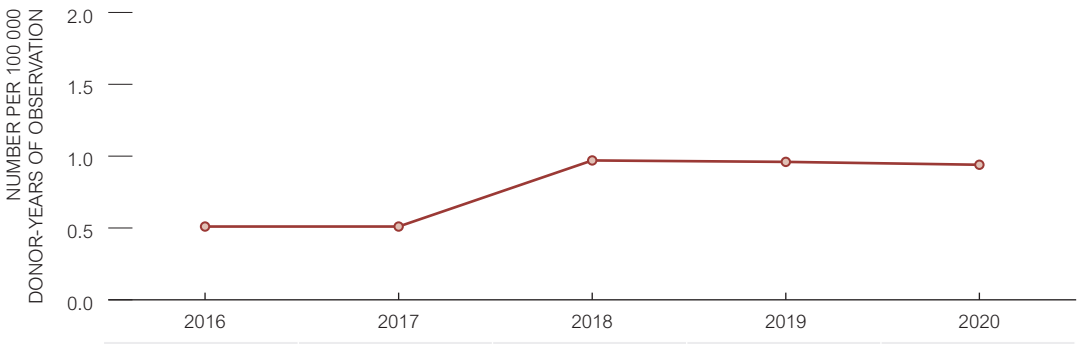


	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020
Prevalence in first-time donors	72.17	82.23	83.4	71.49	80.23	64.76	68.67	76.26	67.73	83.34

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). For the five-year period 2016-2020, there were a total of eight HBV incident donors detected with no statistically significant trend observed for incidence rates (between 0.5 and 0.9 per 100 000 donor-years of observation; (IRR: 1.18; 95% CI: 0.71-1.95) (Figure 9). In 2020, only two incident HBV donors were detected.

Figure 9 Incidence of HBV in repeat blood donors in Australia, 2016-2020



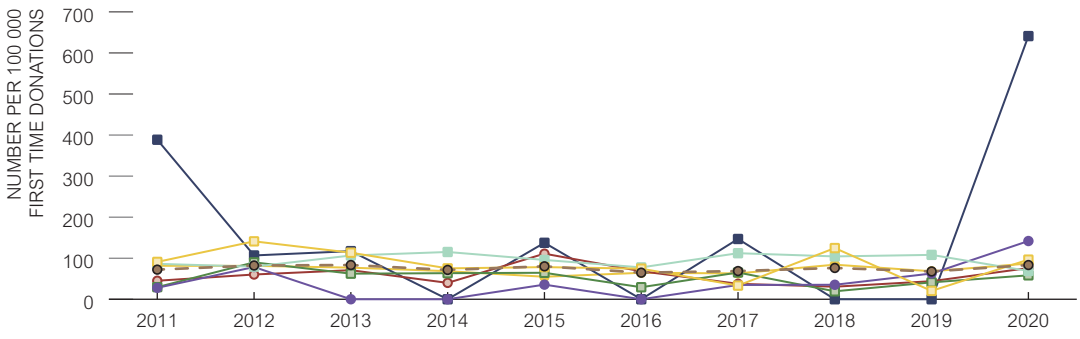
	2016	2017	2018	2019	2020
Incidence	0.51	0.51	0.97	0.96	0.94

No transfusion-transmitted HBV infections were reported in 2020. 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 HBV prevalence among first-time donors varied markedly by jurisdiction in 2020. While the national prevalence was 83.3 per 100 000 donations, this ranged from 58.2 to 641.0 per 100 000 donations across jurisdictions (Figure 10). In 2020, the Northern Territory recorded the highest prevalence among first-time donors (641.0 per 100 000 donations) as compared to the other states. For the ten-year period 2011-2020, the highest average prevalence among first-time donors was also observed in the Northern Territory, at 148.1 per 100 000 donations, followed by Victoria at 94.3 per 100 000 donations (given the small number of positive donors for the Northern Territory, which ranged between 0-4 per year, this should be interpreted with caution). However, no significant trend was observed during this period in the Northern Territory and Victoria or in any other state and territories. In comparison, Northern Territory had the highest rate of diagnosis of HBV infection reported in the 2019 national surveillance data (31 per 100 000 population), followed by New South Wales (27 per 100 000 population) and Victoria (26 per 100 000 population).[6]

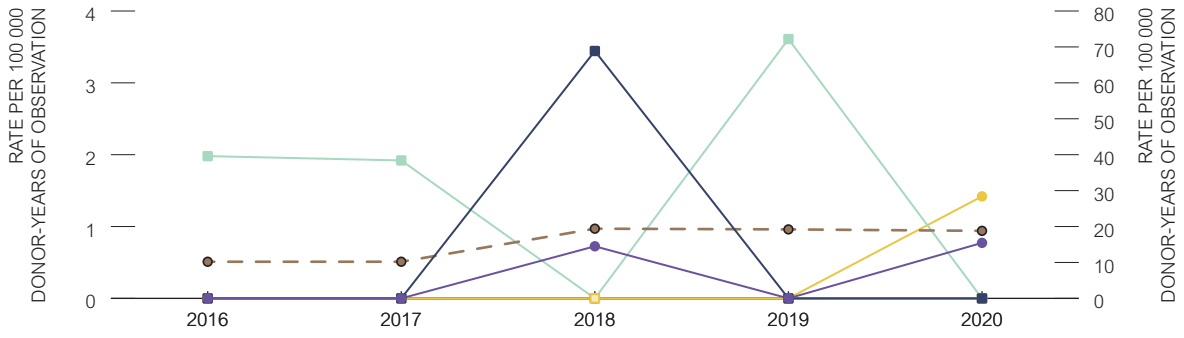
Figure 10 HBV prevalence among first time donors by state/territory and year of donation, 2011-2020



	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020
NSW/ACT	81.51	81.38	77.01	68.41	54.83	64.44	62.97	84.23	68.16	87.07
NT	388.60	106.72	117.23	0.00	137.55	0.00	146.84	0.00	0.00	641.03
QLD	45.08	60.29	70.82	39.91	111.03	68.25	37.63	30.58	43.99	76.03
SA	29.52	89.89	62.33	63.53	64.50	29.31	65.15	19.38	41.15	58.28
TAS	27.88	78.47	0.00	0.00	35.63	0.00	34.79	35.29	62.72	141.84
VIC	86.30	79.37	106.58	115.15	95.79	77.63	112.18	104.37	108.11	68.87
WA	90.98	141.06	113.44	75.26	78.28	74.48	33.31	124.69	20.32	96.50
National	72.17	82.23	83.40	71.49	80.23	64.76	68.67	76.26	67.73	83.34

Incident HBV donors continue to be rare with only two recorded nationally in 2020, one from Tasmania and one from Australian Capital Territory. Overall, there was no obvious trend in HBV incidence in any state/territory during the five-year study period 2016-2020 (Figure 11). Among donors in Queensland, South Australia and Western Australia, HBV incidence has been zero since 2016.

Figure 11 HBV incidence among repeat donors by state/territory and year of donation, 2016-2020[1]



	2016	2017	2018	2019	2020
NSW/ACT	0.00	0.00	0.00	0.00	1.42
NT	0.00	0.00	68.87	0.00	0.00
QLD	0.00	0.00	0.00	0.00	0.00
SA	0.00	0.00	0.00	0.00	0.00
TAS	0.00	0.00	14.50	0.00	15.45
VIC	1.98	1.92	0.00	3.61	0.00
WA	0.00	0.00	0.00	0.00	0.00
National	0.51	0.51	0.97	0.96	0.94

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.[10] To the end of 2020, 195 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 2020, 23 of the 108 (21.3%) HBV positive donors detected were classified as OBI, as compared to 29 of 90 (32.2%) in 2019, the highest recorded proportion to date. Most (14/23; 61%) OBIs in 2020 were men and the majority (16/23; 69.6%) were repeat donors, with an average age of 53.3 years. The majority, 15/23; 65.2%, of donors with OBI in 2020 were born in Asia (South-East/North East Asia – 13, Southern and Central Asia – 2).

Comparison of HBV prevalence among blood donors and the general population

This section presents a comparison of HBV prevalence among first-time blood donors and the general population. As noted above, general population data for 2020 were not available at the time of report preparation, therefore although blood donor data are presented for 2011-2020 and 2020, comparison with the general population was made with a combined period of 2010-2019 and 2019, 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[11,12] and expected, based on effective donor selection/education. HBV prevalence 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 2010/11-2019/20, and 11 times lower prevalence for the year 2019/20. 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 HBV prevalence in blood donors with population prevalence, 2010/11-2019/20

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	
	2010-2019	2019	2011-2020	2020	2010/11-2019/20	2019/20
HBV	932	896	75.1	83.3	12 times lower	11 times lower

* The 2019 HBV prevalence in the general population was calculated by taking the estimated number of people living with chronic HBV,[1] and dividing it by the estimated mid-year resident Australian population in 2019 as reported by the Australian Bureau of Statistics. For the period 2010-2019, an average of the ten years' prevalence rates was calculated.

Demographic factors associated with HBV positive blood donors

Data on the demographic characteristics (sex, age group, state/territory and year of donation) for all blood donors were analysed (see Methodological Notes for details) to determine any association between demographic factors and HBV-positivity among Australian blood donors in 2020, and the five-year period, 2016-2020, 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 2020, female donors were 45% less likely to be HBV positive compared to male donors. In 2020, donors between 30-39 years of age and donors from the Northern Territory were almost two and six times more likely to be HBV positive as compared to the reference groups, respectively (Supplementary Table 4).

In the five-year period, 2016-2020, 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 of HBV-positivity as compared to the reference groups (1.8 and 1.3 times, respectively, see Supplementary Table 5). In comparison, during 2010-2019, 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, likely as a result of universal HBV vaccination), with little or no variation in those aged 30+ years, and has consistently been highest in the Northern Territory (69 per 100 000 in 2010 to 31.5 per 100 000 in 2019). In most other jurisdictions the rate of HBV diagnosis has fluctuated over the ten-year period 2010-2019, with a small decline observed in recent years in New South Wales (36.1 in 2010 to 27.2 in 2019), Victoria (33.9 in 2010 to 25.8 in 2019), and Western Australia (26.5 in 2010 to 17.1 in 2019).[6]

Risk factors associated with HBV-positive donors

Of the 428 HBV positive donors during 2016-2020, 81% were first-time donors, 72% were male, and the mean age was 41 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 (86%) was the most frequent risk factor for HBV-positivity, with 56% born in North & South-East Asia in 2020 (Figure 12). There were only eight incident hepatitis B blood donors in the last five years, consistent with a low and stable incidence rate.

Table 3 Characteristics of HBV-positive donors by year of donation, 2016-2020

Characteristics	2016	2017	2018	2019	2020	2016-2020
Number of positive donors	76	75	79	90	108	428
Number of positive first-time donors (%)	62 (82%)	63 (84%)	62 (78%)	71 (79%)	89 (82.4%)	347 (81%)
% male	60 (79%)	47 (63%)	60 (76%)	73 (81%)	68 (62.9%)	308 (72%)
Mean age (range) in years	40 (16-68)	41 (17-78)	41 (19-71)	40 (19-73)	41 (18-74)	41 (16-78)
Number of incident donors	1	1	2	2	2	8
% born in Australia	5 (7%)	14 (19%)	8 (10%)	11 (15%)	9 (8.3%)	47 (11%)
Main reported risk factor	Ethnicity/COB[1] 97%*	Ethnicity/COB[1] 87%*	Ethnicity/COB[1] 91%*	Ethnicity/COB[1] 90%*	Ethnicity/COB[1] 71%	Ethnicity/COB[1] 86%
Second reported risk factor	Other, Unknown each 1%	FH/HC[2], PRP[3], OR[4] EHS[5] each 3%	Undetermined 3%	PUSR[6] 3%	FH/HC[2] 16%	FH/HC[2] 5%

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, 4 out of 11 and 1 out of 9 donors born in Australia had Ethnicity as their major risk factor in 2016, 2017, 2018, 2019, and 2020 respectively

Figure 12 HBV-positive donors by country/region of birth, 2020 (n=108)

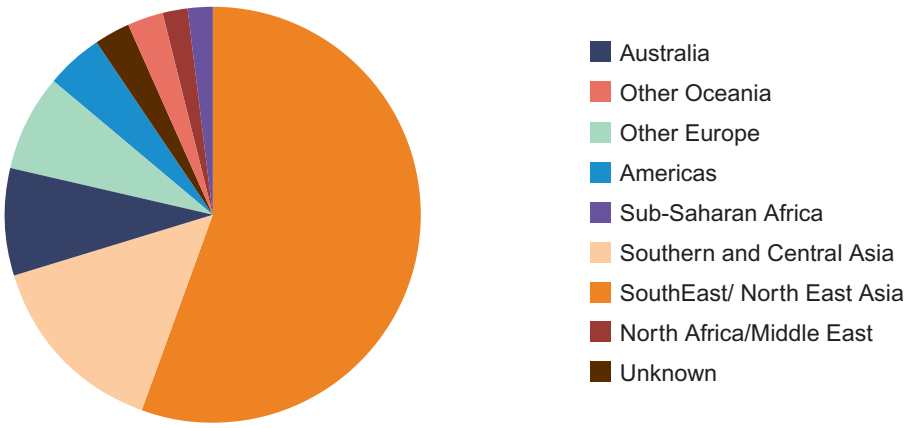
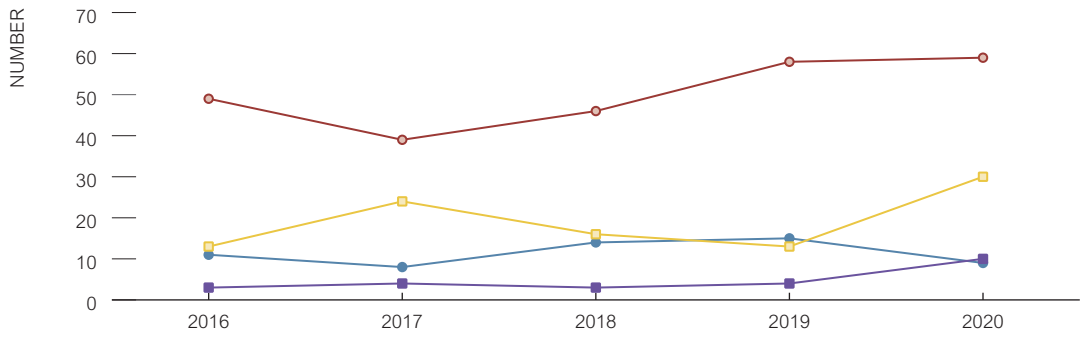


Figure 13 HBV-positive donors by sex and donor status, 2016-2020



	2016	2017	2018	2019	2020
Male (first-time)	49	39	46	58	59
Male (repeat)	11	8	14	15	9
Female (first-time)	13	24	16	13	30
Female (repeat)	3	4	3	4	10

Since 2016, a slight upward trend has been observed in the number of male and female HBV- positive first-time donors. The number of HBV-positive repeat donors remained relatively stable for men and saw a slight increase in women, during the same period of time (Figure 13). In comparison, there have been small declines in HBV notification rates by sex in the ten-year period, 2010-2019 from 32.6 to 25.3 per 100 000 male population and 29.1 to 21.0 per 100 000 female population.[6] 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 HBV-positive donors by sex, age group, donor status, country of birth and exposure category for the year 2020 and the period 2016-2020, 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 HBV-positive blood donors and the general population was conducted to determine if any unique source of exposure exists for Australian donors (Table 4). The comparison should be interpreted with caution as blood donors are asked about multiple potential sources of exposure. 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-positive donors was ethnicity or country of birth, which accounted for 71.3% of the HBV-positive donors in 2020. 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.[13-15]

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 2019, for newly acquired HBV infection in the general population, 30% had injecting drug use and 5.0% had country of birth as a major risk factor; importantly, for 28% of newly acquired HBV infections in the general population, the risk category was undetermined or not reported (Table 4).[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 blood donors have chronic HBV infection as opposed to acute infection.

Table 4 Comparison between HBV-positive blood donors (2020) and general population (2019) in Australia by infection and major potential risk categories, 2020

		HBV[1]
Major risk category	**General population (2019) (%)**	**Blood donors (2020) (%)**
Injecting drug use	29.6	0.0
Country of birth/Ethnicity[2]	4.9	71.3
Sexual contact[3]	7.0	2.8
Blood or tissue recipient	2.1	0.0
Tattoo or body piercing	9.9	0.0
Exposure in health care setting	6.3	0.9
Household contact/Family history	2.1	15.7
Other blood to blood contact	2.8	0.0
Other/undetermined/unknown/not reported	28.2	9.3
Imprisonment	1.4	0.0
Occupational risk	0.0	0.0
No risk factor identified	5.6	0.0

1 Includes exposure categories for newly acquired HBV infections only in general population
2 Includes 1 out of 9 HBV-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, which are not included in the Table above

Conclusion

- HBV prevalence in first time blood donors has shown no significant trend since 2011 and is substantially lower (12 times) than the general population estimates for the period 2010-2019.
- HBV incidence in blood donors 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 - OBI (23 of the 108 HBV infections in 2020).
- Acknowledging the limitations of direct comparison, putative risk factors in HBV-positive blood donors 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

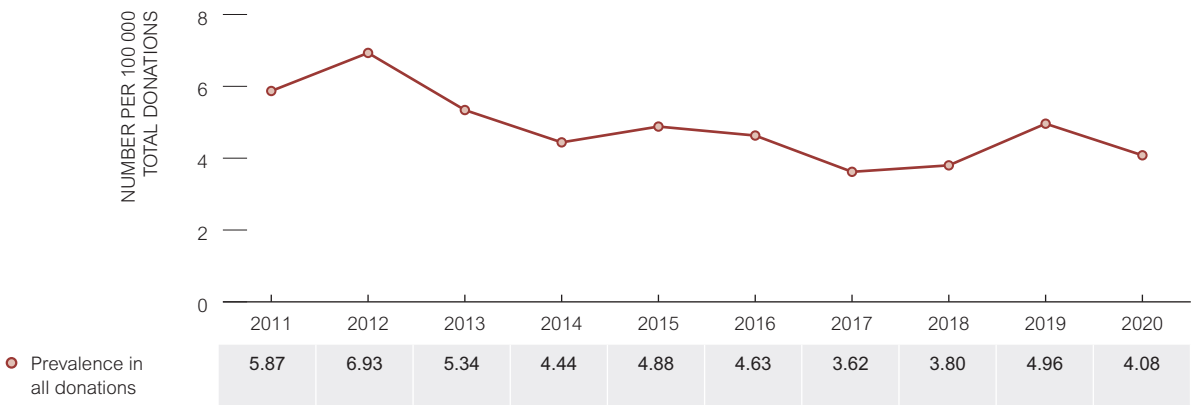
To the end of 2019, an estimated 122 264 people were living with chronic hepatitis C in Australia, of which an estimated 78% or 95 828 were diagnosed with chronic hepatitis C.[3] Australia has a concentrated chronic hepatitis C epidemic among key populations: people who inject drugs, prisoners, people from high prevalence countries and HIV positive men who have sex with men. The rate of diagnosis of HCV infection in 2019 was 36.6 per 100 000 which indicates a decrease from 2018, where the rate was 40.4 per 100 000.[6] However, in the period 2012-2016 the rate increased by over 20% from 44 per 100 000 to 52 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 26% decline in the rate of notification of hepatitis C over the ten-year period, 2010-2019, from 49.9 per 100 000 to 36.6 per 100 000. The rate of diagnosis in those aged 15-24 years has declined by 12% in the past ten years, 2010-2019.[6] In comparison, between 2015 and 2019, the rate of diagnosis in the Aboriginal and Torres Strait Islander population aged 15-24 years has increased by 8%.[6] Similarly, in 2019, the diagnosis rate of HCV was nearly six times higher in the Aboriginal and Torres Strait Islander population (199 per 100 000) than that of the non-indigenous population (31 per 100 000). In 2019, most cases (69%) of newly diagnosed HCV infection were in male persons and 77% were in people aged 30 years and above.[6]

Trends in prevalence

All donations:

In the past ten years, 2011-2020, 659 HCV-positive donors have been detected (489 first-time donors & 170 repeat donors) (Table 1A). This is the lowest ten-year total since universal donor testing commenced. During the last ten years, HCV prevalence among all donations has declined significantly (IRR: 0.95; 95% CI: 0.92-0.97). There has been an overall reduction of 31% over the period, from 5.8 per 100 000 donations in 2011 to 4.0 per 100 000 donations in 2020 (Figure 14). For detail on the number and prevalence rate of HCV infections among all donations for 2020, see Supplementary Table 2.

Figure 14 HCV prevalence in all blood donations in Australia, 2011-2020, by year of donation

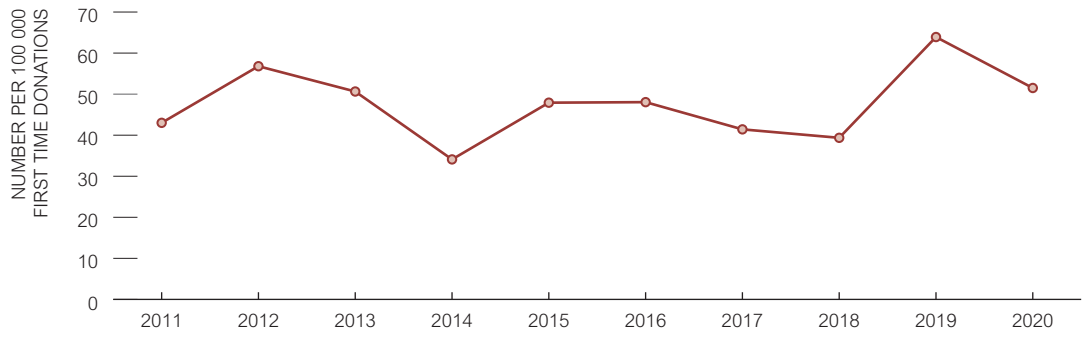


First-time donors:

No significant trend was observed in HCV prevalence in first-time donors in the 2011-2020 period (IRR: 1.01; 95% CI: 0.98-1.04); from 43.0 per 100 000 donations in 2011, to 47.9 per 100 000 donations in 2015 and 51.5 per 100 000 donations in 2020 (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 and 2020 at 63.9 and 51.5, respectively as compared to 39.3 observed in 2018. The increase observed in the last two years is likely to be the result of 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 and then answer 'No' to the question about ever having a positive test for hepatitis C.

In comparison, the national rate of diagnosis of HCV infection declined from 50 per 100 000 in 2010 to 37 per 100 000 in 2019.[6] 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.[16]

Figure 15 HCV prevalence in first time blood donors in Australia, 2011-2020, by year of donation

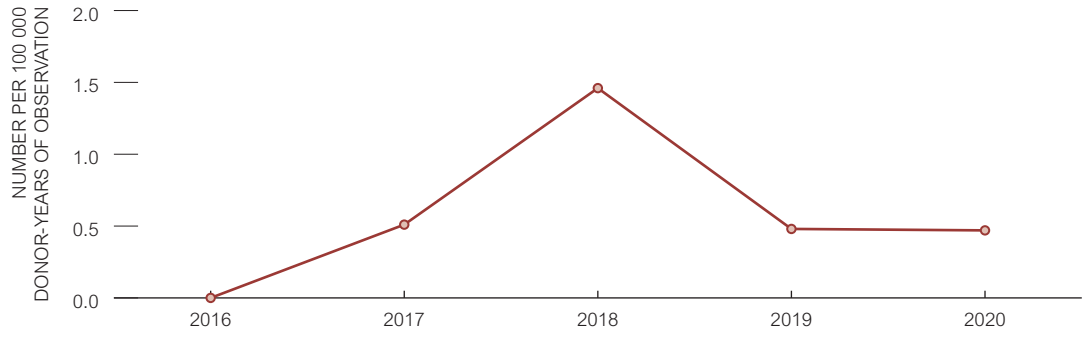


	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020
Prevalence in first-time donors	43.01	56.80	50.64	34.10	47.92	48.05	41.42	39.36	63.91	51.5

Trends in incidence

Over the five-year period 2016-2020, a total of six incident HCV donors were detected with no statistically significant trend observed for incidence rates (between 0.0 and 1.5 per 100 000 donor-years of observation; IRR: 1.15; 95% CI: 0.65-2.05) (Figure 16). Only one HCV incident donor was identified in 2020, equating to an incidence rate of ~0.5 per 100 000 donor-years of observation (Figure 16). 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, and was lowest in 2016 at 2.0.[6] No transfusion-transmitted HCV infections were reported in Australia during 2016-2020.

Figure 16 Incidence of HCV in repeat blood donors in Australia, 2016-2020



	2016	2017	2018	2019	2020
Incidence	0.00	0.51	1.46	0.48	0.47

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 will test positive for a mandatory test required for blood release, they are ineligible to donate as well as meeting 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 and to a lesser degree, 2020. The RNA positive proportion increased to 47.3% and 38.5% in 2019 and 2020, respectively, from 32.1% in 2018, and this increase may be associated with an increase in the number of prospective donors with 'resolved' HCV (HCV antibody positive/RNA negative) presenting to donate subsequent to successful treatment.

The majority (84.0%) of the HCV RNA-positive donors in 2020 were first-time donors, equating to a rate of RNA-positive donors among first-time donors at 19.7 per 100 000 donations. As compared to the 2010-2019 period where a declining trend was observed in the rate of RNA-positive donors among first-time donors (or those not previously HCV tested), no significant trend was observed for the 2011-2020 period (IRR: 0.96; 95% CI: 0.92-1.0).

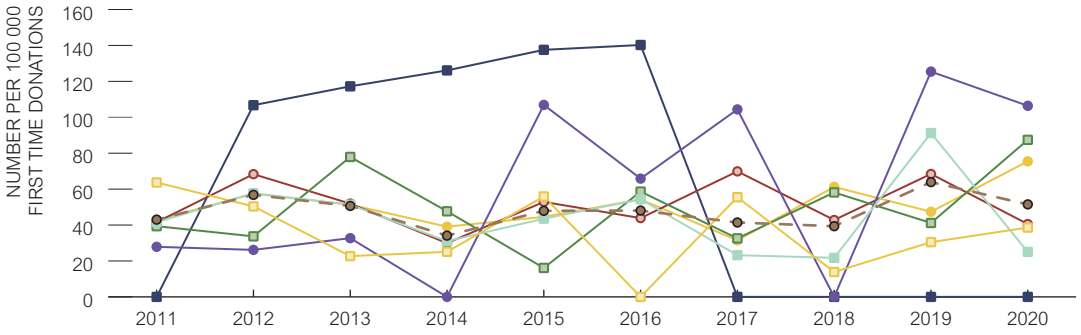
As highlighted above, the increased RNA-positive proportion in 2019 and 2020 compared to pre 2019 could, at least in part, be explained by HCV treatment initiatives. Importantly, the increase in first-time HCV-positive donors does not correlate directly with an increase in the HCV residual transmission 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 each in 2019 and 2020. 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, HCV prevalence among first-time donors varied markedly by jurisdiction in 2020, ranging from 0.0 to 106.4 per 100 000 donations. During the past ten years, 2011-2020, no significant trend was observed for any jurisdiction. In 2020, Tasmania recorded the highest prevalence among first-time donors compared to other states, at 106.4 per 100 000 donations (Figure 17) while the Northern Territory observed the lowest rate of 0.0 per 100 000 donations. The fluctuating trend in HCV prevalence 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 2019 was highest in the Northern Territory (31.5 per 100 000) and Queensland (19.1 per 100 000).[6]

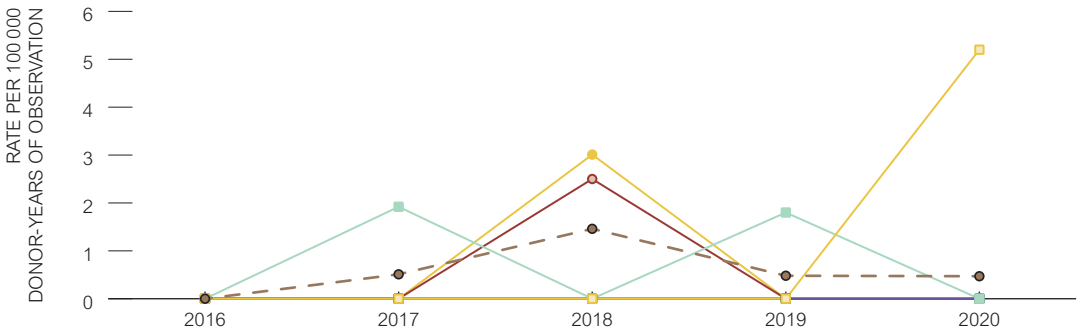
Figure 17 HCV prevalence among first time donors by state/territory and year of donation, 2011-2020



	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020
NSW/ACT	42.70	57.44	51.34	39.09	44.55	54.26	31.48	61.26	47.41	75.46
NT	0.00	106.72	117.23	126.10	137.55	140.25	0.00	0.00	0.00	0.00
QLD	41.61	68.33	51.93	29.94	52.87	43.87	69.88	42.81	68.44	40.55
SA	39.35	33.71	77.92	47.65	16.12	58.62	32.57	58.15	41.15	87.43
TAS	27.88	26.16	32.70	0.00	106.88	65.85	104.38	0.00	125.43	106.38
VIC	41.55	57.72	51.32	31.00	43.54	54.34	23.21	21.74	91.22	25.05
WA	63.68	50.38	22.69	25.09	55.92	0.00	55.51	13.85	30.48	38.60
National	43.01	56.80	50.64	34.10	47.92	48.05	41.42	39.36	63.91	51.50

There was no significant annual trend observed for HCV incidence in repeat donors nationally during the 2016-2020 study period (IRR: 1.15; 95% CI: 0.65-2.05). Generally, HCV incidence 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 2016.

Figure 18 HCV Incidence among repeat donors by state/territory and year of donation, 2016-2020



	2016	2017	2018	2019	2020
NSW/ACT	0.00	0.00	3.01	0.00	0.00
NT	0.00	0.00	0.00	0.00	0.00
QLD	0.00	0.00	2.50	0.00	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	0.00	1.92	0.00	1.80	0.00
WA	0.00	0.00	0.00	0.00	5.20
National	0.00	0.51	1.46	0.48	0.47

Comparison of HCV prevalence among blood donors and the general population

This section presents a comparison of HCV prevalence among first-time blood donors and the general population. As noted above, general population data for 2019 and 2020 were not available at the time of report preparation, therefore, although blood donor data are presented for 2011-2020 and 2020, 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 compared to the general population.

HCV prevalence is much higher in the general population than in blood donors, which is consistent with a previous Lifeblood studies.[11,12] The prevalence in first-time donors was 21 and 12 times lower than the prevalence in the general population for the period 2010/11-2019/20, and the year 2019/20, 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 HCV prevalence in blood donors with population prevalence by infection, 2010/11-2019/20

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	
	2010-2019	**2019**	**2011-2020**	**2020**	**2010/11-2019/20**	**2019/20**
HCV	997	593	48.1	51.5	21 times lower	12 times lower

* The 2019 HCV prevalence in the general population was calculated by taking the estimated number of people living with chronic HCV,[3] and dividing it by the estimated mid-year resident Australian population in 2019 reported by the Australian Bureau of Statistics. For the period 2010-2019, 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) to determine the association between demographic factors and presence of HCV-positivity among Australian blood donors in 2020, and the five-year period, 2016-2020, 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 2020, female donors were 46% less likely to be HCV-positive compared to male donors. Donors between 30-39 and over 50 years of age were 2.3 and 2.2 times more likely to be HCV-positive compared to the reference group (Supplementary Table 4). In 2020, donors from Victoria were 59% less likely to be HCV-positive compared to the reference group.

During the five-year period, 2016-2020, female donors were 41% less likely to be HCV-positive compared to male donors. There was a significantly greater risk of HCV infection among donors aged 30 years or above. During 2016-2020, donors from Western Australia were 46% less likely to be HCV-positive as compared to the reference group (Supplementary Table 5).

Risk factors associated with HCV-positive donors

Of the 300 HCV-positive donors during 2016-2020, 79% were first-time donors and 63% were male. Over the last five years, the mean age was 47 years with a wide range (18-70) (Table 6). Unlike HBV where birth overseas predominated, the majority (67%) of HCV-positive donors during 2016-2020 were born in Australia, and 55% in 2020 (Figure 19).

Overall, the main reported putative risk factors for HCV positivity during 2016-2020 were injecting drug use and tattoo or body piercing (23% and 21%, respectively). 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.[7] 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 21% 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 was conducted to further investigate the risk of tattooing in the context of blood donation,[8] 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 donors in the last five years, the highest among all TTIs.

Table 6 Characteristics of HCV-positive donors by year of donation, 2016-2020

Characteristics	2016	2017	2018	2019	2020	2016-2020
Number of positive donors	60	48	53	74	65	300
Number of positive first-time donors (%)	46 (77%)	38 (79%)	32 (60%)	67 (91%)	55 (85%)	238 (79%)
% male	40 (67%)	35 (73%)	27 (51%)	44 (59%)	42 (65%)	188 (63%)
Mean age (range) in years	48 (22-67)	48 (23-67)	45 (18-67)	47 (18-70)	45 (20-69)	47 (18 to70)
Number of incident donors	0	1	3	1	1	6
% born in Australia	40 (67%)	37 (77%)	40 (75%)	47 (64%)	36 (55%)	200 (67%)
Main reported risk factor	IDU[2] 27%	TBP[1]; IDU[2] 23% each	TBP[1] 26%	IDU[2] 26%	IDU[2] 20%	IDU[2] 23%
Second reported risk factor	TBP[1] 20%	Other 10%	IDU[2] 21%	TBP[1] 23%	TBP[1] 15%	TBP[1] 21%

1 TBP= Tattoo/Body piercing
2 IDU= Injecting drug use
Note: in 2020, 13 (20%) donors positive for HCV had their risk factors unknown or undetermined

Figure 19 Donors with HCV infection by country/region of birth, 2020 (n=65)

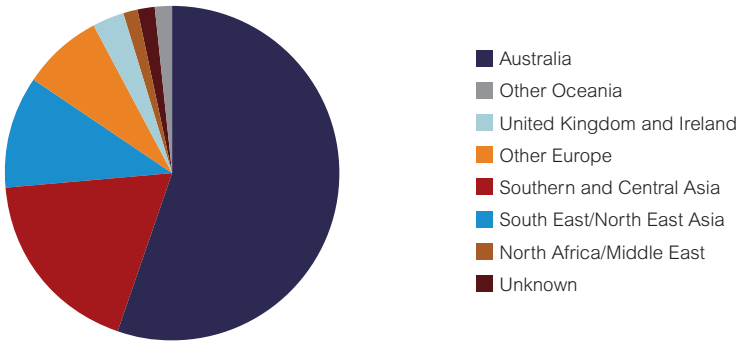
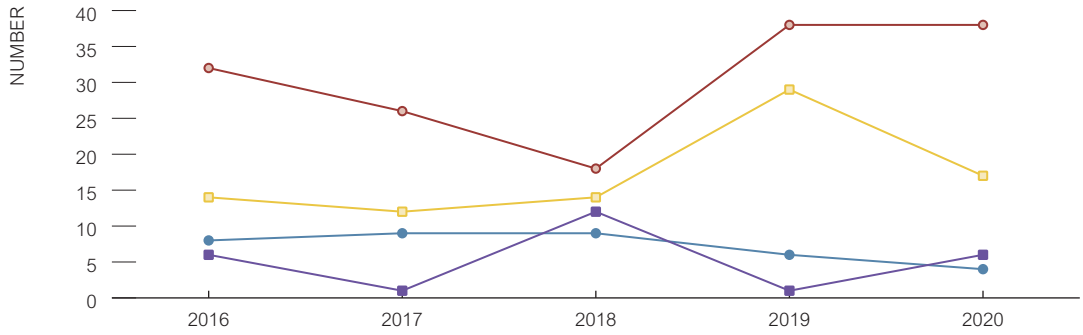


Figure 20 HCV-positive donors by sex and donor status, 2016-2020



	2016	2017	2018	2019	2020
Male (first-time)	32	26	18	38	38
Male (repeat)	8	9	9	6	4
Female (first-time)	14	12	14	29	17
Female (repeat)	6	1	12	1	6

Over the five-year period, 2016-2020, there has been a downward trend in the number of HCV-positive repeat male donors. A slight upward trend was seen in the number of HCV-positive first-time male and female donors (Figure 20). For more information on the number and percentage of HCV-positive donors by sex, age group, donor status, country of birth and exposure category for the year 2020 and the period 2016-2020, see Supplementary Tables 6-12. In comparison, there have been small declines in HCV notification rates by sex in the ten-year period, 2010-2019 from 62.0 to 50.9 per 100 000 male population and 37.2 to 22.4 per 100 000 female population. Of note, caution must be applied when comparing the trends by sex between blood donors and general population, as they are numbers in the former versus rates in the latter.[6]

HCV - Comparison of major exposure categories between blood donors and the general population, 2020

A comparison of major exposure categories between HCV-positive blood donors and the general population was conducted to determine if any unique source of exposure 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 exposure 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-positivity in blood donors in 2020 was IDU (20.0%), followed by tattoo or body piercing (15.4%). Of note, in 2020, for 20.0% blood donors, the risk factor remained unknown/undetermined. In comparison, for the newly acquired HCV infections in Australia in 2019, 19% had IDU as their major risk factor in the general population. Importantly, for 68% of the newly acquired HCV infection in the general population, no risk factor was identified (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).[4]

Table 7 Comparison between HCV-positive blood donors (2020) and general population (2019) in Australia by major potential risk categories

		HCV[1]
Major risk category	**General population (2019) (%)**	**Blood donors (2020) (%)**
Injecting drug use	19.2	20
Country of birth/Ethnicity	0.1	12.3
Sexual contact[2]	1	3.1
Blood or tissue recipient	0	3.1
Tattoo or body piercing	0.4	15.4
Exposure in health care setting	0.5	9.2
Household contact/Family history	0.1	3.1
Other blood to blood contact	0.6	6.2
Undetermined/unknown/not reported	8.2	20
Imprisonment	1.5	6.2
Occupational risk	0	1.5
No risk factor Identified	68.3	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, which are not included in the Table above

Conclusion

- HCV prevalence among first-time donors in 2020 and for the period 2011-2020 was 12 and 21 times lower among first-time blood donors than the general population estimates in 2019, and for the period 2010-2019, respectively.
- HCV incidence has not shown a significant trend in the five-year study period 2016-2020. 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.
- Unlike the 2010-2019 period where a downward trend was observed in the proportion of HCV first-time donors (or previously untested) with detectable RNA, no significant trend was observed during the 2011-2020 period. This is due to an increase in the proportion of RNA positive donors in 2019 and 2020, which in part might be explained by treated individuals assuming they are eligible and attending to donate.
- Acknowledging limitations in direct comparison, putative risk factors identified in blood donors with HCV infection in 2020 parallel those for the general population with no 'unique' risk factors identified to date among HCV-positive blood donors.

Human Immunodeficiency Virus (HIV)

Epidemiology of HIV in Australia

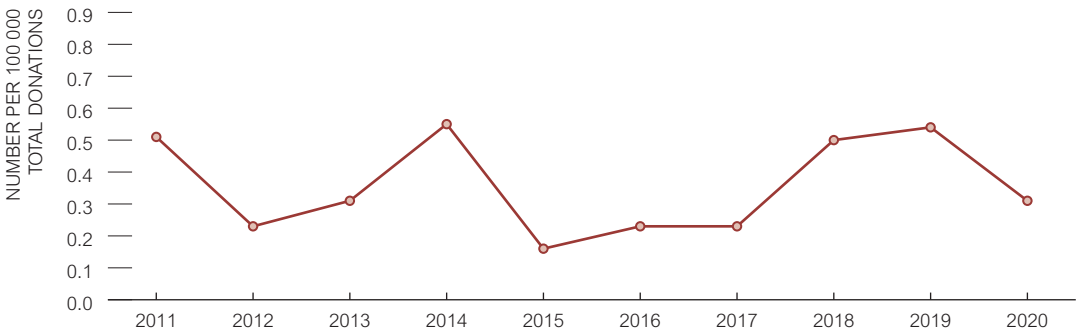
During 2019, an estimated 28 918 people were living with HIV and an estimated majority (90%) or 25 890 were diagnosed.[5] Transmission of HIV in Australia continues to occur primarily through sexual contact between men, with 71% of newly acquired cases of HIV infection in Australia in the period 2010 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 1 029 diagnoses in 2015 to 901 in 2019. Of these newly diagnosed HIV infections in 2019, 89% were in men, 59% 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, 2011-2020, a total of 49 HIV-positive donors have been detected (24 first-time donors & 25 repeat donors) (Table 1A). During this period, no significant trend was observed in HIV prevalence among all donations (IRR: 1.00; 95% CI: 0.91-1.10). Overall, the prevalence has fluctuated in the past ten years, 2011-2020, 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 2020, see Supplementary Table 2.

Figure 21 HIV prevalence in all blood donations in Australia, 2011-2020, by year of donation

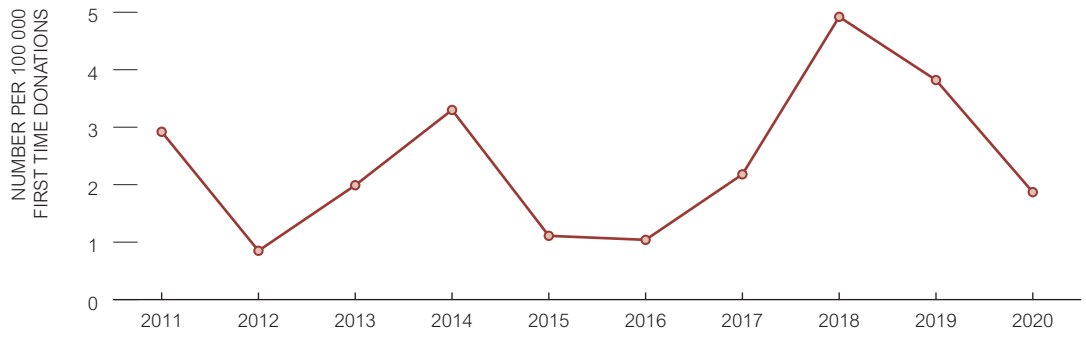


	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020
Prevalence in all donations	0.51	0.23	0.31	0.55	0.16	0.23	0.23	0.50	0.54	0.31

First-time donors:

HIV prevalence in first-time donors remained very low at ~2.4 per 100 000 over the ten-year period 2011-2020 (Table 1A); it was lowest in 2012 at 0.8 per 100 000 donations, followed by a fluctuating rate between the years 2013 to 2017 before peaking at 4.9 per 100 000 donations in 2018, then declining to 1.8 in 2020 (Figure 22). Overall, no significant trends were observed in HIV prevalence among first-time donors in the past ten years (IRR: 1.04; 95% CI: 0.91-1.19). In comparison, the number of newly diagnosed HIV infections in the general Australian population slightly decreased from 913 diagnoses in 2010 to 901 cases of newly diagnosed HIV infection in Australia in 2019.[5]

Figure 22 HIV prevalence in first-time blood donors in Australia, 2011-2020, by year of donation

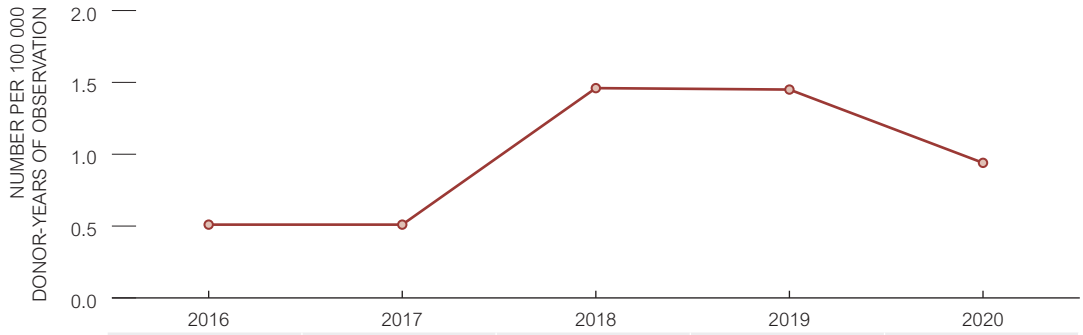


	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020
Prevalence in first-time donors	2.92	0.85	1.99	3.30	1.11	1.04	2.18	4.92	3.82	1.87

Trends in incidence

In 2020, two incident donors were detected for HIV, equating to an incidence rate of 0.9 per 100 000 donor-years of observation (Figure 23). For the five years 2016-2020, there were a total of 10 incident donors identified for HIV, and no significant trend was observed for HIV incidence during this time (IRR: 1.19; 95% CI: 0.76-1.87). While not directly comparable, no significant trend was observed for the HIV incidence 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 person-years (fluctuating between 0.58 per 100 person-years to 0.85 per 100 person-years).[17]

Figure 23 Incidence of HIV in repeat blood donors in Australia, 2011-2020, by year of donation



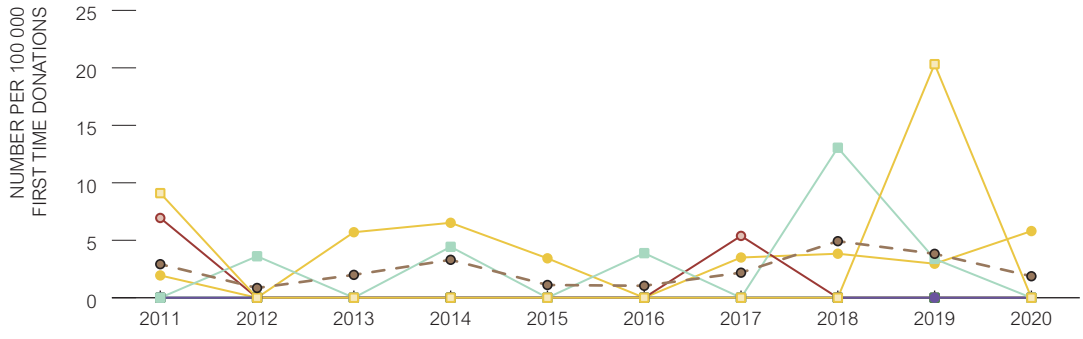
	2016	2017	2018	2019	2020
Incidence	0.51	0.51	1.46	1.45	0.94

No transfusion-transmitted HIV was reported in Australia during 2011-2020.

Trends in HIV by state/territory

HIV prevalence in first-time donors remained substantially lower than for hepatitis B and hepatitis C throughout the 2011-2020 period, with an average national prevalence of 2.3 per 100 000 donations (Table 1A).
No significant annual trend was observed during the 2011-2020 period in any jurisdiction (Figure 25). In 2020, New South Wales and the Australian Capital Territory observed the highest HIV prevalence in first-time donors at the rate of 5.8 per 100 000 donations (Figure 24), which is the highest recorded for these jurisdictions in the 2011-2020 period. 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 2011-2020, HIV prevalence in first-time donors was zero in the Northern Territory, South Australia and Tasmania (Table 1A and Figure 24).

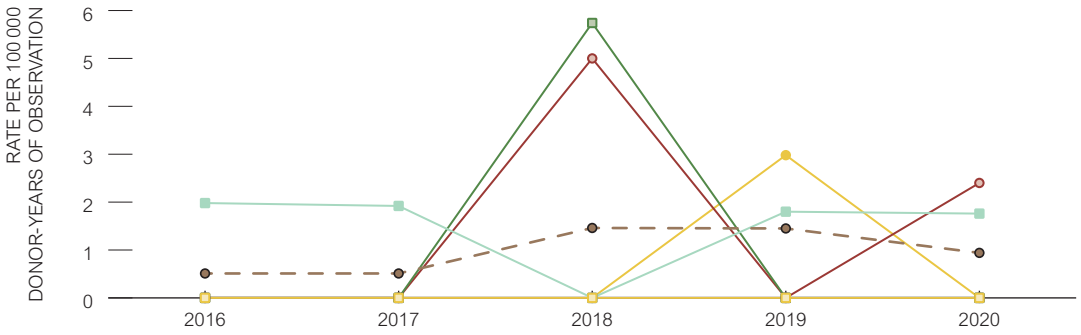
Figure 24 HIV prevalence among first time donors by state/territory and year of donation, 2011-2020



	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020
NSW/ACT	1.94	0.00	5.70	6.52	3.43	0.00	3.50	3.83	2.96	5.80
NT	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
QLD	6.94	0.00	0.00	0.00	0.00	0.00	5.38	0.00	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	3.61	0.00	4.43	0.00	3.88	0.00	13.05	3.38	0.00
WA	9.10	0.00	0.00	0.00	0.00	0.00	0.00	0.00	20.32	0.00
National	2.92	0.85	1.99	3.30	1.11	1.04	2.18	4.92	3.82	1.87

In 2020, there were two incident donors, one from Victoria and one from Queensland. 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 2016-2020.

Figure 25 Incidence of HIV among repeat donors by state/territory and year of donation, 2016-2020



	2016	2017	2018	2019	2020
NSW/ACT	0.00	0.00	0.00	2.98	0.00
NT	0.00	0.00	0.00	0.00	0.00
QLD	0.00	0.00	5.00	0.00	2.40
SA	0.00	0.00	5.74	0.00	0.00
TAS	0.00	0.00	0.00	0.00	0.00
VIC	1.98	1.92	0.00	1.80	1.76
WA	0.00	0.00	0.00	0.00	0.00
National	0.51	0.51	1.46	1.45	0.94

Comparison of HIV prevalence among blood donors and the general population

This section presents a comparison of HIV prevalence among first-time blood donors and the general population. General population data for 2020 were not available at the time of report preparation, therefore although blood donor data are presented for 2011-2020 and 2020, separately, comparison with the general population was made with 2010-2019 and 2019. Subsequently, a discussion is presented on the prevalence reduction in first-time donors as compared to the general population.

HIV prevalence is much higher in the general population than in blood donors, which is consistent with previous Lifeblood studies.[11,12] Prevalence in first-time donors was 47 times lower for the period 2010/11-2019/20, and 62 times lower in 2019/20 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 HIV prevalence in blood donors with population prevalence, 2010/11-2019/20

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	2011-2020	2020	2010/11-2019/20	2019/20
HIV	111	116	2.36	1.87	47 times lower	62 times lower

* The 2019 HIV prevalence in the general population was calculated by taking the estimated number of people living with chronic HIV,[5] and dividing it by the estimated mid-year resident Australian population in 2019 reported by the Australian Bureau of Statistics. For the period 2010-2019, an average of the ten years' prevalence rates was calculated.

Demographic factors associated with HIV-positivity in blood donors

Data on the demographic characteristics (sex, age group, state/territory and year of donation) for all blood donors were analysed (see Methodological Notes for details) to determine the association between demographic factors and HIV-positivity among Australian blood donors in 2020, and the five-year period, 2016-2020, 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 2020, there was no significant association between gender, age or state/territory and HIV-positivity (Supplementary Table 4). During the five-year period, 2016-2020, female donors, and donors between 30-39 years, 40-49 years and 50-years-and-above age groups were 68%, 81% and 63% less likely to be HIV-positive, respectively, compared to the reference groups. There was no association between state/territory and HIV positivity (Supplementary Table 5).

Risk factors associated with HIV-positive donors

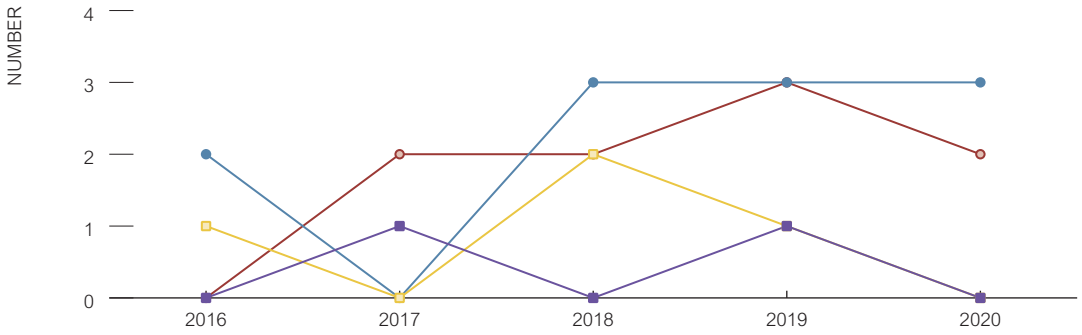
During 2016-2020, 50% of the 26 HIV-positive donors were first-time donors (Table 9). Most donors were male (70%) and had a mean age of 37 years. Of 26 HIV-positive donors in the five-year period 2016-2020, 10 were incident HIV donors. Male-to-male sexual contact and having a sexual partner with a known risk, or known to be positive for HIV infection were the most common reported risk factors for HIV-positivity in blood donors during 2016-2020 (27%, each), followed by underdetermined risk factor and having a sexual partner with unspecified risk (23%, each). In comparison, male-to-male sexual contact and heterosexual contact accounted for 59% and 23% of the new HIV diagnoses in the general population in 2019, respectively.

Table 9 Characteristics of HIV-positive donors by year of donation, 2016-2020

Characteristics	2016	2017	2018	2019	2020	2016-2020
Number of positive donors	3	3	7	8	5	26
Number of positive first-time donors (%)	1 (33%)	2 (67%)	4 (57%)	4 (50%)	2 (40%)	13 (50%)
% male	2 (67%)	2 (67%)	5 (71%)	6 (75%)	5 (100%)	20 (77%)
Mean age (range) in years	46 (30-56)	36 (24-57)	32 (20-66)	37 (21-70)	38 (25-67)	37 (20 to 70)
Number of incident donors	1	1	3	3	2	10
% born in Australia	2 (67%)	2 (67%)	2 (29%)	4 (50%)	2 (40%)	12 (46%)
Main reported risk factor	MSM[1] contact, PRP[2], undetermined each	PRP[2]	MSM[1] contact	MSM[1], PRP[2], PUSR[3], undetermined each	PUSR[3]	MSM[1], PRP[2] each
	33%	100%	43%	25%	40%	27%
Second reported risk factor	…	…	PUSR[3], undetermined each	…	MSM[1], PRP[2], undetermined each	PUSR[3], undetermined each
			29%		20%	23%

1 MSM= Male to male contact
2 PRP= Partner with known risk/known to be positive
3 PUSR=Partner with unspecified risk

Figure 26 HIV-positive donors, by sex and donor status, 2016-2020



	2016	2017	2018	2019	2020
Male (first-time)	0	2	2	3	2
Male (repeat)	2	0	3	3	3
Female (first-time)	1	0	2	1	0
Female (repeat)	0	1	0	1	0

Over the past five years, 2016-2020, 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 HIV-positive donors by sex, age group, donor status, country of birth and exposure category for period 2016-2020, see Supplementary Tables 6-12.

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

A comparison of major exposure categories between HIV-positive blood donors and the general population was conducted to determine if any unique source of exposure exists for HIV-positive Australian donors (Table 10). The comparison should be interpreted with caution as blood donors are asked about multiple potential sources of exposure. 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, in 2019, 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 (80%) of infected donors.

Table 10 Comparison between HIV-positive blood donors (2020) and general population (2019) in Australia by major potential risk categories, 2019/20

		HIV[1]
Major risk category	**General population (2019) (%)**	**Blood donors (2020) (%)**
Injecting drug use[2]	9.7	0.0
Country of birth/Ethnicity	0.0	0.0
Sexual contact[3]	82.2	80.0
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	20.0
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

- HIV prevalence was 62 times lower among first-time blood donors than in the general population in 2019/20, and 47 times lower for the period 2010/11-2019/20.
- The incidence of newly acquired HIV 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 2020.

This page intentionally left blank

Human T-Lymphotropic Virus (HTLV)

Epidemiology of HTLV in Australia

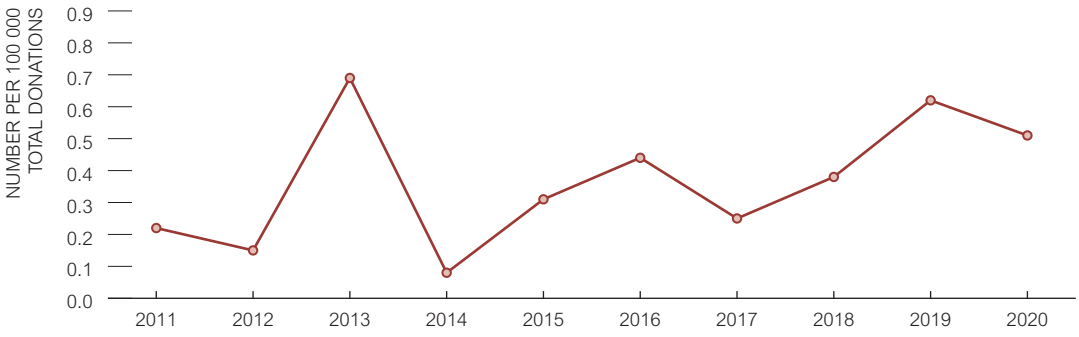
HTLV is not a notifiable infection in Australia except in the Northern Territory. Several studies have been conducted in Central Australian populations, but few have comprehensively examined the nationwide epidemiology. The international literature focuses on HTLV-1 as this is more pathogenic than HTLV-2, with disease outcomes including HTLV-1-associated myelopathy and adult T-cell leukaemia/lymphoma.[18,19]
The HTLV-1 prevalence in Australia reported in published studies varies considerably, from 1.7% among Aboriginal and/or Torres Strait Islander adults in the Northern Territory as a whole to 51.7% among adults in the Anangu Pitjantjatjara Lands of South Australia.[20-22] An HTLV-1 seroprevalence study conducted in a remote Aboriginal and/or Torres Strait Islander 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.[23]

Trends in prevalence

All donations:

From September 2016 to December 5 2020, repeat donors donating plasma for fractionation only no longer required testing for HTLV; and from December 6 2020 onwards, repeat donors no longer require testing for HTLV, irrespective of the type of donation, resulting in a different test denominator for this TTI, a point that needs due consideration when assessing recent trends. It will also mean that HTLV incidence will not be able to be estimated from repeat donation testing beyond December 5, 2020. In the past ten years, 2011-2020, a total of 38 HTLV-positive donors have been detected (36 first-time donors and two repeat donors) (Table 1B). During the period 2011-2020, the overall HTLV prevalence among all donations was 0.35 per 100 000 donations (Table 1B) and has shown no statistically significant trend (IRR: 1.08; 95% CI: 0.96-1.21) (Figure 27). For detail on the number and prevalence rate of HTLV-positive donors among all donations for 2020, see Supplementary Table 3A.

Figure 27 HTLV prevalence in all blood donations in Australia, 2011-2020, by year of donation

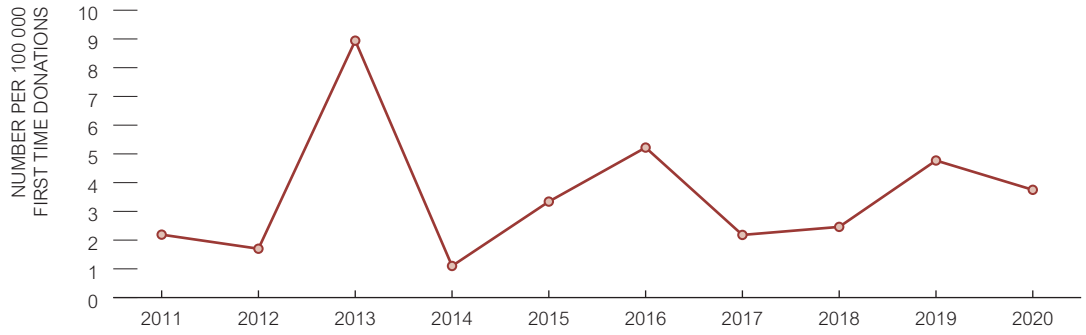


	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020
Prevalence in all donations	0.22	0.15	0.69	0.08	0.31	0.44	0.25	0.38	0.62	0.51

First-time donors:

HTLV prevalence in first-time donors remained very low over the past ten years, 2011-2020 with an overall rate of 3.5 per 100 000 donations and has shown no significant trend (Table 1B) (IRR: 1.02; 95% CI: 0.91-1.14). The prevalence fluctuated between 1.1 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 HTLV prevalence in first-time blood donors in Australia, 2011-2020, by year of donation



	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020
Prevalence in first-time donors	2.19	1.70	8.94	1.10	3.34	5.22	2.18	2.46	4.77	3.75

Trends in incidence

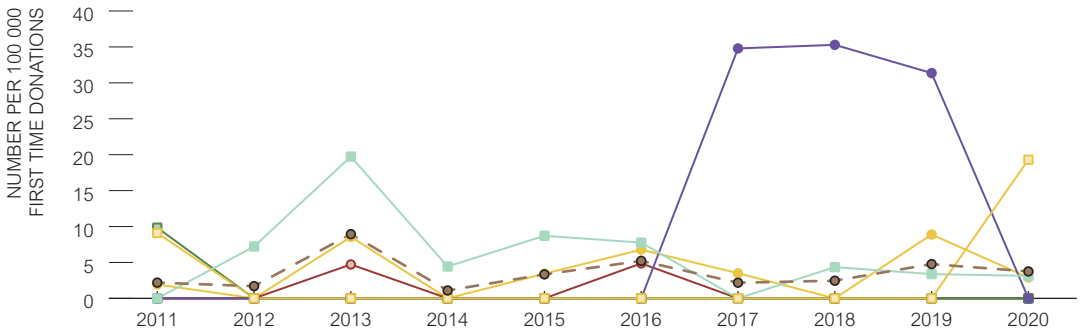
HTLV incidence among repeat Australian donors in 2020 (Jan 1 to December 5) was zero, as it was for the averaged ten-year period 2011-2020. Of note, two lapsed donors from 2007 and 2010 seroconverted in 2015 and 2018, respectively; however, these cases did not meet the definition for an incident donor 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 2011-2020.

Trends in HTLV-positivity by state/territory

In 2020, HTLV prevalence in first-time donors was zero in most jurisdictions except for New South Wales / Australian Capital Territory, Victoria and Western Australia where the prevalence was 2.9, 3.1 and 19.3 per 100 000 donations, respectively (Figure 30). Caution should be taken in interpretation of HTLV prevalence in first-time donors in Western Australia as this rate equates to only two positive donors. No significant trend was observed for prevalence in first-time donors during the period 2011-2020 in any jurisdiction. HTLV prevalence in first-time donors has remained zero in the Northern Territory during the ten-year study period, 2011-2020 (Figure 29).

No incident HTLV donors were reported during 2020 in any jurisdiction, and HTLV incidence has remained zero in the ten-year period 2011-2020 with the last incident donor identified in 2004.

Figure 29 HTLV prevalence among first time donors by state/territory and year of donation, 2011-2020



	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020
NSW/ACT	1.94	0.00	8.56	0.00	3.43	6.78	3.50	0.00	8.89	2.90
NT	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
QLD	0.00	0.00	4.72	0.00	0.00	4.87	0.00	0.00	0.00	0.00
SA	9.84	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	34.79	35.29	31.36	0.00
VIC	0.00	7.22	19.74	4.43	8.71	7.76	0.00	4.35	3.38	3.13
WA	9.10	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	19.30
National	2.19	1.70	8.94	1.10	3.34	5.22	2.18	2.46	4.77	3.75

Comparison of HTLV prevalence among blood donors and the general population

HTLV population prevalence is largely unknown with only the Northern Territory requiring formal notification; therefore, it is not possible to meaningfully compare prevalence among Australian blood donors and the general population.

Demographic factors associated with HTLV-positivity in blood donors

Data on the demographic characteristics (sex, age group, state/territory and year of donation) for all blood donors were analysed (see Methodological Notes for details) to determine the association between demographic factors and HTLV-positivity among Australian blood donors in 2020, and the five-year period, 2016-2020, 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 2020, there was no significant association between gender, donors' age group or location and HTLV-positivity (Supplementary Table 4). During the five-year period, 2016-2020, there was no significant association between gender or age and HTLV-positivity, although donors from the Australian Capital Territory and Tasmania are nearly seven times more likely to be HTLV-positive than the reference group (Supplementary Table 5).

Risk factors associated with HTLV-positive donors

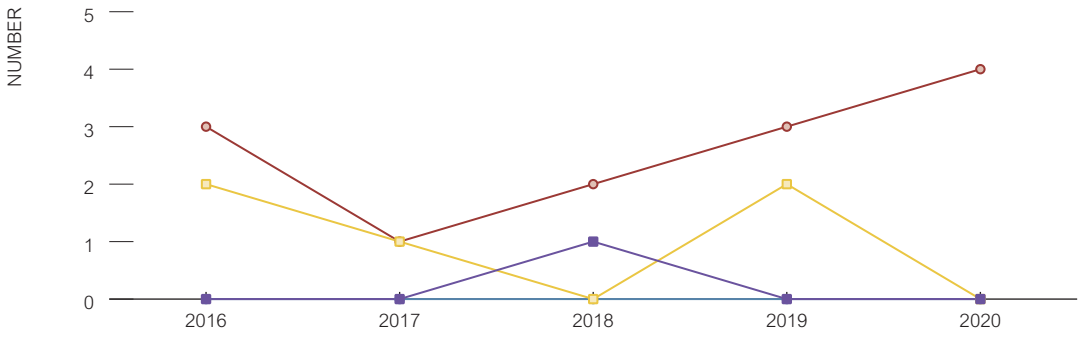
Only 19 HTLV-positive donors were detected during the 2016-2020 period; 18 were first-time donors, one repeat positive donor was identified in 2018, who did not meet the incident donor criterion; 68% were male, and the mean age was 39 years with a wide range (20-64 years) (Table 11). The majority of HTLV-positive donors (74%) were born overseas. Ethnicity or country of birth (68%) was the most common risk factor for HTLV-positivity in blood donors in Australia during the study period, followed by partner with known risk or known to be positive for any TTI (21%). As noted, equivalent data were not available for risk factors in the general population. There were no incident HTLV donors during the five-year period 2016-2020. Of note, literature also identifies self-flagellation as a possible unique risk factor for HTLV infection.[24] 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.[25]

Table 11 Characteristics of HTLV-positive donors by year of donation, 2016-2020

Characteristics	2016	2017	2018	2019	2020	2016-2020
Number of positive donors	5	2	3	5	4	19
Number of positive first-time donors (%)	5 (100%)	2 (100%)	2 (67%)	5 (100%)	4 (100%)	18 (95%)
% male	3 (60%)	1 (50%)	2 (67%)	3 (60%)	4 (100%)	13 (68%)
Mean age (range) in years	32 (20-45)	54 (44-64)	38 (26-54)	44 (32-60)	35 (27-41)	39 (20-64)
Number of incident donors	0	0	0	0	0	0
% born in Australia	0 (0%)	1 (50%)	1 (33%)	2 (40%)	1 (25%)	5 (26%)
Main reported risk factor	Ethnicity/COB[1] 80%	Ethnicity/COB[1] 50%	Ethnicity/COB[1] 67%	Ethnicity/COB[1] 40%	Ethnicity/COB[1] 100%	Ethnicity/COB[1] 68%
Second reported risk factor	PRP[2] 20%	PRP[2] 50%	PRP[2] 33%	PRP[2], PUSR[3], Other each 20%	…	PRP[2] 21%

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

Figure 30 HTLV-positive donors by sex and donor status, 2016-2020



	2016	2017	2018	2019	2020
Male (first-time)	3	1	2	3	4
Male (repeat)	0	0	0	0	0
Female (first-time)	2	1	0	2	0
Female (repeat)	0	0	1	0	0

During the past five years, 2016-2020, there was an upward trend in the number of HTLV-positive first-time male donors. No discernible overall trend has been observed for first-time and repeat female donors. The number of HTLV-positive repeat male donors has remained zero for the study period 2016-2020 (Figure 30). For more information on the number and percentage of HTLV-positive donors by sex, age group, donor status and country of birth for year 2020 and period 2016-2020, 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/or Torres Strait Islander populations in inland Australian regions are known to represent a high HTLV-1-prevalence population.[26] 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.[27] This is consistent with the finding that ethnicity or country of birth was the likely exposure risk in all four HTLV-positive donors in 2020.

Conclusion

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

This page intentionally left blank

Potentially Infectious Syphilis (PIS)

Epidemiology of infectious syphilis in Australia

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),[28] plasma stored at -20°C for 48 hours was shown to be non-infectious in an animal model,[29] and oxygen flow levels in platelet storage bags are believed to be toxic to *T.paliidum*.[30] 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).[31] 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 (treponemal antibody test negative to positive) with a positive confirmatory result, or had a history of syphilis treatment since their last treponemal antibody test 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[32]). 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[33]). 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 was primarily an infection of men having male to male sex in urban settings, and of heterosexual Aboriginal and/or Torres Strait Islander people in remote and outer regional areas, however the outbreak has expanded beyond these subgroups with an increase observed in women as well. The number of cases of infectious syphilis (infections of less than 2 years' duration) notified in 2019 was 5 880.[6] The notification rate of infectious syphilis among men has increased in the ten-year period, 2010-2019, from 9 per 100 000 in 2009 to 40 per 100 000 in 2019; similarly the rate among women has increased from 1 per 100 000 in 2010 to 8 per 100 000 in 2019.[6]

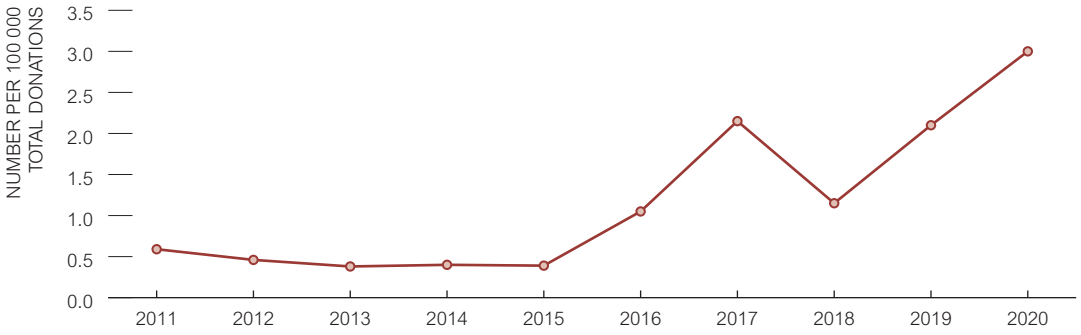
Trends in prevalence

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, 2011-2020, a total of 109 donors with PIS/active syphilis have been detected (46 first-time donors and 63 repeat donors) (Table 1C). During the period 2011-2020, the prevalence of PIS/active syphilis among all donations remained very low at 1.0 per 100 000 donations (Table 1C); however, the prevalence in all donations has increased substantially in recent years from 0.6 per 100 000 donations in 2011 to 2.1 in 2017 and 3.0 per 100 000 donations in 2020. As a result, a significant increase in the prevalence of PIS/active syphilis among all donations was observed during 2011-2020 (IRR 1.27; 95% CI: 1.18-1.36) (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 2020, see Supplementary Table 3B.

Figure 31 Prevalence of PIS/active syphilis in all blood donations in Australia, 2011-2020, by year of donation

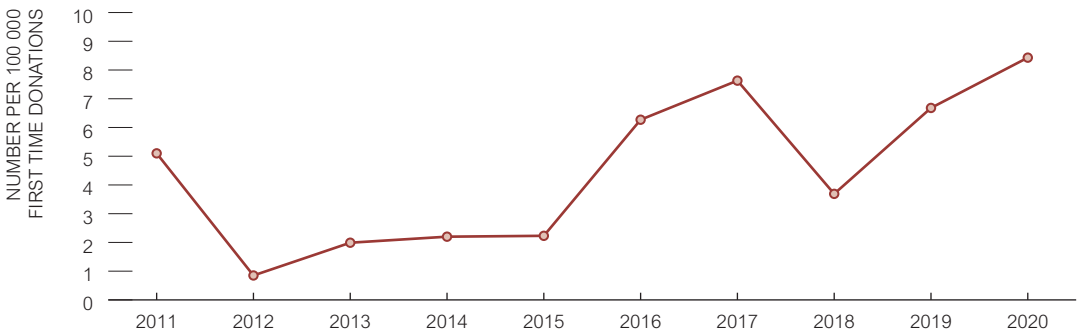


	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020
Prevalence in all donations	0.59	0.46	0.38	0.40	0.39	1.05	2.15	1.15	2.10	3.00

First-time donors:

In the ten years, 2011-2020, the prevalence of PIS/active syphilis in first-time donors was 4.5 per 100 000 donations (Table 1C). Overall, the prevalence of PIS/active syphilis in first-time donors showed a significant upward trend during 2011-2020 (IRR: 1.13; 95% CI: 1.02-1.25) (Figure 32). In 2020, the rate of 8.4 is the peak recorded prevalence rate of PIS/active syphilis in first-time donors (Figure 32). By comparison, the national rate of diagnoses of infectious syphilis was 5.0 per 100 000 population in 2010; 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 23.9 per 100 000 in 2019 corresponding to the highest recorded number of notifications, with 5 880 diagnoses of infectious syphilis.[6] Caution should be taken in interpretation, as the infectious case definition changed in July 2015, to include more cases of likely recent acquisition.[33]

Figure 32 Prevalence of PIS/active syphilis in first-time blood donors in Australia, 2011-2020, by year of donation

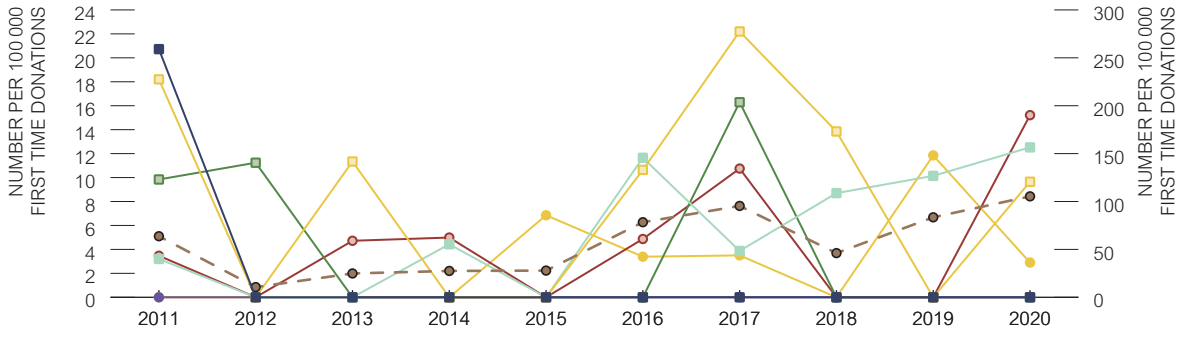


	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020
Prevalence in first-time donors	5.10	0.85	1.99	2.20	2.23	6.27	7.63	3.69	6.68	8.43

Trends in PIS/active syphilis infection by state/territory

In 2020, PIS/active syphilis prevalence in first-time donors was zero for the Northern Territory, South Australia and Tasmania. The prevalence rate in first-time donors was the highest in Queensland at 15.2 per 100 000 donations, followed by Victoria, Western Australia and New South Wales / the Australian Capital Territory where rates were 12.5, 9.6 and 2.9 per 100 000 donations, respectively (Figure 33). Prevalence in first-time donors in Tasmania remained zero over the 2011-2020 period. Similarly, in the Northern Territory, prevalence has remained at zero since 2012 after peaking at 259 per 100 000 donations in 2011. There were no significant trends observed in most jurisdictions during 2011-2020, except for New South Wales / the Australian Capital Territory and Victoria, where prevalence in first-time donors showed a significant upward trend (IRR: 1.35 95% CI: 1.04-1.76; IRR: 1.28 95% CI: 1.04-1.56, respectively). In comparison, the trend in the general population during the period 2010-2019, showed an increase in rates of diagnosis of infectious syphilis in all jurisdictions, except Tasmania.[6]

Figure 33 Prevalence[1] of PIS/active syphilis among first time donors by state/territory and year of donation, 2011-2020



	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020
NSW/ACT	0.00	0.00	0.00	0.00	6.85	3.39	3.50	0.00	11.85	2.90
NT	259.07	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
QLD	3.47	0.00	4.72	4.99	0.00	4.87	10.75	0.00	0.00	15.21
SA	9.84	11.24	0.00	0.00	0.00	0.00	16.29	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	3.20	0.00	0.00	4.43	0.00	11.65	3.87	8.70	10.14	12.52
WA	18.20	0.00	11.34	0.00	0.00	10.64	22.20	13.85	0.00	9.65
National	5.10	0.85	1.99	2.20	2.23	6.27	7.63	3.69	6.68	8.43

1 Prevalence in NT is provided according to the scale on the secondary axis on the right-hand side

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

As noted above, prevalence of PIS/active syphilis in first-time donors in 2020 and the ten-year study period 2011-2020 was 8.43 and 4.52 per 100 000 donations, respectively (Supplementary Table 3B and Table 1C). However, estimates on population prevalence for infectious syphilis are unknown and information is only available on infectious syphilis notifications.[6] It is therefore difficult to compare the prevalence of PIS/active syphilis 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 were analysed (see Methodological Notes for details) to determine the association between demographic factors and presence of PIS/active syphilis among Australian blood donors in 2020, and the five-year period, 2016-2020, 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 2020, female donors were significantly less likely (74%) compared to male donors to be classified as PIS (Supplementary Table 4). Donors in 50-years-and-above group were less likely (82%) to be positive with PIS/active syphilis as compared to the reference group of 20-29 years. Donors from Victoria were 3.3 times more likely to be positive for PIS/active syphilis compared to the reference group.

During the five-year period, 2016-2020, female donors were 72% less likely to be PIS/active syphilis as compared to male donors. Donors between 30-39 years, 40-49 years and 50-years-and-above age groups were 49%, 67% and 81% less likely to be 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 status among Australian blood donors during this period.

Risk factors associated with PIS/active syphilis donors

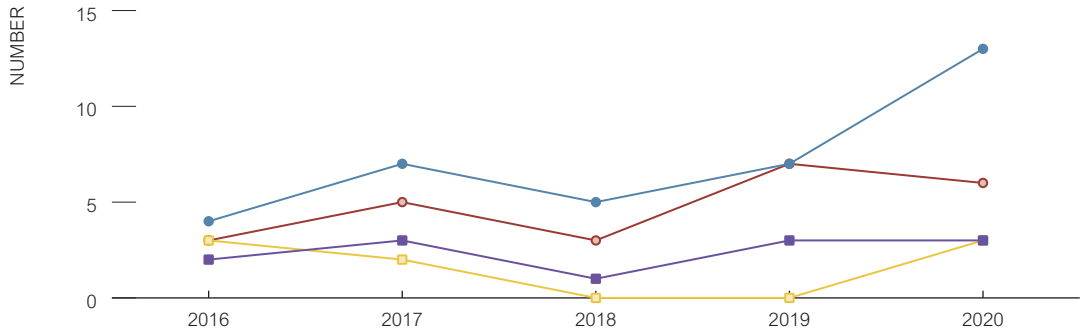
During 2016-2020, a total of 60 donors were classified as PIS/active syphilis, 40% were first-time donors, 75% were male, and 60% were born in Australia (Table 12). The mean age was 34 (range 19-66). Partner with unspecified risk (34%) was the most frequent likely risk factor for PIS/active status. In comparison, in 2019, nationally, 83% of infectious syphilis diagnoses were in males, and 62% were in people aged 20 – 39 years.[6]

Table 12 Characteristics of PIS/active syphilis donors by year of donation, 2016-2020

Characteristics	2016	2017	2018	2019	2020	2016-2020
Number of positive donors	12	17	9	17	25	60
Number of positive first-time donors (%)	6 (50%)	7 (41%)	3 (33%)	7 (41%)	9 (36%)	32 (40%)
% male	7 (58%)	12 (71%)	8 (89%)	14 (82%)	19 (76%)	60 (75%)
Mean age (range) in years	37 (24-55)	30 (19-51)	42 (25-63)	30 (21-42)	36 (20-66)	34 (19-66)
% born in Australia	9 (75%)	12 (71%)	7 (78%)	10 (59%)	10 (40%)	48 (60%)
Main reported risk factor	PUSR[1] Unknown - each	PUSR[1]	PUSR[1]	MSM[2]	PUSR[1]	PUSR[1]
	42%	47%	56%	41%	48%	34%
Second reported risk factor	PRP[3]	PRP[2]/ Undetermined each	MSM[1]/ Undetermined each	PUSR[1]	Undetermined/ unknown	Undetermined/ unknown
	17%	18%	22%	24%	36%	30%

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

Figure 34 Donors with PIS/active syphilis status by sex and donor status, 2016-2020



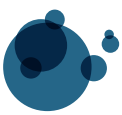
	2016	2017	2018	2019	2020
Male (first-time)	3	5	3	7	6
Male (repeat)	4	7	5	7	13
Female (first-time)	3	2	0	0	3
Female (repeat)	2	3	1	3	3

Over the past five years, 2016-2020, there has been an upward trend in the number of PIS/active syphilis first-time / repeat male donors (Figure 34). No discernible trend was observed in first-time / repeat female donors. For more information on the number and percentage of donors with PIS/active syphilis status by sex, age group, donor status, country of birth and exposure category for year 2020 and period 2016-2020, see Supplementary Tables 6-12.

Conclusion

- Overall, during 2011-2020, the prevalence of PIS/active syphilis among all blood donations and first-time blood donations has shown a significant upward trend. This parallels increasing syphilis notifications in the general population.
- A meaningful comparison between the prevalence of PIS/active syphilis in blood donors and the general population could not be done as accurate estimates on population prevalence for infectious syphilis are unknown and information is only available on infectious syphilis notifications.

This page intentionally left blank



Additional information

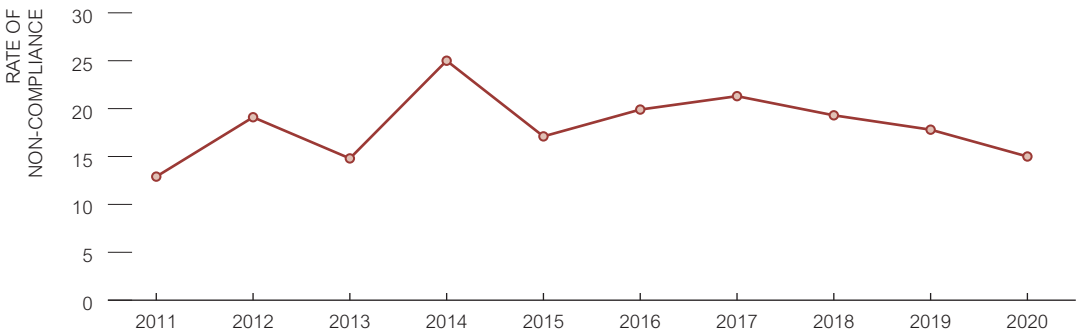
Screening compliance

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 they can donate. Lifeblood is therefore highly reliant on donors truthfully answering all questions (termed '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 quarantine/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.

Eighteen percent (157/849) of infected donors in 2016-2020 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, 75% (117 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[11] for 2000-2006 was 22%.

Figure 35 Rate of reported non-compliance in TTI-positive donors, 2011-2020



	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020
Rate of non-compliance	12.9	19.1	14.8	25.0	17.1	19.9	21.3	19.3	17.8	15.0

Table 13 Non-compliance category and rate among donors who were positive for any transfusion-transmissible infection, 2016-2020

Non-compliance by year and reason for deferral	2016[a]	2017	2018[b]	2019[c]	2020	2016-2020
Number (%) of non-compliant donors by reasons for deferral						
Intravenous drug use	15 (48.3)	9 (29.0%)	9 (31.0%)	7 (20.6%)	1 (3.1%)	41 (26.11)
Known status/previous positive^	17 (54.8)	16 (51.6%)	17 (58.6%)	17 (50.0%)	26 (81.3%)	93 (59.24)
Male-to-male-sexual contact	1 (3.2)	2 (6.4%)	4 (13.8%)	5 (14.7%)	2 (6.3%)	14 (8.92)
Partner with known risk or known to be positive	2 (6.4)	4 (12.9%)	3 (10.3%)	6 (17.6%)	3 (9.4%)	18 (11.46)
Others	0 (0)	0 (0)	1 (3.4%)	2 (5.9%)	0 (0)	3 (1.91)
						0
Total number (%) of non-compliant donors by year	31 (20%)	31 (21%)	29 (19%)	34 (18%)	32 (15.4%)	157 (18.49)

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

Each year between 2016-2020 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, 50.0% in 2019 and 81.3% in 2020. 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 2016-2020, 59.2% of non-compliance was attributed to known status of previously being positive for a virus followed by injecting drug use (26.1%), and having a sexual partner with known risk or known to be positive for any transfusion-transmissible infection (11.4%) (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 92% for the 2019-20 period (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 2019 and 2020 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.[31] 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 (2019-2020)

	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 1.6million 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 2005-2020 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 2020 were referred to their doctor with a copy of their results.

In 2020, 132 338 donations were tested for malaria antibody of which 2 052 (1.6%) were found to be repeat reactive for malaria antibodies. This rate of antibody detection is comparable to the 1.9% rate recorded in 2019. No cases of transfusion transmitted malaria were reported in Australia in 2020 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, at Perth Processing Centre (PPC) on 9 December 2019 and at the Brisbane and Sydney Processing Centres (BPC and SPC respectively) on 3 February 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 prerelease 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 prior to November 2020, the same absolute sample volume was extracted regardless of the final number of split components. For both single and split 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 aerobic (BPA) and one anaerobic (BPN) 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 beginning of February 2020.

In mid-2018, Lifeblood reviewed the BCS testing strategy with the aim of extending platelet shelf-life to 7 days while improving the sensitivity for testing. In the lead-up to this change, the minimum sample volume for BCS testing was increased in 2020.

On 25 May 2020, the minimum sample volume removed from the pooled platelet pack, or from the combined apheresis platelet collection, was increased from 15 mL to 16-20 mL with the inoculation volume for each culture bottle being 8-10 mL (previously 6-7 mL).

On 30 November 2020, the minimum sample volume removed from the combined apheresis platelet collection is based on the final number of split components. Therefore, double apheresis platelets have four culture bottles (two BPA, two BPN) and triple apheresis platelets have six culture bottles (three BPA, three BPN). The inoculation volume for each culture bottle is 8-10 mL.

Due to the short 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 2020 a total of 119 856 BCS samples were tested.

Of 93 657 pooled platelet units tested, 363 (0.39%) were flagged by the BacT/ALERT as initial machine positive. Of these, 125 (0.13 %) were designated “confirmed positive”, 60 (0.06%) were “indeterminate” and the remaining 178 (0.19%) were considered to be “false positive”.

Of 26 199 apheresis collections tested, 89 (0.34%) were flagged by the BacT/ALERT as initial machine positive. Of the total apheresis collections tested, 11 (0.04%) were designated “confirmed positive”, 17 (0.06%) were “indeterminate” and the remaining 61 (0.23%) were considered to be “false positive” (Table 15).

Table 15 Summary of bacterial testing of platelets by BacT/ALERT 3D and BacT/ALERT VIRTUO, 2020

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 136 confirmed positives, the most frequently isolated genera were *Cutibacterium and Propionibacterium* (hereafter collectively referred to as "propionibacteria"), which were isolated from 119 samples (87.5%). Coagulase-negative staphylococci (CoNS) were isolated from 8 BCS samples (5.9%). Propionibacteria and CoNS cultured from 127 of the 136 confirmed positives 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. One of the confirmed positives was a *Bacillus* species that most likely represents environmental contamination and is unlikely to be clinically significant in the absence of recent injury or trauma. Specific risk factors in donors are excluded by the Lifeblood medical officers to determine clinical significance and requirement of further follow up and investigations.

The remaining 8 (5.8%) confirmed positives were potentially pathogenic species, which are listed in Table 16. None of the associated components from these donations were transfused and all the donors were followed up and reported to be healthy with no specific risk factors.

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]

There was one isolate of *Fusobacterium* species, Gram-negative strict anaerobic bacilli that could not be confirmed on repeat culture. The clinical significance of non-spore forming strict anaerobes is questionable since, these 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 2020, there were 52 cases of suspected transfusion-transmitted bacterial infections. There were no confirmed cases of TTBI in 2020.

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 overall. 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 Service (now Lifeblood) rate was similarly low at 0.04 per 100 000 transfused units.[43]

Table 16 Summary of confirmed positive contaminants from platelets, 2020 (n=136 BCS samples)

Confirmed positives: organism isolated	Number
Cutibacterium and *Propionibacterium* species	119
Coagulase-negative staphylococci	8
Enterococcus faecium	1
Bacillus cereus / *Bacillus thuringiensis*	1
Listeria monocytogenes	1
Streptococcus agalactiae (Lancefield Group B)	1
Streptococcus dysgalactiae	2
Streptococcus pyogenes (Lancefield Group A)	1
Streptococcus species (Lancefield Group G)	1
Streptococcus gallolyticus	1
Total	136

Surveillance and risk assessment for emerging infections

Lifeblood maintains surveillance for emerging infections through close liaison with Australian Government communicable disease control units, 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 other 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 (DENV)	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.	For the period 2020-2021 (to 7 September) the only reported outbreak of dengue fever was in Townsville where 2 locally-acquired cases occurred.[50] With decreased overseas travel by Australians and international arrivals due to COVID-19 pandemic-related travel restrictions and no direct international arrivals permitted 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 virus (HAV)	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 HAV infections in Australia prior to the COVID-19 pandemic were overseas-acquired infections. With the reduction in international travel during the COVID-19 pandemic, the numbers of HAV infections in Australia have decreased. For the 12-month period, 18 January 2020 to 17 January 2021, there 80 reported cases of HAV infection in Australia, although the annual rolling average for the 5 years to 2020 was 245.[51] In 2021, to 15 August, 15 cases of HAV infection had been reported in Australia. Modelling has previously demonstrated hepatitis A is a negligible risk to blood safety in Australia, even with previous local outbreaks and returning travellers. In the current context of limited overseas travel by Australians and reduced numbers of international visitors due to COVID-19 pandemic-related restrictions, the potential risk of HAV to blood safety in Australia significantly lower than reported previously.	Most hepatitis A cases in Australia in the past have been associated with overseas travel. Existing donor geographical restrictions to mitigate the risk of other overseas-acquired infectious diseases such as malaria also mitigate the risk of overseas-acquired 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, a number of cases have been 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. For the 12-month period 18 January 2020 to 17 January 2021, there were 34 reported HEV cases in Australia (most reported in the first quarter of 2020), compared to the rolling 5-year average of 45.4. In 2021, to 1 August, 10 HEV cases have been reported.[51]	Lifeblood has a deferral for HEV infection and close contact with a confirmed case. Developing countries with reported cases of HEV are subject to malaria-related restrictions. Donations from donors who have recently returned from these countries are restricted to plasma for fractionation for a period of time after returning. The low risk of HEV to blood safety in Australia would have further decreased since 2019 due to the decrease in reported case numbers in 2020 and 2021. This is possibly due to COVID-19-related travel restrictions. In addition, any potential risk to blood safety would be further mitigated by Lifeblood's 4-week deferral of all donors who have recently returned from overseas and required to quarantine on return.

Pathogen	Transfusion-transmission reported	Infectious risk period	Surveillance/Risk assessment	Additional risk management for blood safety
Parvovirus B19 (B19V)	Yes, three probable cases of transfusion-transmission have occurred in recent years in Australia.[52]	The majority of B19V infections are either asymptomatic or accompanied by non-specific symptoms that may not be 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 at least 5 days and at lower levels for several more days.	A risk assessment of B19V in Australia has been completed.[52] 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 between 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 deferral period for donors with a current B19V infection or contact with an infected person.
Ross River virus (RRV)	Yes, a single case in Australia has been reported.[53]	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 transfusion-transmission case was reported in 2015, Lifeblood has completed a comprehensive risk assessment for RRV.[54] During the largest outbreak in Australia to date in 2015, no TT-RRV cases were reported and PCR testing of 7 500 donations in highest risk areas 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 Nino 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. In 2021, to 18 August, 2 762 cases of RRV were reported.[51]	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 typically represent infectious virus and is associated with more severe disease symptoms. SARS-CoV-2 antibodies become detectable in blood between approximately 1 to 2 weeks post-symptom onset and rising antibody titres are associated with a decline in the level of plasma 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.[55]	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 transmitted to humans by an intermediate animal host. Human-to-human transmission, predominantly close contact through respiratory transmission from larger droplets to aerosols, is the primary mode of transmission.	In Australia, 64 628 confirmed COVID-19 cases and 1 053 COVID-19-related deaths had been reported by 7 August 2021. The highest number of cases have been reported in NSW with 36 267 confirmed cases (194 deaths), followed by Victoria with 23 429 confirmed cases (823 deaths). Of these cases 8 320 (12.9%) were confirmed as overseas acquired while 55 694 (86.2%) were confirmed as locally-acquired. In 2020, most of Australia's locally-acquired cases were reported in Victoria during a large outbreak from approximately mid-June to October.[56] In 2021, there have been several local outbreaks in Australia's mainland states and territories, primarily associated with the delta variant. The largest outbreak to date (8 September) has been in NSW where 30 456 locally acquired cases have been reported since 16 June 2021, when the first case in the outbreak was reported.[57] There is also an ongoing outbreak in Victoria where 2 466 cases have been reported since 4 August to 8 September.[58] A national vaccination programme is now well under way in Australia. As at 7 September, 63.8% of the population have had at least one dose of the vaccine and 39.0% have been fully vaccinated.[59]	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 defers for 4 weeks all donors returning from overseas and who are required to quarantine on 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 for 4 weeks from date of testing and donors reporting close contact with a confirmed case for 2 weeks from date of last contact.

Pathogen	Transfusion-transmission reported	Infectious risk period	Surveillance/Risk assessment	Additional risk management for blood safety
Variant CJD (vCJD)	Three 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).[60] 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 PrP^{res} is in the blood but before the person develops 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 scientific and medical evidence to inform a review of Lifeblood's deferral policies relating to vCJD. Any change to Lifeblood's vCJD deferral policies would require approval by the Therapeutic Goods Administration (TGA).	Lifeblood has an existing indefinite deferral for cumulative residence of 6 months in the UK during this period, which mitigates the potential risk to blood safety associated with vCJD 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.[61]	In symptomatic WNV infection (16–26% of cases), the estimated time from infection to the appearance of symptoms is typically reported as 3–14 days,[62] WNV RNA becomes detectable 1–2 days post-infection followed by anti-WNV IgM and IgG approximately 8–11 days post-infection, respectively.[63]	Lifeblood monitors WNV outbreaks in the EU and neighbouring countries, most of which do not have specific donor deferrals, based on regular updates 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 to date WNV transmission seasons did not exceed the threshold (established for local dengue outbreaks) that requires cessation of fresh blood component manufacture.[64,65] 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.[66]	WNV is also 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 with all cases asymptomatic, at least four cases of probable transfusion-transmitted ZIKV infection were reported during the outbreak in the Americas.[67,68]	Approximately 80% of ZIKV infections are asymptomatic and most symptomatic infections are accompanied by mild symptoms including rash and fever.[69,70] 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).[66] All outbreak areas are covered by existing travel deferrals. Risk assessments have demonstrated the risk to blood safety is negligible.	In addition to a geographical deferral 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 appropriate 'self-deferral' to reduce the risk of collecting blood from a potentially infected donor whose infection may not be detected by testing.
- While non-compliance among positive donors has been routinely monitored since 2000, the rate among TTI test-negative donors is more difficult to track. Results from a large national survey conducted in 2012-2013 showed a comparatively low rate of non-compliance (in the range 0.05 to 0.29%) among TTI test-negative donors for several sexual activity-based donor deferrals.
- The estimated residual risk of transmission for HIV, HCV, HBV, HTLV and syphilis are all less than 1 in 1 million per unit transfused, which Lifeblood considers a 'negligible' risk.
- In 2020, 136 (0.11%) of a total 119 856 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 potential pathogens which may have have been due to transient or occult bacteraemia in the donor, or contamination. None of the associated components from these donations were transfused and all the donors were followed up and reported to be healthy with no specific risk factors. There were no confirmed cases of transfusion-transmitted bacterial infections in 2020.
- 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 2020-2021. 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[31]
	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) 1992 (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 Abbott PRISM (Abbott Diagnostics, Wiesbaden-Delkenheim, Germany) Chemiluminescent Immunoassay system until October 2020, subsequently Abbott Alinity (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 TTI-positive donors (HBV, HCV and HIV) in Australia, by state/territory, 2020

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	34 454	475 727	510 181	30	5	35	26	4	30	2	0	2	58	9	67
Number *(Number per 100 000 donations)*				*87.07*	*1.05*	*6.86*	*75.46*	*0.84*	*5.88*	*5.80*	*0.00*	*0.39*	*168.34*	*1.89*	*13.13*
NT	624	9 984	10 608	4	0	4	0	0	0	0	0	0	4	0	4
Number *(Number per 100 000 donations)*				*641.03*	*0.00*	*37.71*	*0.00*	*0.00*	*0.00*	*0.00*	*0.00*	*0.00*	*641.03*	*0.00*	*37.71*
QLD	19 728	296 254	315 982	15	5	20	8	2	10	0	1	1	23	8	31
Number *(Number per 100 000 donations)*				*76.03*	*1.69*	*6.33*	*40.55*	*0.68*	*3.16*	*0.00*	*0.34*	*0.32*	*116.59*	*2.70*	*9.81*
SA	6 863	125 102	131 965	4	3	7	6	0	6	0	0	0	10	3	13
Number *(Number per 100 000 donations)*				*58.28*	*2.40*	*5.30*	*87.43*	*0.00*	*4.55*	*0.00*	*0.00*	*0.00*	*145.71*	*2.40*	*9.85*
TAS	2 820	52 294	55 114	4	2	6	3	0	3	0	0	0	7	2	9
Number *(Number per 100 000 donations)*				*141.84*	*3.82*	*10.89*	*106.38*	*0.00*	*5.44*	*0.00*	*0.00*	*0.00*	*248.23*	*3.82*	*16.33*
VIC	31 942	385 645	417 587	22	2	24	8	3	11	0	1	1	30	6	36
Number *(Number per 100 000 donations)*				*68.87*	*0.52*	*5.75*	*25.05*	*0.78*	*2.63*	*0.00*	*0.26*	*0.24*	*93.92*	*1.56*	*8.62*
WA	10 363	142 881	153 244	10	2	12	4	1	5	0	1	1	14	4	18
Number *(Number per 100 000 donations)*				*96.50*	*1.40*	*7.83*	*38.60*	*0.70*	*3.26*	*0.00*	*0.70*	*0.65*	*135.10*	*2.80*	*11.75*
National	106 794	1 487 887	1 594 681	89	19	108	55	10	65	2	3	5	146	32	178
Number *(Number per 100 000 donations)*				*83.34*	*1.28*	*6.77*	*51.50*	*0.67*	*4.08*	*1.87*	*0.20*	*0.31*	*136.71*	*2.15*	*11.16*

Supplementary Table 3 The number and prevalence rate of TTI-positive (HTLV and potentially infectious syphilis) donors in Australia, by state/territory, 2020

Table 3A HTLV, by state/territory, 2020

State/Territory of donation	All accepted donations			HTLV		
	First time	Repeat	All	First time	Repeat	All
NSW/ACT	34 454	243 460	277 914	1	0	1
Number *(Number per 100 000 donations)*				*2.90*	*0.00*	*0.36*
NT	624	2 998	3 622	0	0	0
Number *(Number per 100 000 donations)*				*0.00*	*0.00*	*0.00*
QLD	19 728	132 673	152 401	0	0	0
Number *(Number per 100 000 donations)*				*0.00*	*0.00*	*0.00*
SA	6 863	46 756	53 619	0	0	0
Number *(Number per 100 000 donations)*				*0.00*	*0.00*	*0.00*
TAS	2 820	15 831	18 651	0	0	0
Number *(Number per 100 000 donations)*				*0.00*	*0.00*	*0.00*
VIC	31 942	181 429	213 371	1	0	1
Number *(Number per 100 000 donations)*				*3.13*	*0.00*	*0.47*
WA	10 363	55 650	66 013	2	0	2
Number *(Number per 100 000 donations)*				*19.30*	*0.00*	*3.03*
National	106 794	678 797	785 591	4	0	4
Number *(Number per 100 000 donations)*				*3.75*	*0.00*	*0.51*

Table 3B Potentially infectious syphilis, by state/territory, 2020

State/Territory of donation	All accepted donations			Potentially infectious syphilis		
	First time	Repeat	All	First time	Repeat	All
NSW/ACT	34 454	261 234	295 688	1	3	4
Number *(Number per 100 000 donations)*				*2.90*	*1.15*	*1.35*
NT	624	3 162	3 786	0	0	0
Number *(Number per 100 000 donations)*				*0.00*	*0.00*	*0.00*
QLD	19 728	142 845	162 573	3	2	5
Number *(Number per 100 000 donations)*				*15.21*	*1.40*	*3.08*
SA	6 863	50 121	56 984	0	1	1
Number *(Number per 100 000 donations)*				*0.00*	*2.00*	*1.75*
TAS	2 820	16 966	19 786	0	0	0
Number *(Number per 100 000 donations)*				*0.00*	*0.00*	*0.00*
VIC	31 942	193 582	225 524	4	8	12
Number *(Number per 100 000 donations)*				*12.52*	*4.13*	*5.32*
WA	10 363	59 545	69 908	1	2	3
Number *(Number per 100 000 donations)*				*9.65*	*3.36*	*4.29*
National	106 794	727 455	834 249	9	16	25
Number *(Number per 100 000 donations)*				*8.43*	*2.20*	*3.00*

Supplementary Table 4 Association of demographic characteristics with TTI-positive blood donors in Australia, 2020

		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	*238 808*	*68 (28.47)*	*1 (ref)*	*…*	*42 (17.59)*	*1 (ref)*	*…*
Female	*260 466*	*40 (15.36)*	*0.55 (0.37-0.81)*	***0.00***	*23 (8.83)*	*0.54 (0.32-0.90)*	***0.01***
Age group (years)							
20-29	*126 711*	*20 (15.78)*	*1 (ref)*	*…*	*9 (7.1)*	*1 (ref)*	*…*
Less than 20	*15 696*	*2 (12.74)*	*0.83 (0.19-3.57)*	*0.81*	*0 (0)*	*…*	*0.99*
30-39	*111 353*	*37 (33.23)*	*1.97 (1.14-3.41)*	***0.01***	*19 (17.06)*	*2.28 (1.03-5.05)*	***0.04***
40-49	*87 786*	*20 (22.78)*	*1.37 (0.73-2.55)*	*0.32*	*10 (11.39)*	*1.52 (0.61-3.75)*	*0.35*
50 and above	*157 727*	*29 (18.39)*	*1.07 (0.60-1.90)*	*0.80*	*27 (17.12)*	*2.20 (1.03-4.69)*	***0.04***
State/Territory							
NSW	*147 055*	*31 (21.08)*	*1 (ref)*	*…*	*29 (19.72)*	*1 (ref)*	*…*
ACT	*16 637*	*4 (24.04)*	*1.12 (0.39-3.19)*	*0.82*	*1 (6.01)*	*0.31 (0.04-2.30)*	*0.25*
NT	*3 229*	*4 (123.88)*	*5.73 (2.02-16.24)*	***0.00***	*0 (0)*	*…*	*0.99*
QLD	*96 375*	*20 (20.75)*	*0.98 (0.56-1.73)*	*0.96*	*10 (10.38)*	*0.52 (0.25-1.06)*	***0.07***
SA	*39 047*	*7 (17.93)*	*0.86 (0.37-1.95)*	*0.72*	*6 (15.37)*	*0.75 (0.31-1.82)*	*0.53*
TAS	*14 727*	*6 (40.74)*	*1.98 (0.82-4.75)*	*0.12*	*3 (20.37)*	*1.01 (0.30-3.32)*	*0.98*
VIC	*136 455*	*24 (17.59)*	*0.83 (0.49-1.42)*	*0.51*	*11 (8.06)*	*0.41 (0.20-0.82)*	***0.01***
WA	*45 735*	*12 (26.24)*	*1.21 (0.62-2.36)*	*0.57*	*5 (10.93)*	*0.53 (0.20-1.39)*	*0.20*
Total	499 275	*108 (21.63)*			65 (13.02)		

		HIV			HTLV		
	Number of donors	Number of positive donors *(Number per 100 000 donors)*	IRR and their 95% CI (Multivariate adjusted)	p-value	Number of positive donors *(Number per 100 000 donors)*	IRR and their 95% CI (Multivariate adjusted)	p-value
Sex							
Male	*238 808*	*5 (2.09)*	*1 (ref)*	*…*	*4 (1.67)*	*1 (ref)*	*…*
Female	*260 466*	*0 (0)*	*..*	*0.99*	*0 (0)*	*..*	*0.99*
Age group (years)							
20-29	*126 711*	*3 (2.37)*	*1 (ref)*	*…*	*1 (0.79)*	*1 (ref)*	*…*
Less than 20	*15 696*	*0 (0)*	*..*	*0.99*	*0 (0)*	*…*	*0.99*
30-39	*111 353*	*0 (0)*	*..*	*0.99*	*1 (0.9)*	*0.85 (0.05-13.68)*	*0.91*
40-49	*87 786*	*1 (1.14)*	*0.40 (0.04-3.90)*	*0.43*	*2 (2.28)*	*2.33 (0.21-25.75)*	*0.49*
50 and above	*157 727*	*1 (0.63)*	*0.21 (0.02-2.09)*	*0.18*	*0 (0)*	*…*	*0.99*
State/Territory							
NSW	*147 055*	*1 (0.68)*	*1 (ref)*	*…*	*1 (0.68)*	*1 (ref)*	*…*
ACT	*16 637*	*1 (6.01)*	*8.08 (0.50-129.55)*	*0.14*	*0 (0)*	*…*	*0.99*
NT	*3 229*	*0 (0)*	*…*	*0.99*	*0 (0)*	*…*	*0.99*
QLD	*96 375*	*1 (1.04)*	*1.55 (0.09-24.86)*	*0.75*	*0 (0)*	*…*	*0.99*
SA	*39 047*	*0 (0)*	*…*	*0.99*	*0 (0)*	*…*	*0.99*
TAS	*14 727*	*0 (0)*	*…*	*0.99*	*0 (0)*	*…*	*0.99*
VIC	*136 455*	*1 (0.73)*	*1.12 (0.07-17.93)*	*0.63*	*1*	*1.11 (0.06-17.77)*	*0.94*
WA	*45 735*	*1 (2.19)*	*3.32 (0.20-53.23)*	*0.39*	*2 (4.37)*	*6.18 (0.56-68.29)*	*0.13*
Total	499 275	5 (1)			4 (0.8)		

	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	*238 808*	*19 (7.96)*	*1 (ref)*	*…*
Female	*260 466*	*6 (2.3)*	*0.26 (0.10-0.65)*	***0.00***
Age group (years)				
20-29	*126 711*	*11 (8.68)*	*1 (ref)*	*…*
Less than 20	*15 696*	*0 (0)*	*…*	*0.99*
30-39	*111 353*	*7 (6.29)*	*0.63 (0.24-1.65)*	*0.35*
40-49	*87 786*	*4 (4.56)*	*0.47 (0.15-1.49)*	*0.20*
50 and above	*157 727*	*3 (1.9)*	*0.18 (0.05-0.68)*	***0.01***
State/Territory				
NSW	*147 055*	*4 (2.72)*	*1 (ref)*	*…*
ACT	*16 637*	*0 (0)*	*…*	*0.99*
NT	*3 229*	*0 (0)*	*…*	*0.99*
QLD	*96 375*	*5 (5.19)*	*1.96 (0.52-7.33)*	*0.31*
SA	*39 047*	*1 (2.56)*	*1.01 (0.11-9.04)*	*0.99*
TAS	*14 727*	*0 (0)*	*…*	*0.99*
VIC	*136 455*	*12 (8.79)*	*3.26 (1.05-10.11)*	***0.04***
WA	*45 735*	*3 (6.56)*	*2.41 (0.53-10.77)*	*0.24*
Total	499 275	25 (5.01)		

Supplementary Table 5 Association of demographic characteristics with TTI-positive blood donors* in Australia, 2016-2020

		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	*1 161 465*	*308 (26.52)*	*1 (ref)*	*…*	*188 (16.19)*	*1 (ref)*	*…*
Female	*1 208 349*	*120 (9.93)*	*0.37 (0.30-0.46)*	***0.00***	*112 (9.27)*	*0.59 (0.47-0.75)*	***0.00***
Age group (years)							
20-29	*576 053*	*81 (14.06)*	*1 (ref)*	*…*	*36 (6.25)*	*1 (ref)*	*…*
Less than 20	*112 857*	*11 (9.75)*	*0.76 (0.40-1.44)*	*0.40*	*5 (4.43)*	*1.08 (0.48-2.45)*	*0.84*
30-39	*488 963*	*142 (29.04)*	*1.88 (1.43-2.48)*	***0.00***	*59 (12.07)*	*1.95 (1.28-2.98)*	***0.00***
40-49	*413 259*	*80 (19.36)*	*1.29 (0.94-1.76)*	*0.10*	*58 (14.03)*	*2.28 (1.49-3.48)*	***0.00***
50 and above	*778 681*	*114 (14.64)*	*0.99 (0.74-1.32)*	*0.96*	*142 (18.24)*	*3.03 (2.08-4.41)*	***0.00***
State/Territory							
NSW	*692 431*	*121 (17.47)*	*1 (ref)*	*…*	*100 (14.44)*	*1 (ref)*	*…*
ACT	*70 791*	*15 (21.19)*	*1.13 (0.66-1.93)*	*0.65*	*7 (9.89)*	*0.66 (0.30-1.43)*	*0.29*
NT	*16 377*	*6 (36.64)*	*1.98 (0.87-4.51)*	*0.10*	*2 (12.21)*	*0.83 (0.20-3.36)*	*0.79*
QLD	*464 771*	*62 (13.34)*	*0.74 (0.54-1.00)*	***0.06***	*63 (13.56)*	*0.87 (0.63-1.20)*	*0.41*
SA	*195 256*	*22 (11.27)*	*0.63 (0.40-1.00)*	***0.05***	*21 (10.76)*	*0.67 (0.41-1.07)*	***0.09***
TAS	*77 327*	*11 (14.23)*	*0.82 (0.44-1.53)*	*0.54*	*12 (15.52)*	*0.98 (0.53-1.78)*	*0.95*
VIC	*636 453*	*153 (24.04)*	*1.32 (1.04-1.67)*	***0.02***	*77 (12.1)*	*0.79 (0.59-1.07)*	*0.13*
WA	*216 384*	*38 (17.56)*	*0.94 (0.65-1.36)*	*0.76*	*18 (8.32)*	*0.54 (0.32-0.89)*	***0.01***
Total	2 369 815	428 (18.06)			300 (12.66)		

		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	*1 161 465*	*20 (1.72)*	*1 (ref)*	*…*	*13 (1.12)*	*1 (ref)*	*…*
Female	*1 208 349*	*6 (0.5)*	*0.26 (0.10-0.64)*	***0.00***	*6 (0.5)*	*0.44 (0.16-1.16)*	***0.09***
Age group (years)							
20-29	*576 053*	*13 (2.26)*	*1 (ref)*	*…*	*4 (0.69)*	*1 (ref)*	*…*
Less than 20	*112 857*	*0 (0)*	*…*	*0.99*	*0 (0)*	*…*	*0.99*
30-39	*488 963*	*4 (0.82)*	*0.32 (0.10-0.98)*	***0.04***	*7 (1.43)*	*1.90 (0.55-6.53)*	*0.30*
40-49	*413 259*	*2 (0.48)*	*0.19 (0.04-0.87)*	***0.03***	*4 (0.97)*	*1.29 (0.32-5.18)*	*0.71*
50 and above	*778 681*	*7 (0.9)*	*0.37 (0.14-0.94)*	***0.03***	*4 (0.51)*	*0.69 (0.17-2.78)*	*0.60*
State/Territory							
NSW	*692 431*	*8 (1.16)*	*1 (ref)*	*…*	*4 (0.58)*	*1 (ref)*	*…*
ACT	*70 791*	*1 (1.41)*	*1.10 (0.13-8.81)*	*0.92*	*3 (4.24)*	*6.83 (1.52-30.54)*	***0.01***
NT	*16 377*	*0 (0)*	*…*	*0.99*	*0 (0)*	*…*	*0.99*
QLD	*464 771*	*4 (0.86)*	*0.71 (0.21-2.38)*	*0.58*	*1 (0.22)*	*0.36 (0.04-3.26)*	*0.36*
SA	*195 256*	*1 (0.51)*	*0.44 (0.05-3.56)*	*0.44*	*1 (0.51)*	*0.88 (0.09-7.97)*	*0.91*
TAS	*77 327*	*0 (0)*	*…*	*0.99*	*3 (3.88)*	*6.95 (1.55-31.16)*	***0.01***
VIC	*636 453*	*9 (1.41)*	*1.16 (0.44-3.01)*	*0.75*	*5 (0.79)*	*1.30 (0.34-4.84)*	*0.69*
WA	*216 384*	*3 (1.39)*	*1.15 (0.30-4.34)*	*0.83*	*2 (0.92)*	*1.50 (0.27-8.21)*	*0.63*
Total	2 369 815	26 (1.1)			19 (0.8)		

	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	*1 161 465*	*60 (5.17)*	*1 (ref)*	…
Female	*1 208 349*	*20 (1.66)*	*0.28 (0.17-0.47)*	***0.00***
Age group (years)				
20-29	*576 053*	*39 (6.77)*	*1 (ref)*	…
Less than 20	*112 857*	*1 (0.89)*	*0.15 (0.02-1.10)*	***0.06***
30-39	*488 963*	*19 (3.89)*	*0.51 (0.29-0.88)*	***0.01***
40-49	*413 259*	*10 (2.42)*	*0.33 (0.16-0.66)*	***0.00***
50 and above	*778 681*	*11 (1.41)*	*0.19 (0.10-0.38)*	***0.00***
State/Territory				
NSW	*692 431*	*24 (3.47)*	*1 (ref)*	…
ACT	*70 791*	*0 (0)*	…	*0.99*
NT	*16 377*	*1 (6.11)*	*1.63 (0.22-12.05)*	*0.63*
QLD	*464 771*	*15 (3.23)*	*0.92 (0.48-1.76)*	*0.82*
SA	*195 256*	*2 (1.02)*	*0.31 (0.07-1.33)*	*0.11*
TAS	*77 327*	*0 (0)*	…	*0.99*
VIC	*636 453*	*30 (4.71)*	*1.31 (0.76-2.24)*	*0.32*
WA	*216 384*	*8 (3.7)*	*1.03 (0.46-2.30)*	*0.93*
Total	2 369 815	80 (3.38)		

* The total of 2.3 million donors over a five-year period, 2016-2020, 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 TTI-positive donors, by sex and age group, 2020

	HBV (2020)				HCV (2020)				HIV (2020)				HTLV (2020)				Potentially infectious syphilis (2020)			
Donor status	M	F	Total	%	M	F	Total	%	M	F	Total	%	M	F	Total	%	M	F	Total	%
First time donors																				
<20 years	1	1	2	1.9	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0
20-29 years	13	7	20	18.5	7	1	8	12.3	2	0	2	40.0	1	0	1	25.0	2	1	3	12.0
30-39 years	26	10	36	33.3	12	1	13	20.0	0	0	0	0.0	1	0	1	25.0	2	0	2	8.0
40-49 years	9	3	12	11.1	3	6	9	13.8	0	0	0	0.0	2	0	2	50.0	2	2	4	16.0
50-59 years	5	7	12	11.1	6	2	8	12.3	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0
60 years and above	5	2	7	6.5	10	7	17	26.2	0	0	0	0.0	0	0	0	0.0	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	0.0
20-29 years	0	0	0	0.0	4	1	5	7.7	1	0	1	20.0	0	0	0	0.0	5	3	8	32.0
30-39 years	0	1	1	0.9	0	2	2	3.1	0	0	0	0.0	0	0	0	0.0	5	0	5	20.0
40-49 years	2	6	8	7.4	0	1	1	1.5	1	0	1	20.0	0	0	0	0.0	0	0	0	0.0
50-59 years	2	2	4	3.7	0	1	1	1.5	0	0	0	0.0	0	0	0	0.0	1	0	1	4.0
60 years and above	5	1	6	5.6	0	1	1	1.5	1	0	1	20.0	0	0	0	0.0	2	0	2	8.0
Total	**68**	**40**	**108**	**100**	**42**	**23**	**65**	**100**	**5**	**0**	**5**	**100**	**4**	**0**	**4**	**100**	**19**	**6**	**25**	**100**

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

Supplementary Table 7 Number and percentage of TTI-positive donors, by sex and age group, 2016-2020

	HBV (2016-2020)				HCV (2016-2020)				HIV (2016-2020)				HTLV (2016-2020)				PIS/active syphilis (2016-2020)			
Donor status	M	F	Total	%	M	F	Total	%	M	F	Total	%	M	F	Total	%	M	F	Total	%
First time donors																				
<20 years	5	6	11	2.6	2	2	4	1.3	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0
20-29 years	54	25	79	18.5	21	6	27	9.0	7	1	8	30.8	4	0	4	21.1	14	5	19	23.8
30-39 years	98	30	128	29.9	38	10	48	16.0	0	1	1	3.8	5	2	7	36.8	5	1	6	7.5
40-49 years	46	15	61	14.3	20	23	43	14.3	0	0	0	0.0	3	1	4	21.1	5	2	7	8.8
50-59 years	26	14	40	9.3	38	30	68	22.7	1	2	3	11.5	0	0	0	0.0	0	0	0	0.0
60 years and above	22	6	28	6.5	33	15	48	16.0	1	0	1	3.8	1	2	3	15.8	0	0	0	0.0
Repeat donors																				
<20 years	0	0	0	0.0	1	0	1	0.3	0	0	0	0.0	0	0	0	0.0	1	0	1	1.3
20-29 years	2	0	2	0.5	8	5	13	4.3	4	1	5	19.2	0	0	0	0.0	11	9	20	25.0
30-39 years	11	3	14	3.3	2	5	7	2.3	2	1	3	11.5	0	0	0	0.0	12	1	13	16.3
40-49 years	10	9	19	4.4	8	7	15	5.0	2	0	2	7.7	0	0	0	0.0	2	1	3	3.8
50-59 years	17	6	23	5.4	8	5	13	4.3	1	0	1	3.8	0	1	1	5.3	6	1	7	8.8
60 years and above	17	6	23	5.4	9	4	13	4.3	2	0	2	7.7	0	0	0	0.0	4	0	4	5.0
Total	308	120	428	100	188	112	300	100	20	6	26	100	13	6	19	100	60	20	80	100

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

Supplementary Table 8 Number and percentage of TTI-positive donors, by country/region of birth^, 2016-2020

	HBV (2016-2020)		HCV (2016-2020)		HIV (2016-2020)		HTLV (2016-2020)		Potentially infectious syphilis (2016-2020)	
Region of birth	Number	%	Number	%	Number	%	Number	%	Number	%
Australia	47	11.0	200	66.7	12	46.2	5	26.3	48	60.0
Overseas born										
Other Oceania	35	8.2	9	3.0	0	0.0	0	0.0	4	5.0
United Kingdom and Ireland	0	0.0	9	3.0	0	0.0	0	0.0	0	0.0
Other Europe	28	6.5	11	3.7	3	11.5	0	0.0	4	5.0
Middle East/North Africa	18	4.2	7	2.3	0	0.0	3	15.8	1	1.3
Sub-Saharan Africa	12	2.8	0	0.0	1	3.8	0	0.0	3	3.8
South & North East Asia	194	45.3	23	7.7	3	11.5	3	15.8	8	10.0
Southern and Central Asia	86	20.1	32	10.7	5	19.2	8	42.1	7	8.8
North America	3	0.7	1	0.3	2	7.7	0	0.0	2	2.5
South/Central America and the Caribbean	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Total with a reported country of birth	423	98.8	292	97.3	26	100.0	19	100.0	77	96.3
Not reported	5	1	8	3	0	0	0	0	3	4
Total	428	100	300	100	26	100	19	100	80	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 TTI-positive first time donors, by potential reported exposure category and sex, 2020

	HBV (2020)				HCV (2020)				HIV (2020)				HTLV (2020)				Active Syphilis (2020)			
Exposure categories	M	F	Total	%	M	F	Total	%	M	F	Total	%	M	F	Total	%	M	F	Total	%
Ethnicity/Country of birth	47	19	66	74.2	8	0	8	14.5	0	0	0	0.0	4	0	4	100.0	0	0	0	0.0
Intravenous drug use	0	0	0	0.0	8	4	12	21.8	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0
Tattoo/Piercing	0	0	0	0.0	5	2	7	12.7	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0
Partners with known risks or known to be positive	0	0	0	0.0	1	1	2	3.6	0	0	0	0.0	0	0	0	0.0	1	0	1	11.1
Partner with unspecified risks	0	0	0	0.0	0	0	0	0.0	1	0	1	0.0	0	0	0	0.0	0	2	2	22.2
Male-to-male sexual contact	1	0	1	1.1	0	0	0	0.0	1	0	1	50.0	0	0	0	0.0	1	0	1	11.1
Exposure in health care setting	0	1	1	1.1	4	1	5	9.1	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0
Engaged in sex work	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0
Blood or tissue recipient	0	0	0	0.0	1	0	1	1.8	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0
Household contact/Family history	7	6	13	14.6	0	2	2	3.6	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	3	1	4	7.3	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0
Other*	0	0	0	0.0	4	1	5	9.1	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0
No risk factors identified/Unknown	4	4	8	9.0	4	5	9	16.4	0	0	0	0.0	0	0	0	0.0	4	1	5	55.6
Total	59	30	89	100.0	38	17	55	100.0	2	0	2	100.0	4	0	4	100.0	6	3	9	100.0

* For HCV, all four male first-time donors in "Others" had imprisonment as a risk factor
Note: Percentages may not add to exact 100% due to rounding

Supplementary Table 10 Number and percentage of TTI-positive first time donors, by potential reported exposure category and sex, 2016-2020

	HBV (2016-2020)				HCV (2016-2020)				HIV (2016-2020)				HTLV (2016-2020)				Active Syphilis (2016-2020)			
Exposure categories	M	F	Total	%	M	F	Total	%	M	F	Total	%	M	F	Total	%	M	F	Total	%
Ethnicity/Country of birth	229	81	310	89.3	19	1	20	8.4	0	0	0	0.0	12	1	13	72.2	0	0	0	0.0
Intravenous drug use	1	0	1	0.3	40	18	58	24.4	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0
Tattoo/Piercing	1	0	1	0.3	26	25	51	21.4	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0
Partners with any risks or known to be positive	0	1	1	0.3	7	6	13	5.5	2	2	4	30.8	0	3	3	16.7	2	1	3	9.4
Partners with unspecified risks	1	0	1	0.3	0	1	1	0.4	1	0	1	7.7	0	1	1	5.6	7	6	13	40.6
Male-to-male sexual contact	2	0	2	0.6	0	0	0	0.0	3	0	3	23.1	0	0	0	0.0	9	0	9	28.1
Exposure in health care setting	0	2	2	0.6	8	8	16	6.7	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	10	7	17	7.1	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0
Household contact	10	7	17	4.9	3	4	7	2.9	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	6	1	7	2.9	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0
Other*	1	0	1	0.3	20	4	24	10.1	0	2	2	15.4	1	0	1	5.6	0	0	0	0.0
No risk factors identified/Unknown	6	5	11	3.2	13	11	24	10.1	3	0	3	23.1	0	0	0	0.0	6	1	7	21.9
Total	251	96	347	100	152	86	238	100.0	9	4	13	100.0	13	5	18	100.0	24	8	32	100.0

* For HCV, 50% (10/20) first-time male donors in 'Others' had imprisonment as a risk factor; 25% (1/4) first-time female donors in 'Others' had imprisonment as a risk factor
Note: Percentages may not add to exact 100% due to rounding

Supplementary Table 11 Number and percentage of TTI-positive repeat donors, by potential reported exposure category and sex, 2020

	HBV (2020)				HCV (2020)				HIV (2020)				HTLV (2020)				Active Syphilis (2020)			
Exposure categories	M	F	Total	%	M	F	Total	%	M	F	Total	%	M	F	Total	%	M	F	Total	%
Ethnicity/Country of birth	4	7	11	57.9	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0
Intravenous drug use	0	0	0	0.0	0	1	1	10.0	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0
Tattoo/Piercing	0	0	0	0.0	2	1	3	30.0	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0
Partners with any risks or known to be positive	1	0	1	5.3	0	0	0	0.0	1	0	1	33.3	0	0	0	0.0	1	0	1	6.3
Partner with unspecified risks	1	0	1	5.3	0	0	0	0.0	1	0	1	33.3	0	0	0	0.0	8	2	10	62.5
Male-to-male sexual contact	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0	1	0	1	6.3
Exposure in health care setting	0	0	0	0.0	1	0	1	10.0	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0
Engaged in sex work	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0
Blood or tissue recipient	0	0	0	0.0	0	1	1	10.0	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0
Household contact	3	1	4	21.1	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0
Other blood to blood contact	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0
Other	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	0		
No risk factors identified/Unknown	0	2	2	10.5	1	3	4	40.0	1	0	1	33.3	0	0	0	0.0	3	1	4	25.0
Not reported	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0
Total	9	10	19	100.0	4	6	10	100.0	3	0	3	100	0	0	0	0.0	13	3	16	100.0

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

Supplementary Table 12 Number and percentage of TTI-positive repeat donors, by potential reported exposure category and sex, 2016-2020

	HBV (2016-2020)				HCV (2016-2020)				HIV (2016-2020)				HTLV (2016-2020)				Active Syphilis (2016-2020)			
Exposure categories	M	F	Total	%	M	F	Total	%	M	F	Total	%	M	F	Total	%	M	F	Total	%
Ethnicity/Country of birth	42	17	59	72.8	0	1	1	1.6	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0
Intravenous drug use	1	0	1	1.2	10	2	12	19.4	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0
Tattoo/Piercing	2	0	2	2.5	8	5	13	21.0	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0
Partners with any risks or known to be positive	3	0	3	3.7	1	5	6	9.7	1	2	3	23.1	0	1	1	100.0	3	3	6	12.5
Partners with unspecified risks	2	1	3	3.7	0	0	0	0.0	3	0	3	23.1	0	0	0	0.0	16	5	21	43.8
Male-to-male sexual contact	0	0	0	0.0	0	0	0	0.0	4	0	4	30.8	0	0	0	0.0	4	0	4	8.3
Exposure in health care setting	1	0	1	1.2	5	3	8	12.9	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	2	3	4.8	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0
Household contact	3	1	4	4.9	2	0	2	3.2	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0
Other blood to blood contact	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0
Other	1	2	3	3.7	1	1	2	3.2	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0
No risk factors identified/Unknown	2	3	5	6.2	8	7	15	24.2	3	0	3	23.1	0	0	0	0.0	13	4	17	35.4
Total	57	24	81	100.0	36	26	62	100.0	11	2	13	100.0	0	1	1	100.0	36	12	48	100.0

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

This page intentionally left blank

Supporting information for transfusion-transmissible infections surveillance report

Blood donation: from volunteer to recipient

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

Australian volunteer blood donors may be aged 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, and from December 6 2020, repeat donors no longer required testing for HTLV, irrespective of donation type, resulting in a different test denominator for these TTIs. Additional testing for other TTIs (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.lifeblood.com.au.

The 'tiered' safety approach

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

1. Through pre-donation public education using the www.lifeblood.com.au website, Lifeblood Community Relations staff, the media and 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 (first time donors only after December 5, 2020) 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.[71] 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.[72] An updated NAT triplex (HIV-1/HCV/HBV) test was implemented during 2013 reducing the HBV window period to approximately 16 days. These advances incrementally lowered the risk of not detecting a recently infected donor but importantly the WP is not eliminated. Thus, despite state-of-the-art donation testing there remains a small but nonzero risk of transmission from donors with very recently acquired infection, who may test negative if they donate during the window period.

Using donation testing results, Lifeblood monitors for trends in both prevalence (i.e. the frequency of positive first-time donors) and incidence (i.e. the rate of newly positive 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 TTI-positive 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 TTI-positive 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, ten 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 2020. There were small increases in the prevalence of HBV and syphilis infections among first time donors, but only syphilis was statistically significant. Positive first-time donors in 2020 mostly had undiagnosed prevalent infections but a small number of incident donors continued to be identified.

This is the eleventh 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 detection 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 2011-2020 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 exposure 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 2011 to 2020. Anonymous donor data for all donors who donated blood between January 2011 and December 2020 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 2011-2020. Demographic factors associated with TTIs in blood donors were analysed for donations made in 2020 and were compared with the findings from 2016-2020. Likely routes of exposure (termed 'putative risk factors') for each TTI in blood donors were also identified and analysed. Data from the 2019 and 2020 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 2019 to 31 December 2020. HBV OBI risk based on Lifeblood data from 1 January to 31 December 2020. 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 2019 to 31 December 2020.

Methodological notes

Age-specific rate

Age-specific rate is defined as the proportion of blood donors in a particular age group who test positive, 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 2020 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 repeat donors who only made one negative donation in 2020, the average DYO per repeat negative donor was applied to calculate their individual IDI. For repeat positive donors, donor-years of observation were calculated as the sum of all inter-donation intervals between the first negative and the positive donation of incident donors. An average DYO per incident donor was then calculated and adjusted for all repeat positive donors.

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:

$$\text{Incidence per 100 000 donor-years of observation} = \left(\frac{\text{Number of incident donors}}{\text{Total donor-years of observation, i.e. total DYO for repeat positive donors plus total DYO for repeat negative donors}} \right) \times 100\,000$$

Incidence rate of any TTI over the five-year period, 2016-2020, was calculated as follows:

$$\text{Incidence per 100 000 donor-years of observation} = \left(\frac{\text{Total number of incident donors in 2016-2020}}{\text{Average of 2016-2020 total donor-years of observation}} \right) \times 100\,000$$

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. In addition, in this report, the methodology was revised again, whereby the DYO was calculated as the sum of inter-donation intervals for unique donors only and was not adjusted for all repeat donations. For this reason, updated data were used for a five-year period, 2016-2020, 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 were overly conservative, estimating the probability of collecting a WP donation, rather than the more appropriate estimate of the risk of infection in a recipient. The adoption of the method of Weusten *et al*[73] 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*.[74]

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, 2011-2020, and the five-year period, 2016-2020, 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 2011-2020 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 2020, and five-year period, 2016-2020 (for HBV, HCV, HIV, HTLV and PIS/active syphilis). The association between demographic factors and TTI-positivity (HBV, HCV, HIV, HTLV and PIS/active syphilis) among Australian blood donors were assessed using multivariate Poisson regression model for each infection separately. The predictor variables were analysed simultaneously thus adjusting for all variables in the model. A p-value of less than 0.05 was considered as statistically significant.

References

1. Kirby Institute. National Hepatitis B Strategy. Diagnosis and care cascade, 2019. Available at: https://data.kirby.unsw.edu.au/national-hepatitis-b-strategy. 2020.
2. Kirby Institute. Estimated number of people living with chronic hepatitis B and estimated prevalence, 2019, by subpopulation. (unpublished data). 2019.
3. Kirby Institute. National Hepatitis C Strategy. Diagnosis and care cascade, 2019. Available at: https://data.kirby.unsw.edu.au/national-hepatitis-c-strategy. 2020.
4. Australian Government Department of Health. National notifiable diseases surveillance system. Available at: http://www9.health.gov.au/cda/source/cda-index.cfm Access date: August 5, 2020. 2018.
5. Kirby Institute. HIV. Available at: https://data.kirby.unsw.edu.au/hiv Accessed: August 13, 2021. 2020.
6. Kirby Institute. HIV, hepatitis and STIs in Australia - National surveillance data. Available at: https://data.kirby.unsw.edu.au/.
7. Tohme RA and Holmberg SD. Transmission of hepatitis C virus infection through tattooing and piercing: a critical review. *Clinical infectious diseases* 2012; 54: 1167-1178.
8. Hoad VC, Guy RJ, Seed CR and R H. Tattoos, blood-borne viruses and blood donors: a blood donor cohort and risk assessment. Vox Sang. 2019 Aug 8. PubMed PMID: 31396975.
9. Health and Safety Executive, Government of UK. Hepatitis B virus. Available at: https://www.hse.gov.uk/biosafety/blood-borne-viruses/hepatitis-b.htm Access date: August 13, 2021.
10. Kiely P, Margaritis AR, Seed CR, Yang H and Australian Red Cross Blood Service NATSG. Hepatitis B virus nucleic acid amplification testing of Australian blood donors highlights the complexity of confirming occult hepatitis B virus infection. *Transfusion* 2014; 54: 2084-2091. DOI: 10.1111/trf.12556.
11. Polizzotto MN, Wood EM, Ingham H and Keller AJ. Reducing the risk of transfusion-transmissible viral infection through blood donor selection: the Australian experience 2000 through 2006. *Transfusion* 2008; 48: 55-63.
12. Lucky TT, Seed CR, Keller A, *et al*. Trends in transfusion-transmissible infections among A ustralian blood donors from 2005 to 2010. *Transfusion* 2013; 53: 2751-2762.
13. Nguyen VTT, Razali K, Amin J, Law MG and Dore GJ. Estimates and projections of hepatitis B-related hepatocellular carcinoma in Australia among people born in Asia-Pacific countries. *Journal of gastroenterology and hepatology* 2008; 23: 922-929.
14. O'Sullivan BG, Gidding HF, Law M, Kaldor JM, Gilbert GL and Dore GJ. Estimates of chronic hepatitis B virus infection in Australia, 2000. *Australian and New Zealand journal of public health* 2004; 28: 212-216.
15. Williams S, Vally H, Fielding J and Cowie B. Hepatitis B prevention in Victoria, Australia: the potential to protect. *Euro Surveill* 2011; 16: 19879.
16. Heard S, Iversen J, Geddes L and Maher L. Australian NSP survey: Prevalence of HIV, HCV and injecting and sexual behaviour among NSP attendees, 25-year National Data Report 1995-2019. Sydney: The Kirby Institute, UNSW Sydney. 2020.
17. Kirby Institute. HIV, viral hepatitis and sexually transmissible infections in Australia: annual surveillance report 2017. Sydney: Kirby Institute, UNSW Sydney. 2017.
18. Gallo RC. History of the discoveries of the first human retroviruses: HTLV-1 and HTLV-2. *Oncogene* 2005; 24: 5926-5930.
19. Feuer G and Green PL. Comparative biology of human T-cell lymphotropic virus type 1 (HTLV-1) and HTLV-2. *Oncogene* 2005; 24: 5996-6004.

20. Bastian I, Hinuma Y and Doherty RR. HTLV-I among Northern Territory aborigines. *The Medical journal of Australia* 1993; 159: 12-16.

21. Einsiedel L, Spelman T, Goeman E, Cassar O, Arundell M and Gessain A. Clinical associations of Human T-lymphotropic Virus type 1 infection in an indigenous Australian population. *PLoS Negl Trop Dis* 2014; 8: e2643.

22. Davies J, Jabbar Z, Gagan F and Baird RW. Blood-borne viruses in the haemodialysis-dependent population attending Top End Northern Territory facilities 2000–2009. *Nephrology* 2012; 17: 501-507.

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

24. Tang AR, Taylor GP and Dhasmana D. Self-flagellation as possible route of human T-cell lymphotropic virus type-1 transmission. *Emerging Infectious Diseases* 2019; 25: 811.

25. Styles CE, Hoad VC, Denham-Ricks P, Brown D and Seed CR. Self-Flagellation as Possible Route of Human T-Cell Lymphotropic Virus Type 1 Transmission. 2019.

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

27. Verdonck K, González E, Van Dooren S, Vandamme A-M, Vanham G and Gotuzzo E. Human T-lymphotropic virus 1: recent knowledge about an ancient infection. *The Lancet infectious diseases* 2007; 7: 266-281.

28. Van der Sluis J, Onvlee P, Kothe F, Vuzevski V, Aelbers G and Menke H. Transfusion Syphilis, Survival of Treponema pallidum in Donor Blood: I. Report of an Orientating Study. *Vox sanguinis* 1984; 47: 197-204.

29. Ravitch MM and Chambers JW. Spirochetal survival in frozen plasma. *Bull Johns Hopkins Hosp* 1942; 71: 299.

30. Orton S. Syphilis and blood donors: what we know, what we do not know, and what we need to know. *Transfusion medicine reviews* 2001; 15: 282-292.

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

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

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

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

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

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

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

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

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

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

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

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

43. Thyer J, Perkowska-Guse Z, Ismay S, *et al*. Bacterial testing of platelets–has it prevented transfusion-transmitted bacterial infections in Australia? *Vox sanguinis* 2018; 113: 13-20.

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

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

46. Thomson A, Farmer S, Hofmann A, Isbister J and Shander A. Patient blood management–a new paradigm for transfusion medicine? *ISBT Science Series* 2009; 4: 423-435.

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

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

49. Benjamin R, Dy B, Perez J, Eder A and Wagner S. Bacterial culture of apheresis platelets: a mathematical model of the residual rate of contamination based on unconfirmed positive results. *Vox sanguinis* 2014; 106: 23-30.

50. Queensland Government. Dengue outbreaks. Available at: https://www.health.qld.gov.au/clinical-practice/guidelines-procedures/diseases-infection/diseases/mosquito-borne/dengue/dengue-outbreaks Accessed: November 30, 2020. 2020.

51. Australian Government Department of Health. National Notifiable Diseases Surveillance (NNDSS). NNDSS Fortnightly summary notes – 2021. Available at: https://www1.health.gov.au/internet/main/publishing.nsf/Content/nndss-fortnightly-summary-notes-2021.

52. Styles CE, Hoad VC, Gorman E, Roulis E, Flower R and Faddy HM. Modeling the parvovirus B19 blood safety risk in Australia. *Transfusion* 2019; 59: 295-302.

53. Hoad VC, Speers DJ, Keller AJ, *et al*. First reported case of transfusion-transmitted Ross River virus infection. *Med J Aust* 2015; 202: 267-270.

54. Seed C, Hoad V, Faddy HM, Kiely P, Keller A and Pink J. Re-evaluating the residual risk of transfusion-transmitted Ross River virus infection. *Vox sanguinis* 2016; 110: 317-323.

55. Kiely P, Hoad VC, Seed CR and Gosbell IB. Severe acute respiratory syndrome coronavirus-2: implications for blood safety and sufficiency. *Vox sanguinis* 2020.

56. Australian Government Department of Health. Coronavirus (COVID-19) current situation and case numbers. Available at: https://www.health.gov.au/news/health-alerts/novel-coronavirus-2019-ncov-health-alert/coronavirus-covid-19-current-situation-and-case-numbers Accessed: November 30, 2020, (2020).

57. NSW Government. Health. COVID-19 (Coronavirus) statistics. Available at: https://www.health.nsw.gov.au/news/Pages/20210907_00.aspx.

58. COVID19 data. Victoria. Available at: https://www.covid19data.com.au/victoria.

59. Australian Government Department of Health. Australia's COVID-19 vaccine rollout. Available at: https://www.health.gov.au/initiatives-and-programs/covid-19-vaccines/australias-covid-19-vaccine-rollout.

60. Valleron A-J, Boelle P-Y, Will R and Cesbron J-Y. Estimation of epidemic size and incubation time based on age characteristics of vCJD in the United Kingdom. *Science* 2001; 294: 1726-1728.

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

62. Rudolph KE, Lessler J, Moloney RM, Kmush B and Cummings DA. Incubation periods of mosquito-borne viral infections: a systematic review. *The American journal of tropical medicine and hygiene* 2014; 90: 882.

63. Busch MP, Kleinman SH, Tobler LH, *et al*. Virus and antibody dynamics in acute West Nile virus infection. *The Journal of infectious diseases* 2008; 198: 984-993.

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

65. Kiely P, Gosbell IB, Hoad VC, Cheng AC, Wood EM and McQuilten ZK. Modelling the Transfusion-Transmission Risk of West Nile Virus in Australia Associated with Travelling Donors. In: *Transfusion* 2018, pp.203A-204A. WILEY 111 RIVER ST, HOBOKEN 07030-5774, NJ USA.

66. Kiely P, Seed CR, Hoad VC, *et al*. Modeling the West Nile virus transfusion transmission risk in a nonoutbreak country associated with traveling donors. *Transfusion* 2020.

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

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

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

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

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

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

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

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

This page intentionally left blank

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