Transfusion-transmissible infections in Australia

2022

Surveillance Report

Australian Red Cross Lifeblood

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Foreword

This report is jointly produced by Australian Red Cross Lifeblood (Lifeblood) and the Kirby Institute via the Surveillance and Evaluation 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 2021 testing data, during which time the COVID-19 pandemic was ongoing, the potential impacts of the public health response, including non-pharmaceutical measures such as physical distancing, lockdowns as well as the nationwide COVID-19 vaccination programmes, are considered in the analysis. Unlike many countries where blood donation rates fell substantially and blood shortages ensued as a direct result of the pandemic, Australia was generally able to meet demand for fresh blood products during 2021, even during state specific lockdowns and the height of the COVID-19 vaccination programme, where donor availability was impacted by a short blood donation deferral period, post-vaccination. This deferral policy for recent vaccinees was instituted to ensure that donor health was not negatively impacted by donation, considering mild post-vaccination adverse reactions were quite common within the first few days of vaccination.

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 and is referred for clinical follow-up.

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 2020, repeat donors are not required to be tested for HTLV, irrespective of donation type (there are exceptions where some repeat donors still get tested for HTLV, see HTLV section for details). Consistent with previous years, the overall number of TTIs detected remained low in 2021 (n=197). Of these, 83% were either hepatitis B (HBV) or hepatitis C (HCV) virus. Reflecting the effectiveness of donor screening strategies, the prevalence of TTI in first-time donors in 2021 continues to be substantially (5-109 times) lower than the estimated national population prevalence for 2021. Four (all HCV, 2% of all) infections in 2021 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, 2017-2021.

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 2021, 18% had risk factors identified in their post-donation interview which were not disclosed in their initial donation interview (termed 'noncompliance'). As minimising noncompliance is an organisational imperative, Lifeblood continually reviews the donor assessment process for potential improvements. 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.

Injecting drug use (IDU)
Corresponds to the public health definition of People Who Inject Drugs (PWID). Specifically, defined in the context of blood donation as; "used drugs" in the past 5 years by injection or been injected, even once, with drugs not prescribed by a doctor or a dentist.

Incidence
The rate of newly acquired infection among repeat donors.

Incident donor
A positive repeat donor whose most recent previous donation was within the last 12 months and tested negative for the same TTI, excluding donors with occult hepatitis B virus infection (OBI), and HCV antibody positive/RNA negative donors deemed to be 'partial seroreverters' (see 'Seroreversion' definition on page 7).

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

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

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

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

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

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

Positive donor
A donor confirmed (by additional testing as necessary) to have tested positive to the relevant transfusion-transmissible infection consistent with national case definitions.

Potentially infectious syphilis (PIS)
This is a blood safety specific surveillance definition designed to capture donors who are at theoretical risk of transmitting syphilis by blood transfusion. PIS includes repeat donors if they had seroconverted within the last two years (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.

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

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

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

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

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

Summary of the main findings

General characteristics of blood donors in Australia

1. Over the ten-year period 2012-2021, there were over 13.8 million blood donations in Australia with an average of 1.4 million donations per year. In this ten-year period, there has been a significant increasing trend in the total number of annual donations (see Methodological notes for details), from 1.31 to 1.60 million.
2. Of the 'age-eligible' Australian population (aged between 18-80 years), 2.7% donated blood during 2021. Male donors constituted 48.7% of all donors in 2021, 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 17.0% and 83.0% of all blood donors in Australia over the period 2012-2021, respectively. The ratio of first-time donors increased gradually, from 15.2% in 2012 to 19.9% in 2017 and 21.4% in 2020 and showed a slight decrease to 18.4% in 2021. However, the proportion of total donations made by first time donors (6% in 2021) 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 informed and referred for medical follow-up.

1. In 2021, a total of 195 blood donors were detected as positive for at least one of the TTIs 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, with a total of 197 TTIs detected. In the ten-year period 2012-2021 a total of 1 762 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 2021, 83.2% were positive for either HBV or HCV, similar to 83.6% in 2020.
3. Overall HIV was the least common TTI detected among all donors in 2021, with just two donors testing positive. In the ten-year period 2012-2021, HIV and HTLV were the least common TTIs detected among all donors, with 44 donors each.
4. Although representing only 18.4% of the donor population, first-time blood donors contributed to 79% of detected TTIs in Australia in 2021. This proportion has remained relatively stable since 2012 (77%-79% range), except for 2014 and 2018 where the proportion went down to 67% and 68%, respectively (see Main Findings below).
5. No transfusion-transmitted HIV, HBV, HCV, HTLV or syphilis cases were reported in Australia during 2021.
6. Consistent with previous years, in 2021, the prevalence of TTIs was substantially lower among first-time blood donors (5 to 109 times) compared with national prevalence estimates for 2021.

HBV-positive Australian blood donors

1. There were 83 HBV-positive donors detected among all donations in 2021 (76 in first-time donors and 7 in repeat donors).
2. Of all TTIs detected, HBV continued to have the highest prevalence among first-time donors.
3. During 2012-2021, no significant trend was observed in HBV prevalence in first-time donors in Australia. The prevalence among first-time donors in 2021 has remained relatively stable, with a slight decrease of ~4% as compared to that observed in 2020, 80.0 versus 83.3 per 100 000 donations, respectively. This equates to 0.08% of the total first-time donations in 2021, which is 11 times lower than the estimated ~0.9% prevalence reported in national HBV surveillance data for 2021.
4. Among the 83 HBV-positive donors, 20 (13 first-time and 7 repeat donors) were classified as occult HBV (OBI) based on the detection of HBV DNA without HBsAg. Of these OBI positive donors, most (75%) were men, Asian-born (65%) and had an average age of 52.1 years.
5. There were no incident HBV donors in 2021. There was no significant temporal trend in HBV donor incidence nationally or in any state/territory during the five-year study period 2017-2021.
6. In 2021, HBV-positive donors were the same age as compared to all donors (41.0 years versus the mean age 41.6 years), more likely to be male (71% in HBV-positive donors versus 48.7% in all donors) and more likely to be born in the Northeast/Southeast Asia (over 62%). 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, 2017-2021, was ethnicity/country of birth (83%). In Australia, an estimated 42% of people living with hepatitis B were born in the Northeast/Southeast Asia at the end of 2021.[1]
8. No transfusion-transmitted HBV cases were recorded in 2021. 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 81 HCV-positive donors detected among all donors in 2021 (66 in first-time donors and 15 in repeat donors). In 2021, the proportion of HCV RNA positive (considered infectious) donors was 37.0% (30/81 – 28 first-time and two repeat donors), as compared to 38.5% in 2020. 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 2012-2021, 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, 51.5 and 69.5 per 100 000 donations in 2019, 2020 and 2021, respectively, as compared to 39.3 per 100 000 observed in 2018. This increase is likely to be, at least in part, associated with prospective donors with 'resolved' HCV (HCV antibody positive/RNA negative) presenting to donate subsequent to successful treatment and donors being eligible 5 years after last injecting drugs. The 0.07% first-time donor prevalence in 2021 is 5 times lower than the estimated 0.3% living with chronic hepatitis C reported for HCV national surveillance data for 2021.
4. In 2021, there were 15 repeat donors who tested positive, and of these, four met the incidence definition, although only one was considered definitive true infection. The average incidence rate of HCV among previously negative repeat donors during 2017-2021 was low at 0.96 per 100 000 donor-years of observation (see Methodological notes for details). HCV incidence has shown no significant trend during the study period, 2017-2021.
5. In 2021, the mean age of HCV-positive donors was 48.6 years compared to 41.6 years for all donors. They were more likely to be male (63% versus 48.7% in all donors), and the majority (70%) were born in Australia.
6. The most common putative risk factor reported by HCV-positive donors during 2017-2021 was injecting drug use (25%), followed by tattoo/piercing (19%). Note this reporting does not confirm causation and the increasing background tattoo prevalence likely accounts for this apparent association. In comparison, for the newly acquired HCV in the general population, 65% had imprisonment as their route of exposure in 2021, followed by injecting drug use at 21%.
7. No transfusion-transmitted HCV cases were reported in Australia during 2012-2021.

HIV-positive Australian blood donors

1. There were two HIV-positive donors detected among all donations in 2021 (one first-time and one repeat donor).
2. The prevalence of HIV-positive first-time donors during 2012-2021 remained very low at 2.1 per 100 000 donations (or 0.002% of the total first-time donations) and comparatively much lower than HBV (76.0 per 100 000 donations) and HCV (50.9 per 100 000 donations). No significant HIV prevalence trend was observed during 2012-2021. The 0.001% HIV prevalence in first-time donors is 109 times lower than the 0.1% prevalence reported for HIV national surveillance data in 2021.
3. There were no incident HIV donors in 2021. There is no statistically significant incidence trend in the 2017-2021 period.
4. In 2021, the mean age of HIV-positive donors (n=2) was 44 years as compared to 41.6 years for all donors. Like HBV, HIV-positive donors were more likely to be male as compared to all donors (100% vs 48.7%). In 2021, 50% (1/2) of the HIV-positive donors were born in Australia.
5. The most common reported routes of exposure for HIV-positive donors during 2017-2021 was having a partner with an unspecified risk (32%). In comparison, for the new HIV diagnoses notification data in Australia, men who have sex with men accounted for 68% of new HIV diagnoses in Australia in 2021 (including those who reported injecting drug use), followed by heterosexual sex (27%).
6. No transfusion-transmitted HIV cases were reported in Australia during 2012-2021.

HTLV-positive Australian blood donors

1. There were nine HTLV-positive donors detected among all donations in 2021 (seven in first-time donors and two in repeat donors).
2. The prevalence of HTLV-positive first-time donors during 2012-2021 has remained low at 4.1 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 2021, the mean age of the nine HTLV-positive donors was 45 years; the majority (62.5%) were male, and all were born overseas (100%).
4. The most common putative risk factor for HTLV-positive donors during 2017-2021 was ethnicity or country of birth (65%). There are no data to compare risk factors in the general population.
5. No transfusion-transmitted HTLV cases were reported in Australia during 2012-2021.

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

1. There were 22 potentially infectious syphilis donors (6 first-time and 16 repeat donors) detected in 2021.
2. The prevalence of active/potentially infectious syphilis in first-time donors has shown a significant increasing trend in the past ten years, 2012-2021. This is reflective of increasing syphilis notifications in the general population.
3. The mean age of donors with potentially infectious syphilis in 2021 was 31.9 years (compared to 41.6 years for all donors); and they were more likely to be male as compared to all donors (72.7% versus 48.7%).
4. The most common reported route of exposure by donors with active/potentially infectious syphilis during 2017-2021 period was having a partner with an unspecified risk (41%).

Donor compliance

1. Of the 888 TTI-positive donors in 2017-2021, 18.1% (161 donors) were identified as 'non-compliant' in that they had risk factors identified during their post-donation interview that would have deferred them from donating had they disclosed them at the pre-donation interview. Proportionally, first time donors accounted for 75% (120 donors) of 'non-compliant' donors.
2. Eighteen percent (35/195) of a TTI-positive donors in 2021 disclosed risk factors during their post-donation interview (non-compliant donors). The detected non-compliance rate of all TTI-positive donors has fluctuated in the past decade between 14.8 and 25.0%. The non-compliance rate among TTI-negative donors is not determined on a regular basis; however, results from a large national survey from 2012-13 showed a comparatively much lower rate of non-compliance (in the range of 0.05-0.29%). See Additional information section for more information.

Malaria testing

1. In 2021, 69 125 donations were tested for malaria antibody, substantially less than the 132 338 donations tested in 2020. This decline is due to decreased overseas travel by donors due to COVID-19 associated international border closures. Of the tested donations, 1834 (2.7%) were repeatedly reactive for malaria antibodies. This rate is increased compared to the 1.6% for 2020, and due to a higher proportion of donors tested for malaria being former residents of malaria endemic countries who are at higher risk of having reactive malaria serology.
2. There were no reported cases of transfusion-transmitted malaria during 2021, with the last reported Australian case occurring in 1991.

Bacterial pre-release testing for platelets

1. In 2021, 161 (0.13%) of a total of 124 052 screened platelet units had confirmed bacterial contamination.
2. Consistent with previous years, by far the most common species isolated (137 isolates) was *Cutibacterium* species, commensal skin organisms of low pathogenicity which are rarely (if ever) associated with septic transfusion reactions. The next most common group was coagulase-negative staphylococci (13 isolates), which along with propionibacteria are usually considered skin contaminants.
3. Other confirmed positive pathogens (one isolate each unless stated) included;
   Bacillus species (2 isolates), *Enterococcus faecalis, Lactococcus lactis, Serratia marcescens, Staphylococcus aureus* (2 isolates), *Streptococcus agalactiae* (2 isolates), *Streptococcus cristatus, Steptococcus dysgalactiae* and *Streptococcus sanguinis.*
4. In 2021, 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 A and malaria, significantly decreased in 2021.
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

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Abbreviations

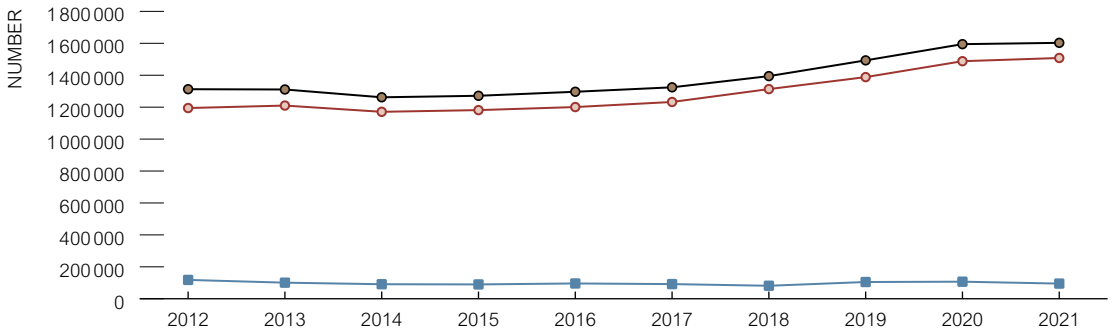
ACCESS	the Australian Collaboration for Coordinated Enhanced Sentinel Surveillance
anti-HAV	antibody to hepatitis A
anti-HBc	antibody to hepatitis B core antigen
anti-HBe	antibody to hepatitis B e antigen
anti-HBs	antibody to hepatitis B surface antigen
B19V	primate erythroparvovirus 1
DQ	donor questionnaire
DENV	dengue virus
DYO	donor-years of observation
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
mpox	mpox (formerly Monkeypox)
MPXV	monkeypox virus
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
TTIs	transfusion-transmissible infections
vCJD	variant Creutzfeldt-Jakob disease
WNV	West Nile virus
WP	window period
ZIKV	Zika virus

Main Findings

Blood donors in Australia

Over 13.8 million donations were tested for TTIs in Australia during the ten-year period 2012-2021, with an average of 1.4 million donations per year. Despite the challenges of maintaining sufficient donors during the ongoing COVID-19 pandemic, there were 1.6 million donations in 2021, an increase of 0.5% as compared to 2020. Over the entire ten-year period there was a significant increasing trend in the number of donations, from 1.31 to 1.60 million (p-value=0.001) (Figure 1) (see Methodological notes for details). Donations undergo mandatory testing for specific TTIs including HBV, HCV and HIV, and selective testing for HTLV and syphilis. From 2016, repeat donors donating plasma for fractionation only are not tested for syphilis. From December 2020 and with some exceptions, repeat donors do not require HTLV testing, irrespective of the type of donation resulting in differing denominators for syphilis and HTLV. Therefore, a total of 1.60 million donations were tested for HBV, HCV and HIV in 2021, as compared to slightly over 0.10 million donations for HTLV and 0.87 million donations for syphilis.

Figure 1 **Number of blood donations in Australia by year of donation, 2012-2021**



	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021
Total	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	1.60 M
First-time	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	0.09 M
Repeat	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	1.51 M

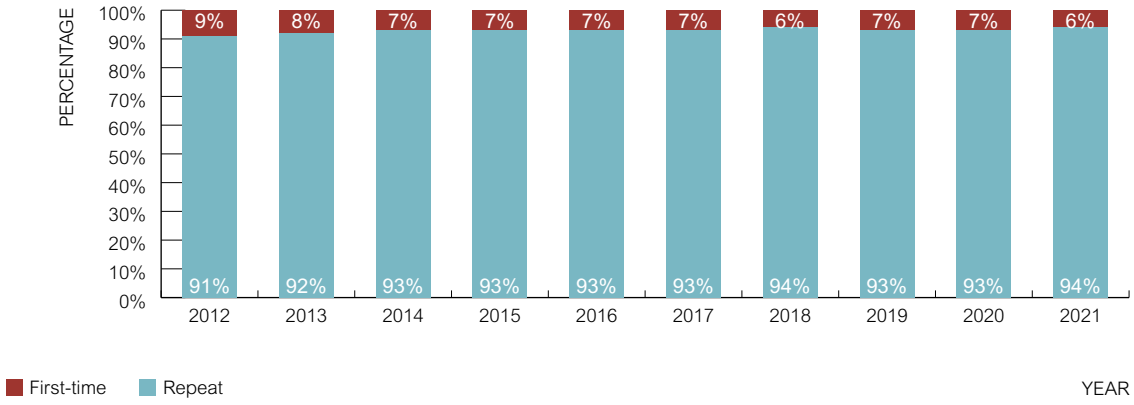
In 2021, 2.7% of the general population aged 18-80 years (age-eligible* to donate – see Figure 2 note) donated blood in Australia. Together, New South Wales, Queensland and Victoria accounted for 76% of all blood donations. The jurisdiction where the greatest proportion of the age-eligible local population donated blood in 2021 was the Australian Capital Territory (5.3%), followed by Tasmania at 3.9% (Figure 2).

Figure 2 **Percentage of age eligible* general population who donated blood in 2021, by state/territory**

Note: for 161 donors, their state/territory of residence was unknown
* There is no upper age restriction for existing donors but donors over 80 years only make up a small proportion of total donors. New donors are eligible if aged <76 years

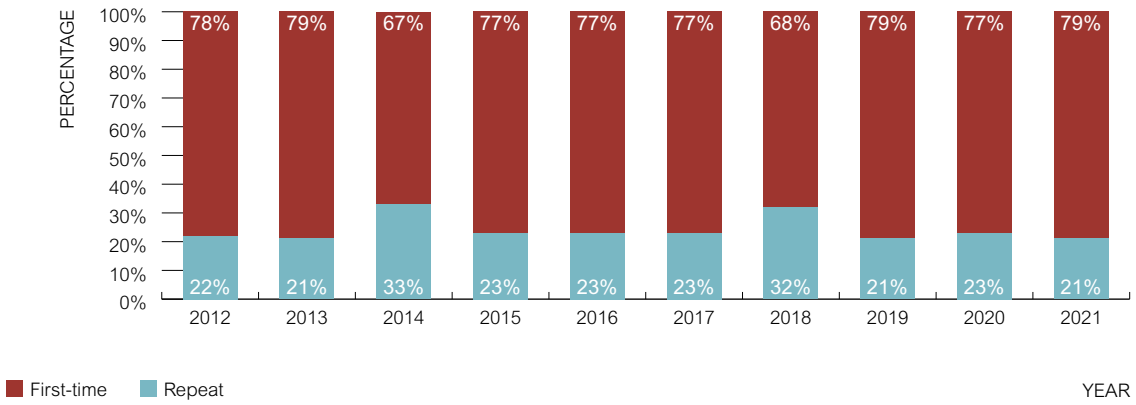
As in previous years, more than 90% of all donations in 2021 were from repeat donors (Figure 3). In the past ten years, 2012-2021, there has been a gradual decrease in the percentage of donations by first-time donors, from 9% in 2012 to 6% in 2021. While first-time blood donors represented only 18% of the donor population, and 6% of the total donations, they contributed the majority (79%) of TTIs in Australian blood donors in 2021, reflecting detection of prevalent cases rather than incident cases (Figure 4).

Figure 3 **Percentage of donations made by first time and repeat donors among all blood donations in Australia, 2012-2021**



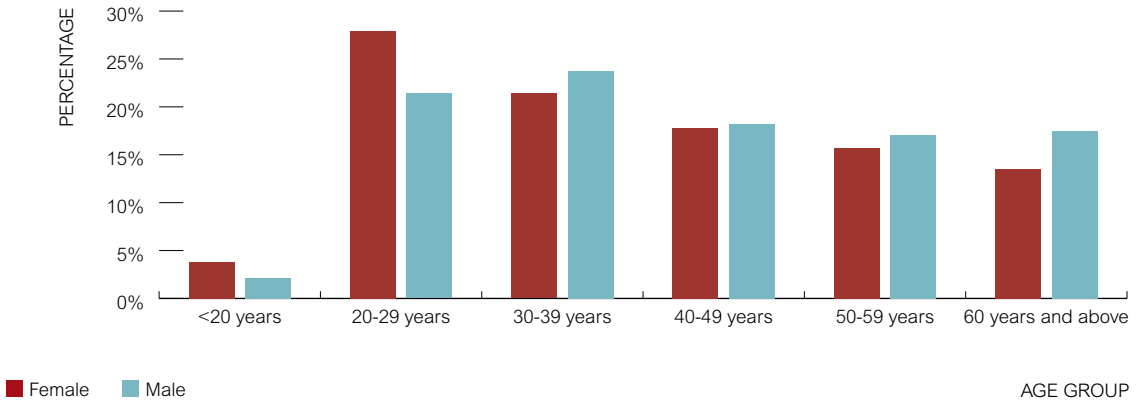
Overall, in the past ten years, the proportion of repeat donors among all TTI-positive blood donations in Australia was stable (21-23%), except for 2014 and 2018, where the proportions increased to 33% and 32%, respectively (Figure 4). For details on the proportional increase in repeat donors among all 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, 2012-2021**



Among all blood donors who donated in 2021, 51.3% were female and 48.7% 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, 2021**



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

This section focuses on national and jurisdictional trends in prevalence and incidence of TTIs during the ten-year period, 2012-2021. In addition, the association of demographic characteristics with the presence of TTIs for the year 2021 and the five-year period 2017-2021 are discussed. Putative risk factors associated with positive blood donors in Australia are also reported for the five-year period, 2017-2021. The findings are presented in respective sections by TTIs.

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 2021, trends in the ten-year period, 2012-2021, notifications of newly diagnosed TTIs in Australia, and risk exposure categories associated with respective infections. The information is drawn from the Kirby Institute's report - HIV, viral hepatitis and sexually transmissible infections in Australia: Annual Surveillance report 2022.[1]

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 meeting the incidence definition. 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 2017-2021 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.

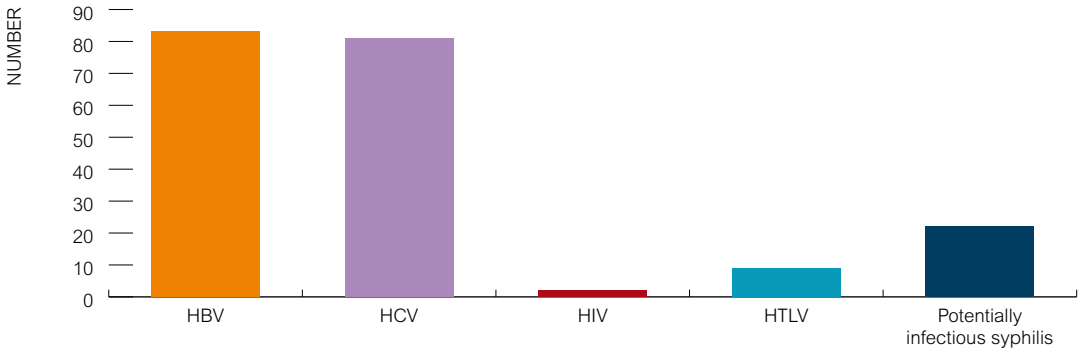
Lifeblood closely monitors donor incidence rates since this correlates directly with the risk of transmission in the window period. Incident donors are defined as positive repeat donors whose last donation tested negative for the same TTI within the last twelve months (with some exceptions; see Glossary). 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 2012-2021, a total of 1 762 donations (1 343 first-time and 419 repeat donations) were positive for at least one of the TTIs subject to mandatory donation testing. Of these, 1 595 were positive for HBV, HCV and HIV (11.5 per 100 000 donations), 123 (1.2 per 100 000 donations) were positive for active/potentially infectious syphilis and 44 (0.46 per 100 000 donations) were positive for HTLV. As noted above, due to a different total number of donations tested for these TTIs during the last ten years 2012-2021, (13.8 million donations for HBV, HCV and HIV, as opposed to 9.5 million and 10.4 donations tested for HTLV and syphilis, respectively), these data are presented separately (Table 1A, 1B and IC). Of the positive donations, 88.0% were positive for either HBV or HCV.

In 2021, a total of 195 donors were found positive for at least one of the TTIs subject to mandatory donation testing; one donor was positive for HBV and HCV, and one donor was positive for HCV and HTLV, making a total of 197 TTIs detected in 2021. Overall, HBV and HCV were the two most frequent TTIs identified in Australian blood donors in 2021, together contributing to 83.2% of positive donors (Figure 6). This proportion has decreased by a relative 12.3% as compared to 94.9% in 2012. Prevalence in all donations decreased from 8.6 in 2012 to 5.2 in 2021 for HBV and 6.9 in 2012 to 5.1 in 2021 for HCV. In 2021, HBV and HCV were the most frequent TTIs in first-time donors, while HCV 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. From 2020 onward, the methodology for calculating incidence was 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 (see Transfusion-transmissible infections in Australia 2021 Surveillance Report). Therefore, the incidence rates calculated cannot be directly compared to previous reports published prior to 2021 (see Methodological notes for details). For this reason, updated data are presented for a five-year period, 2017-2021 which retrospectively apply the updated DYO calculation method. During 2017-2021, a total of 26 incident donors were identified, seven for HBV, 10 for HCV and nine for HIV. In 2021, a total of four incident donors were detected, all for HCV.

Figure 6 **Distribution of TTI positive blood donations in Australia, in 2021**



	HBV	HCV	HIV	HTLV	Potentially infectious syphilis
Positive Donations 2021	83	81	2	9	22

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 2021, and the five-year period, 2017-2021, 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.[2] Lifeblood undertook a risk assessment which determined that the HCV incidence rate in donors returning after a tattoo was negligible.[3] 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 2017 to 2021. A total of 888 positive donors with at least one of the TTIs were observed over the period 2017-2021 (representing a total of 894 TTIs). The data on these donors were analysed for the period 2017-2021 to determine the key characteristics of positive blood donors, stratified by year of donation, and findings are presented in the respective TTIs sections.

Table 1 Raw number and prevalence of positive donations in Australia, by state/territory, 2012-2021

1A HBV, HCV and HIV, by state/territory, 2012-2021

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	321 143	3 966 799	4 287 942	236	46	282	174	51	225	10	7	17	420	104	524
Number *(Number per 100 000 donations)*				*73.49*	*1.16*	*6.58*	*54.18*	*1.29*	*5.25*	*3.11*	*0.18*	*0.40*	*130.78*	*2.62*	*12.22*
NT	7 283	95 904	103 187	10	2	12	5	3	8	0	0	0	15	5	20
Number *(Number per 100 000 donations)*				*137.31*	*2.09*	*11.63*	*68.65*	*3.13*	*7.75*	*0.00*	*0.00*	*0.00*	*205.96*	*5.21*	*19.38*
QLD	198 128	2 588 511	2 786 639	115	21	136	103	46	149	1	5	6	219	72	291
Number *(Number per 100 000 donations)*				*58.04*	*0.81*	*4.88*	*51.99*	*1.78*	*5.35*	*0.50*	*0.19*	*0.22*	*110.53*	*2.78*	*10.44*
SA	66 146	1 184 579	1 250 725	38	11	49	36	15	51	0	2	2	74	28	102
Number *(Number per 100 000 donations)*				*57.45*	*0.93*	*3.92*	*54.43*	*1.27*	*4.08*	*0.00*	*0.17*	*0.16*	*111.87*	*2.36*	*8.16*
TAS	29 854	498 553	528 407	14	5	19	24	5	29	0	0	0	38	10	48
Number *(Number per 100 000 donations)*				*46.89*	*1.00*	*3.60*	*80.39*	*1.00*	*5.49*	*0.00*	*0.00*	*0.00*	*127.29*	*2.01*	*9.08*
VIC	262 090	3 273 900	3 535 990	254	47	301	124	35	159	8	7	15	386	89	475
Number *(Number per 100 000 donations)*				*96.91*	*1.44*	*8.51*	*47.31*	*1.07*	*4.50*	*3.05*	*0.21*	*0.42*	*147.28*	*2.72*	*13.43*
WA	90 003	1 279 358	1 369 361	74	18	92	30	9	39	2	2	4	106	29	135
Number *(Number per 100 000 donations)*				*82.22*	*1.41*	*6.72*	*33.33*	*0.70*	*2.85*	*2.22*	*0.16*	*0.29*	*117.77*	*2.27*	*9.86*
National	974 647	12 887 604	13 862 251	741	150	891	496	164	660	21	23	44	1 258	337	1 595
Number *(Number per 100 000 donations)*				*76.03*	*1.16*	*6.43*	*50.89*	*1.27*	*4.76*	*2.15*	*0.18*	*0.32*	*129.07*	*2.61*	*11.51*

1B HTLV, by state/territory, 2012-2021

State/Territory of donation	All accepted donations			HTLV		
	First time	Repeat	All	First time	Repeat	All
NSW/ACT	321 143	2 720 097	3 041 240	15	3	18
Number (Number per 100 000 donations)				*4.67*	*0.11*	*0.59*
NT	7 283	57 962	65 245	0	0	0
Number (Number per 100 000 donations)				*0.00*	*0.00*	*0.00*
QLD	198 128	1 741 931	1 940 059	2	0	2
Number *(Number per 100 000 donations)*				*1.01*	*0.00*	*0.10*
SA	66 146	776 884	843 030	1	1	2
Number *(Number per 100 000 donations)*				*1.51*	*0.13*	*0.24*
TAS	29 854	316 707	346 561	3	0	3
Number *(Number per 100 000 donations)*				*10.05*	*0.00*	*0.87*
VIC	262 090	2 168 790	2 430 880	17	0	17
Number *(Number per 100 000 donations)*				*6.49*	*0.00*	*0.70*
WA	90 003	810 976	900 979	2	0	2
Number *(Number per 100 000 donations)*				*2.22*	*0.00*	*0.22*
National	974 647	8 593 347	9 567 994	40	4	44
Number *(Number per 100 000 donations)*				*4.10*	*0.05*	*0.46*

1C Active/potentially infectious syphilis, by state/territory, 2012-2021

State/Territory of donation	All accepted donations			PIS/Active Syphilis		
	First time	Repeat	All	First time	Repeat	All
NSW/ACT	321 143	3 005 408	3 326 551	10	31	41
Number (Number per 100 000 donations)				*3.11*	*1.03*	*1.23*
NT	7 283	61 772	69 055	0	1	1
Number (Number per 100 000 donations)				*0.00*	*1.62*	*1.45*
QLD	198 128	1 896 342	2 094 470	9	15	24
Number *(Number per 100 000 donations)*				*4.54*	*0.79*	*1.15*
SA	66 146	836 338	902 484	2	1	3
Number *(Number per 100 000 donations)*				*3.02*	*0.12*	*0.33*
TAS	29 854	337 366	367 220	0	0	0
Number *(Number per 100 000 donations)*				*0.00*	*0.00*	*0.00*
VIC	262 090	2 393 239	2 655 329	18	25	43
Number *(Number per 100 000 donations)*				*6.87*	*1.04*	*1.62*
WA	90 003	882 340	972 343	6	5	11
Number *(Number per 100 000 donations)*				*6.67*	*0.57*	*1.13*
National	974 647	9 412 805	10 387 452	45	78	123
Number *(Number per 100 000 donations)*				*4.62*	*0.83*	*1.18*

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Hepatitis B Virus (HBV)

Epidemiology of HBV in Australia

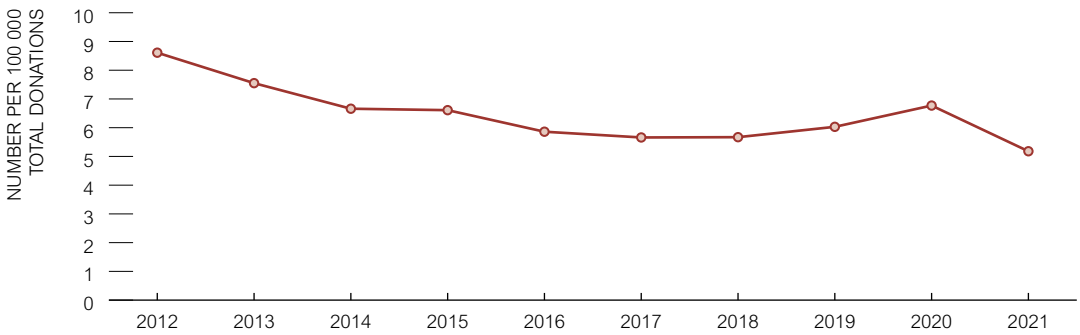
At the end of 2021, an estimated 223 220 people were living with chronic HBV in Australia, of whom an estimated 74% (165 249) were diagnosed with chronic hepatitis B, 23% and 19% were born in the Northeast and Southeast Asia, respectively, and 7% were among Aboriginal and Torres Strait Islander peoples.[1] In total, there were 4 732 notifications of newly diagnosed HBV in Australia in 2021; of these, over half (54%) were male, and 58% were people aged 25 years and above. Australia has a concentrated hepatitis B epidemic among key populations: migrants from high prevalence countries, particularly Southeast Asia; men who have sex with men; Aboriginal and Torres Strait Islander peoples; and people who inject drugs. Over the ten-year period, 2012-2021, the population rate of diagnosis of HBV in Australia has declined in younger age groups: 25 – 29 years (from 63.7 to 21.9 per 100 000); 20 – 24 years (from 35.9 to 12.0 per 100 000); and 15 – 19 years (from 13.4 to 3.3 per 100 000).[1] 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 22% from 0.9 per 100 000 in 2012 to 0.3 per 100 000 in 2021.[1] The estimated prevalence of chronic HBV among people living in Australia is ~0.9%, which is higher than for people living in the United Kingdom (<0.5%)[4] but lower than many other countries in South East Asia and the Pacific.

Trends in prevalence

All donations:

In the past ten years, 2012-2021, a total of 891 HBV-positive donors have been detected (741 first-time donors andw 150 repeat donors) (Table 1A). During this period, HBV prevalence among all donations has declined significantly (IRR 0.96; 95% CI: 0.94-0.98). There has been an overall reduction of 40% from 2012 to 2021, from 8.6 to 5.1 per 100 000 total donations (Figure 7). This significant decline is not 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=145) with occult HBV (OBI) since HBV NAT commenced in 2010 (see OBI section below) and increased donation frequency from repeat donors. Donors with OBI characteristically have very low HBV viral loads (<200 IU/mL) which are often close to the limit of detection of the most sensitive HBV DNA tests.[5] For detail on the number and prevalence rate of HBV-positive donors among all donations for 2021, see Supplementary Table 2.

Figure 7 **Prevalence of HBV-positive donations among all blood donations in Australia, 2012-2021**

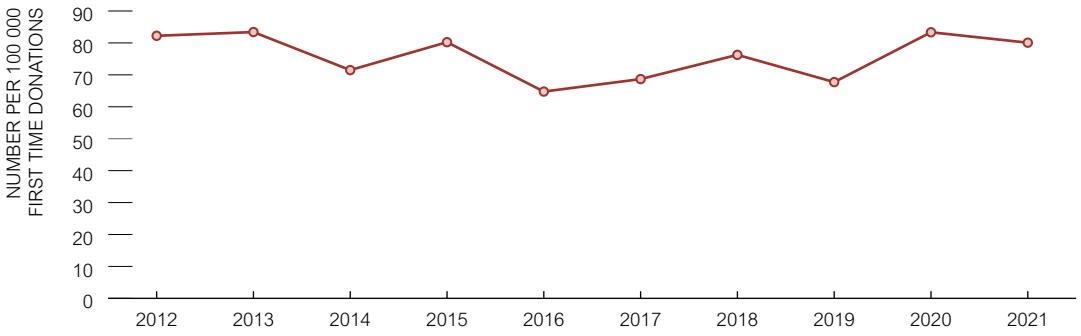


	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021
Prevalence in all donations	8.61	7.55	6.66	6.61	5.86	5.66	5.67	6.03	6.77	5.18

First-time donors:

Although the 2021 HBV prevalence decreased marginally compared to 2020, over the ten-year period 2012-2021, no significant annual trend is apparent among first-time donors (Figure 8) (IRR: 0.99; 95% CI: 0.97-1.02). However, the average prevalence for the period 2012-2021 shows a decline to 76.0 per 100 000 donations (0.08% of the total first-time donations) (Table 1A) as compared to 82.6 and 77.9 per 100 000 donations for the 2005-2014 and 2008-2017 periods, respectively. This trend is reflected in the Australian general population with the notification rate showing a downward trend in the past ten years, at 27.8 per 100 000 in 2012, 24.4 per 100 000 in 2017, and 18.4 per 100 000 in 2021.[1]

Figure 8 **Prevalence of HBV-positive donations among first time blood donors in Australia, 2012-2021**

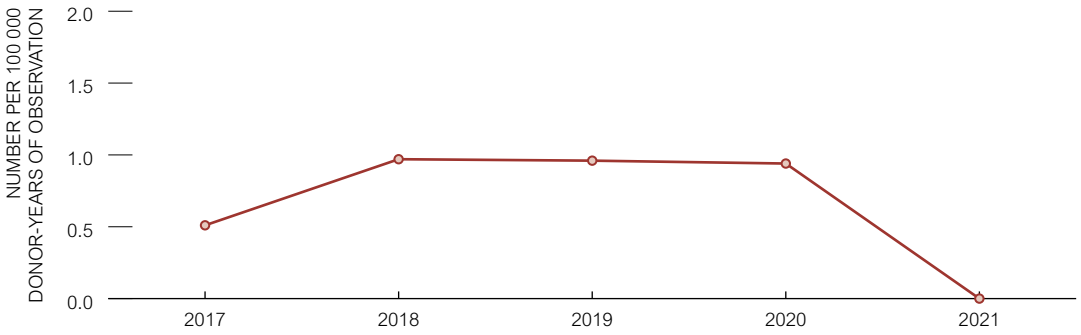


	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021
Prevalence in first-time donors	82.23	83.4	71.49	80.23	64.76	68.67	76.26	67.73	83.34	80.07

Trends in incidence

For the five-year period 2017-2021, there were a total of seven HBV incident donors detected with no statistically significant trend observed for incidence rates (between 0.0 and 0.9 per 100 000 donor-years of observation; (IRR: 0.83; 95% CI: 0.49-1.41) (Figure 9). For the first time in the past five years, no incident HBV donor was detected in 2021.

Figure 9 **Incidence of HBV in repeat blood donors, in Australia, 2017-2021**



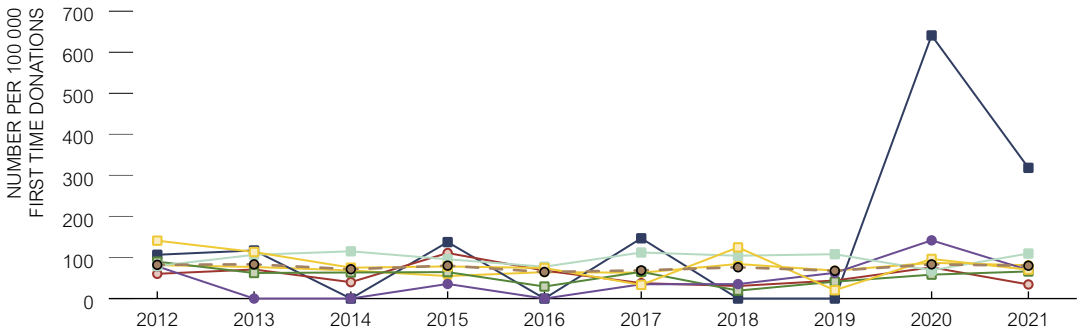
	2017	2018	2019	2020	2021
Incidence	0.51	0.97	0.96	0.94	0

No transfusion-transmitted HBV cases were reported in 2021. 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 by state/territory

Consistent with previous TTI-surveillance reports, the HBV prevalence among first-time donors varied markedly by jurisdiction in 2021. While the national prevalence was 80.0 per 100 000 donations, this ranged from 34.3 to 318.4 per 100 000 donations across jurisdictions (Figure 10). In 2021, the Northern Territory recorded the highest prevalence among first-time donors (318.4 per 100 000 donations) as compared to the other states, but this was due to only two positive donors. For the ten-year period 2012-2021, the highest average prevalence among first-time donors was also observed in the Northern Territory, at 146.7 per 100 000 donations, followed by Victoria at 97.7 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, although Northern Territory had the highest rate of diagnosis of HBV reported in the national surveillance data for the 2012-2020 period (between 79.2 per 100 000 in 2012 and 34.3 per 100 000 in 2020), the highest recorded rate in 2021 was in New South Wales, at 21.5 per 100 000, followed by Victoria at 19.9 per 100 000, whereas a marked decrease in Northern Territory was observed in 2021, at 12.2 per 100 000 population.[1]

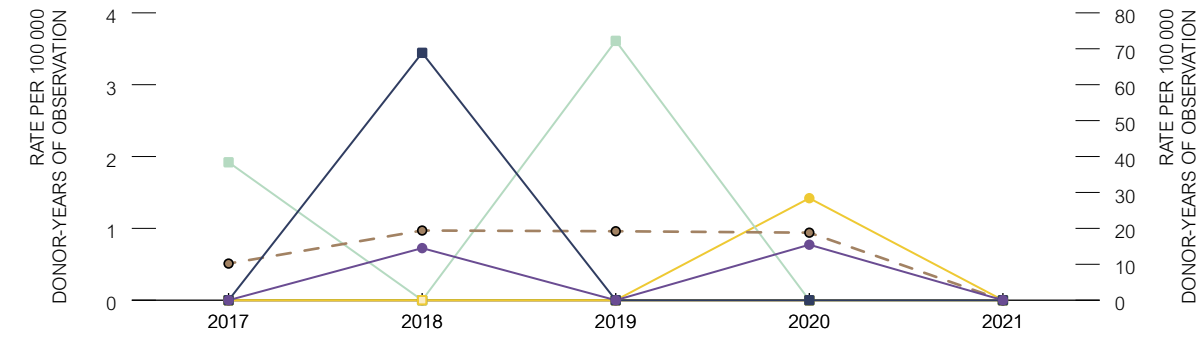
Figure 10 **HBV prevalence among first time donors by state/territory and year of donation, 2012-2021**



	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021
NSW/ACT	81.38	77.01	68.41	54.83	64.44	62.97	84.23	68.16	87.07	81.16
NT	106.72	117.23	0.00	137.55	0.00	146.84	0.00	0.00	641.03	318.47
QLD	60.29	70.82	39.91	111.03	68.25	37.63	30.58	43.99	76.03	34.37
SA	89.89	62.33	63.53	64.50	29.31	65.15	19.38	41.15	58.28	66.06
TAS	78.47	0.00	0.00	35.63	0.00	34.79	35.29	62.72	141.84	69.59
VIC	79.37	106.58	115.15	95.79	77.63	112.18	104.37	108.11	68.87	109.71
WA	141.06	113.44	75.26	78.28	74.48	33.31	124.69	20.32	96.50	70.41
National	82.23	83.40	71.49	80.23	64.76	68.67	76.26	67.73	83.34	80.07

There were no incident donors recorded nationally in 2021. Overall, there was no obvious trend in HBV incidence in any state/territory during the five-year study period 2017-2021 (Figure 11). Among donors in Queensland, South Australia and Western Australia, HBV incidence has been zero since 2017.

Figure 11 HBV incidence among repeat donors, by state/territory and year of donation, 2017-2021[1]



	2017	2018	2019	2020	2021
NSW/ACT	0.00	0.00	0.00	1.42	0.00
NT	0.00	68.87	0.00	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	14.50	0.00	15.45	0.00
VIC	1.92	0.00	3.61	0.00	0.00
WA	0.00	0.00	0.00	0.00	0.00
National	0.51	0.97	0.96	0.94	0.00

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

Occult HBV

As noted, the implementation of HBV DNA testing for all donations from 2010 has facilitated the identification of OBI among the donor population.[5] To the end of 2021, 215 donors with OBI have been detected, notified and referred for external clinical assessment which both reduces the residual risk of HBV and contributes to the identification of undiagnosed HBV in Australia. In 2021, 20 of the 83 (24.1%) HBV positive donors detected were classified as OBI, as compared to 23 of 108 (21.3%) in 2020. Most (15/20; 75%) OBIs in 2021 were men and the majority (13/20; 65%) were repeat donors, with an average age of 52.1 years. The majority (13/20; 65%) of donors with OBI in 2021 were born in Asia (South-East/North-East Asia – 10, Southern and Central Asia – 3).

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 for a combined period of 2012-2021 and then 2021 separately. Subsequently, 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[6, 7] 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 2012-2021, and 11 times lower prevalence for the year 2021. 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, 2021 and 2012-2021

TTI	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	
	2012-2021	2021	2012-2021	2021	2012-2021	2021
HBV	892	867	76.03	80.07	12 times lower	11 times lower

* The 2021 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 2021 as reported by the Australian Bureau of Statistics. For the period 2012-2021, an average of the ten years' prevalence rates was calculated. Due to updated modelling methods for calculating estimated number of people living with chronic HBV, estimates may be different from those presented in previous years of reporting

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 2021, and the five-year period, 2017-2021, 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 2021, female donors were 61% less likely to be HBV positive compared to male donors. In 2021, there was no significant association between other age groups and HBV positivity as compared to the reference age group of 20-29 years, however, donors from Queensland were 65% less likely to be HBV positive as compared to the reference group of New South Wales (Supplementary Table 4).

In the five-year period, 2017-2021, female donors were 61% less likely to be HBV positive as compared to male donors. Donors aged between 30-39 and 40-49 years were 1.9 times and 1.4 times more likely to be HBV positive than the reference age group, respectively. During the same period, donors from the Northern Territory and Victoria had a significantly greater rate of HBV-positivity as compared to the reference groups (2.6 and 1.3 times, respectively, see Supplementary Table 5), while donors from Queensland were 38% less likely to be HBV positive. In comparison, during 2012-2021, the notification rates of HBV in Australia have been consistently higher in male (30.3 per 100 000 in 2012 to 20.0 per 100 000 in 2021), than female persons (25.2 per 100 000 in 2012 to 16.7 per 100 000 in 2021). The notification rates have declined in all age groups, however the greatest declines were seen among the younger age groups (aged under 35 years, likely as a result of universal HBV vaccination), with relatively stable rates in those aged 35+ years. The rate has consistently been highest in the Northern Territory between 2012-2020 (79.2 per 100 000 in 2012 to 34.3 per 100 000 in 2020) but fell by 64% in 2021 to 12.2 per 100 000 population. In all other jurisdictions the rate of HBV diagnosis has also declined during the ten-year period 2012-2021, ranging between a 6% decline in Tasmania (15.5 per 100 000 in 2012 to 14.5 per 100 000 in 2021) and a 55% decline in South Australia (25.3 per 100 000 in 2012 to 11.3 per 100 000 in 2021).[1]

Risk factors associated with HBV-positive donors

Of the 435 HBV positive donors during 2017-2021, 83% were first-time donors, 70% were male, and the mean age was 41 years (Table 3). Most (90%) of the HBV positive donors were born overseas, which reflects the epidemiology of hepatitis B in the general population. Ethnicity or country of birth (83%) was the most frequent risk factor for HBV-positivity, with over 62% born in North & South-East Asia in 2021 (Figure 12). There were only seven 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, 2017-2021

Characteristics	2017	2018	2019	2020	2021	2017-2021
Number of positive donors	75	79	90	108	83	435
Number of positive first-time donors (%)	63 (84%)	62 (78%)	71 (79%)	89 (82%)	76 (92%)	361 (83%)
Number of male donors (%)	47 (63%)	60 (76%)	73 (81%)	68 (62%)	59 (71%)	307 (70%)
Mean age (range) in years	41 (17-78)	41 (19-71)	40 (19-73)	41 (18-74)	41 (20-76)	41 (17-78)
Number of incident donors	1	2	2	2	0	7
Number of donors born in Australia (%)	14 (19%)	8 (10%)	11 (15%)	9 (8.3%)	2 (2%)	44 (10%)
Main reported risk factor	Ethnicity/COB[1] 87%*	Ethnicity/COB[1] 91%*	Ethnicity/COB[1] 90%*	Ethnicity/COB[1] 71%	Ethnicity/COB[1] 78%	Ethnicity/COB[1] 83%
Second reported risk factor	FH/HC[2], PRP[3], OR[4], EHS[5] 3%	Undetermined 3%	PUSR[6] 3%	FH/HC[2] 16%	FH/HC[2] 18%	FH/HC[2] 8%

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
* 7 out 14, 3 out of 8, 4 out of 11, 1 out of 9, and 1 out of 2 donors born in Australia had Ethnicity as their major risk factor in 2017, 2018, 2019 2020 and 2021, respectively

Figure 12 HBV-positive donors by country/region of birth, 2021 (n=83)

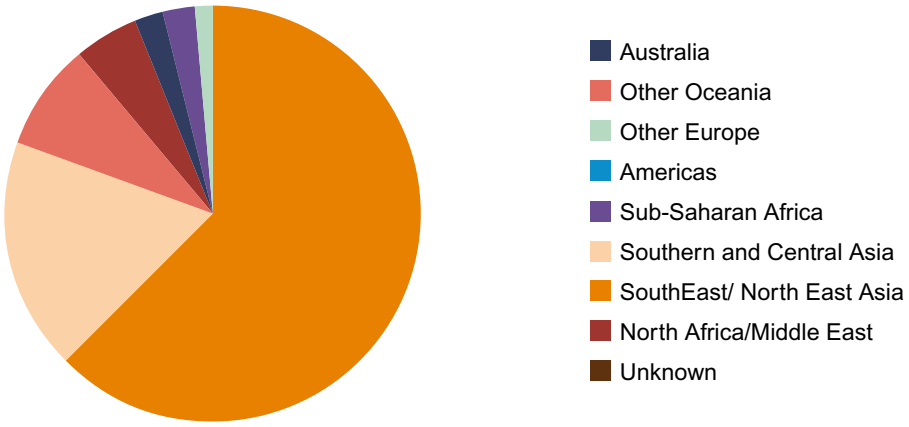
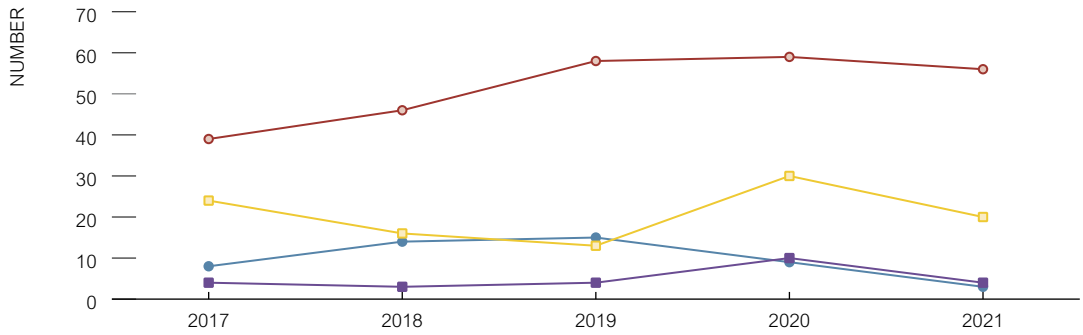


Figure 13 **HBV-positive donors by sex and donor status, 2017-2021**



	2017	2018	2019	2020	2021
Male (first-time)	39	46	58	59	56
Male (repeat)	8	14	15	9	3
Female (first-time)	24	16	13	30	20
Female (repeat)	4	3	4	10	4

Since 2017, a slight increase has been observed in the number of male HBV-positive first-time donors, while the number of female HBV-positive donors remained relatively stable. The number of HBV-positive repeat donors remained stable for men and women, during the same period (Figure 13). In comparison, there have been declines in HBV notification rates by sex in the ten-year period, 2012-2021 from 30.3 to 20.0 per 100 000 male population and 25.2 to 16.7 per 100 000 female population.[1] Of note, caution must be applied in comparing the trends by sex between blood donors and general population as they are numbers in the former versus rates in the latter.

For more information on the number and percentage of HBV-positive donors by sex, age group, donor status, country of birth and exposure category for the year 2021 and the period 2012-2021, 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 78.3% of the HBV-positive donors in 2021. This finding also parallels the general population data that shows that country of birth is the strongest risk factor for chronic HBV in Australia.[8-10]

Nationally, enhanced information on potential risk categories is collected for the newly acquired HBV only (defined as newly diagnosed HBV with laboratory or clinical evidence of acquisition in the 24 months prior to diagnosis). In 2021, for newly acquired HBV in the general population, 22% and 12% had injecting drug use and sexual contact as their major risk factors, respectively; importantly, for 21% and 36% of newly acquired HBV in the general population, the risk factor was either not reported or could not be identified, respectively (Table 4).[11] 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 as opposed to acute.

Table 4 **Comparison between HBV-positive blood donors and general population in Australia by major potential risk categories, 2021**

	HBV	
Major risk category	**Newly acquired HBV cases in general population (2021) (%)**	**Blood donors (2021) (%)**
Injecting drug use	22.5	0.0
Country of birth/Ethnicity	1.25	78.3
Sexual contact[1]	12.5	2.4
Blood or tissue recipient	1.25	0.0
Tattoo or body piercing	1.25	0.0
Exposure in health care setting	1.25	0.0
Household contact/Family history	0	18.1
Other blood to blood contact	2.5	0.0
Other/undetermined/unknown/not reported	21.3	1.2
Imprisonment	0.0	0.0
Occupational risk	0.0	0.0
Other	0.0	0.0
No risk factor identified	36.3	0.0

1 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

Conclusion

- HBV prevalence in first time blood donors has shown no significant trend since 2012 and is substantially lower (12 times) than the general population estimates for the period 2012-2021.
- 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 (20 of the 83 HBV infections in 2021).
- Putative risk factors in HBV-positive blood donors closely parallel those for the general population with no 'unique' risk factors identified to date among blood donors.

Hepatitis C Virus (HCV)

Epidemiology of HCV in Australia

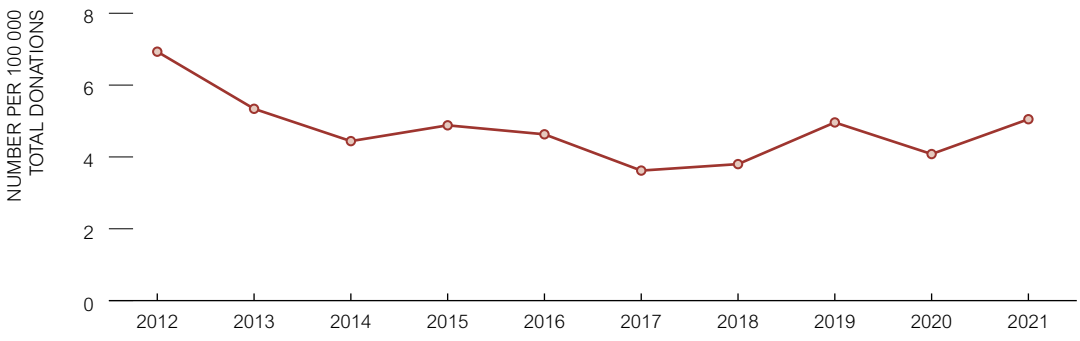
To the end of 2021, an estimated 81 304 people were living with chronic hepatitis C in Australia, of which an estimated 76% or 61 961 were diagnosed with chronic hepatitis C.[1] Australia has a concentrated chronic hepatitis C epidemic among key populations: people who inject drugs, prisoners, people from high prevalence countries and HIV positive men who have sex with men. The rate of diagnosis of HCV in 2021 was 29.2 per 100 000 which reflects a 33% decline from 43.7 per 100 000 population in 2012.[1] However, in the period 2012-2016 the rate increased by 15% from 47.7 per 100 000 to 50.3 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. The rate of diagnosis in those aged 15-24 years, which, as compared to other age groups, reflects recently acquired infection and therefore taken as a proxy of incidence, has declined by 36% in the past ten years, 2012-2021.[1] In comparison, between 2017 and 2021, the rate of diagnosis in the Aboriginal and Torres Strait Islander population aged 15-24 years fluctuated and was 194.5 per 100 000 in 2021, whereas the rate in non-indigenous people in the same age group declined by 22% from 25.3 in 2017 to 19.8 per 100 000 in 2021.[1] Similarly, in 2021, the diagnosis rate of HCV was more than seven times higher in the Aboriginal and Torres Strait Islander population (194.3 per 100 000) than that of the non-indigenous population (26.2 per 100 000). In 2021, most cases (68%) of newly diagnosed HCV were in male persons and 90% were in people aged 25 years and above.[1]

Trends in prevalence

All donations:

In the past ten years, 2012-2021, 660 HCV-positive donors have been detected (496 first-time donors and 164 repeat donors) (Table 1A). During the last ten years, HCV prevalence among all donations has declined significantly (IRR: 0.97; 95% CI: 0.94-0.99). There has been an overall reduction of 27% over the period, from 6.9 per 100 000 donations in 2012 to 5.0 per 100 000 donations in 2021 (Figure 14). For detail on the number and prevalence rate of HCV among all donations for 2021 see Supplementary Table 2.

Figure 14 HCV prevalence in all blood donations in Australia, 2012-2021, by year of donation



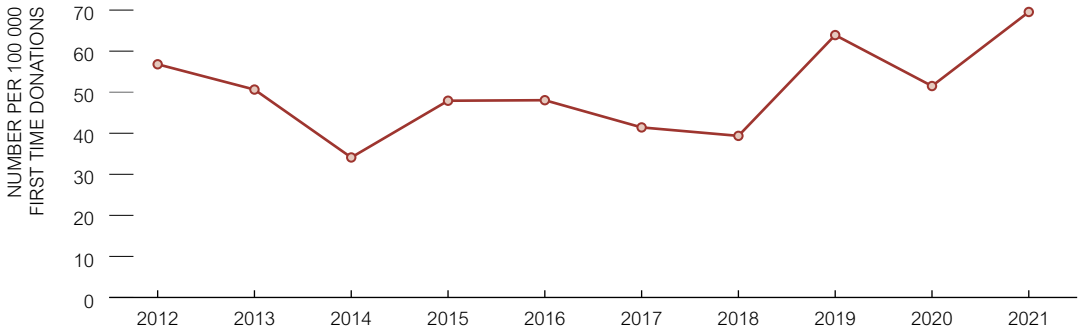
	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021
Prevalence in all donations	6.93	5.34	4.44	4.88	4.63	3.62	3.80	4.96	4.08	5.05

First-time donors:

No significant trend was observed in HCV prevalence in first-time donors in the 2012-2021 period (IRR: 1.02; 95% CI: 0.99-1.05) (Figure 15). Despite no significant trend, an increase in HCV prevalence in first-time donors seen in the recent years 2019, 2020 and 2021 is likely to be the combined impact of two factors. Firstly, 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. Secondly, a change in policy from indefinite deferral for injecting drug use to a 5-year deferral, which occurred in September 2018.

In comparison, the national rate of diagnosis of HCV declined from 43.7 per 100 000 in 2012 to 29.2 per 100 000 in 2021.[1] In addition, there has also been a decrease in the prevalence of hepatitis C antibody among people seen at needle and syringe programs, from 49% in 2017 to 36% in 2021, whilst the rates of receptive needle and syringe sharing in the same period remained stable (range: 16 to 18%), highlighting the importance of sustaining and enhancing harm reduction services.[12]

Figure 15 HCV prevalence in first time blood donors in Australia, 2012-2021, by year of donation



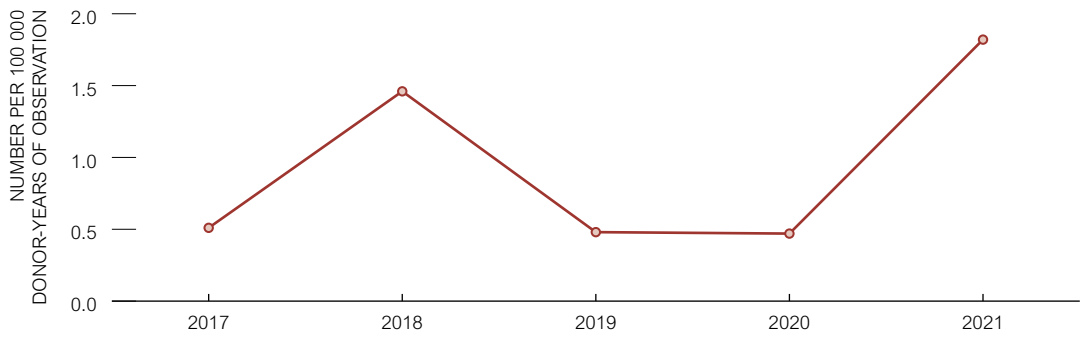
	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021
Prevalence in first-time donors	56.8	50.64	34.10	47.92	48.05	41.42	39.36	63.91	51.5	69.54

Trends in incidence

Over the five-year period 2017-2021, a total of 10 incident HCV donors were detected with no statistically significant trend observed for incidence rates (between 0.4 and 1.8 per 100 000 donor-years of observation; IRR: 1.19; 95% CI: 0.76-1.87) (Figure 16). Four HCV incident donors were identified in 2021, equating to an incidence rate of 1.82 per 100 000 donor-years of observation, the highest in the past five years (Figure 16). However, test false-positivity or distant past infection was considered a possibility in three of the four donors. Modelled national HCV incidence estimates for 2021 were not available at the time of this report preparation. However, among people attending the Australian Collaboration for Coordinated Enhanced Sentinel Surveillance (ACCESS) care sites, the HCV incidence declined from 1.5 to 0.4 new infections per 100 person-years between 2012-2020 before slightly increasing to 0.6 new infections per 100 person-years in 2021[1].

No transfusion-transmitted HCV cases were reported in Australia during 2017-2021.

Figure 16 **Incidence of HCV in repeat blood donors in Australia, 2017-2021**



	2017	2018	2019	2020	2021
Incidence	0.51	1.46	0.48	0.47	1.82

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 notify and refer them for medical follow-up. There had been a steady decline in the proportion of HCV RNA positive (infectious) donors during 2010-2018. However, an increase was observed in both this proportion and the overall HCV prevalence rate from 2019. The RNA positive proportion increased to 47.3%, 38.5% and 37.0% in 2019, 2020 and 2021, respectively, from 32.1% in 2018. This increase may be at least in part explained by the September 2018 change in the deferral period for people who inject drugs from indefinite to 5 years, resulting in the subsequent attendance of newly eligible donors with undiagnosed HCV.

The majority (93.3% - 28/30) of the HCV RNA-positive donors in 2021 were first-time donors, equating to a rate of RNA-positive donors among first-time donors at 29.5 per 100 000 donations. Both returned donors who were RNA positive had long (greater than 10 years) inter-donation intervals. 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) and the 2012-2021 period (IRR: 0.99; 95% CI: 0.95-1.03).

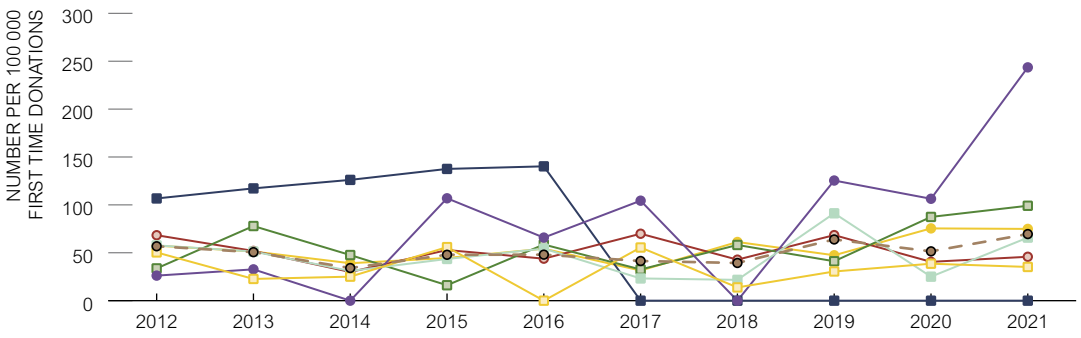
Importantly, first-time HCV-positive donors do not correlate directly with an increase in the HCV residual transmission risk. This is because the increase is among prevalent (long-standing) infections, readily detectable by Lifeblood's dual NAT/Ab testing strategy. The transmission risk for transfused 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 WP. Importantly, the number of HCV incident donors identified by Lifeblood declined from 3 in 2018, to 1 each in 2019 and 2020, however it increased to 4 in 2021. 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 by state/territory

Similar to patterns in previous years' TTI surveillance reports, HCV prevalence among first-time donors varied markedly by jurisdiction in 2021, ranging from 0.0 to 243.5 per 100 000 donations. During the past ten years, 2012-2021, a significant increasing trend was observed for Tasmania (IRR: 1.25; 95% CI: 1.07-1.46), where the highest prevalence among first-time donors was recorded in 2021 compared to other states, at 243.5 per 100 000 donations (Figure 17) (equating to seven HCV-positive first-time donors); this is also the highest ever prevalence rate of HCV recorded for Tasmania during the past ten years. During the same period of time, no significant trend was observed for any other jurisdiction. Notably, since 2017, the Northern Territory has recorded

the lowest rate of 0.0 per 100 000 donations. Of note, the fluctuating trend in HCV prevalence in first-time donors in Tasmania over the past ten years should be interpreted with caution due to small number of positive donors, ranging between zero and seven. National notifications data indicate the notification rate of HCV in Australia in 2021 was highest in Queensland (41.3 per 100 000), followed by the Northern Territory (39.9 per 100 000), New South Wales and Tasmania (30.9 per 100 000 each).[1]

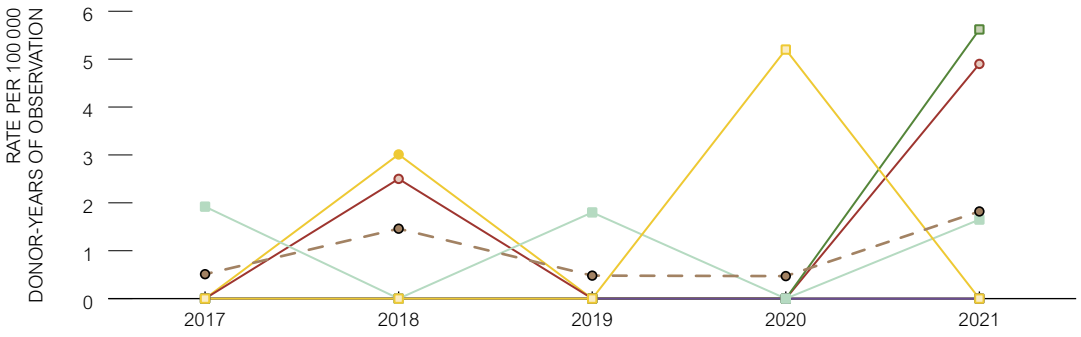
Figure 17 HCV prevalence among first time donors by state/territory and year of donation, 2012-2021



	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021
NSW/ACT	57.44	51.34	39.09	44.55	54.26	31.48	61.26	47.41	75.46	74.92
NT	106.72	117.23	126.10	137.55	140.25	0.00	0.00	0.00	0.00	0.00
QLD	68.33	51.93	29.94	52.87	43.87	69.88	42.81	68.44	40.55	45.82
SA	33.71	77.92	47.65	16.12	58.62	32.57	58.15	41.15	87.43	99.09
TAS	26.16	32.70	0.00	106.88	65.85	104.38	0.00	125.43	106.38	243.56
VIC	57.72	51.32	31.00	43.54	54.34	23.21	21.74	91.22	25.05	65.83
WA	50.38	22.69	25.09	55.92	0.00	55.51	13.85	30.48	38.60	35.21
National	56.80	50.64	34.10	47.92	48.05	41.42	39.36	63.91	51.50	69.54

There was no significant annual trend observed for HCV incidence in repeat donors nationally during the 2017-2021 study period (IRR: 1.19; 95% CI: 0.76-1.87). Generally, HCV incidence in repeat donors has remained low across most Australian jurisdictions during the past five years (Figure 18) and no significant decrease was observed for any state or territory. However, HCV incidence in South Australia was at 5.62 per 100 000 donor-years of observation, after remaining zero during the 2017-2020 period. This increase in incidence in 2021 in South Australia should be interpreted with caution as it equates to just one incident donor. Notably, in the Northern Territory and Tasmania, HCV incidence has remained zero since 2017.

Figure 18 HCV Incidence among repeat donors by state/territory and year of donation, 2017-2021



	2017	2018	2019	2020	2021
NSW/ACT	0.00	3.01	0.00	0.00	0.00
NT	0.00	0.00	0.00	0.00	0.00
QLD	0.00	2.50	0.00	0.00	4.90
SA	0.00	0.00	0.00	0.00	5.62
TAS	0.00	0.00	0.00	0.00	0.00
VIC	1.92	0.00	1.80	0.00	1.65
WA	0.00	0.00	0.00	5.20	0.00
National	0.51	1.46	0.48	0.47	1.82

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 for a combined period of 2012-2021 and then 2021 separately. 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.[6,7] The prevalence in first-time donors was 15 and 5 times lower than the prevalence of people living with chronic hepatitis C in the general population for the period 2012-2021, and 2021, respectively (Table 5). Of note, this proportional prevalence risk reduction would be far greater if we only include the RNA-positive donors (active infection) and exclude the ant-HCV-only donors (potentially false positive) from our analysis.

Table 5 Comparison of HCV prevalence in blood donors with population prevalence, 2021 and 2012-2021

TTI	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	
	2012-2021	2021	2012-2021	2021	2012-2021	2021
HCV	758	316	50.89	69.5	15 times lower	5 times lower

* The 2021 HCV prevalence in the general population was calculated by taking the estimated number of people living with chronic HCV,[1] and dividing it by the estimated mid-year resident Australian population in 2021 reported by the Australian Bureau of Statistics. For the period 2012-2021, an average of the ten years' prevalence rates was calculated.

Due to updated modelling methods for calculating estimated number of people living with chronic HCV, estimates may be different from those presented in previous years of reporting

Demographic factors associated with HCV 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 2021, and the five-year period, 2017-2021, 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 2021, female donors were 41% less likely to be HCV-positive compared to male donors. Donors over 50 years of age were 3.9 times more likely to be HCV-positive compared to the reference group (Supplementary Table 4). In 2021, there was no significant association between donors' state of residence and HCV positivity as compared to the reference group.

During the five-year period, 2017-2021, female donors were 40% less likely to be HCV-positive compared to male donors. There was a significantly greater risk of HCV among donors aged 30 years or above. During 2017-2021, 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 321 HCV-positive donors during 2017-2021, 80% were first-time donors and 62% were male. Over the last five years, the mean age was 47 years with a wide range (18-72) (Table 6). Unlike HBV where birth overseas predominated, the majority (68%) of HCV-positive donors during 2017-2021 were born in Australia, reaching 70% in 2021 (Figure 19).

Overall, the main reported putative risk factors for HCV positivity during 2017-2021 were injecting drug use and tattoo or body piercing (25% and 19%, 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.[2] 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 19% 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,[3] 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 10 incident HCV donors in the last five years, the highest among all TTIs, however, test false-positivity or distant past infection may explain some of these detections.

Table 6 Characteristics of HCV-positive donors by year of donation, 2017-2021

Characteristics	2017	2018	2019	2020	2021	2017-2021
Number of positive donors	48	53	74	65	81	321
Number of positive first-time donors (%)	38 (79%)	32 (60%)	67 (91%)	55 (85%)	66 (81%)	258 (80%)
Number of male donors (%)	35 (73%)	27 (51%)	44 (59%)	42 (65%)	51 (63%)	199 (62%)
Mean age (range) in years	48 (23-67)	45 (18-67)	47 (18-70)	45 (20-69)	49 (18-72)	47 (18-72)
Number of incident donors	1	3	1	1	4	10
Number of donors born in Australia (%)	37 (77%)	40 (75%)	47 (64%)	36 (55%)	57 (70%)	217 (68%)
Main reported risk factor	TBP[1]; IDU[2] 23% each	TBP[1] 26%	IDU[2] 26%	IDU[2] 20%	IDU[2] 32%	IDU[2] 25%
Second reported risk factor	Other 10%	IDU[2] 21%	TBP[1] 23%	TBP[1] 15%	TBP[1] 11%	TBP[1] 19%

1 TBP = Tattoo/Body piercing
2 IDU = Injecting drug use
Note: in 2021, 17 (21%) donors positive for HCV had their risk factors unknown or undetermined

Figure 19 Donors with HCV by country/region of birth, 2021 (n=81)

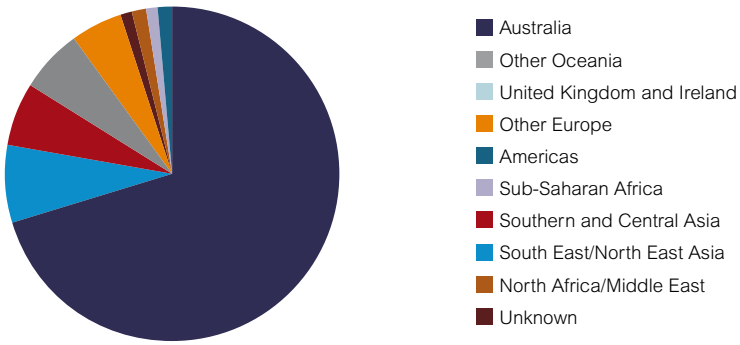
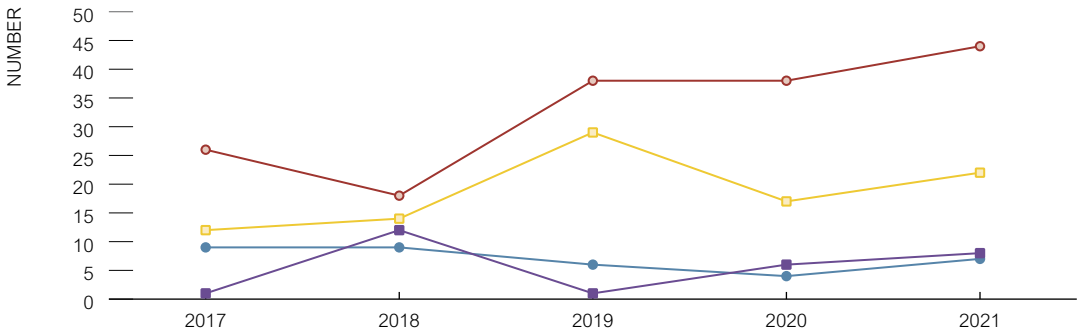


Figure 20 HCV-positive donors by sex and donor status, 2017-2021



	2017	2018	2019	2020	2021
Male (first-time)	26	18	38	38	44
Male (repeat)	9	9	6	4	7
Female (first-time)	12	14	29	17	22
Female (repeat)	1	12	1	6	8

Over the five-year period, 2017-2021, there has been an increase in the number of HCV-positive first-time male and female donors; this increase in numbers (from 2019 onward) in HCV positive first-time donors may be at least in part explained by the September 2018 change in the deferral period for people who inject drugs from indefinite to 5 years. During the same period of time, the number of HCV-positive male repeat donors remained stable, while the number of female repeat HCV-positive donors fluctuated between 1 and 12 (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 2021 and the period 2017-2021, see Supplementary Tables 6-12. In comparison, there have been gradual declines in HCV notification rates by sex in the ten-year period, 2012-2021 from 56.4 to 40.2 per 100 000 male population and 30.8 to 18.2 per 100 000 female population.[1] 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.

HCV – Comparison of major exposure categories between blood donors and the general population, 2021

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 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 potential risk factor reported for HCV-positivity in blood donors in 2021 was IDU (32.1%), followed by tattoo or body piercing (11.1%). Of note, in 2021, for 20.9% blood donors, the risk factor remained unknown/undetermined. In comparison, for the newly acquired HCV in Australia in 2021, 65% had imprisonment as their major risk factor in the general population, which could potentially be due to enhanced testing in prisons owing to the availability of treatment. This was followed by 21% of the newly acquired HCV in the general population that had IDU as their major risk factor (newly acquired HCV is defined as newly diagnosed HCV with laboratory or clinical evidence of acquisition in the 24 months prior to diagnosis).[11]

Table 7 Comparison between HCV-positive blood donors and general population in Australia by major potential risk categories, 2021

	HCV	
Major risk category	Newly acquired HCV cases in general population (2021) (%)	Blood donors (2021) (%)
Injecting drug use	20.8	32.1
Country of birth/Ethnicity	0	7.4
Sexual contact[1]	0.3	10.0
Blood or tissue recipient	0.1	4.9
Tattoo or body piercing	0.0	11.1
Exposure in health care setting	0.0	2.5
Household contact/Family history	0.0	2.5
Other blood to blood contact	0.1	2.5
Undetermined/unknown/not reported	0	20.9
Imprisonment	64.8	2.5
Occupational risk	0.0	1.2
Other	0.0	2.5
No risk factor Identified	14.8	0.0

1 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

Conclusion

- HCV prevalence among first time blood donors in 2021 was the highest since 2012. However, during 2012-2021, no significant trend was observed. Higher rates since 2018 may be explained in some part at least by donors with 'cured' HCV, or with IDU more than 5 years ago, donating. As such donors have long standing infection, they do not substantially contribute to any increase in the risk of HCV transfusion transmission.
- HCV prevalence among first-time donors in 2021 and for the period 2012-2021 was 5 and 15 times lower among first-time blood donors than the general population estimates in 2021, and for the period 2012-2021, respectively.
- HCV incidence, the best correlate of transfusion-transmission risk, has not shown a significant trend in the five-year study period 2017-2021. It remains 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.
- Putative risk factors identified in blood donors with HCV infection in 2021 are likely different to those for the general population due to a potential increase in HCV testing in prisons since the availability of treatment.

Human Immunodeficiency Virus (HIV)

Epidemiology of HIV in Australia

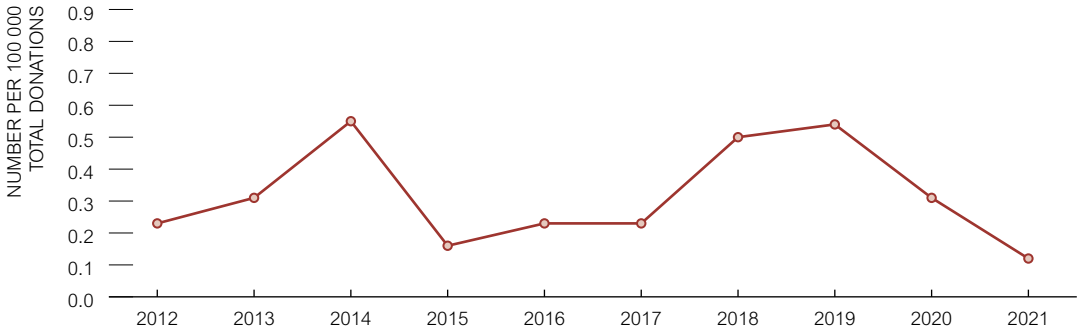
During 2021, an estimated 29 460 people were living with HIV and an estimated majority (91%) or 26 830 were diagnosed.[1] Transmission of HIV in Australia continues to occur primarily through sexual contact between men, with 68% of newly acquired cases of HIV in Australia in the period 2012 to 2021 involving men who reported sexual contact with men (including those reporting male-to-male sex and injecting drug use). The annual number of new HIV diagnoses (first ever in Australia) has decreased by 43% over the past five years, from 961 diagnoses in 2017, to 552 in 2021. Of those newly diagnosed HIV in 2021, 88% were in men, 60% occurred among men who have sex with men, 8% due to male-to-male sex and injecting drug use, 27% were attributed to heterosexual sex, and 1.6% 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.[1]

Trends in prevalence

All donations:

In the past ten years, 2012-2021, a total of 44 HIV-positive donors have been detected (21 first-time donors & 23 repeat donors) (Table 1A). During this period, no significant trend was observed in HIV prevalence among all donations (IRR: 0.99; 95% CI: 0.90-1.10). Overall, the prevalence has fluctuated within a tight range in the past ten years between 0.1-0.5 per 100 000 donations (Figure 21). For detail on the number and prevalence rate of HIV among all donations for 2021, see Supplementary Table 2.

Figure 21 **HIV prevalence in all blood donations in Australia, 2012-2021, by year of donation**

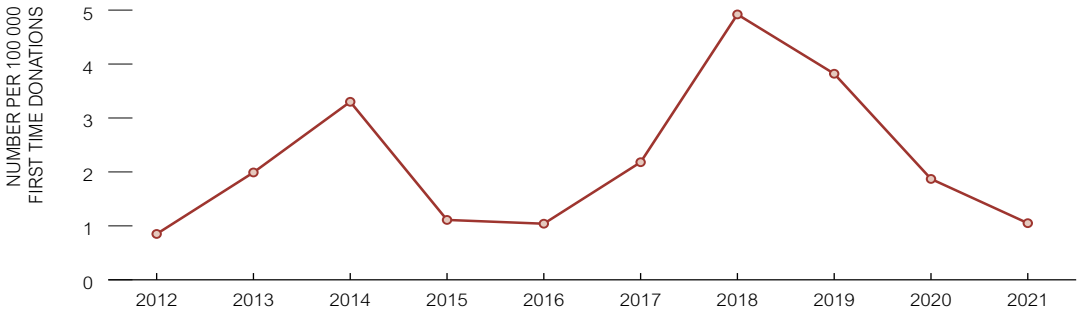


	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021
Prevalence in all donations	0.23	0.31	0.55	0.16	0.23	0.23	0.50	0.54	0.31	0.12

First-time donors:

HIV prevalence in first-time donors remained very low at 2.1 per 100 000 over the ten-year period 2012-2021 (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 and 1.0 in 2020 and 2021, respectively (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: 0.90-1.21). In comparison, the number of newly diagnosed HIV in the general Australian population decreased by 48%, from 1 068 diagnoses in 2012 to 552 cases of newly diagnosed HIV in Australia in 2021.[1] The annual number of new HIV cases has been declining in Australia since 2015, thanks to a combination of prevention measures, including sustained community-led responses, increased testing and treatment strategies and high uptake of the HIV prevention medication PrEP. While a downward trajectory of cases was occuring before 2020, the sharp decline of 38% seen in 2021 as compared to 2019 was most likely influenced by the COVID-19 pandemic. With COVID-19 social restrictions in place, there is evidence of a decrease in testing, a decrease in casual sexual partners, as well as a decrease in travel in and out of Australia.[13]

Figure 22 HIV prevalence in first-time blood donors in Australia, 2012-2021, by year of donation

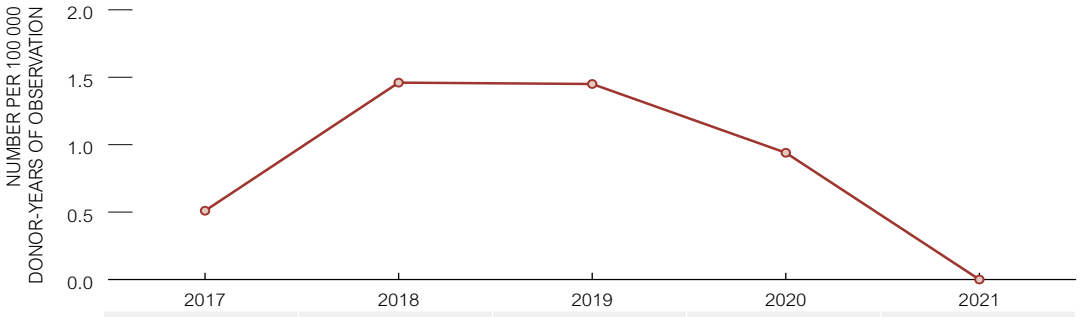


	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021
Prevalence in first-time donors	0.85	1.99	3.30	1.11	1.04	2.18	4.92	3.82	1.87	1.05

Trends in incidence

For the first time in the past five years, there was no incident HIV donor detected in 2021 (Figure 23). For the five years 2017-2021, there were a total of nine incident donors identified for HIV, and no significant trend was observed for HIV incidence during this time (IRR: 0.81; 95% CI: 0.51-1.29). While not directly comparable, the HIV incidence during 2017-2021 among gay and bisexual men attending sexual health services remained less than 0.2 per 100 persons years (fluctuating between 0.09 per 100 person years to 0.15 per 100 person years).[1]

Figure 23 Incidence of HIV in repeat blood donors in Australia, 2012-2021, by year of donation



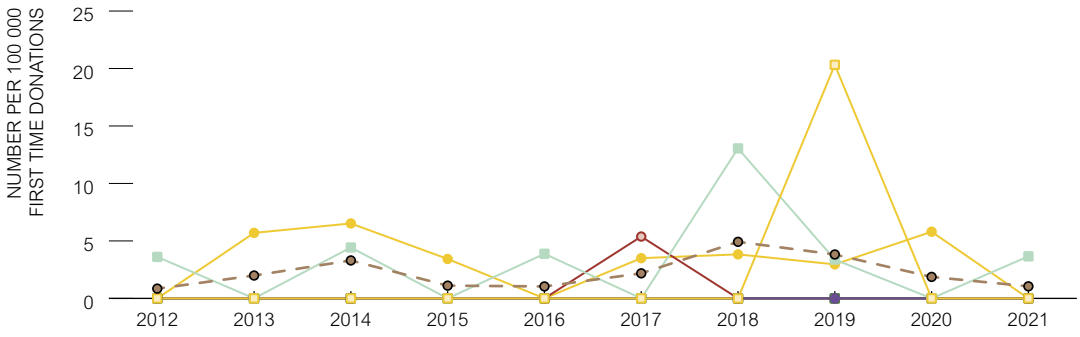
	2017	2018	2019	2020	2021
Incidence	0.51	1.46	1.45	0.94	0.00

No transfusion-transmitted HIV cases were reported in Australia during 2012-2021.

Trends in HIV by state/territory

HIV prevalence in first-time donors remained substantially lower than for HBV and HCV throughout the 2012-2021 period, with an average national prevalence of 2.1 per 100 000 donations (Table 1A). No significant annual trend was observed during the 2012-2021 period in any jurisdiction (Figure 25). There was only one HIV-positive first-time donor in 2021, from Victoria, where the HIV prevalence in first-time donors was at 3.6 per 100 000 donations (Figure 24). Given small numbers, caution should be taken in interpretation. During 2012-2021, HIV prevalence in first-time donors was zero in the Northern Territory, South Australia and Tasmania (Table 1A and Figure 24).

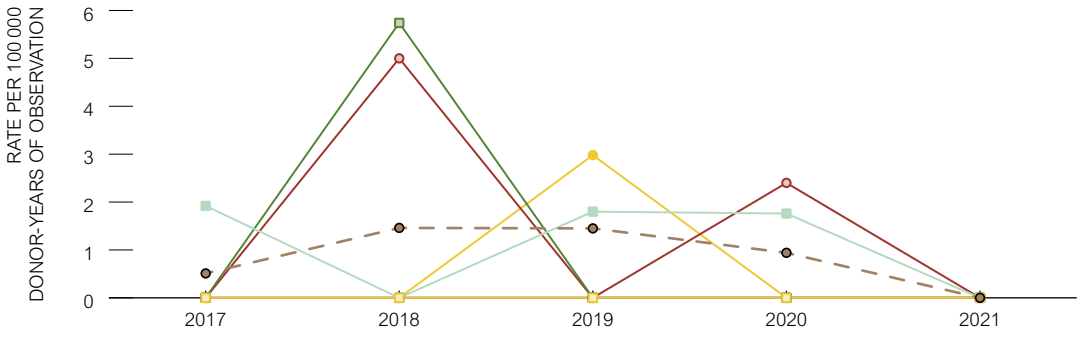
Figure 24 HIV prevalence among first time donors by state/territory and year of donation, 2012-2021



	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021
NSW/ACT	0.00	5.70	6.52	3.43	0.00	3.50	3.83	2.96	5.80	0.00
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	0.00	0.00	0.00	5.38	0.00	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	3.61	0.00	4.43	0.00	3.88	0.00	13.05	3.38	0.00	3.66
WA	0.00	0.00	0.00	0.00	0.00	0.00	0.00	20.32	0.00	0.00
National	0.85	1.99	3.30	1.11	1.04	2.18	4.92	3.82	1.87	1.05

In 2021, there were no HIV incident donors. No incident HIV donors were recorded in Tasmania, Western Australia or the Northern Territory in the past five years, 2017-2021 (Figure 25). No significant annual trend was observed in any jurisdiction during 2017-2021.

Figure 25 Incidence of HIV among repeat donors by state/territory and year of donation, 2017-2021



	2017	2018	2019	2020	2021
NSW/ACT	0.00	0.00	2.98	0.00	0.00
NT	0.00	0.00	0.00	0.00	0.00
QLD	0.00	5.00	0.00	2.40	0.00
SA	0.00	5.74	0.00	0.00	0.00
TAS	0.00	0.00	0.00	0.00	0.00
VIC	1.92	0.00	1.80	1.76	0.00
WA	0.00	0.00	0.00	0.00	0.00
National	0.51	1.46	1.45	0.94	0.00

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 for a combined period of 2012-2021 and then 2021 separately. 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.[6, 7] Prevalence in first-time donors was 52 times lower for the period 2012-2021, and 109 times lower in 2021 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, 2021 and 2012-2021

TTI	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	
	2012-2021	2021	2012-2021	2021	2012-2021	2021
HIV	112	114	2.15	1.05	52 times lower	109 times lower

* The 2021 HIV prevalence in the general population was calculated by taking the estimated number of people living with HIV,[1] and dividing it by the estimated mid-year resident Australian population in 2021 reported by the Australian Bureau of Statistics. For the period 2012-2021, an average of the ten years' prevalence rates was calculated. Due to updated modelling methods for calculating estimated number of people living with HIV, estimates may be different from those presented in previous years of reporting

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 2021, and the five-year period, 2017-2021, 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 2021, there was no significant association between gender, age or state/territory and HIV-positivity (Supplementary Table 4). During the five-year period 2017-2021, female donors, and donors between 30-39 years, 40-49 years and 50-years-and-above age groups were 79%, 69%, 81% and 68% 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

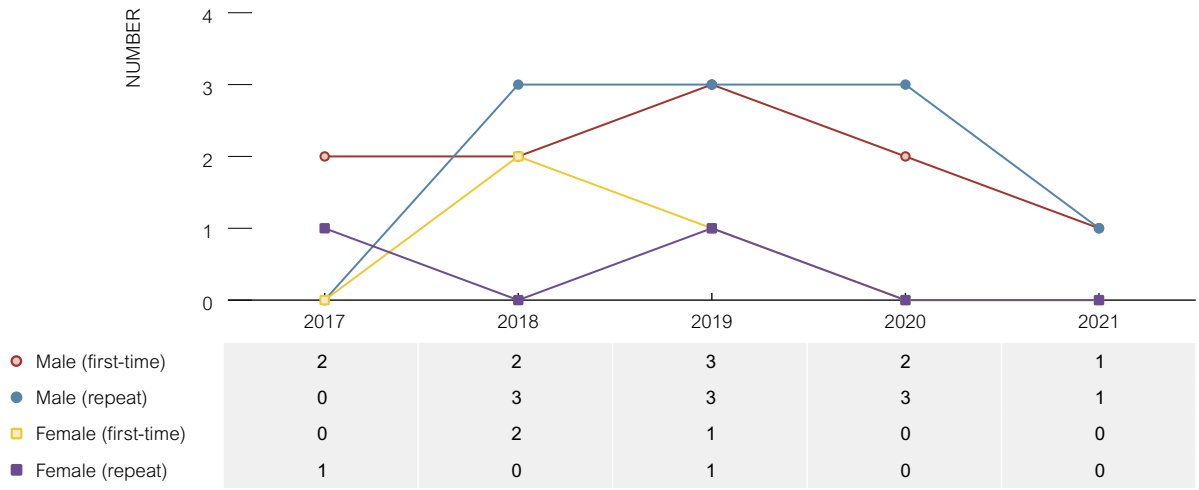
During 2017-2021, 52% of the 25 HIV-positive donors were first-time donors (Table 9). Most donors were male (80%) and had a mean age of 36 years, with a wide range of 20-70 years. Of 25 HIV-positive donors in the five-year period 2017-2021, nine were incident HIV donors. Having a sexual partner with unspecified risk for HIV was the most common reported risk factors for HIV-positivity in blood donors during 2017-2021 (32%), followed by male-to-male sexual contact and having a sexual partner with known risk or known to be positive for HIV (24%, each). In comparison, male-to-male sexual contact and heterosexual contact accounted for 60% and 27% of the new HIV diagnoses in the general population in 2021, respectively.

Table 9 Characteristics of HIV-positive donors by year of donation, 2017-2021

Characteristics	2017	2018	2019	2020	2021	2017-2021
Number of positive donors	3	7	8	5	2	25
Number of positive first-time donors (%)	2 (67%)	4 (57%)	4 (50%)	2 (40%)	1 (50%)	13 (52%)
Number of male donors (%)	2 (67%)	5 (71%)	6 (75%)	5 (100%)	2 (100%)	20 (80%)
Mean age (range) in years	36 (24-57)	32 (20-66)	37 (21-70)	38 (25-67)	44 (30-58)	36 (20-70)
Number of incident donors	1	3	3	2	0	9
Number of donors born in Australia (%)	2 (67%)	2 (29%)	4 (50%)	2 (40%)	1 (50%)	11 (44%)
Main reported risk factor	PRP[2]	MSM[1] contact	MSM[1], PRP[2], PUSR[3], undetermined each	PUSR[3]	PUSR[3]	PUSR[3]
	100%	43%	25%	40%	100%	32%
Second reported risk factor	…	PUSR[3], undetermined each	…	MSM[1], PRP[2], undetermined each	…	MSM[1], PRP[2]
		29%		20%	…	24%

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, 2017-2021



	2017	2018	2019	2020	2021
Male (first-time)	2	2	3	2	1
Male (repeat)	0	3	3	3	1
Female (first-time)	0	2	1	0	0
Female (repeat)	1	0	1	0	0

Over the past five years, 2017-2021, no discernible overall trend was seen in repeat or first-time male and 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 2017-2021, 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 2021, the majority of newly diagnosed HIV in the general population was attributed to sexual contact (87%).[1] This is consistent with the findings among blood donors, where sexual contact was identified as the primary risk factor for 100% of the positive donors.

Table 10 Comparison between HIV-positive blood donors and general population in Australia by major potential risk categories, 2021

		HIV[1]
Major risk category	**Newly diagnosed HIV cases in general population (2021) (%)**	**Blood donors (2021) (%)**
Injecting drug use[2]	9.6	0.0
Country of birth/Ethnicity	0.0	0.0
Sexual contact[3]	86.9	100.0
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	3.4	0.0
Imprisonment	0.0	0.0
Occupational risk	0.0	0.0
Other	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 among first-time blood donors was the lowest since 2012 and 109 times lower than in the general population in 2021, and 52 times lower for the period 2012-2021.
- 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 2021.

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.[14, 15] 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.[16-18] 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.[19]

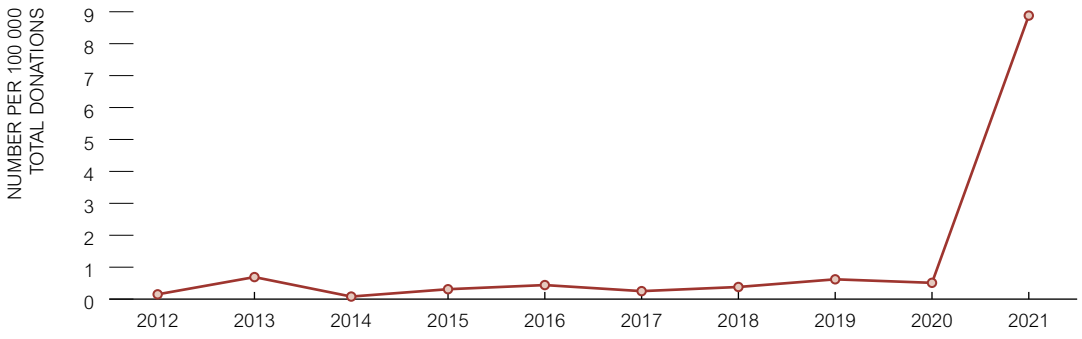
Trends in prevalence

All donations:

From September 2016 to December 2020, repeat donors donating plasma for fractionation only no longer required testing for HTLV; and from December 6, 2020, repeat donors no longer require testing for HTLV, irrespective of the type of donation. This results in a different test denominator for the 2020 and 2021 TTI reports, a point that needs due consideration when assessing recent trends. Of note, some repeat / lapsed donors are still being tested for HTLV if: a) they are giving a donation that will be made into a granulocyte component, which is very rare; b) they are returning after being deferred for contact with an HTLV-positive sexual partner; and c) they were deemed ineligible and prevented from donating due to their previous testing results (equivocal /indeterminate/ false positive). They then go through a sample-only process with additional testing. Their results are then reviewed by medical staff, and they can proceed to donation if their results are considered acceptable.

In the past ten years, 2012-2021, a total of 44 HTLV-positive donors have been detected (40 first-time donors and four repeat donors) (Table 1B). During the period 2012-2021, the overall HTLV prevalence among all donations was 0.46 per 100 000 donations (Table 1B) and, for the first time, has shown a statistically significant upward trend (IRR: 1.23; 95% CI: 1.10-1.38) (Figure 27). The rate slightly increased from 0.15 per 100 000 donations in 2012 to 0.44 and 0.51 per 100 000 donations in 2016 and 2020, respectively, however a sharp increase was observed in 2021 where the rate went up to 8.8 per 100 000 donations. This increase in the rate in all donations should be interpreted with caution as although there was an increase in the total number of positive donors (nine - the highest since 2013), the major reason for this increase is a smaller denominator in 2021 composed almost entirely of first-time donors (101 408 versus ~0.95 million average annual donations tested for HTLV for the 2012-2020 period). Thus, it is not appropriate to compare the prevalence among all donations, as the mix of tested donors has changed substantially. Comparison therefore should be restricted to first time donations (see below). For detail on the number and prevalence rate of HTLV-positive donors among all donations for 2021, see Supplementary Table 3A.

Figure 27 HTLV prevalence in all blood donations in Australia, 2012-2021, by year of donation

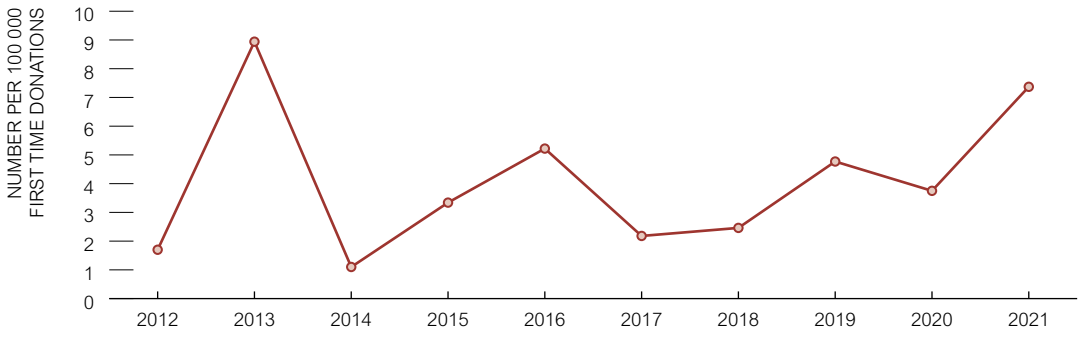


	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021
Prevalence in all donations	0.15	0.69	0.08	0.31	0.44	0.25	0.38	0.62	0.51	8.88

First-time donors:

HTLV prevalence in first-time donors remained low over the past ten years, 2012-2021 with an overall rate of 4.1 per 100 000 donations and has shown no significant trend (Table 1B) (IRR: 1.04; 95% CI: 0.93-1.15). 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 HTLV prevalence in first-time blood donors in Australia, 2012-2021, by year of donation



	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021
Prevalence in first-time donors	1.70	8.94	1.10	3.34	5.22	2.18	2.46	4.77	3.75	7.37

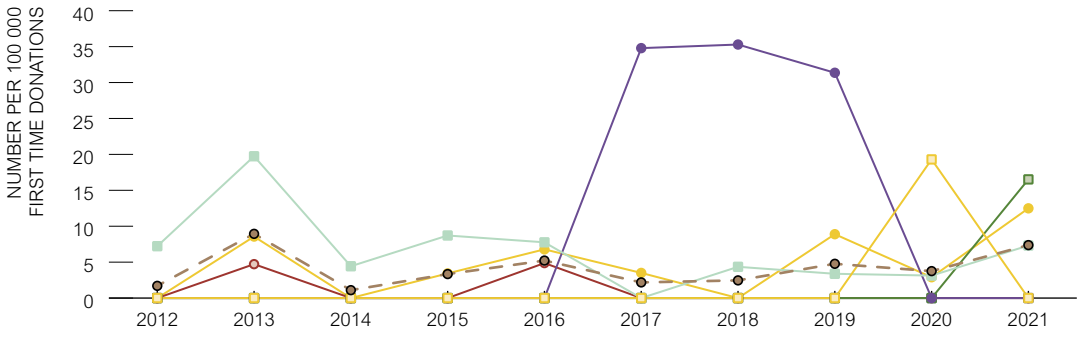
Trends in incidence

No incident donors have been identified since 2004. Given so few repeat donors are now tested for HTLV, it is no longer appropriate to derive an incidence rate from tested repeat donors. Lifeblood has derived a calculation method to indirectly derive the incidence from prevalence in first-time donors. A risk threshold for repeat donors was investigated based on previous modelling and a conservative ratio between prevalent and incident infections. It was estimated that 26 infections per 100 000 new-donor donations would be associated with an incidence in repeat donors approaching the tolerable risk threshold if sustained over several years.[20] Lifeblood intends to monitor HTLV prevalence, and trigger risk assessment should it exceed the threshold. No transfusion-transmitted HTLV cases were reported in Australia during 2012-2021.

Trends in HTLV-positivity by state/territory

In 2021, HTLV prevalence in first-time donors was the highest in South Australia, at 16.52 per 100 000 donations (after remaining at zero during the 2012-2020 period), followed by New South Wales / Australian Capital Territory and Victoria where the prevalence was 12.49 and 7.31 per 100 000 donations, respectively (Figure 30). For all other states, HTLV prevalence in first-time donors was zero in 2021. Caution should be taken in interpretation of HTLV prevalence in first-time donors in South Australia as this rate equates to only one positive donor. No significant trend was observed for prevalence in first-time donors during the period 2012-2021 in any jurisdiction. HTLV prevalence in first-time donors has remained zero in the Northern Territory during the ten-year study period, 2012-2021 (Figure 29).

Figure 29 HTLV prevalence among first time donors by state/territory and year of donation, 2012-2021



	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021
NSW/ACT	0.00	8.56	0.00	3.43	6.78	3.50	0.00	8.89	2.90	12.49
NT	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
QLD	0.00	4.72	0.00	0.00	4.87	0.00	0.00	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	16.52
TAS	0.00	0.00	0.00	0.00	0.00	34.79	35.29	31.36	0.00	0.00
VIC	7.22	19.74	4.43	8.71	7.76	0.00	4.35	3.38	3.13	7.31
WA	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	19.3	0.00
National	1.70	8.94	1.10	3.34	5.22	2.18	2.46	4.77	3.75	7.37

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 2021, and the five-year period, 2017-2021, 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 2021, there was no significant association between gender, donors' age group or location and HTLV-positivity (Supplementary Table 4). Similarly, during the five-year period, 2017-2021, there was no significant association between gender, age or location and HTLV-positivity (Supplementary Table 5).

Risk factors associated with HTLV-positive donors

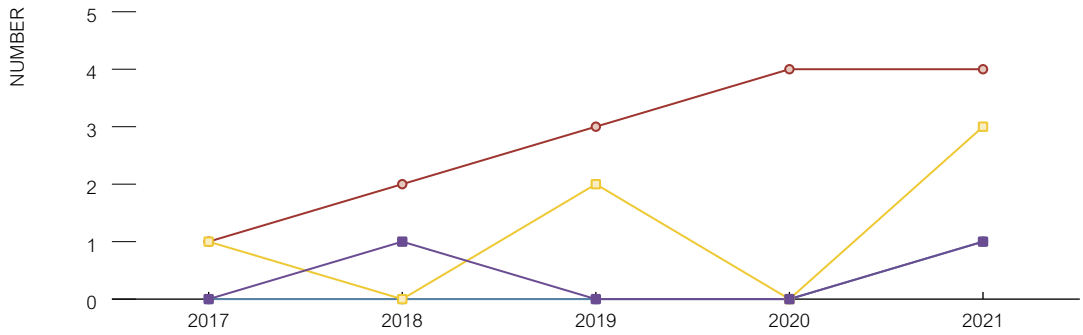
Only 23 HTLV-positive donors were detected during the 2017-2021 period; 20 (87%) were first-time donors, while three were repeat positive donors – one in 2018 and two in 2021, who did not meet the incident donor criterion; 65% were male, and the mean age was 43 years with a wide range (24-67 years) (Table 11). The majority of HTLV-positive donors (78%) were born overseas. Ethnicity or country of birth (65%) 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 (22%). 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 2017-2021. Of note, literature also identifies self-flagellation as a possible unique risk factor for HTLV.[21] 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.[22]

Table 11 Characteristics of HTLV-positive donors by year of donation, 2017-2021

Characteristics	2017	2018	2019	2020	2021	2017-2021
Number of positive donors	2	3	5	4	9	23
Number of positive first-time donors (%)	2 (100%)	2 (67%)	5 (100%)	4 (100%)	7 (78%)	20 (87%)
Number of male donors (%)	1 (50%)	2 (67%)	3 (60%)	4 (100%)	5 (56%)	15 (65%)
Mean age (range) in years	54 (44-64)	38 (26-54)	44 (32-60)	35 (27-41)	45 (24-67)	43 (24-67)
Number of incident donors	0	0	0	0	0	0
Number of donors born in Australia (%)	1 (50%)	1 (33%)	2 (40%)	1 (25%)	0 (0%)	5 (22%)
Main reported risk factor	Ethnicity/COB[1] 50%	Ethnicity/COB[1] 67%	Ethnicity/COB[1] 40%	Ethnicity/COB[1] 100%	Ethnicity/COB[1] 67%	Ethnicity/COB[1] 65%
Second reported risk factor	PRP[2] 50%	PRP[2] 33%	PRP[2], PUSR[3], Other each 20%	…	PRP[2] 22%	PRP[2] 22%

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, 2017-2021



	2017	2018	2019	2020	2021
Male (first-time)	1	2	3	4	4
Male (repeat)	0	0	0	0	1
Female (first-time)	1	0	2	0	3
Female (repeat)	0	1	0	0	1

During the past five years, 2017-2021, there was an upward trend in the number of HTLV-positive first-time male and female donors. No discernible overall trend has been observed for repeat male or female donors (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 2021 and period 2017-2021, 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.[23] 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.[24] This is consistent with the finding that ethnicity or country of birth was the likely exposure risk in 67% HTLV-positive donors in 2021.

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.

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Potentially Infectious Syphilis (PIS)

Epidemiology of infectious syphilis in Australia

Potentially infectious syphilis (PIS) is a blood safety definition designed to capture donors that have a theoretical risk of transmitting syphilis by transfusion. Importantly, the risk of syphilis transfusion-transmission is quite distinct from the viral TTIs. Storage of blood products reduces the transmission risk; red cell storage at <20°C for >120 hours inactivates *T. pallidum* spirochaetes (the causative agent),[25] plasma stored at -20°C for 48 hours was shown to be non-infectious in an animal model,[26] and oxygen flow levels in platelet storage bags are believed to be toxic to *T. pallidum*.[27] 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).[28] 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[29]). 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[30]). Of note, an expanded infectious syphilis national case definition was implemented in 2015, which includes 'probable' infectious syphilis (to capture infectious syphilis cases in people without prior testing history). This new subcategory is included in the number of infectious syphilis notifications since 2015.[30] Although the PIS and infectious syphilis definitions are slightly different, this section provides information on the epidemiology of infectious syphilis in Australia to provide a context for the report.

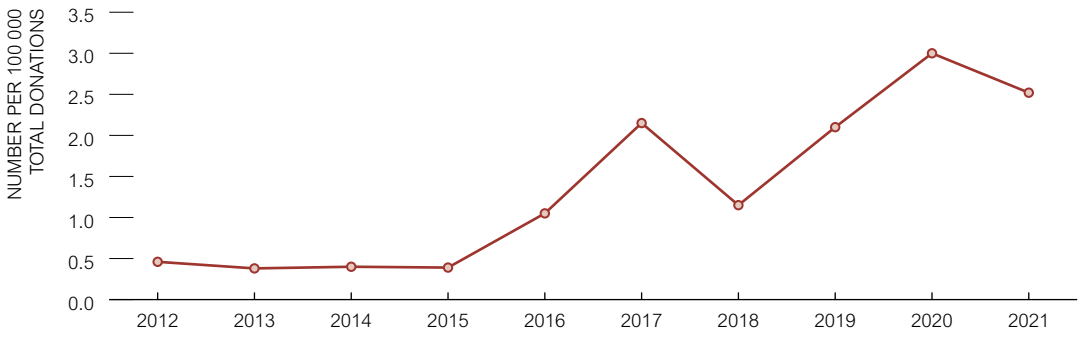
Infectious syphilis in Australia was primarily an infection of men having male to male sex in urban settings, and of heterosexual Aboriginal and/or Torres Strait Islander people in remote and outer regional areas, however the epidemiology has changed with expansion beyond these subgroups with an increase observed in females and heterosexual males. The number of cases of infectious syphilis notified in 2021 was 5570.[1] The notification rate of infectious syphilis tripled from 6.7 to 23.9 per 100 000 between 2012 and 2019, followed by a 5% decline between 2019 and 2021 to 22.7 per 100 000. This decline between 2019-2021 is likely a reflection of decreased testing rates related to the ongoing COVID-19 pandemic. Notification rates among males remained higher than females for the entire 2012-2021 period.[1]

Trends in prevalence

All donations:

According to the revised testing panel for plasma for fractionation in repeat donors, syphilis testing is not required, resulting in fewer donations screened for syphilis, and therefore the impact of this needs due consideration when assessing recent trends. Notwithstanding this, in the past ten years, 2012-2021, a total of 123 donors with PIS/active syphilis have been detected (45 first-time donors and 78 repeat donors) (Table 1C). During the period 2012-2021, the prevalence of PIS/active syphilis among all donations remained very low at 1.1 per 100 000 donations (Table 1C); however, the prevalence in all donations has increased substantially in recent years from ~0.5 per 100 000 donations in 2012 to 2.1 in 2019, 3.0 in 2020 and 2.5 per 100 000 donations in 2021. As a result, a significant increase in the prevalence of PIS/active syphilis among all donations was observed during 2012-2021 (IRR 1.27; 95% CI: 1.19-1.36) (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 2021, see Supplementary Table 3B.

Figure 31 Prevalence of PIS/active syphilis in all blood donations in Australia, 2012-2021, by year of donation

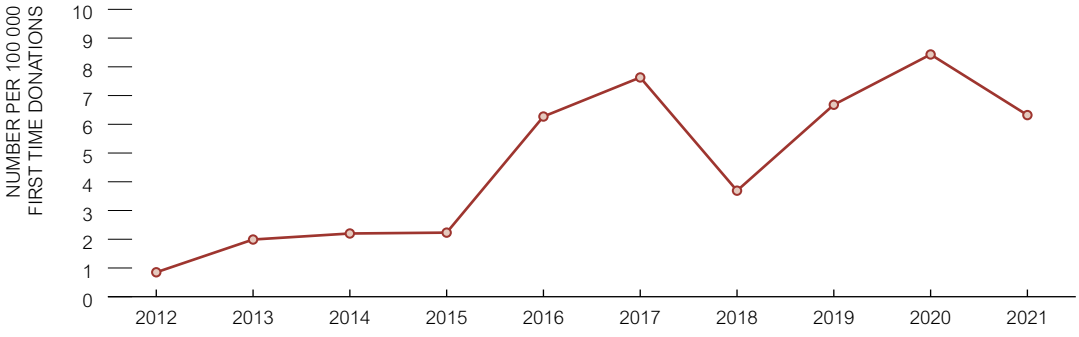


	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021
Prevalence in all donations	0.46	0.38	0.40	0.39	1.05	2.15	1.15	2.10	3.00	2.52

First-time donors:

In the ten years, 2012-2021, the prevalence of PIS/active syphilis in first-time donors was 4.6 per 100 000 donations (Table 1C). Overall, the prevalence of PIS/active syphilis in first-time donors showed a significant upward trend during 2012-2021 (IRR: 1.18; 95% CI: 1.06-1.32) (Figure 32). In 2021, the rate was 6.3 as compared to 8.4 per 100 000 first-time donations in 2020, which was 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 6.7 per 100 000 population in 2012, which tripled to 23.9 per 100 000 in 2019 before slightly reducing to 22.7 in 2021.[1] Caution should be taken in interpretation, as the infectious case definition changed in July 2015, to include more cases of likely recent acquisition.[30]

Figure 32 **Prevalence of PIS/active syphilis in first-time blood donors in Australia, 2012-2021, by year of donation**

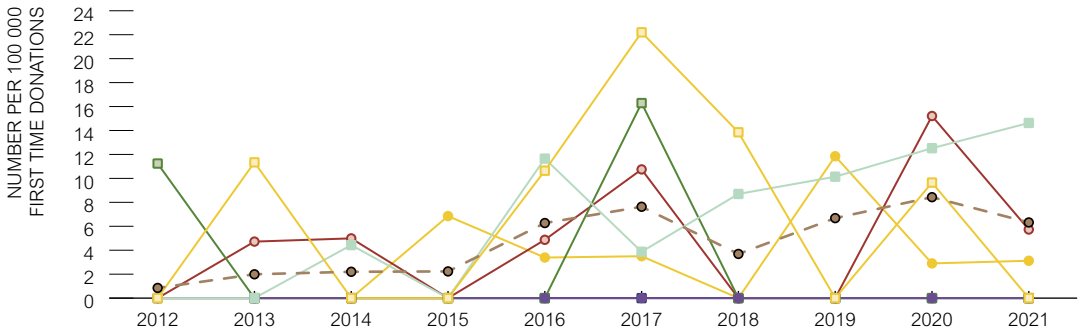


	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021
Prevalence in first-time donors	0.85	1.99	2.20	2.23	6.27	7.63	3.69	6.68	8.43	6.32

Trends in PIS/active syphilis by state/territory

In 2021, PIS/active syphilis prevalence in first-time donors was zero for the Northern Territory, South Australia, Tasmania and Western Australia. The prevalence rate in first-time donors was the highest in Victoria at 14.6 per 100 000 donations, followed by Queensland and New South Wales / the Australian Capital Territory where rates were 5.7 and 3.1 per 100 000 first-time donations, respectively (Figure 33). Prevalence in first-time donors in Northern Territory and Tasmania remained zero over the 2012-2021 period. There were no significant trends observed in most jurisdictions during 2012-2021, except for Victoria, where prevalence in first-time donors showed a significant upward trend (IRR: 1.31 95% CI: 1.08-1.60). In comparison, infectious syphilis rates were the highest in the Northern Territory in 2021, at 85.3 per 100 000.[1] The trend in the general population over during the period 2012-2019, showed an increase in rates of diagnosis of infectious syphilis in all jurisdictions, except Tasmania, followed by declines in most states and territories between 2019-2021, except for South Australia and Western Australia.[1]

Figure 33 **Prevalence of PIS/active syphilis among first time donors by state/territory and year of donation, 2012-2021**



	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021
NSW/ACT	0.00	0.00	0.00	6.85	3.39	3.50	0.00	11.85	2.90	3.12
NT	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
QLD	0.00	4.72	4.99	0.00	4.87	10.75	0.00	0.00	15.21	5.73
SA	11.24	0.00	0.00	0.00	0.00	16.29	0.00	0.00	0.00	0.00
TAS	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
VIC	0.00	0.00	4.43	0.00	11.65	3.87	8.70	10.14	12.52	14.63
WA	0.00	11.34	0.00	0.00	10.64	22.2	13.85	0.00	9.65	0.00
National	0.85	1.99	2.20	2.23	6.27	7.63	3.69	6.68	8.43	6.32

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 2021 and the ten-year study period 2012-2021 was 6.32 and 4.62 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.[1] 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 2021, and the five-year period, 2017-2021, 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 2021, female donors were significantly less likely (69%) compared to male donors to be classified as PIS (Supplementary Table 4). Donors in 50-years-and-above group were less likely (94%) to be positive with PIS/active syphilis as compared to the reference group of 20-29 years. No significant trend was observed between donors' state of residence and PIS/active syphilis positivity.

During the five-year period, 2017-2021, female donors were 75% less likely to be PIS/active syphilis positive as compared to male donors. Donors between 30-39 years, 40-49 years and 50-years-and-above age groups were 42%, 71% and 86% less likely to be PIS/active syphilis positive, 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

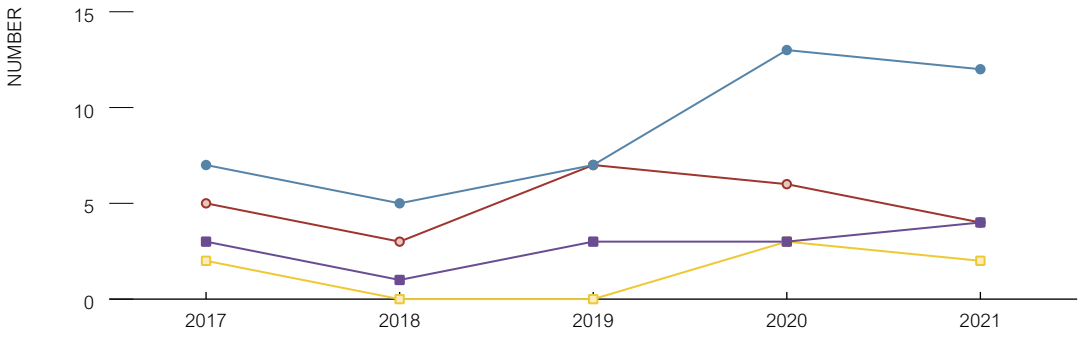
During 2017-2021, a total of 90 donors were classified as PIS/active syphilis positive, 32 (36%) were first-time donors, 69 (77%) were male, and 57 (63%) were born in Australia (Table 12). The mean age was 33 (range 19-66). Partner with unspecified risk (41%) was the most frequent likely risk factor for PIS/active status. In comparison, in 2021, nationally, 81% of infectious syphilis diagnoses were in males, and 53% were in people aged 20 – 39 years.[1]

Table 12 Characteristics of PIS/active syphilis-positive donors by year of donation, 2017-2021

Characteristics	2017	2018	2019	2020	2021	2017-2021
Number of positive donors	17	9	17	25	22	90
Number of positive first-time donors (%)	7 (41%)	3 (33%)	7 (41%)	9 (36%)	6 (27%)	32 (36%)
Number of male donors (%)	12 (71%)	8 (89%)	14 (82%)	19 (76%)	16 (73%)	69 (77%)
Mean age (range) in years	30 (19-51)	42 (25-63)	30 (21-42)	36 (20-66)	32 (19-66)	33 (19-66)
Number of donors born in Australia (%)	12 (71%)	7 (78%)	10 (59%)	10 (40%)	18 (82%)	57 (63%)
Main reported risk factor	PUSR[1]	PUSR[1]	MSM[2]	PUSR[1]	PUSR[1], undetermined each	PUSR[1]
	47%	56%	41%	48%	36%	41%
Second reported risk factor	PRP[2]/ Undetermined each	MSM[1]/ Undetermined each	PUSR[1]	Undetermined/ unknown	MSM[2]	Undetermined/ unknown
	18%	22%	24%	36%	23%	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, 2017-2021**



	2017	2018	2019	2020	2021
Male (first-time)	5	3	7	6	4
Male (repeat)	7	5	7	13	12
Female (first-time)	2	0	0	3	2
Female (repeat)	3	1	3	3	4

Over the past five years, 2017-2021, there has been an upward trend in the number of PIS/active syphilis positive repeat male donors (Figure 34). No discernible trend was observed in first-time male and 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 2021 and period 2017-2021, see Supplementary Tables 6-12.

Conclusion

- Overall, during 2012-2021, the prevalence of PIS/active syphilis among all blood donations and first-time blood donations has shown a significant upward trend. This trend parallels population data, with the caveat that reporting definitions are not equivalent.
- 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.

Additional information

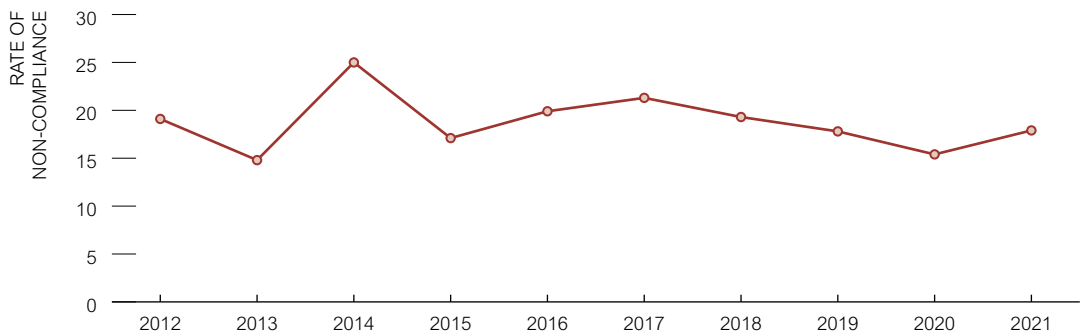
Screening compliance

Every donor is required to self-complete a comprehensive Donor Questionnaire (DQ) prior to each donation. The DQ for a plasma for fractionation donation omits some of the questions asked. Once the donor has completed the DQ, a Lifeblood staff member assesses the donor's eligibility to donate. All donors have to sign a legal binding declaration before the donor can donate and they are informed that fines and penalties apply for deliberate misinformation. Lifeblood is 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 (161/888) of TTI-positive donors in 2017-2021 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% (120 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 15-21%) after peaking at 25% in 2014 (Figure 35). The average rate observed in a previous Lifeblood study[6] for 2000-2006 was 22%.

Figure 35 Rate of reported non-compliance in TTI-positive donors, 2012-2021



	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021
Rate of non-compliance	19.1	14.8	25.0	17.1	19.9	21.3	19.3	17.8	15.4	17.9

Table 13 Non-compliance category and rate among donors who were positive for any transfusion-transmissible infection, 2017-2021

Non-compliance by year and reason for deferral	2017	2018*	2019*	2020	2021*	2017-2021
Number (%) of non-compliant donors by reasons for deferral						
Injecting drug use	9 (29.0%)	9 (31.0%)	7 (20.6%)	1 (3.1%)	4 (11.43)	30 (18.63)
Known status/previous positive^	16 (51.6%)	17 (58.6%)	17 (50.0%)	26 (81.3%)	31 (88.57)	107 (66.46)
Male-to-male-sexual contact	2 (6.4%)	4 (13.8%)	5 (14.7%)	2 (6.3%)	1 (2.86)	14 (8.7)
Partner with known risk or known to be positive	4 (12.9%)	3 (10.3%)	6 (17.6%)	3 (9.4%)	0 (0)	16 (9.94)
Others	0 (0)	1 (3.4%)	2 (5.9%)	0 (0)	1 (2.86)	4 (2.48)
Total number (%) of non-compliant donors by year	31 (21%)	29 (19%)	34 (18%)	32 (15%)	35 (18%)	161 (18%)

^ Includes people with a history of jaundice
* In these years, some donors had more than one reason for non-compliance hence the total % is more than 100%

Each year between 2017-2021 the most common risk behaviour identified was known status of previously being positive for a virus (including history of jaundice): 51.6% in 2017, 58.6% in 2018, 50.0% in 2019, 81.3% in 2020 and 88.5% in 2021. To some extent this might reflect an increasing number of returning/prospective donors with past HCV 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 2017-2021, 66.4% of non-compliance was attributed to known status of previously being positive for a virus followed by injecting drug use (18.6%) and having a sexual partner with known risk or known to be positive for any transfusion-transmissible infection (9.9%) (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 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.[31] More recent estimation indicates an increasing proportion of OBI risk, about 99% for the 2020-21 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*[32] led generally to lower estimates and standardised the method with HBV. Using viral testing data including the number of incident donors reported for the 2020 and 2021 calendar year periods and applying these to Lifeblood[32] and Weusten risk models, residual risk estimates[33] (per unit transfused) were derived for the four transfusion-transmissible viral infections subject to mandatory testing (Table 14). Of note, the HBV risk estimate include a separate model specifically addressing the risk of OBI.[34] The risk estimate for active syphilis is derived periodically with the most recent estimate being less than 1 in 49 million per unit transfused[28] 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 HBV, HCV, HIV, HTLV and syphilis in Australian blood donations (2020-2021)

	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 1.6 million donations collected per annum, less than one transfusion-transmission for the above-mentioned infectious agents (most likely HBV) would be predicted per annum. The lower reported frequency of cases of transfusion-transmission supports that the modelled estimates are conservative with no cases of transfusion-transmitted HCV reported in Australia since 1991, none for HTLV since universal testing commenced in 1993, none for HIV since 1998 and three probable cases of HBV in the 2005-2021 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.[35] 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 2021 were referred to their doctor with a copy of their results.

In 2021, 69 125 donations were tested for malaria antibody, substantially less than the 132 338 donations tested in 2020. This decline is due to decreased overseas travel by donors due to COVID-19 associated international border closures. Of the tested donations, 1 834 (2.7%) were repeatedly reactive for malaria antibodies. This rate is increased compared to the 1.6% for 2020, and due to a higher proportion of donors tested for malaria being former residents of malaria endemic countries who are at higher risk of having reactive malaria serology. No cases of transfusion transmitted malaria were reported in Australia in 2021 with the last recorded Australian case in 1991.[36] 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[37] and 1 in 500 000 for red cells.[38] 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.[39]

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,[40] this procedure had been previously shown to reduce the bacterial contamination of platelet concentrates by more than 70%.[41]

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.[42] 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 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.[43]

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

7. **Pre-transfusion platelet unit inspection**
   Lifeblood recommends that platelets issued to Australian health providers undergo a pre-transfusion visual inspection by the transfusing laboratory assessing for a number of characteristics including, but not limited to; platelet 'swirl', colour, presence of gas or fibrin strands. Non-conforming platelets should not be transfused, adding a further risk mitigation strategy.

8. **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.[44] Methods are available for platelets and plasma and are in late stage clinical trials for red cells, however there are currently no licensed technologies in Australia. Platelet components in Australia already carry low residual risk which, together with the low cost-effectiveness and potential adverse impacts on product quality associated with PI/PRT, makes implementation of this technology undesirable at this time.

Bacterial pre-release testing for platelets

Platelet concentrates are manufactured either directly by apheresis, or by pooling the buffy coats from four whole blood donations into a single platelet unit. Apheresis collections may be split into one, two or three platelet units. BCS samples are collected from the combined platelet volume prior to splitting, and 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).

From 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 2021 a total of 124 052 BCS samples were tested.

Of 101 098 pooled platelet units tested, 497 (0.49%) were flagged by the BacT/ALERT as initial machine positive. Of these, 149 (0.15%) were designated "confirmed positive", 91 (0.09%) were "indeterminate" and the remaining 258 (0.26%) were considered to be "false positive".

Of 22 954 apheresis collections tested, 114 (0.50%) were flagged by the BacT/ALERT as initial machine positive. Of the total apheresis collections tested, 12 (0.05%) were designated "confirmed positive", 19 (0.08%) were "indeterminate" and the remaining 83 (0.36%) were considered to be "false positive" (Table 15).

Table 15 Summary of bacterial testing of platelets by BacT/ALERT 3D and BacT/ALERT VIRTUO, 2021

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]	101 098 (81.49)	497 (0.49)	149 (0.15)	91 (0.09)	258 (0.26)
Apheresis platelets[v]	22 954 (18.51)	114 (0.50)	12 (0.05)	19 (0.08)	83 (0.36)
Total	**124 052 (100)**	**611 (0.49)**	**161 (0.13)**	**110 (0.09)**	**341 (0.27)**

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 161 confirmed positives, the most frequently isolated genera were *Cutibacterium* species, which were isolated from 137 samples (85.09%). Coagulase-negative staphylococci (CoNS) were isolated from 13 BCS samples (8.07%). *Cutibacterium* and CoNS cultured from 150 of the 161 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. *Bacillus* species was identified in two confirmed positive donations and most likely represent environmental contamination 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 9 (5.59%) 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.

Only one confirmed positive pool platelet component growing *Staphylococcus saccharolyticus* was transfused. All other associated components were recalled and discarded. The recipient remained asymptomatic with no adverse transfusion reaction and donors remained well. *Staphylococcus saccharolyticus* is a CoNS that is part of normal skin flora representing contamination and is unlikely to be clinically significant.

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[45]

There were two isolates of *Bacteroides* species and one unidentified Gram-negative anaerobic bacillus species that could not be confirmed on repeat culture and were classified as Indeterminate. Platelet components had been transfused in these three instances, but all three recipients remained well and no adverse transfusion reactions were observed. Donor follow up was performed and all the donors remained well and had no risk factors. 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).

There were no confirmed cases of transfusion-transmitted bacterial infection (TTBI) in 2021.

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 TTBI was 0.4 per 100 000 platelet units transfused.[40] This compares favourably with US data indicating a rate of 0.9 per 100 000 platelet units.[46] For red cells, the Australian Red Cross Blood Service (now Lifeblood) rate was similarly low at 0.04 per 100 000 transfused units.[40]

Table 16 Summary of confirmed positive contaminants from platelets, 2021 (n=161 BCS samples)

Confirmed positives: organism isolated	Number
Cutibacterium species	137
Coagulase-negative staphylococci	13
Enterococcus faecalis	1
Bacillus species	2
Serratia marcescens	1
Lactococcus lactis	1
Streptococcus agalactiae (Lancefield Group B)	2
Streptococcus dysgalactiae	1
Staphylococcus aureus	2
Streptococcus sanguinis	1
Total	161

Surveillance and risk assessment for emerging infections

Lifeblood maintains surveillance for emerging infections through close liaison with Australian Government communicable disease control units, CSL Behring, membership of international medical/infectious disease groups and active horizon scanning. Potential threats are regularly reviewed by Lifeblood's Donor and Product Safety Committee (DAPS Committee) and risk assessment performed if 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).

2020-2021 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 8 August 2021 to 7 August 2022, there were no reported cases of locally acquired dengue fever in Queensland.[47]	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 number of HAV infections in Australia decreased in 2020 and 2021. This downward trend in reported HAV cases has continued into 2022. For the 12-month period from 8 August 2021 to 7 August 2022, there 84 reported cases of HAV infection in Australia compared to an annual rolling average for the 5-year period 2015-20 of 245.8.[48] Modelling has previously demonstrated that even during local outbreaks and cases in returning travellers, HAV is a negligible risk to blood safety in Australia.	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 1–6 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 compared to Australia, the risk and cost-benefit in Australia, as documented in our risk assessment,[49] stands if the incidence in Australia has not appreciably changed. Similar to reported HAV cases, the number of reported HEV cases in Australia has decreased since the start of the COVID-19 pandemic. For the 12-month period 8 August 2021 to 7 August 2022, there were 9 reported HEV cases in Australia, compared to an annual rolling average for the 5-year period 2015-20 of 45.[48]	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.

Pathogen	Transfusion-transmission reported	Infectious risk period	Surveillance/Risk assessment	Additional risk management for blood safety
Japanese encephalitis virus (JEV)	Yes, there have been two reported transfusion-transmitted cases. Two recipients were infected by blood components from a single donor/donation.[50]	Most human JEV infections are asymptomatic. For symptomatic infections, the incubation period can vary from 5 to 15 days. Although data are limited, it appears that the viraemic period is typically brief and low level.[51]	Until 2022, human JEV virus cases were rarely reported in Australia and most were likely acquired overseas. In March 2022, JEV outbreaks were reported in piggeries in several states, along with reported human cases. Since the start of the outbreak to mid-August 2022, there had been 40 human cases in four states: 13 in NSW, 5 in QLD, 9 in SA, 12 in VIC and 1 in NT.[52] An internal Lifeblood risk assessment has indicated that the JEV risk to blood safety in Australia associated with the 2022 outbreak is negligible.[53]	Lifeblood defers donors who report encephalitis for 6 months from the date of recovery. Donors who have received a live JEV vaccine are deferred from donating fresh components for 4 weeks from date of vaccination.
Monkeypox virus (MPXV)	Transfusion transmission of MPXV has not been reported.	Most human MPXV infections are symptomatic, with symptoms typically lasting 2–5 weeks. The incubation period following infection can vary from 4 to 21 days but is usually between 5–13 days. Although data are limited, detection of MPXV DNA in peripheral blood (DNAaemia) has been reported[54] but this has not been confirmed to be live virus.	Prior to 2022, human mpox was rarely reported outside Africa. In May 2022, a mpox outbreak in historically non-endemic countries was reported. The WHO declared the outbreak a Public Health Emergency of International Concern (PHEIC) on 23 July. The outbreak has now become the largest reported human mpox outbreak. As of 23 August 2022, there had been 44 503 confirmed cases globally (reported new cases numbers were declining globally by this time), of which 44 116 cases had been reported in 89 countries that have not historically reported human mpox. Countries reporting highest case numbers were the US (15 908 cases), Spain (6 284), Brazil (3 788), Germany (3 329), UK (3 207) and France (2 889). In a number of these countries, particularly those reporting high case numbers, there is evidence of substantial local transmission.[55] Australia's Chief Medical Officer declared the mpox outbreak a Communicable Disease Incident of National Significance on 26 July 2022. As of 20 October 2022, there were 140 cases (confirmed and probable) of mpox in Australia: 69 in Victoria, 54 in New South Wales, 7 in Western Australia, 5 In Queensland, 3 in the Australian Capital Territory, and 2 in South Australia.[56] MPXV is a negligible risk to blood safety.[57]	Lifeblood defers donors who have had a live smallpox (vaccinia) vaccine for 8 weeks. This would identify donors at risk of MPXV infection. In addition, Lifeblood performs ongoing surveillance of mpox outbreaks.
Primate erythroparvovirus 1 (B19V)	Yes, three probable cases of transfusion-transmission have occurred in recent years in Australia.	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. The risk to general recipients was negligible and less than 1 in 1 million.[58] 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 transfusion transmission of B19V, 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. 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.

Pathogen	Transfusion-transmission reported	Infectious risk period	Surveillance/Risk assessment	Additional risk management for blood safety
Ross River virus (RRV)	Yes, a single case in Australia has been reported.[59]	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 RRV transfusion-transmission case was reported in 2015, Lifeblood has completed a comprehensive risk assessment for RRV.[60] During the largest outbreak in Australia to date in 2015 (9 649 reported cases), 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. Since the 2015 outbreak, there have been two years with a high number of reported cases: 2017 (7 584 cases) and 2020 (6 159 cases). Reported RRV case numbers declined to 3 190 in 2021 and 2 387 cases were reported in 2022 to 7 August. Lifeblood continues to perform enhanced surveillance and to ensure extra awareness of the importance of post donation illness reporting in areas with significant outbreaks.	Lifeblood has a deferral for RRV. Donors are encouraged to notify Lifeblood if they become aware post-donation that they may have donated in the pre-symptomatic period. This ensures timely recall of the potentially at-risk donation.
Severe acute respiratory syndrome coronavirus (SARS-CoV-2)	Transfusion transmission of SARS-CoV-2, or other human coronaviruses, has not been reported and appears unlikely based on the following considerations. For symptomatic cases, the incubation period is relatively brief, typically between 3.5 to 7 days. Only a small proportion of COVID-19 patients have detectable SARS-CoV-2 RNA in blood (RNAaemia). The RNAaemiac 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 1–2 weeks post-symptom onset and rising antibody titres are associated with a decline in the level of plasma viral RNA.[61]	The associated disease is referred to as coronavirus disease 2019 (COVID-19). The incubation period is typically between 3 and 7 days but can vary between 1–14 days. Delta and Omicron variants typically have shorter incubation periods compared to other variants.[62] Human-to-human transmission, predominantly close contact through respiratory droplets, is the primary mode of transmission.	The first COVID-19 cases were reported in China in late 2019 and have been continuously reported globally since then. By mid-August 2022, WHO had reported almost 600 million confirmed cases globally since late 2019. The largest outbreak occurred between December 2021 and March 2022. In line with global trends, reported confirmed COVID-19 cases in Australia peaked in January 2022 when reported daily case numbers were over 100 000. By mid-August 2022, reported daily case numbers were approximately 15 000.[63, 64] During the course of the COVID-19 pandemic, SARS-CoV-2 has continued to mutate and a number of variants of concern have been recognised, some of which are more efficiently transmitted than previous variants. During the second half of 2021, the dominantly reported variant globally was the Delta variant, followed by the Omicron variant and subvariants from December 2021 to August 2022.[65, 66] A very high proportion of the Australian population has now been vaccinated against SARS-CoV-2. As of 22 August 2022, 96.2% of Australians 16 years or over had received at least two doses of a SARS-CoV-2 vaccine and 71.6% had received 3 doses.[67]	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. Donors with a current coronavirus infection are deferred for 7 days from date of recovery or, if asymptomatic, from date of positive test. Donors who are a suspected coronavirus case and waiting RT-PCR test results are deferred for 7 days from the date of testing.

Pathogen	Transfusion-transmission reported	Infectious risk period	Surveillance/Risk assessment	Additional risk management for blood safety
Abnormal prion protein (PrP^{res} or PrP^{Sc}) associated with variant Creutzfeldt-Jakob disease (vCJD)	Three human cases of vCJD associated with transfusion-transmission and one possible case 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 is not well defined. Estimates of the mean incubation period vary from 12.6 to 16.7 years. (95% CI, 12-23 years).[68, 69] 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. Recent modelling performed by Lifeblood and the Kirby Institute demonstrated a very low risk to blood safety in Australia associated with donors who were resident in or travelled to the UK between 1980 and 1996, the period associated with risk of exposure to BSE. The overall mean risk of contamination per unit was 1 in 29 900 000. The risks of resulting vCJD transmission (infection) and clinical case were 1 in 389 000 000 and 1 in 1 450 000 000, respectively. As a result of this study and with TGA approval, on 25 July 2022 Lifeblood removed the deferral for donors who have spent at least 6 months in the UK between 1 January 1980 and 31 December 1996.[70]	Donors who have received fresh blood products in the UK since 1980, those who have received fractionated plasma products in the UK between 1980 and 2001, and donors with vCJD are currently deferred (Lifeblood is gathering the evidence to apply to have these deferrals removed).
West Nile virus (WNV)	Yes, transmission of West Nile virus (WNV) by blood, tissue and organ transplantation has been documented.[71]	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,[51] WNV RNA becomes detectable 1–2 days post-infection followed by anti-WNV IgM and IgG approximately 8–11 days post-infection, respectively.[72]	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).[73] Lifeblood performed weekly risk modelling to estimate the risk of a donor returning from these countries and donating while infectious (i.e. viraemic). This modelling indicated that the additional level of risk to the Australian blood supply associated with donors returning from these countries during the 2018 WNV transmission season did not exceed the threshold (established for local dengue outbreaks) that requires cessation of fresh blood component manufacture. 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.[74]	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 (ZIKV)	Yes, at least four cases of probable transfusion-transmitted ZIKV infection were reported during the 2014-16 outbreak in the Americas.[75] However, adverse clinical outcomes from transfusion transmission has not been demonstrated as reported cases were asymptomatic.	Approximately 80% of ZIKV infections are asymptomatic and most symptomatic infections are accompanied by mild symptoms including rash and fever.[76] 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.[77]	Between 2014 to 2016, the largest ever reported Zika virus outbreak was reported in the Americas. However, in the latter part of 2016 the number of reported cases dramatically declined and only a small number of cases have been reported since that time. Local transmission of ZIKV has not been reported in Australia and only a relatively small number of imported cases have been notified, although there was a substantial increase in 2016.	Most countries that have reported autochthonous cases of ZIKV transmission are subject to donor travel deferrals related to either malaria, DENV or chikungunya virus (CHIKV). In addition, Lifeblood has a 4-month deferral from date of recovery for donors with a current ZIKV infection and a 4-week deferral from date of last contact for donors who have had sexual contact with someone infected with ZIKV.

Conclusion

- The reported non-compliance rate during the ten-year study period has fluctuated between 15%-25%. The rate highlights the importance of promoting donor education to ensure that the potential donors understand the importance of 'self-deferral' to reduce the risk of collecting blood from a potentially infected donor whose infection may not be detected by testing.
- While non-compliance among positive donors has been routinely monitored since 2000, the rate among TTI test-negative donors is more difficult to track. Results from a large national survey conducted in 2012-2013 showed a comparatively low rate of non-compliance (in the range 0.05 to 0.29%) among TTI test-negative donors for several sexual activity-based donor deferrals.
- The estimated residual risk of transmission for HIV, HCV, HBV, HTLV and syphilis are all less than 1 in 1 million per unit transfused, which is considered a 'negligible' risk.
- In 2021, 161 (0.13%) of a total 124 052 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 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 2021.
- 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 2021-2022. In addition, during 2022 a local outbreak of JEV and imported cases of mpox associated with a global monkeypox virus outbreak were monitored. Both outbreaks were assessed as a negligible risk to blood safety. Lifeblood also continues to monitor hepatitis A virus, HEV and B19V in Australia and a significant change in the risk profile has not occurred since the risk assessments were performed.

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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[28]
	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 1/2 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. Ulrio Plus assay replaced by Grifols/Hologic HIV-1/2/HCV/HBV Procleix Ultrio Elite assay in May 2021.

Supplementary Table 2 **The number and prevalence rate of TTI-positive donors (HBV, HCV and HIV) in Australia, by state/territory, 2021**

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	32 035	480 929	512 964	26	2	28	24	5	29	0	1	1	50	8	58
Number *(Number per 100 000 donations)*				*81.16*	*0.42*	*5.46*	*74.92*	*1.04*	*5.65*	*0.00*	*0.21*	*0.19*	*156.08*	*1.66*	*11.31*
NT	628	10 327	10 955	2	0	2	0	0	0	0	0	0	2	0	2
Number *(Number per 100 000 donations)*				*318.47*	*0.00*	*18.26*	*0.00*	*0.00*	*0.00*	*0.00*	*0.00*	*0.00*	*318.47*	*0.00*	*18.26*
QLD	17 458	284 579	302 037	6	0	6	8	4	12	0	0	0	14	4	18
Number *(Number per 100 000 donations)*				*34.37*	*0.00*	*1.99*	*45.82*	*1.41*	*3.97*	*0.00*	*0.00*	*0.00*	*80.19*	*1.41*	*5.96*
SA	6 055	122 608	128 663	4	0	4	6	1	7	0	0	0	10	1	11
Number *(Number per 100 000 donations)*				*66.06*	*0.00*	*3.11*	*99.09*	*0.82*	*5.44*	*0.00*	*0.00*	*0.00*	*165.15*	*0.82*	*8.55*
TAS	2 874	54 181	57 055	2	0	2	7	0	7	0	0	0	9	0	9
Number *(Number per 100 000 donations)*				*69.59*	*0.00*	*3.51*	*243.56*	*0.00*	*12.27*	*0.00*	*0.00*	*0.00*	*313.15*	*0.00*	*15.77*
VIC	27 345	410 526	437 871	30	4	34	18	5	23	1	0	1	49	9	58
Number *(Number per 100 000 donations)*				*109.71*	*0.97*	*7.76*	*65.83*	*1.22*	*5.25*	*3.66*	*0.00*	*0.23*	*179.19*	*2.19*	*13.25*
WA	8 521	144 884	153 405	6	1	7	3	0	3	0	0	0	9	1	10
Number *(Number per 100 000 donations)*				*70.41*	*0.69*	*4.56*	*35.21*	*0.00*	*1.96*	*0.00*	*0.00*	*0.00*	*105.62*	*0.69*	*6.52*
National	94 916	1 508 034	1 602 950	76	7	83	66	15	81	1	1	2	143	23	166
Number *(Number per 100 000 donations)*				*80.07*	*0.46*	*5.18*	*69.54*	*0.99*	*5.05*	*1.05*	*0.07*	*0.12*	*150.66*	*1.53*	*10.36*

Supplementary Table 3 The number and prevalence rate of TTI-positive (HTLV and potentially infectious syphilis) donors in Australia, by state/territory, 2021

Table 3A HTLV, by state/territory, 2021

State/Territory of donation	All accepted donations			HTLV		
	First time	Repeat	All	First time	Repeat	All
NSW/ACT	32 035	2 644	34 679	4	2	6
Number *(Number per 100 000 donations)*				*12.49*	*75.64*	*17.30*
NT	628	29	657	0	0	0
Number *(Number per 100 000 donations)*				*0.00*	*0.00*	*0.00*
QLD	17 458	980	18 438	0	0	0
Number *(Number per 100 000 donations)*				*0.00*	*0.00*	*0.00*
SA	6 055	454	6 509	1	0	1
Number *(Number per 100 000 donations)*				*16.52*	*0.00*	*15.36*
TAS	2 874	97	2 971	0	0	0
Number *(Number per 100 000 donations)*				*0.00*	*0.00*	*0.00*
VIC	27 345	1 840	29 185	2	0	2
Number *(Number per 100 000 donations)*				*7.31*	*0.00*	*6.85*
WA	8 521	448	8 969	0	0	0
Number *(Number per 100 000 donations)*				*0.00*	*0.00*	*0.00*
National	94 916	6 492	101 408	7	2	9
Number *(Number per 100 000 donations)*				*7.37*	*30.81*	*8.88*

Table 3B Potentially infectious syphilis, by state/territory, 2021

State/Territory of donation	All accepted donations			Potentially infectious syphilis		
	First time	Repeat	All	First time	Repeat	All
NSW/ACT	32 035	270 181	302 216	1	8	9
Number *(Number per 100 000 donations)*				*3.12*	*2.96*	*2.98*
NT	628	3 675	4 303	0	0	0
Number *(Number per 100 000 donations)*				*0.00*	*0.00*	*0.00*
QLD	17 458	145 219	162 677	1	4	5
Number *(Number per 100 000 donations)*				*5.73*	*2.75*	*3.07*
SA	6 055	56 543	62 598	0	0	0
Number *(Number per 100 000 donations)*				*0.00*	*0.00*	*0.00*
TAS	2 874	19 621	22 495	0	0	0
Number *(Number per 100 000 donations)*				*0.00*	*0.00*	*0.00*
VIC	27 345	214 136	241 481	4	4	8
Number *(Number per 100 000 donations)*				*14.63*	*1.87*	*3.31*
WA	8 521	67 917	76 438	0	0	0
Number *(Number per 100 000 donations)*				*0.00*	*0.00*	*0.00*
National	94 916	777 292	872 208	6	16	22
Number *(Number per 100 000 donations)*				*6.32*	*2.06*	*2.52*

Supplementary Table 4 Association of demographic characteristics with TTI-positive blood donors in Australia, 2021

		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	*250 799*	*59 (23.52)*	*1 (ref)*	*…*	*51 (20.34)*	*1 (ref)*	*…*
Female	*264 290*	*24 (9.08)*	*0.39 (0.24-0.62)*	***0.00***	*30 (11.35)*	*0.59 (0.38-0.93)*	***0.02***
Age group (years)							
20-29	*127 448*	*17 (13.34)*	*1 (ref)*	*…*	*8 (6.28)*	*1 (ref)*	*…*
Less than 20	*15 184*	*0 (0)*	*…*	*0.99*	*1 (6.59)*	*1.09 (0.13-8.76)*	*0.93*
30-39	*115 867*	*25 (21.58)*	*1.48 (0.80-2.75)*	***0.20***	*15 (12.95)*	*1.20 (0.84-4.70)*	*0.11*
40-49	*92 540*	*21 (22.69)*	*1.62 (0.85-3.08)*	*0.13*	*14 (15.13)*	*2.34 (0.98-5.60)*	*0.06*
50 and above	*164 050*	*20 (12.19)*	*0.85 (0.44-1.63)*	*0.64*	*43 (26.21)*	*3.91 (1.83-8.33)*	***0.00***
State/Territory*							
NSW	*152 210*	*27 (17.74)*	*1 (ref)*	*…*	*28 (18.4)*	*1 (ref)*	*…*
ACT	*17 264*	*1 (5.79)*	*0.32 (0.04-2.35)*	*0.26*	*1 (5.79)*	*0.33 (0.04-2.44)*	*0.27*
NT	*3 396*	*2 (58.89)*	*3.23 (0.77-13.62)*	*0.10*	*0 (0)*	*…*	*0.99*
QLD	*95 477*	*6 (6.28)*	*0.35 (0.14-0.85)*	***0.02***	*12 (12.57)*	*0.66 (0.33-1.30)*	*0.22*
SA	*40 054*	*4 (9.99)*	*0.57 (0.20-1.62)*	*0.29*	*7 (17.48)*	*0.88 (0.38-2.02)*	*0.77*
TAS	*15 984*	*2 (12.51)*	*0.72 (0.17-3.05)*	*0.66*	*7 (43.79)*	*2.25 (0.98-5.16)*	*0.05*
VIC	*142 984*	*34 (23.78)*	*1.34 (0.81-2.23)*	*0.25*	*23 (16.09)*	*0.88 (0.50-1.53)*	*0.65*
WA	*47 559*	*7 (14.72)*	*0.80 (0.34-1.83)*	*0.59*	*3 (6.31)*	*0.33 (0.10-1.09)*	*0.07*
Total	515 089	*83 (16.11)*			81 (15.73)		

		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	*250 799*	*2 (0.8)*	*1 (ref)*	*…*	*5 (1.99)*	*1 (ref)*	*…*
Female	*264 290*	*0 (0)*	*...*	*0.99*	*4 (1.51)*	*0.80 (0.21-2.98)*	*0.73*
Age group (years)							
20-29	*127 448*	*0 (0)*	*1 (ref)*	*…*	*1 (0.78)*	*1 (ref)*	*…*
Less than 20	*15 184*	*0 (0)*	*...*	*1.00*	*0 (0)*	*…*	*0.99*
30-39	*115 867*	*1 (0.86)*	*...*	*0.99*	*2 (1.73)*	*2.22 (0.20-24.62)*	*0.51*
40-49	*92 540*	*0 (0)*	*...*	*1.00*	*3 (3.24)*	*4.21 (0.43-40.60)*	*0.21*
50 and above	*164 050*	*1 (0.61)*	*...*	*0.99*	*3 (1.83)*	*2.34 (0.24-22.67)*	*0.46*
State/Territory*							
NSW	*152 210*	*1 (0.66)*	*1 (ref)*	*…*	*6 (3.94)*	*1 (ref)*	*…*
ACT	*17 264*	*0 (0)*	*...*	*0.99*	*0 (0)*	*…*	*0.99*
NT	*3 396*	*0 (0)*	*...*	*0.99*	*0 (0)*	*…*	*0.99*
QLD	*95 477*	*0 (0)*	*...*	*0.99*	*0 (0)*	*…*	*0.99*
SA	*40 054*	*0 (0)*	*...*	*0.99*	*1 (2.5)*	*061 (0.07-5.09)*	*0.65*
TAS	*15 984*	*0 (0)*	*...*	*0.99*	*0 (0)*	*…*	*0.99*
VIC	*142 984*	*1 (0.7)*	*1.08 (0.07-17.33)*	*0.95*	*2 (1.4)*	*0.35 (0.07-1.75)*	*0.20*
WA	*47 559*	*0 (0)*	*...*	*0.99*	*0 (0)*	*…*	*0.99*
Total	515 089	2 (0.39)			9 (1.75)		

	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	*250 799*	*16 (6.38)*	*1 (ref)*	…
Female	*264 290*	*6 (2.27)*	*0.30 (0.11-0.78)*	***0.01***
Age group (years)				
20-29	*127 448*	*11 (8.63)*	*1 (ref)*	…
Less than 20	*15 184*	*1 (6.59)*	*0.84 (0.10-6.53)*	*0.87*
30-39	*115 867*	*7 (6.04)*	*0684 (0.24-1.66)*	*0.36*
40-49	*92 540*	*2 (2.16)*	*0.23 (0.05-1.05)*	*0.06*
50 and above	*164 050*	*1 (0.61)*	*0.06 (0.09-0.49)*	***0.01***
State/Territory*				
NSW	*152 210*	*9 (5.91)*	*1 (ref)*	…
ACT	*17 264*	*0 (0)*	…	*0.99*
NT	*3 396*	*0 (0)*	…	*0.99*
QLD	*95 477*	*5 (5.24)*	*0.94 (0.31-2.81)*	*0.91*
SA	*40 054*	*0 (0)*	…	*0.99*
TAS	*15 984*	*0 (0)*	…	*0.99*
VIC	*142 984*	*8 (5.6)*	*0.96 (0.37-2.49)*	*0.93*
WA	*47 559*	*0 (0)*	…	*0.99*
Total	515 089	22 (4.27)		

* 161 donors with unknown state/territory of residence are not included in the state/territory stratification of the Poisson regression analysis

Supplementary Table 5 Association of demographic characteristics with TTI-positive blood donors* in Australia, 2017-2021

		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	*1 182 538*	*307 (25.96)*	*1 (ref)*	…	*199 (16.83)*	*1 (ref)*	…
Female	*1 244 233*	*128 (10.29)*	*0.39 (0.32-0.48)*	***0.00***	*122 (9.81)*	*0.60 (0.48-0.76)*	***0.00***
Age group (years)							
20-29	*598 933*	*81 (13.52)*	*1 (ref)*	…	*39 (6.51)*	*1 (ref)*	…
Less than 20	*95 235*	*8 (8.4)*	*0.67 (0.32-1.39)*	*0.28*	*6 (6.3)*	*1.42 (0.66-3.06)*	*0.36*
30-39	*520 769*	*146 (28.04)*	*1.90 (1.45-2.50)*	***0.00***	*63 (12.1)*	*1.87 (1.24-2.81)*	***0.00***
40-49	*427 709*	*88 (20.57)*	*1.43 (1.06-1.94)*	***0.02***	*61 (14.26)*	*2.21 (1.47-3.33)*	***0.00***
50 and above	*784 124*	*112 (14.28)*	*1.01 (0.75-1.34)*	*0.94*	*152 (19.38)*	*3.06 (2.13-4.40)*	***0.00***
State/Territory							
NSW	*710 220*	*125 (17.6)*	*1 (ref)*	…	*111 (15.63)*	*1 (ref)*	…
ACT	*76 025*	*14 (18.41)*	*0.98 (0.56-1.71)*	*0.95*	*6 (7.89)*	*0.49 (0.21-1.12)*	*0.09*
NT	*16 513*	*8 (48.45)*	*2.61 (1.27-5.34)*	***0.00***	*0 (0)*	…	*0.97*
QLD	*468 915*	*53 (11.3)*	*0.62 (0.45-0.85)*	***0.00***	*62 (13.22)*	*0.79 (0.58-1.08)*	*0.14*
SA	*194 944*	*24 (12.31)*	*0.68 (0.44-1.06)*	*0.09*	*23 (11.8)*	*0.68 (0.43-1.07)*	*0.09*
TAS	*77 940*	*13 (16.68)*	*0.95 (0.53-1.68)*	*0.86*	*17 (21.81)*	*1.28 (0.77-2.13)*	*0.33*
VIC	*660 003*	*162 (24.55)*	*1.34 (1.06-1.69)*	***0.01***	*82 (12.42)*	*0.76 (0.57-1.01)*	*0.06*
WA	*222 026*	*36 (16.21)*	*0.86 (0.59-1.25)*	*0.44*	*20 (9.01)*	*0.54 (0.33-0.87)*	***0.01***
Total**	2 426 772	435 (17.93)			321 (13.23)		

		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	*1 182 538*	*20 (1.69)*	*1 (ref)*	…	*15 (1.27)*	*1 (ref)*	…
Female	*1 244 233*	*5 (0.4)*	*0.21 (0.07-0.56)*	***0.00***	*8 (0.64)*	*0.52 (0.22-1.23)*	*0.13*
Age group (years)							
20-29	*598 933*	*13 (2.17)*	*1 (ref)*	…	*3 (0.5)*	*1 (ref)*	…
Less than 20	*95 235*	*0 (0)*	…	*0.99*	*0 (0)*	…	*0.99*
30-39	*520 769*	*4 (0.77)*	*0.31 (0.10-0.96)*	***0.04***	*7 (1.34)*	*2.50 (0.64-9.72)*	*0.18*
40-49	*427 709*	*2 (0.47)*	*0.19 (0.04-0.86)*	***0.03***	*6 (1.4)*	*2.68 (0.67-10.74)*	*0.16*
50 and above	*784 124*	*6 (0.77)*	*0.32 (0.12-0.85)*	***0.02***	*7 (0.89)*	*1.72 (0.44-6.70)*	*0.43*
State/Territory							
NSW	*710 220*	*8 (1.13)*	*1 (ref)*	…	*9 (1.27)*	*1 (ref)*	…
ACT	*76 025*	*1 (1.32)*	…	*0.99*	*2 (2.63)*	*1.97 (0.42-9.14)*	*0.38*
NT	*16 513*	*0 (0)*	…	*0.99*	*0 (0)*	…	*0.99*
QLD	*468 915*	*4 (0.85)*	*0.64 (0.19-2.10)*	*0.47*	*0 (0)*	…	*0.99*
SA	*194 944*	*1 (0.51)*	*0.40 (0.05-3.19)*	*0.39*	*2 (1.03)*	*0.79 (0.17-3.67)*	*0.76*
TAS	*77 940*	*0 (0)*	…	*0.99*	*3 (3.85)*	*3.05 (0.82-11.30)*	*0.09*
VIC	*660 003*	*8 (1.21)*	*0.91 (0.35-2.36)*	*0.85*	*5 (0.76)*	*0.58 (0.19-1.73)*	*0.33*
WA	*222 026*	*3 (1.35)*	*1.02 (0.27-3.77)*	*0.97*	*2 (0.9)*	*0.67 (0.14-3.11)*	*0.61*
Total**	2 426 772	25 (1.03)			23 (0.95)		

	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	*1 182 538*	*69 (5.83)*	*1 (ref)*	…
Female	*1 244 233*	*0*	*0.25 (0.15-0.41)*	***0.00***
Age group (years)				
20-29	*598 933*	*44 (7.35)*	*1 (ref)*	…
Less than 20	*95 235*	*2 (2.1)*	*0.32 (0.07-1.35)*	*0.12*
30-39	*520 769*	*25 (4.8)*	*0.58 (0.35-0.94)*	***0.03***
40-49	*427 709*	*10 (2.34)*	*0.29 (0.14-0.57)*	***0.00***
50 and above	*784 124*	*9 (1.15)*	*0.14 (0.07-0.29)*	***0.00***
State/Territory				
NSW	*710 220*	*30 (4.22)*	*1 (ref)*	…
ACT	*76 025*	*0 (0)*	…	*0.99*
NT	*16 513*	*1 (6.06)*	*1.36 (0.18-10.00)*	*0.76*
QLD	*468 915*	*17 (3.63)*	*0.87 (0.48-1.59)*	*0.66*
SA	*194 944*	*2 (1.03)*	*0.26 (0.06-1.10)*	*0.06*
TAS	*77 940*	*0 (0)*	…	*0.99*
VIC	*660 003*	*33 (5)*	*1.16 (0.70-1.90)*	*0.55*
WA	*222 026*	*7 (3.15)*	*0.73 (0.32-1.66)*	*0.45*
Total**	2 426 772	90 (3.71)		

* 186 donors with unknown state/territory of residence are not included in the state/territory stratification of the Poisson regression analysis

** The total of 2.4 million donors over a five-year period, 2017-2021, 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, 2021

	HBV (2021)				HCV (2021)				HIV (2021)				HTLV (2021)				Potentially infectious syphilis (2021)			
Donor status	M	F	Total	%	M	F	Total	%	M	F	Total	%	M	F	Total	%	M	F	Total	%
First time donors																				
<20 years	0	0	0	0.0	0	1	1	1.2	0	0	0	0.0	0	0	0	0.0	1	0	1	4.5
20-29 years	5	12	17	20.5	6	1	7	8.6	0	0	0	0.0	0	1	1	11.1	2	1	3	13.6
30-39 years	20	3	23	27.7	9	3	12	14.8	1	0	1	50.0	2	0	2	22.2	1	1	2	9.1
40-49 years	15	5	20	24.1	9	4	13	16.0	0	0	0	0.0	2	1	3	33.3	0	0	0	0.0
50-59 years	7	0	7	8.4	10	8	18	22.2	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0
60 years and above	9	0	9	10.8	10	5	15	18.5	0	0	0	0.0	0	1	1	11.1	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	0	1	1	1.2	0	0	0	0.0	0	0	0	0.0	6	2	8	36.4
30-39 years	0	2	2	2.4	1	2	3	3.7	0	0	0	0.0	0	0	0	0.0	3	2	5	22.7
40-49 years	1	0	1	1.2	1	0	1	1.2	0	0	0	0.0	0	0	0	0.0	2	0	2	9.1
50-59 years	2	1	3	3.6	2	3	5	6.2	1	0	1	50.0	1	0	1	11.1	0	0	0	0.0
60 years and above	0	1	1	1.2	3	2	5	6.2	0	0	0	0.0	0	1	1	11.1	1	0	1	4.5
Total	**59**	**24**	**83**	**100**	**51**	**30**	**81**	**100**	**2**	**0**	**2**	**100**	**5**	**4**	**9**	**100**	**16**	**6**	**22**	**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, 2017-2021

	HBV (2017-2021)				HCV (2017-2021)				HIV (2017-2021)				HTLV (2017-2021)				PIS/active syphilis (2017-2021)			
Donor status	M	F	Total	%	M	F	Total	%	M	F	Total	%	M	F	Total	%	M	F	Total	%
First time donors																				
<20 years	3	5	8	1.8	2	3	5	1.6	0	0	0	0.0	0	0	0	0.0	1	0	1	1.1
20-29 years	49	30	79	18.2	25	5	30	9.3	7	1	8	32.0	2	1	3	13.0	14	3	17	18.9
30-39 years	101	31	132	30.3	39	12	51	15.9	1	1	2	8.0	6	1	7	30.4	6	2	8	8.9
40-49 years	54	18	72	16.6	25	24	49	15.3	0	0	0	0.0	5	1	6	26.1	4	2	6	6.7
50-59 years	27	13	40	9.2	39	30	69	21.5	1	1	2	8.0	0	0	0	0.0	0	0	0	0.0
60 years and above	24	6	30	6.9	34	20	54	16.8	1	0	1	4.0	1	3	4	17.4	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	1.1
20-29 years	2	0	2	0.5	7	6	13	4.0	4	1	5	20.0	0	0	0	0.0	17	10	27	30.0
30-39 years	9	5	14	3.2	2	6	8	2.5	1	1	2	8.0	0	0	0	0.0	14	3	17	18.9
40-49 years	8	8	16	3.7	7	5	12	3.7	2	0	2	8.0	0	0	0	0.0	4	0	4	4.4
50-59 years	14	5	19	4.4	8	7	15	4.7	1	0	1	4.0	1	1	2	8.7	3	1	4	4.4
60 years and above	16	7	23	5.3	10	4	14	4.4	2	0	2	8.0	0	1	1	4.3	5	0	5	5.6
Total	**307**	**128**	**435**	**100**	**199**	**122**	**321**	**100**	**20**	**5**	**25**	**100**	**15**	**8**	**23**	**100**	**69**	**21**	**90**	**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^, 2017-2021

	HBV (2017-2021)		HCV (2017-2021)		HIV (2017-2021)		HTLV (2017-2021)		Potentially infectious syphilis (2017-2021)	
Region of birth	Number	%	Number	%	Number	%	Number	%	Number	%
Australia	44	10.1	217	67.6	11	44.0	5	21.7	57	63.3
Overseas born										
Other Oceania	32	7.4	10	3.1	0	0.0	0	0.0	5	5.6
United Kingdom and Ireland	0	0.0	7	2.2	0	0.0	0	0.0	0	0.0
Other Europe	23	5.3	13	4.0	2	8.0	0	0.0	4	4.4
Middle East/North Africa	13	3.0	6	1.9	0	0.0	2	8.7	1	1.1
Sub-Saharan Africa	10	2.3	1	0.3	1	4.0	0	0.0	2	2.2
South & North East Asia	214	49.2	26	8.1	3	12.0	3	13.0	9	10.0
Southern and Central Asia	91	20.9	34	10.6	6	24.0	13	56.5	7	7.8
Americas	3	0.7	2	0.6	2	8.0	0	0.0	2	2.2
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	430	98.9	316	98.4	25	100.0	23	100.0	87	96.7
Not reported	5	1	5	2	0	0	0	0	3	3
Total	435	100	321	100	25	100	23	100	90	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, 2021

	HBV (2021)				HCV (2021)				HIV (2021)				HTLV (2021)				Active Syphilis (2021)			
Exposure categories	M	F	Total	%	M	F	Total	%	M	F	Total	%	M	F	Total	%	M	F	Total	%
Ethnicity/Country of birth	48	12	60	78.9	5	1	6	9.1	0	0	0	0.0	3	2	5	71.4	0	0	0	0.0
Intravenous drug use	0	0	0	0.0	16	6	22	33.3	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0
Tattoo/Piercing	0	0	0	0.0	2	4	6	9.1	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	3	4	6.1	0	0	0	0.0	1	1	2	28.6	1	0	1	16.7
Partner with unspecified risks	1	1	2	2.6	1	0	1	1.5	1	0	1	0.0	0	0	0	0.0	0	1	1	16.7
Male-to-male sexual contact	0	0	0	0.0	1	0	1	1.5	0	0	0	0.0	0	0	0	0.0	1	0	1	16.7
Exposure in health care setting	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
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	4	0	4	6.1	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0
Household contact/Family history	6	7	13	17.1	0	1	1	1.5	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0
Other blood to blood contact	0	0	0	0.0	0	1	1	1.5	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0
Other*	0	0	0	0.0	5	0	5	7.6	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0
No risk factors identified/Unknown	1	0	1	1.3	9	6	15	22.7	0	0	0	0.0	0	0	0	0.0	2	1	3	50.0
Total	56	20	76	100.0	44	22	66	100.0	1	0	1	100.0	4	3	7	100.0	4	2	6	100.0

* For HCV, two out of five first time male donors in 2021 in the 'Other' category 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, 2017-2021

	HBV (2017-2021)				HCV (2017-2021)				HIV (2017-2021)				HTLV (2017-2021)				Active Syphilis (2017-2021)			
Exposure categories	M	F	Total	%	M	F	Total	%	M	F	Total	%	M	F	Total	%	M	F	Total	%
Ethnicity/Country of birth	230	80	310	85.9	20	1	21	8.1	0	0	0	0.0	12	2	14	70.0	0	0	0	0.0
Intravenous drug use	1	0	1	0.3	48	21	69	26.7	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0
Tattoo/Piercing	1	0	1	0.3	22	25	47	18.2	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	9	16	6.2	2	1	3	23.1	1	3	4	20.0	3	0	3	9.4
Partners with unspecified risks	2	1	3	0.8	1	1	2	0.8	2	0	2	15.4	0	1	1	5.0	6	5	11	34.4
Male-to-male sexual contact	2	0	2	0.6	1	0	1	0.4	3	0	3	23.1	0	0	0	0.0	10	0	10	31.3
Exposure in health care setting	0	2	2	0.6	6	4	10	3.9	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	10	6	16	6.2	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0
Household contact	16	14	30	8.3	2	5	7	2.7	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	5	2	7	2.7	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0
Other*	0	0	0	0.0	22	3	25	9.7	0	2	2	15.4	1	0	1	5.0	0	0	0	0.0
No risk factors identified/Unknown	6	5	11	3.0	20	17	37	14.3	3	0	3	23.1	0	0	0	0.0	6	2	8	25.0
Total	258	103	361	100	164	94	258	100.0	10	3	13	100.0	14	6	20	100.0	25	7	32	100.0

* For HCV, 45% (10/22) first-time male donors and 33% (1/3) first-time female donors in 'Other' 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, 2021

	HBV (2021)				HCV (2021)				HIV (2021)				HTLV (2021)				Active Syphilis (2021)			
Exposure categories	M	F	Total	%	M	F	Total	%	M	F	Total	%	M	F	Total	%	M	F	Total	%
Ethnicity/Country of birth	3	2	5	71.4	0	0	0	0.0	0	0	0	0.0	0	1	1	0.0	0	0	0	0.0
Injecting drug use	0	0	0	0.0	3	1	4	26.7	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	20.0	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0
Partners with any risks or known to be positive	0	0	0	0.0	1	1	2	13.3	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0
Partner with unspecified risks	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0	1	0	1	0.0	5	2	7	43.8
Male-to-male sexual contact	0	0	0	0.0	0	0	0	0.0	1	0	1	100.0	0	0	0	0.0	4	0	4	25.0
Exposure in health care setting	0	0	0	0.0	1	1	2	13.3	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0
Engaged in sex work	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0
Blood or tissue recipient	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0
Household contact/ Family history	0	2	2	28.6	0	1	1	6.7	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	1	1	6.7	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	0	0	0.0	0	2	2	13.3	0	0	0	0.0	0	0	0	0.0	3	2	5	31.3
Not reported	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0
Total	3	4	7	100.0	7	8	15	100.0	1	0	1	100	1	1	2	0.0	12	4	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, 2017-2021

	HBV (2017-2021)				HCV (2017-2021)				HIV (2017-2021)				HTLV (2017-2021)				Active Syphilis (2017-2021)			
Exposure categories	M	F	Total	%	M	F	Total	%	M	F	Total	%	M	F	Total	%	M	F	Total	%
Ethnicity/Country of birth	34	16	50	67.6	0	1	1	1.6	0	0	0	0.0	0	1	1	33.3	0	0	0	0.0
Intravenous drug use	1	0	1	1.4	9	2	11	17.5	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0
Tattoo/Piercing	2	0	2	2.7	9	5	14	22.2	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	4.1	1	5	6	9.5	1	2	3	25.0	0	1	1	33.3	3	2	5	8.6
Partners with unspecified risks	2	1	3	4.1	0	0	0	0.0	3	0	3	25.0	1	0	1	33.3	20	6	26	44.8
Male-to-male sexual contact	0	0	0	0.0	0	0	0	0.0	4	0	4	33.3	0	0	0	0.0	8	0	8	13.8
Exposure in health care setting	1	0	1	1.4	6	3	9	14.3	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0
Engaged in sex work	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0
Blood or tissue recipient	0	0	0	0.0	0	2	2	3.2	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0
Household contact	3	3	6	8.1	2	1	3	4.8	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0
Other blood to blood contact	0	0	0	0.0	0	1	1	1.6	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0
Other	1	2	3	4.1	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	6.8	7	7	14	22.2	2	0	2	16.7	0	0	0	0.0	13	6	19	32.8
Total	49	25	74	100.0	35	28	63	100.0	10	2	12	100.0	1	2	3	100.0	44	14	58	100.0

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

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Supporting information for transfusion-transmissible infections surveillance report

Blood donation: from volunteer to recipient

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

Australian volunteer blood donors may be aged 18 to 80 years of age. Each donor is required to self-complete a comprehensive donor questionnaire (DQ) every time they donate. A slightly different process is used for regular plasmapheresis donors (see Additional information for more detail). The questionnaire is reviewed to determine eligibility and a legally binding Declaration Form is signed prior to donation. There are penalties including fines and imprisonment for anyone providing false or misleading information. The DQ asks about various medical conditions, travel history and behaviours related to increased risk of a blood-borne infection. Lifeblood is highly reliant on the donor's complete and truthful answers to all interview questions (i.e. 'compliance'). This is particularly important for questions relating to risk behaviour for transfusion-transmissible infection given the existence of the testing window period (see below). Should a donor in the window period fail to truthfully answer a question that would normally result in their deferral from donation, they will place recipients at risk because a potentially infectious unit of blood will be collected that testing will not identify.

Subsequent to satisfactorily completing the above assessment process the donor proceeds to donate. Every first-time donation is processed and undergoes mandatory tests for specific transfusion-transmissible infections (TTIs) including HBV, HCV, HIV, HTLV and syphilis. From September 2016, repeat donors donating plasma for fractionation only no longer required testing for syphilis and HTLV, and from December 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 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.[78] 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.[79] An updated NAT triplex (HIV-1/HCV/HBV) test was implemented during 2013 reducing the HBV window period to approximately 16 days and a further NAT assay upgrade in 2021 added HIV-2 detection. These advances incrementally lowered the risk of not detecting a recently infected donor but importantly the WP is not eliminated. Thus, despite state-of-the-art donation testing there remains a small but non-zero risk of transmission from donors with very recently acquired infection, who may test negative if they donate during the window period.

Using donation testing results, Lifeblood monitors for trends in both prevalence (i.e. the frequency of 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, eleven 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 2021. There was a statistically significant increase in only syphilis prevalence among first time donors for the 2012-2021 period. Positive first-time donors in 2021 mostly had undiagnosed prevalent infections but a small number of incident donors continued to be identified (only four, all for HCV).

This is the twelfth 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 2012 to 2021. Anonymous donor data for all donors who donated blood between January 2012 and December 2021 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 2012-2021. Demographic factors associated with TTIs in blood donors were analysed for donations made in 2021 and were compared with the findings from 2017-2021. Likely routes of exposure (termed 'putative risk factors') for each TTI in blood donors were also identified and analysed. Data from the 2020 and 2021 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 2020 to 31 December 2021. HBV OBI risk based on Lifeblood data from 1 January to 31 December 2021. 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 2020 to 31 December 2021.

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:

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

Donor-years of observation

Data on interval between each donation by all donors who donated at least twice in 2021 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 2021, the average DYO per repeat negative donor was applied to calculate their individual inter-donation interval. 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 / Partners with unspecified risks
    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, 2017-2021, was calculated as follows:

$$\text{Incidence per 100 000 donor-years of observation} = \left(\frac{\text{Total number of incident donors in 2017-2021}}{\text{Average of 2017-2021 total donor-years of observation}} \right) \times 100\,000$$

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*[80] 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*.[81]

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, 2012-2021, and the five-year period, 2017-2021, 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 2012-2021 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 2021, and five-year period, 2017-2021 (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.

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