Transfusion-transmissible infections in Australia

2023

Surveillance Report

Australian Red Cross Lifeblood®

UNSW SYDNEY

UNSW Kirby Institute

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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 TTIs 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 the report is focused on 2022 testing data, during which time the COVID-19 pandemic case numbers peaked, the potential impacts of the COVID-19 public health response in 2022 are considered in the analysis. During 2022, Australia faced multiple COVID-19 waves, including a major wave in January and subsequent smaller waves later in the year. However, in 2022, Australia gradually withdrew non-pharmaceutical interventions to manage the COVID-19 pandemic, such as mandatory face masks, stay at home orders and border closures. In addition, the majority of the nationwide COVID-19 vaccination program was completed in 2021.

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 discarded, and the donor undergoes a post-donation interview and is referred for clinical follow-up.

For 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 that are exclusively sent to CSL Behring for fractionation (i.e. HIV, HCV and HBV only). As of December 2020, repeat donors are not required to be tested for HTLV, irrespective of donation type. Consistent with previous years, the overall number of TTIs detected remained low in 2022 (n=178). Of these, 88% were either hepatitis B (HBV) or hepatitis C (HCV) virus. Reflecting the effectiveness of donor screening strategies, the prevalence of TTIs in first-time donors in 2022 continues to be substantially lower (6-64 times) than the estimated national population prevalence for 2021/2022 (the 2022 estimates of population level prevalence for HBV were not available at the time of the report preparation, therefore comparisons were made with the 2021 data). Two (one HCV, one HIV, 1% of all) infections in 2022 were determined to be incident (newly acquired) based on a past negative test within the last 12 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 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, 2018-2022.

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 2022, 21% had risk factors identified in their post-donation interview which were not disclosed in their initial donation interview (termed 'non-compliance'). As minimising non-compliance 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 has been included in this report as trend data from 2013 to 2016 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 an 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 six 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 they are highly contagious.
- In case of OBI (see below), the presence of viral DNA means that a person is possibly infectious and potentially at increased risk of liver damage.

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

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

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

Incidence
The rate of newly acquired infection among repeat donors.

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

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

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 five years by injection or been injected, even once, with drugs not prescribed by a doctor or a dentist.

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

Non-compliance
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 HBV DNA and usually detectable anti-HBc in the bloodstream.

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

Potentially infectious syphilis
This is a blood safety specific surveillance definition designed to capture donors who are at theoretical risk of transmitting syphilis by blood transfusion. Potentially infectious syphilis 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). Potentially infectious syphilis includes first-time donors if screening and confirmatory tests for treponemal antibodies were positive, in addition to RPR titre >8 or clinical evidence (signs of syphilis) or recent contact with a confirmed case.

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

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

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

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’).

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 blood. The window period varies depending on the infection and the test used.

Summary of the main findings

General characteristics of blood donors in Australia

1. Over the ten-year period 2013-2022, there were over 14 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 1.53 million.
2. Of the 'age-eligible' Australian population (aged between 18-80 years), 2.7% donated blood during 2022. Male donors constituted 49% of all donors in 2022, 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 18.2% and 81.8% of all blood donors in Australia over the period 2013-2022, respectively. The ratio of first-time donors increased gradually, from 13.8% in 2013, to 17.5% in 2018 and 18.4% in 2021 and showed an increase to 21.8% in 2022. The proportion of total donations made by first-time donors increased from 5.9% in 2021 to 7.5% in 2022 which was driven by removing the deferral for people who lived in the UK for more than six months. The overall increase in total donations over the 2013-2022 period is mostly driven by an increased donation frequency among repeat donors.

Trends in transfusion-transmissible infections in Australian blood donors

A blood donation that is found to be positive on Lifeblood testing for a TTI is discarded and the donor is informed and referred for medical follow-up.

1. In 2022, a total of 178 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. In the ten-year period 2013-2022 a total of 1 725 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 2022, 87.6% were positive for either HBV or HCV, slightly higher than 83.2% in 2021.
3. Overall, HIV was the least common TTI detected among all donors in 2022, with just three donors testing positive. In the ten-year period 2013-2022, HIV was the least common TTI detected among all donors, with 44 donors, followed by HTLV, with 47 donors.
4. Although representing 21.8% of the donor population, first-time blood donors contributed to 85% of detected TTIs in Australia in 2022, a 7% increase as compared to the 79% observed in 2021. This proportion has fluctuated since 2013 (77-85% 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 2022.
6. Consistent with previous years, in 2022, the prevalence of TTIs was substantially lower among first-time blood donors (6 to 64 times) compared with national prevalence estimates for 2021/2022.

HBV-positive Australian blood donors

1. There were 92 HBV-positive donors detected among all donations in 2022 (81 in first-time donors and 11 in repeat donors).
2. Of all TTIs detected, HBV continued to have the highest prevalence among first-time donors.
3. During 2013-2022, no significant trend was observed in HBV prevalence in first-time donors in Australia. The prevalence among first-time donors in 2022 has remained relatively stable, with a decrease of 11% as compared to that observed in 2021, 71.0 versus 80.0 per 100 000 donations, respectively. This equates to 0.07% of the total first-time donations in 2022, which is 11 times lower than the estimated ~0.8% prevalence reported in national HBV surveillance data for 2021.
4. Among the 92 HBV-positive donors, 19 (10 first-time and nine repeat donors) were classified as occult HBV (OBI) based on the detection of HBV DNA without HBsAg. Of these OBI positive donors, most were men (89%), Asian-born (74%) and had an average age of 52.3 years.
5. There were no incident HBV donors in 2022. There was no significant temporal trend in HBV donor incidence nationally or in any state/territory during the five-year study period 2018-2022.
6. In 2022, HBV-positive donors were younger as compared to all donors (39 years versus the mean age 43 years), more likely to be male (77% in HBV-positive donors versus 49% in all donors) and more likely to be born in Northeast/Southeast Asia (50%). 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 2018-2022 was ethnicity/country of birth (82%). In Australia, an estimated 46% 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 reported in Australia during 2018-2022. One probable case (in 2011) was reported in the 2010-2019 period (see Transfusion-transmissible infections in Australia Surveillance Report 2017 for details).

HCV-positive Australian blood donors

1. There were 64 HCV-positive donors detected among all donors in 2022 (55 in first-time donors and nine in repeat donors). In 2022, the proportion of HCV RNA positive (considered infectious) donors was 29.7% (19/64 – all 19 first-time donors), a drop from 37.0% in 2021. This figure has incrementally declined from around 75% when HCV RNA donation testing was introduced in 2000.
2. In 2022, HCV was the second most common TTI detected in first-time blood donors after HBV.
3. During 2013-2022, a significant increasing trend was observed in HCV prevalence in first-time donors in Australia. 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 five years after last injecting drugs. The 0.05% first-time donor prevalence in 2022 is six times lower than the estimated ~0.3% living with chronic hepatitis C reported for HCV national surveillance data for 2022. However, these figures are not directly comparable as the majority of HCV-positive donors represent past exposure.
4. In 2022, there were nine repeat donors who tested positive, and of these, only one met the incidence definition. The average incidence rate of HCV among previously negative repeat donors during 2018-2022 was low at 0.93 per 100 000 donor-years of observation (see Methodological Notes for details). HCV incidence has shown no significant trend during the study period 2018-2022.
5. In 2022, the mean age of HCV-positive donors was 50 years compared to 43 years for all donors. They were more likely to be male (55% versus 49% in all donors), and the majority (58%) were born in Australia, a substantial drop as compared to 2021 where 70% were born in Australia.
6. The most common putative risk factor reported by HCV-positive donors during 2018-2022 was injecting drug use (27%). By comparison, for the newly acquired HCV in the general population, 66% had imprisonment as their route of exposure in 2022, followed by injecting drug use at ~14%.
7. No transfusion-transmitted HCV cases were reported in Australia during 2018-2022.

HIV-positive Australian blood donors

1. There were three HIV-positive donors detected among all donations in 2022 (two first-time and one repeat donors).
2. The prevalence of HIV-positive first-time donors during 2013-2022 remained very low at 2.2 per 100 000 donations (or 0.002% of total first-time donations) and comparatively much lower than HBV (74.6 per 100 000 donations) and HCV (49.8 per 100 000 donations). No significant HIV prevalence trend was observed during 2013-2022. The 0.002% HIV prevalence in first-time donors is 64 times lower than the 0.1% prevalence reported for HIV national surveillance data in 2022.
3. There was one incident HIV donor in 2022. There was no statistically significant incidence trend in the 2018-2022 period.
4. In 2022, the mean age of HIV-positive donors was 43 years, the same as for all donors. Like HBV and HCV, HIV-positive donors were more likely to be male as compared to all donors (100% vs 49%). In 2022, 67% (2/3) of the HIV-positive donors were born in Australia.
5. The most common reported routes of exposure for HIV-positive donors during 2018-2022 were having a partner with an unspecified risk and male-to-male sex (28%, each), while for 32%, the risk factor was undetermined. In comparison, men who have sex with men accounted for 57% of cases of HIV first ever diagnosed in Australia in 2022 (including those who reported injecting drug use), followed by heterosexual sex (30%).
6. No transfusion-transmitted HIV cases were reported in Australia during 2018-2022.

HTLV-positive Australian blood donors

1. There were five HTLV-positive donors detected among all donations in 2022 (all five in first-time donors).
2. The prevalence of HTLV-positive first-time donors during 2013-2022 has remained low at 4.4 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 2022, the mean age of the nine HTLV-positive donors was 35 years; the majority (80%) were male, and all were born overseas (100%).
4. The most common putative risk factor for HTLV-positive donors during 2018-2022 was ethnicity or country of birth (73%). There are no data to compare risk factors in the general population.
5. No transfusion-transmitted HTLV cases were reported in Australia during 2018-2022.

Potentially infectious syphilis infection among Australian blood donors

1. There were 14 potentially infectious syphilis donors (eight first-time and six repeat donors) detected in 2022.
2. During the past 10 years, 2013-2022, the prevalence of potentially infectious syphilis in first-time donors has shown no significant trend. However, in 2022, the rate slightly increased to 7.0, from 6.3 per 100 000 first-time donations observed in 2021.
3. The mean age of donors with potentially infectious syphilis in 2022 was 36 years (compared to 43 years for all donors), and 50% were male.
4. The most common reported route of exposure by donors with potentially infectious syphilis during 2018-2022 period was having a partner with an unspecified risk (38%).

Donor compliance

1. Of the 921 TTI-positive donors in 2018-2022, 18.2% (168 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 77% (129 donors) of 'non-compliant' donors.
2. 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 2022, 50 981 donations were tested for malaria antibody, lower than the 69 125 donations tested in 2021, and substantially less than the 132 338 donations tested in 2020. The decline from 2020 was due to decreased overseas travel by donors due to COVID-19 associated international border closures, which are now lifted. Of the tested donations, 1 451 (2.8%) were repeatedly reactive for malaria antibodies. This rate is similar compared to the 2.7% for 2021.
2. There were no reported cases of transfusion-transmitted malaria during 2022, with the last reported Australian case occurring in 1991.

Bacterial pre-release testing for platelets

1. In 2022, 130 (0.11%) of a total of 123 751 screened platelet units had confirmed bacterial contamination.
2. Consistent with previous years, by far the most common species isolated (116 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 (five isolates), which along with propionibacteria are usually considered skin contaminants.
3. Other confirmed positive pathogens (one isolate each unless stated) included:
   Bacillus species, *Escherichia coli*, *Staphylococcus aureus* (two isolates), *Staphylococcus lugdunensis, Staphylococcus saprophyticus, Streptococcus gallolyticus, Streptococcus pneumoniae* and *Streptococcus pyogenes*.
4. In 2022, 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 predominantly overseas acquired, such as dengue, hepatitis A, hepatitis E and malaria, significantly decreased in 2020 and continued to decrease in 2021. Notified case numbers for these four infections increased in 2022 and by October 2023, were near pre-COVID-19 levels.
2. In 2022, a local outbreak of JEV and cases of mpox associated with the global mpox virus outbreak were monitored and both outbreaks were assessed as a negligible risk to blood safety.

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Abbreviations

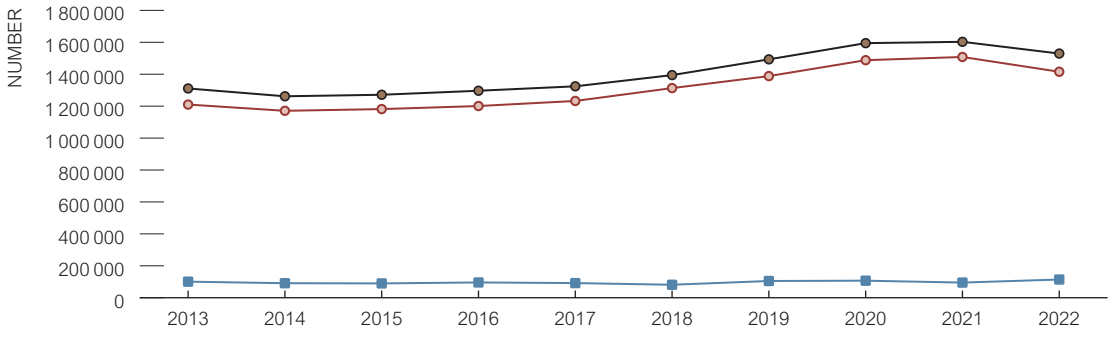
ACCESS	the Australian Collaboration for Coordinated Enhanced Sentinel Surveillance
anti-HAV	antibody to hepatitis A
anti-HBc	antibody to hepatitis B core antigen
anti-HBe	antibody to hepatitis B e antigen
anti-HBs	antibody to hepatitis B surface antigen
BCS	bacterial contamination screening
B19V	primate erythroparvovirus 1
CJD	Creutzfeldt-Jakob disease
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
JEV	Japanese encephalitis virus
Lifeblood	Australian Red Cross Lifeblood
mpox	mpox (formerly Monkeypox)
MPXV	monkeypox virus
NAT	nucleic acid testing
OBI	occult hepatitis B virus infection
RRV	Ross River virus
SARS-CoV	severe acute respiratory syndrome-related coronavirus
STIs	sexually-transmissible infections
TPHA	Treponema pallidum haemagglutination
TTIs	transfusion-transmissible infections
WNV	West Nile virus
WP	window period
ZIKV	Zika virus

Main Findings

Blood donors in Australia

Over 14 million donations were tested for TTIs in Australia during the ten-year period 2013-2022, with an average of 1.4 million donations per year. There were 1.5 million donations in 2022, a decrease of 4.6% as compared to 2021. However, over the entire ten-year period there was a significant increasing trend in the number of donations, from 1.31 to 1.53 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 are not tested for syphilis and HTLV. 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 1.53 million donations were tested for HBV, HCV and HIV in 2022, as compared to slightly over 0.12 million donations for HTLV and 0.88 million donations for syphilis.

Figure 1 **Number of blood donations in Australia, by year of donation, 2013-2022**

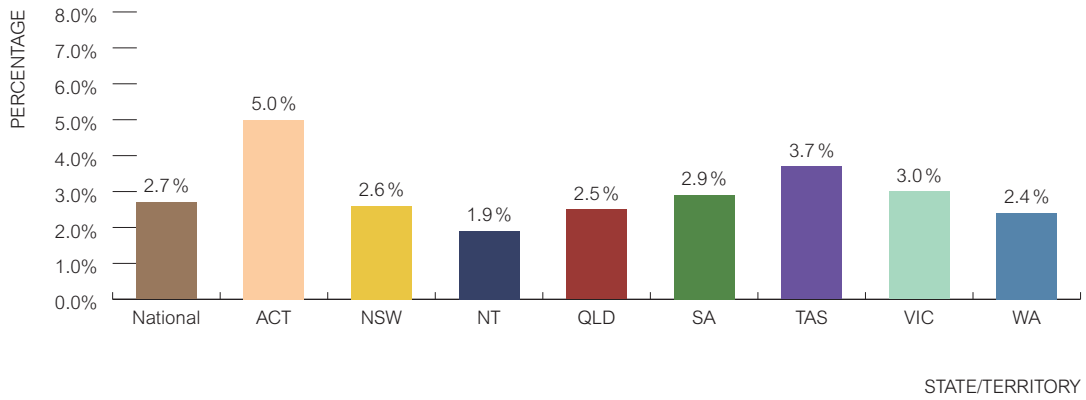


	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022
Total	1.31 M	1.26 M	1.27 M	1.30 M	1.32 M	1.39 M	1.49 M	1.59 M	1.60 M	1.53 M
First-time	0.10 M	0.09 M	0.09 M	0.10 M	0.09 M	0.08 M	0.10 M	0.11 M	0.09 M	0.11 M
Repeat	1.21 M	1.17 M	1.18 M	1.20 M	1.23 M	1.31 M	1.39 M	1.49 M	1.51 M	1.42 M

In 2022, 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 2022 was the Australian Capital Territory (5.0%), followed by Tasmania at 3.7% (Figure 2).

The number of first-time donors increased to 0.11 million in 2022 (from 0.09 million in 2021), largely due the removal of the vCJD geographical deferral for United Kingdom donors on 25 July 2022. In the period the deferral was lifted (~five months), first-time donors from this cohort accounted for 42% of all first-time donor attendances.

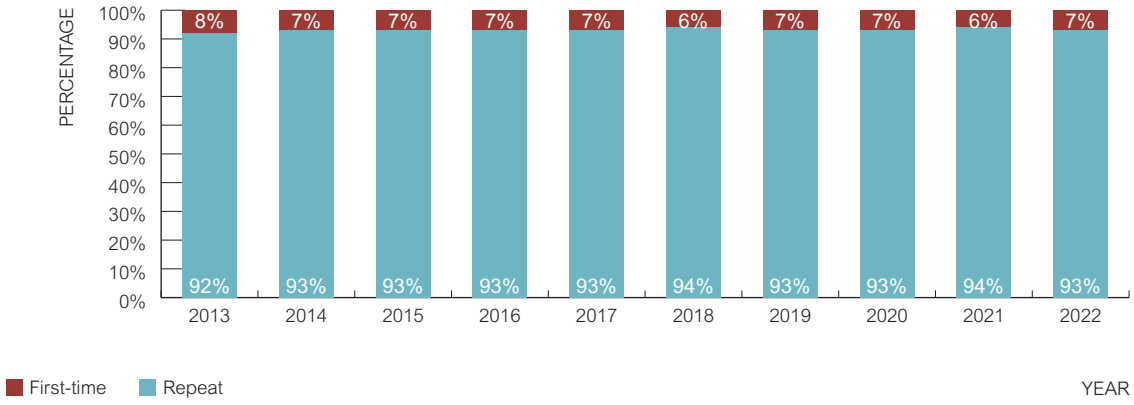
Figure 2 **Percentage of age eligible* general population who donated blood in 2022, by state/territory**



Note: for 361 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

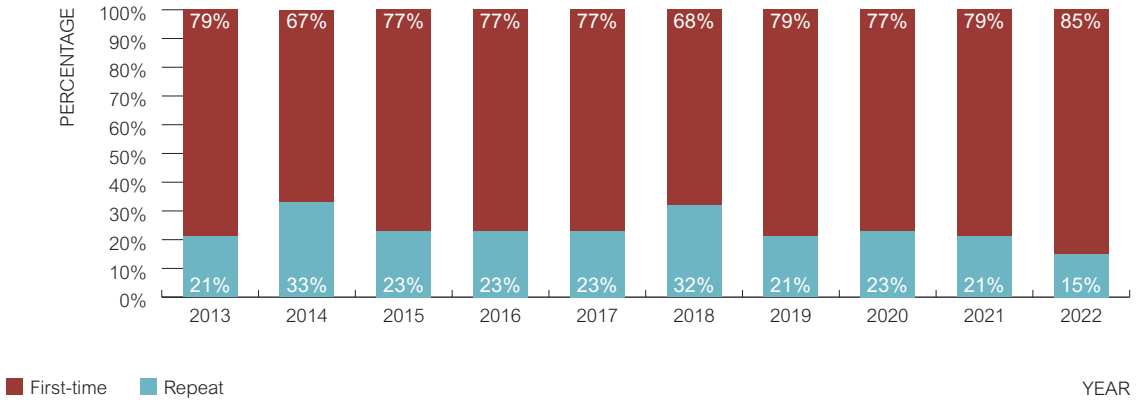
As in previous years, more than 90% of all donations in 2022 were from repeat donors (Figure 3). In the past 10 years, 2013-2022, the percentage of donations by first-time donors remained stable, between 6 and 8%. While first-time blood donors represented only 22% of the donor population, and 7% of the total donations, they contributed the majority (85%) of TTIs in Australian blood donors in 2022, 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, 2013-2022**



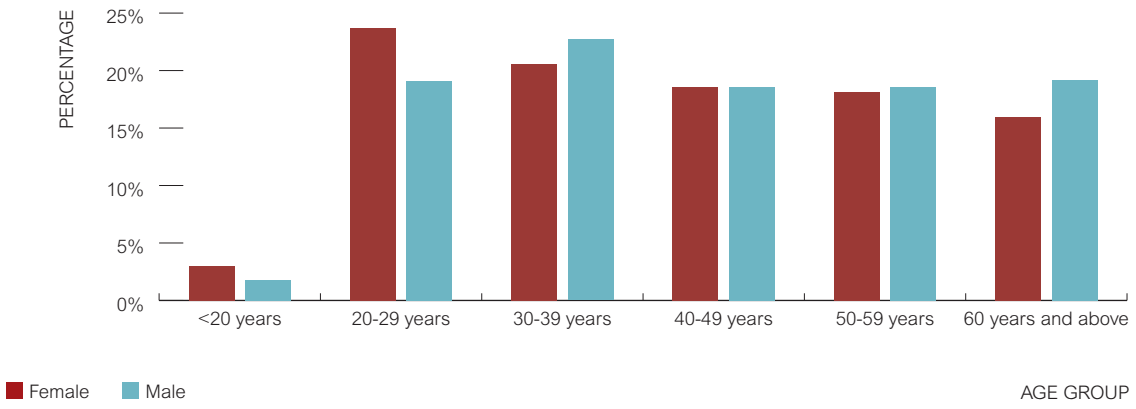
During 2013-2021, the proportion of repeat donors among all TTI-positive blood donations in Australia was generally stable (21-23%), except for 2014 and 2018, where the proportions increased to 33% and 32%, respectively (Figure 4). However, in 2022 this proportion decreased to 15%, the lowest in the past 10 years, 2013-2022. 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, 2013-2022**



Among all blood donors who donated in 2022, 51% were female and 49% 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 36% of donors were aged 50 years and above; the median age of male and female donors was 43 and 41 years, respectively.

Figure 5 **Distribution of blood donors in Australia, by age group and sex, 2022**



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 2013-2022. In addition, the association of demographic characteristics with the presence of TTIs for the year 2022 and the five-year period 2018-2022 are discussed. Putative risk factors associated with positive blood donors in Australia are also reported for the five-year period, 2018-2022. The findings are presented in respective sections by TTI.

Blood donors are a subset of the general population, so to provide context for the report the epidemiology of each relevant TTI in Australia is also discussed in respective sections. Where available, this includes a brief description of the estimated number of people living with TTIs in Australia by the end of 2022, trends in the ten-year period 2013-2022, notifications of newly diagnosed TTIs in Australia, and risk exposure categories associated with respective infections. Of note, the 2022 estimates of number of people living with HBV in the general population in Australia were not available at the time of preparation of this report. Therefore, for HBV, comparisons were made with the 2021 estimates. The information is drawn from the Kirby Institute's report - HIV, viral hepatitis and sexually transmissible infections in Australia: Annual Surveillance report 2023.[2]

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 regarding the strict incidence definition (negative test within the past 12 months). 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.

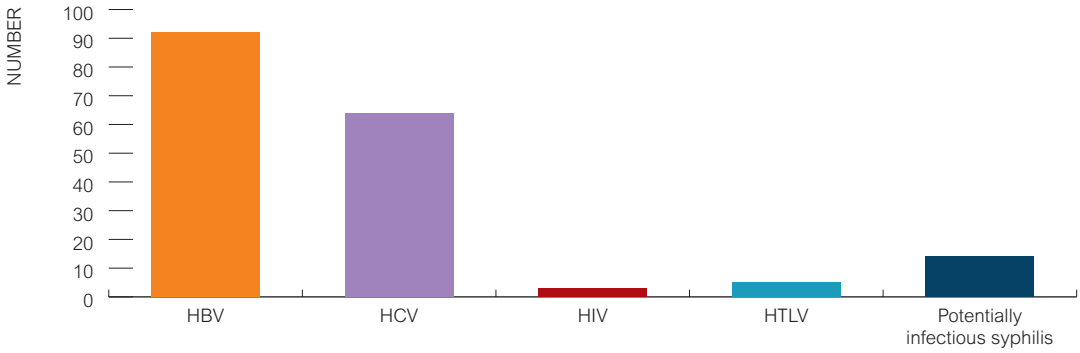
Lifeblood closely monitors donor incidence rates since these correlates directly with the risk of transmission in the window period. Incident donors are defined as positive repeat donors whose last donation tested negative for the same TTI within the last 12 months (with some exceptions; see glossary). 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 2013-2022, a total of 1 725 donations (1 326 first-time and 399 repeat donations) were positive for at least one of the TTIs subject to mandatory donation testing. Of these, 1 547 were positive for HBV, HCV and HIV (10.9 per 100 000 donations), 131 (1.3 per 100 000 donations) were positive for potentially infectious syphilis and 47 (0.6 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 10 years 2013-2022, (14.0 million donations for HBV, HCV and HIV, as opposed to 8.3 million and 9.9 million donations tested for HTLV and syphilis, respectively), these data are presented separately (Table 1A, 1B and IC). Of the positive donations during the ten-year period 2013-2022, 87.1% were positive for either HBV or HCV.

In 2022, a total of 178 donors were found positive for at least one of the TTIs subject to mandatory donation testing. Overall, HBV and HCV were the two most frequent TTIs identified in Australian blood donors in 2022, together contributing 87.6% of positive donors (Figure 6). This proportion has decreased by a relative 3.0% as compared to 90.4% in 2013.

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, 2018-2022, which retrospectively applies the updated DYO calculation method. During 2018-2022, a total of 25 incident donors were identified, six for HBV, 10 for HCV and nine for HIV. In 2022, a total of two incident donors were detected, one for HCV and one for HIV.

Figure 6 **Distribution of test positive blood donations in Australia, in 2022**



	HBV	HCV	HIV	HTLV	Potentially infectious syphilis
Positive Donations 2022	92	64	3	5	14

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 2022 and the five-year period 2018-2022 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.[3] Lifeblood undertook a risk assessment which determined that the HCV incidence rate in donors returning after a tattoo was negligible.[4] Lifeblood subsequently sought and was granted regulatory approval to amend the existing four-month donation deferral. Since 27 September 2020, where tattoos are received at an Australian licenced/registered tattoo parlour or cosmetic clinic, the donor is eligible for donations of plasma for fractionation immediately afterwards. Following a two-year post-implementation review of this change, Lifeblood subsequently sought and was granted regulatory approval to accept donations for fresh blood components from seven days after tattoos received in licensed establishments in Australia. This change was implemented on 26 June 2023. Plasma for fractionation donations continue to be accepted with no waiting period.

This report presents risk factor data for the five-year period 2018 to 2022. A total of 921 positive donors with at least one of the TTIs were observed over the period 2018-2022 (representing a total of 927 TTIs). The data on these donors were analysed for the period 2018-2022 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, 2013-2022

1A HBV, HCV and HIV, by state/territory, 2013-2022

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	317 208	4 033 379	4 350 587	226	46	272	174	46	220	10	7	17	410	99	509
Number *(Number per 100 000 donations)*				*71.25*	*1.14*	*6.25*	*54.85*	*1.14*	*5.06*	*3.15*	*0.17*	*0.39*	*129.25*	*2.45*	*11.70*
NT	6 998	96 231	103 229	9	2	11	4	3	7	0	0	0	13	5	18
Number *(Number per 100 000 donations)*				*128.61*	*2.08*	*10.66*	*57.16*	*3.12*	*6.78*	*0.00*	*0.00*	*0.00*	*185.77*	*5.20*	*17.44*
QLD	194 205	2 615 025	2 809 230	116	16	132	92	39	131	3	5	8	211	60	271
Number *(Number per 100 000 donations)*				*59.73*	*0.61*	*4.70*	*47.37*	*1.49*	*4.66*	*1.54*	*0.19*	*0.28*	*108.65*	*2.29*	*9.65*
SA	65 183	1 174 151	1 239 334	36	11	47	37	15	52	0	2	2	73	28	101
Number *(Number per 100 000 donations)*				*55.23*	*0.94*	*3.79*	*56.76*	*1.28*	*4.20*	*0.00*	*0.17*	*0.16*	*111.99*	*2.38*	*8.15*
TAS	29 226	503 664	532 890	14	5	19	23	5	28	0	0	0	37	10	47
Number *(Number per 100 000 donations)*				*47.90*	*0.99*	*3.57*	*78.70*	*0.99*	*5.25*	*0.00*	*0.00*	*0.00*	*126.60*	*1.99*	*8.82*
VIC	265 535	3 389 613	3 655 148	257	49	306	123	33	156	7	6	13	387	88	475
Number *(Number per 100 000 donations)*				*96.79*	*1.45*	*8.37*	*46.32*	*0.97*	*4.27*	*2.64*	*0.18*	*0.36*	*145.74*	*2.60*	*13.00*
WA	92 390	1 296 446	1 388 836	67	16	83	31	8	39	2	2	4	100	26	126
Number *(Number per 100 000 donations)*				*72.52*	*1.23*	*5.98*	*33.55*	*0.62*	*2.81*	*2.16*	*0.15*	*0.29*	*108.24*	*2.01*	*9.07*
National	970 745	13 108 509	14 079 254	725	145	870	484	149	633	22	22	44	1 231	316	1 547
Number *(Number per 100 000 donations)*				*74.68*	*1.11*	*6.18*	*49.86*	*1.14*	*4.50*	*2.27*	*0.17*	*0.31*	*126.81*	*2.41*	*10.99*

1B HTLV, by state/territory, 2013-2022

State/Territory of donation	All accepted donations			HTLV		
	First time	Repeat	All	First time	Repeat	All
NSW/ACT	317 208	2 347 043	2 664 251	16	3	19
Number *(Number per 100 000 donations)*				*5.04*	*0.13*	*0.71*
NT	6 998	48 341	55 339	0	0	0
Number *(Number per 100 000 donations)*				*0.00*	*0.00*	*0.00*
QLD	194 205	1 505 851	1 700 056	3	0	3
Number *(Number per 100 000 donations)*				*1.54*	*0.00*	*0.18*
SA	65 183	656 705	721 888	2	1	3
Number *(Number per 100 000 donations)*				*3.07*	*0.15*	*0.42*
TAS	29 226	270 486	299 712	4	0	4
Number *(Number per 100 000 donations)*				*13.69*	*0.00*	*1.33*
VIC	265 535	1 886 051	2 151 586	16	0	16
Number *(Number per 100 000 donations)*				*6.03*	*0.00*	*0.74*
WA	92 390	693 823	786 213	2	0	2
Number *(Number per 100 000 donations)*				*2.16*	*0.00*	*0.25*
National	970 745	7 408 300	8 379 045	43	4	47
Number *(Number per 100 000 donations)*				*4.43*	*0.05*	*0.56*

1C Potentially infectious syphilis, by state/territory, 2013-2022

State/Territory of donation	All accepted donations			Potentially infectious syphilis		
	First time	Repeat	All	First time	Repeat	All
NSW/ACT	317 208	2 888 484	3 205 692	13	31	44
Number *(Number per 100 000 donations)*				*4.10*	*1.07*	*1.37*
NT	6 998	55 569	62 567	0	1	1
Number *(Number per 100 000 donations)*				*0.00*	*1.80*	*1.60*
QLD	194 205	1 798 176	1 992 381	11	15	26
Number *(Number per 100 000 donations)*				*5.66*	*0.83*	*1.30*
SA	65 183	771 955	837 138	3	2	5
Number *(Number per 100 000 donations)*				*4.60*	*0.26*	*0.60*
TAS	29 226	310 093	339 319	0	0	0
Number *(Number per 100 000 donations)*				*0.00*	*0.00*	*0.00*
VIC	265 535	2 327 705	2 593 240	18	26	44
Number *(Number per 100 000 donations)*				*6.78*	*1.12*	*1.70*
WA	92 390	833 237	925 627	7	4	11
Number *(Number per 100 000 donations)*				*7.58*	*0.48*	*1.19*
National	970 745	8 985 219	9 955 964	52	79	131
Number *(Number per 100 000 donations)*				*5.36*	*0.88*	*1.32*

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Hepatitis B Virus (HBV)

Epidemiology of HBV in Australia

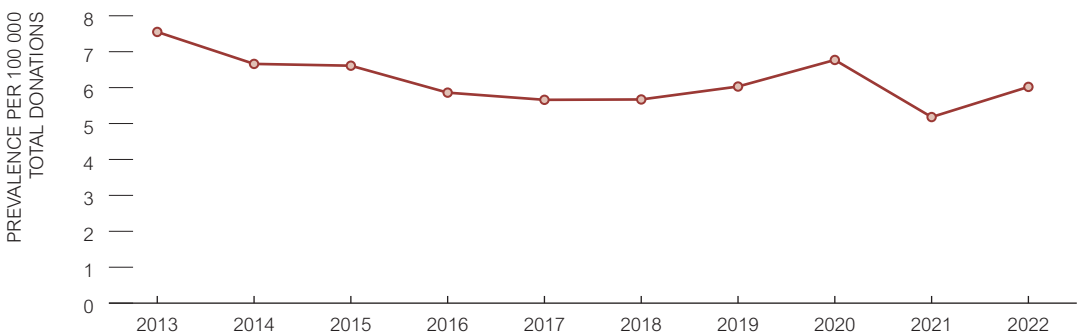
At the end of 2021, an estimated 200 385 people were living with chronic HBV in Australia, of whom an estimated 74% (165 249) were diagnosed with chronic hepatitis B, 23% and 23% were born in the Northeast and Southeast Asia, respectively, and 7% were among Aboriginal and Torres Strait Islander peoples.[1] In total, there were 5 075 notifications of newly diagnosed HBV in Australia in 2022; of these, over half (53%) 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, 2013-2022, the population rate of diagnosis of HBV in Australia has declined in younger age groups: 25-29 years (from 60.6 to 23.5 per 100 000); 20-24 years (from 36.3 to 11.5 per 100 000); and 15-19 years (from 17.3 to 4.0 per 100 000).[2] 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 two years) in the past 10 years by 30% from 0.8 per 100 000 in 2013 to 0.2 per 100 000 in 2022.[2] The estimated prevalence of chronic HBV among people living in Australia is ~0.8%, which is higher than for people living in the United Kingdom (<0.5%)[5] but lower than many other countries in Southeast Asia and the Pacific.

Trends in prevalence

All donations:

In the past 10 years, 2013-2022, a total of 870 HBV-positive donors have been detected (725 first-time donors & 145 repeat donors) (Table 1A). During this period, no significant trend was observed in HBV prevalence among all donations (IRR 0.97; 95% CI: 0.95-1.00). Overall, in the past 10 years HBV prevalence in all donations has fluctuated between 5.1 to 7.5 per 100 000 donations (Figure 7). However, the average prevalence among all donations for the period 2013-2022 shows a decline to 6.2 per 100 000 donations (0.01% of the total donations) (Table 1A) as compared to 8.9 and 7.4 per 100 000 donations for the 2005-2014 and 2009-2018 periods, respectively. This 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=154) 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.[6] For detail on the number and prevalence rate of HBV-positive donors among all donations for 2022, see Supplementary Table 2.

Figure 7 **HBV prevalence in all blood donations in Australia, by year of donation, 2013-2022**

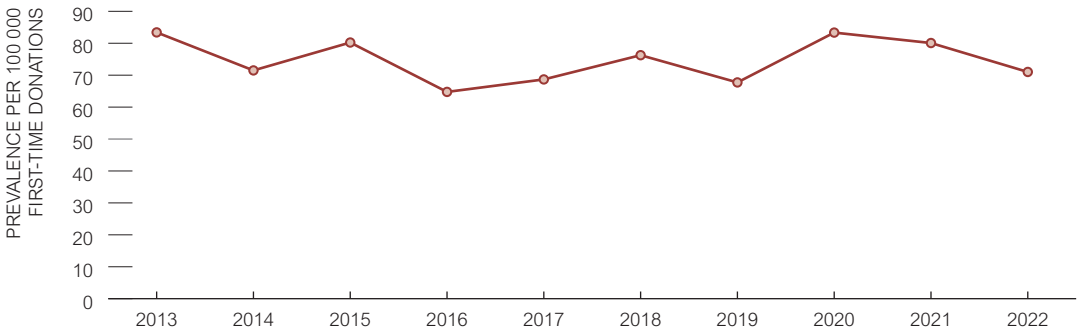


	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022
Prevalence in all donations	7.55	6.66	6.61	5.86	5.66	5.67	6.03	6.77	5.18	6.02

First-time donors:

Although HBV prevalence decreased from 80.0 to 71.0 per 100 000 donations in 2022 as compared to 2021, over the ten-year period 2013-2022, 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 2013-2022 shows a decline to 74.7 per 100 000 donations (0.07% of the total first-time donations) (Table 1A) as compared to 82.6 and 77.2 per 100 000 donations for the 2005-2014 and 2009-2018 periods, respectively. This trend is reflected in the Australian general population with the notification rate showing a downward trend in the past 10 years, at 28.8 per 100 000 in 2013, 26.5 per 100 000 in 2015, and 19.3 per 100 000 in 2022.[2]

Figure 8 **HBV prevalence in first-time blood donors in Australia, by year of donation, 2013-2022**



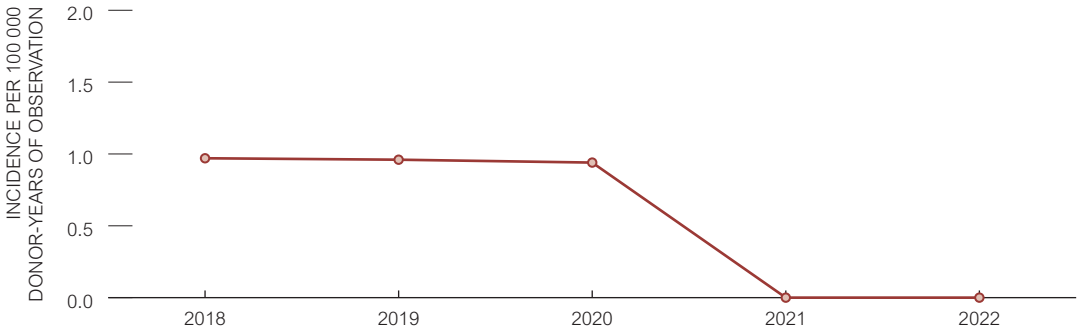
	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022
Prevalence in first-time donors	83.4	71.49	80.23	64.76	68.67	76.26	67.73	83.34	80.07	71.01

Trends in incidence

For the five-year period 2018-2022, there was a total of six 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: 0.54; 95% CI: 0.27-1.08) (Figure 9). Similar to 2021, no incident HBV donor was detected in 2022.

No transfusion-transmitted HBV cases were reported in Australia during 2018-2022. 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.

Figure 9 **HBV incidence in repeat blood donors in Australia, by year of donation, 2018-2022**

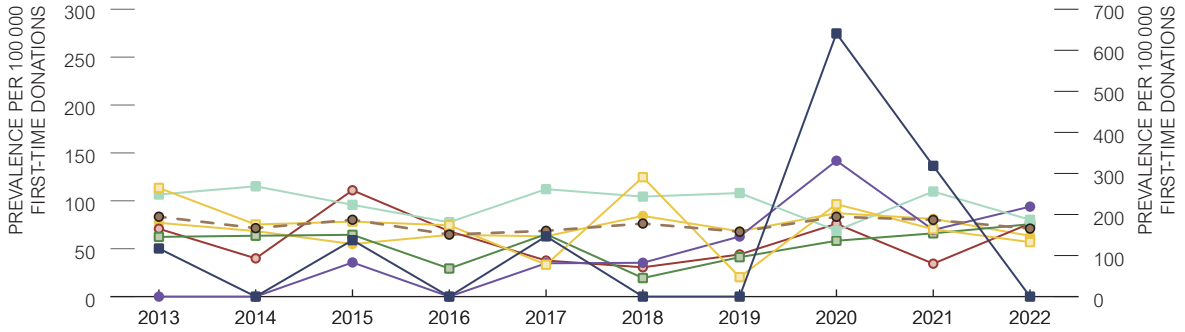


	2018	2019	2020	2021	2022
Incidence	0.97	0.96	0.94	0.00	0.00

Trends in HBV by state/territory

Consistent with previous TTI surveillance reports, the HBV prevalence among first-time donors varied markedly by jurisdiction in 2022, which is expected given random variation with small numbers. While the national prevalence was 71.0 per 100 000 donations, this ranged from 0.0 to 93.9 per 100 000 donations across jurisdictions (Figure 10). During the past 10 years, 2013-2022, a significant increasing trend was observed for Tasmania (IRR: 1.34; 95% CI: 1.07-1.68), where the highest prevalence among first-time donors as compared to the other states was recorded in 2022 (93.9 per 100 000 donations, equating to three positive first-time donors). For the ten-year period 2013-2022, the highest average prevalence among first-time donors was observed in the Northern Territory, at 136.1 per 100 000 donations, followed by Victoria at 97.8 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 except Tasmania. In comparison, although the Northern Territory had the highest rate of diagnosis of HBV reported in national surveillance data for the 2013-2020 period (between 127.7 per 100 000 in 2012 and 35.7 per 100 000 in 2020), the highest recorded rate in 2022 was in New South Wales, at 24.8 per 100 000, followed by Victoria at 20.8 per 100 000, whereas a marked decrease in Northern Territory was observed in 2022, at 17.9 per 100 000 population.[2]

Figure 10 HBV prevalence among first-time donors, by state/territory and year of donation, 2013-2022[i]

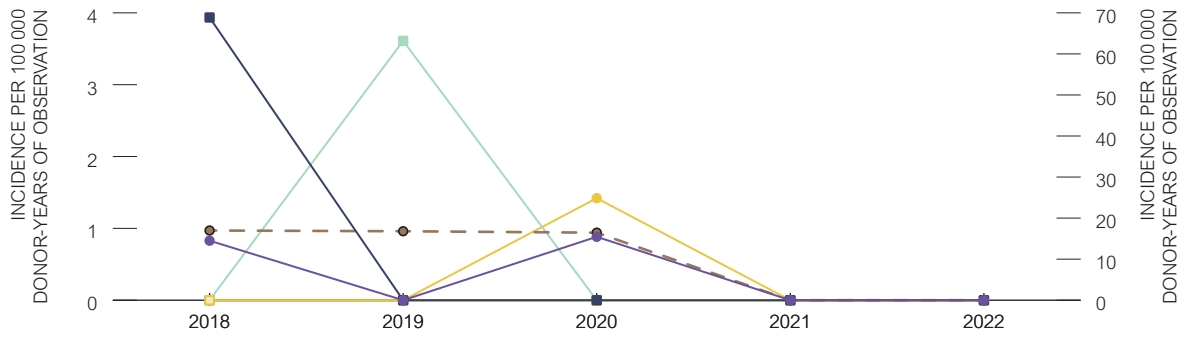


	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022
NSW/ACT	77.01	68.41	54.83	64.44	62.97	84.23	68.16	87.07	81.16	63.42
QLD	70.82	39.91	111.03	68.25	37.63	30.58	43.99	76.03	34.37	76.34
SA	62.33	63.53	64.50	29.31	65.15	19.38	41.15	58.28	66.06	75.60
TAS	0.00	0.00	35.63	0.00	34.79	35.29	62.72	141.84	69.59	93.90
VIC	106.58	115.15	95.79	77.63	112.18	104.37	108.11	68.87	109.71	80.22
WA	113.44	75.26	78.28	74.48	33.31	124.69	20.32	96.50	70.41	56.86
NT	117.23	0.00	137.55	0.00	146.84	0.00	0.00	641.03	318.47	0.00
National	83.40	71.49	80.23	64.76	68.67	76.26	67.73	83.34	80.07	71.01

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

Similar to 2021, there were no HBV incident donors recorded nationally in 2022. Overall, there was no obvious trend in HBV incidence in any state/territory during the five-year study period 2018-2022 (Figure 11). Among donors in Queensland, South Australia and Western Australia, HBV incidence has been zero since 2018.

Figure 11 HBV incidence among repeat donors, by state/territory and year of donation, 2018-2022[i]



	2018	2019	2020	2021	2022
NSW/ACT	0.00	0.00	1.42	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
VIC	0.00	3.61	0.00	0.00	0.00
WA	0.00	0.00	0.00	0.00	0.00
National	0.97	0.96	0.94	0.00	0.00
NT	68.87	0.00	0.00	0.00	0.00
TAS	14.50	0.00	15.45	0.00	0.00

i 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.[6] To the end of 2022, 234 donors with OBI have been detected, notified and referred for external clinical assessment which reduces the residual risk of HBV and contributes to the identification of undiagnosed HBV in Australia. In 2022, 19 of the 92 (20.6%) HBV-positive donors detected were classified as OBI, as compared to 20 of 83 (24.1%) in 2021. Most (17/19; 89%) OBIs in 2022 were men and just over half (10/19; 52%) were new donors, with an average age of 52.3 years. The majority (14/19; 74%) of donors with OBI in 2022 were born in Asia (Southeast/Northeast Asia – 9, Southern and Central Asia – 5).

Comparison of HBV prevalence among blood donors and the general population

This section presents a comparison of HBV prevalence among first-time blood donors and the general population. As noted above, the 2022 estimates for people living with HBV in general population were not available at the time of report preparation, therefore although blood donor data are presented for 2013-2022 and 2022, comparison with the general population was made with a combined period of 2012-2021 and 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[7,8] 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- and 11-times lower prevalence in first-time donors during the period 2012/2013-2021/2022 and for the year 2021/2022, respectively. 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,* 2021/2022 and 2012/2013-2021/2022

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	2013-2022	2022	2012/2013-2021/2022	2021/2022
HBV	883	779	74.68	71.01	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 10 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 in blood donors

Data on the demographic characteristics (sex, age group, state/territory and year of donation) for all blood donors were analysed (see Methodological Notes for details) to determine any association between demographic factors and HBV positivity among Australian blood donors in 2022 and the five-year period 2018-2022 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 2022, female donors were 72% less likely to be HBV positive compared to male donors. Donors over 50 years of age were 59% less likely to be HBV positive compared to the reference age group of 20-29 years. There was no significant association between donors' state of residence and HBV positivity as compared to the reference group of New South Wales (Supplementary Table 4).

In the five-year period 2018-2022, female donors were 66% 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 higher rate of HBV positivity as compared to the reference groups (2.1 and 1.2 times, respectively, see Supplementary Table 5), while donors from Queensland were 35% less likely to be HBV positive. In comparison, during 2013-2022, the notification rates of HBV in Australia have been consistently higher in male (32.5 per 100 000 in 2013 to 20.8 per 100 000 in 2022), than female persons (24.9 per 100 000 in 2013 to 17.8 per 100 000 in 2022). 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 2013-2020 (127.7 per 100 000 in 2013 to 35.7 per 100 000 in 2020) but fell by 50% in 2022 to 17.9 per 100 000 population. In all other jurisdictions the rate of HBV diagnosis has also declined during the ten-year period 2013-2022, ranging between an 8% decline in Tasmania (12.6 per 100 000 in 2013 to 11.3 per 100 000 in 2022) and a 49% decline in South Australia (20.9 per 100 000 in 2013 to 10.6 per 100 000 in 2022).[2]

Risk factors associated with HBV-positive donors

Of the 452 HBV positive donors during 2018-2022, 84% were first-time donors, 73% were male, and the mean age was 40 years (Table 3). Most (92%) of the HBV positive donors were born overseas, which reflects the epidemiology of hepatitis B in the general population. Ethnicity or country of birth (82%) was the most frequent risk factor for HBV positivity, with 50% born in Northeast & Southeast Asia in 2022 (Figure 12). There were only six 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, 2018-2022

Characteristics	2018	2019	2020	2021	2022	2018-2022
Number of positive donors	79	90	108	83	92	452
Number of positive first-time donors (%)	62 (78%)	71 (79%)	89 (82%)	76 (92%)	81 (88%)	379 (84%)
Number of male donors (%)	60 (76%)	73 (81%)	68 (63%)	59 (71%)	71 (77%)	331 (73%)
Mean age (range) in years	41 (19-71)	40 (19-73)	41 (18-74)	41 (20-76)	39 (21-75)	40 (18-76)
Number of incident donors	2	2	2	0	0	6
Number of donors born in Australia (%)	8 (10%)	11 (15%)	9 (8%)	2 (2%)	6 (7%)	36 (8%)
Main reported risk factor	Ethnicity/COB[1] 91%*	Ethnicity/COB[1] 90%*	Ethnicity/COB[1] 71%*	Ethnicity/COB[1] 78.3%*	Ethnicity/COB[1] 80%*	Ethnicity/COB[1] 82%
Second reported risk factor	Undetermined 3%	PUSR[2] 3%	FH/HC[3] 16%	FH/HC[3] 18%	FH/HC[3] 16%	FH/HC[3] 11%

1 COB= Country of birth
2 PUSR= Partner with unspecified risk
3 FH/HC= Family history/Household contact
* 3 out of 8, 4 out of 11, 1 out of 9, 1 out of 2, and 1 out of 6 donors born in Australia had Ethnicity as their major risk factor in 2018, 2019, 2020, 2021 and 2022, respectively

Figure 12 HBV-positive donors, by country/region of birth, 2022 (n=92)

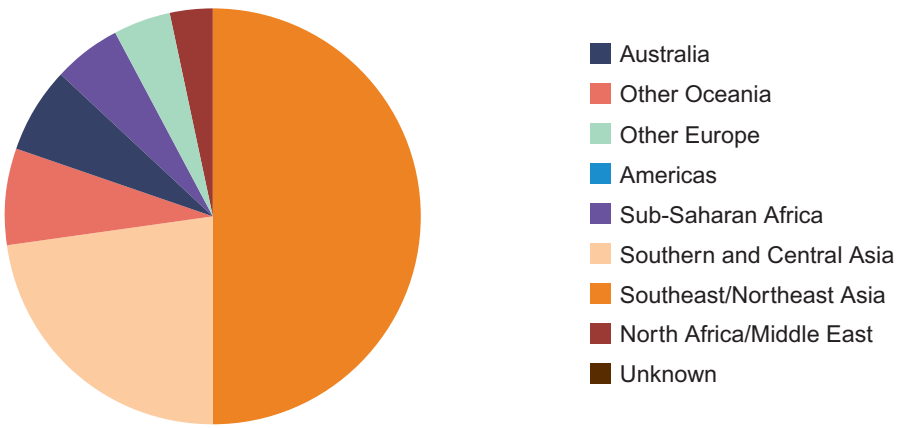
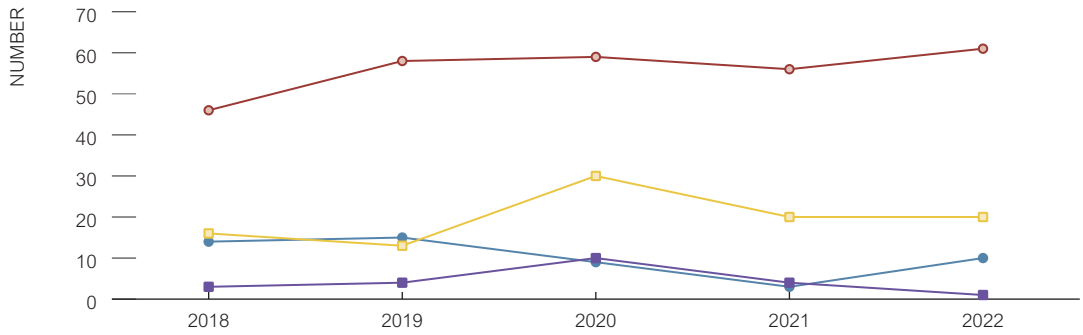


Figure 13 **HBV-positive donors, by sex and donor status, 2018-2022**



	2018	2019	2020	2021	2022
Male (first-time)	46	58	59	56	61
Male (repeat)	14	15	9	3	10
Female (first-time)	16	13	30	20	20
Female (repeat)	3	4	10	4	1

Since 2018, a slight increase has been observed in the number of male HBV-positive first-time donors, while the number of female HBV-positive first-time donors remained relatively stable. The number of HBV-positive repeat male and female donors remained stable during the same period (Figure 13). In comparison, there have been declines in HBV notification rates by sex in the ten-year period 2013-2022, from 32.5 to 20.8 per 100 000 male population and 24.9 to 17.8 per 100 000 female population.[2] 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 2022 and the period 2013-2022, 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 80.4% of the HBV-positive donors in 2022. This finding also parallels the general population data that shows that country of birth is the strongest risk factor for chronic HBV in Australia.[9-11]

Nationally, enhanced information on potential risk categories is collected for newly acquired HBV only (defined as newly diagnosed HBV with laboratory or clinical evidence of acquisition in the 24 months prior to diagnosis). In 2022, for newly acquired HBV in the general population, 15.5% had injecting drug use and 6.8% had sexual contact and tattoo or body piercing as their major risk factors, separately; importantly, for 18.1% and 37.4% of newly acquired HBV in the general population, the risk factor was either not reported or could not be identified, respectively (Table 4).[12] 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, 2022**

	HBV	
Major risk category	Newly acquired HBV cases in general population (2022) (%)	Blood donors (2022) (%)
Injecting drug use	15.5	0.0
Country of birth/Ethnicity	10.3	80.4
Sexual contact[i]	6.8	1.1
Blood or tissue recipient	1.7	0.0
Tattoo or body piercing	6.8	0.0
Exposure in health care setting	1.7	0.0
Household contact/Family history	0.0	16.3
Other blood to blood contact	1.7	0.0
Other/undetermined/unknown/not reported	18.1	2.2
Imprisonment	0.0	0.0
Occupational risk	0.0	0.0
Other	0.0	0.0
No risk factor identified	37.4	0.0

i 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 2013 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, with 19 OBI among 92 HBV infections in 2022.
- 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

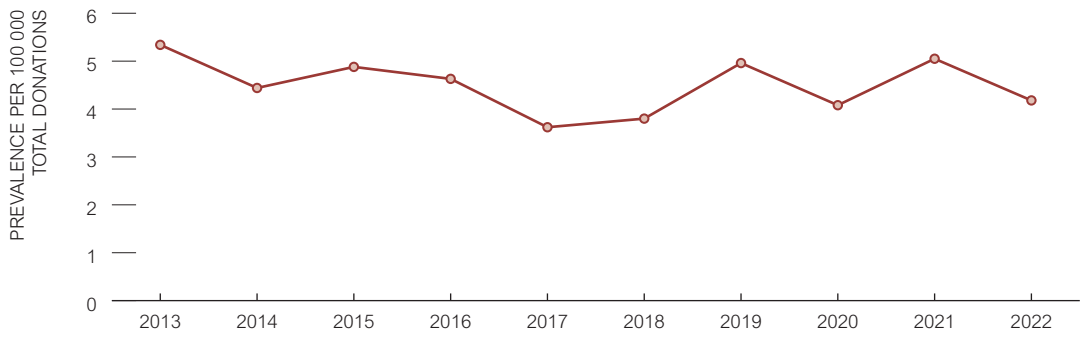
To the end of 2022, an estimated 74 400 people were living with chronic hepatitis C in Australia, of which an estimated 81% or 60 240 were diagnosed with chronic hepatitis C.[2] Australia has a concentrated chronic hepatitis C epidemic among key populations: people who inject drugs, prisoners, people from high prevalence countries and HIV-positive men who have sex with men. The rate of diagnosis of HCV in 2022 was 25.8 per 100 000 which reflects a 42% decline from 44.6 per 100 000 population in 2013.[2] However, in the period 2013-2016 the rate increased by 18%, from 44.6 per 100 000 to 52.5 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 is therefore taken as a proxy of incidence, has declined by 57% in the past 10 years, 2013-2022.[2] 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 188.5 per 100 000 in 2022, whereas the rate in non-indigenous people in the same age group declined by 34% from 28 in 2019 to 18.3 per 100 000 in 2022.[2] Similarly, in 2022, the diagnosis rate of HCV was more than seven times higher in the Aboriginal and Torres Strait Islander population (156.2 per 100 000) than that of the non-indigenous population (21.7 per 100 000). In 2022, most cases (83%) of newly diagnosed HCV were in male persons and 73% were in people aged 25 years and above.[2]

Trends in prevalence

All donations:

In the past 10 years, 2013-2022, 633 HCV-positive donors have been detected (484 first-time donors and 149 repeat donors) (Table 1A). During this period, no significant trend was observed in HCV prevalence among all donations. Overall, in the past 10 years HCV prevalence in all donations has fluctuated between 3.6 and 5.3 per 100 000 donations (Figure 14). For detail on the number and prevalence rate of HCV among all donations for 2022 see Supplementary Table 2.

Figure 14 **HCV prevalence in all blood donations in Australia, by year of donation, 2013-2022**



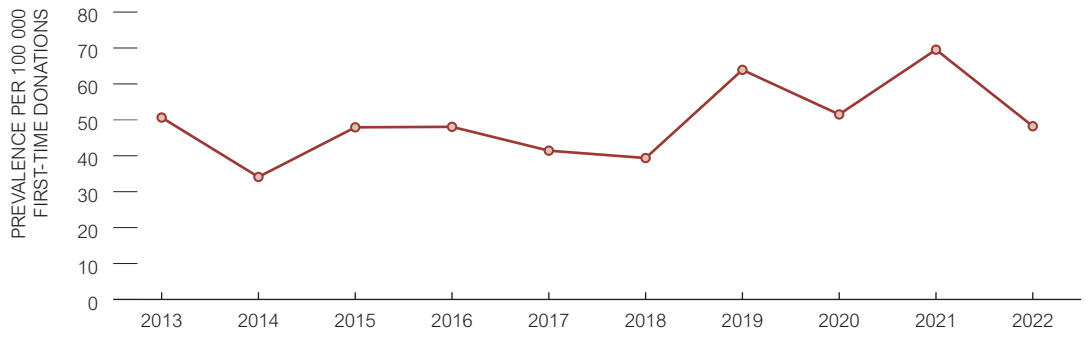
	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022
Prevalence in all donations	5.34	4.44	4.88	4.63	3.62	3.80	4.96	4.08	5.05	4.18

First-time donors:

During the 2013-2022 period, HCV prevalence in first-time donors increased significantly (IRR: 1.03; 95% CI: 1.00-1.06) (Figure 15). This increase in HCV prevalence in first-time donors, especially in the recent years 2018-2022, is likely to be the combined impact of two factors. Firstly, the number of prospective donors attending with a past history of HCV has increased. 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, eligibility policy regarding injecting drug use changed from indefinite deferral to a five-year deferral in September 2018.

In comparison, the national rate of diagnosis of HCV declined from 44.6 per 100 000 in 2013 to 25.8 per 100 000 in 2022.[2] In addition, there has also been a decrease in the prevalence of hepatitis C antibody among people seen at needle and syringe programs, from 45% in 2018 to 32% in 2022. During the same period, the rates of receptive needle and syringe sharing remained stable (range: 16 to 19%), highlighting the importance of sustaining and enhancing harm reduction services.[13]

Figure 15 HCV prevalence in first-time blood donors in Australia, by year of donation, 2013-2022



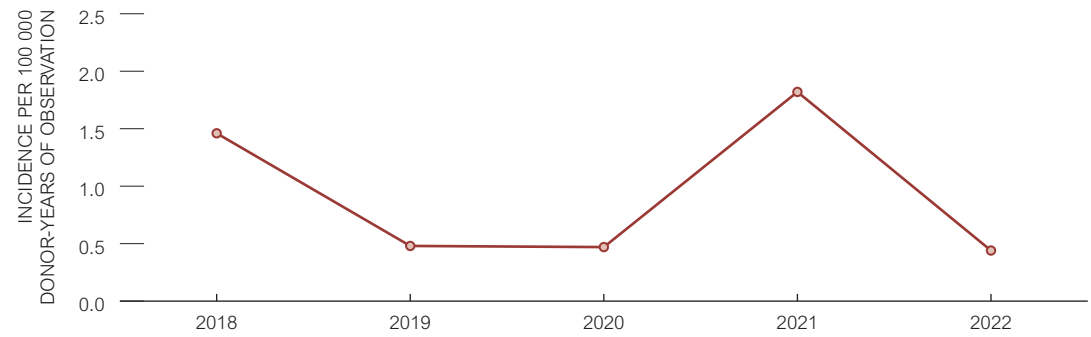
	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022
Prevalence in first-time donors	50.64	34.10	47.92	48.05	41.42	39.36	63.91	51.50	69.54	48.22

Trends in incidence

Over the five-year period 2018-2022, 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: 0.92; 95% CI: 0.59-1.43) (Figure 16). Only one HCV incident donor was identified in 2022, equating to an incidence rate of 0.44 per 100 000 donor-years of observation as compared to 1.82 per 100 000 donor-years of observation in 2021, which was the highest in the past five years (Figure 16). Modelled national HCV incidence estimates for 2022 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, HCV incidence declined from 1.3 to 0.4 new infections per 100 person-years between 2013-2021 before slightly increasing to 0.5 new infections per 100 person-years in 2022.[2]

No transfusion-transmitted HCV cases were reported in Australia during 2018-2022.

Figure 16 HCV incidence in repeat blood donors in Australia, by year of donation, 2018-2022



	2018	2019	2020	2021	2022
Incidence	1.46	0.48	0.47	1.82	0.44

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 but remain ineligible to donate because they will test positive for a mandatory test required for blood release and meet 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 (from 72.6 to 32.1%). However, an increase was observed in both this proportion and the overall HCV prevalence rate during 2019-2021, where the RNA positive proportion increased to 47.3%, 38.5% and 37.0% in 2019, 2020 and 2021, respectively, from 32.1% in 2018, before dropping to 29.7% in 2022. 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 five years, resulting in the subsequent attendance of newly eligible donors with undiagnosed HCV.

All (100% - 19/19) of the HCV RNA-positive donors in 2022 were first-time donors, equating to a rate of RNA-positive donors among first-time donors at 16.7 per 100 000 donations. No significant trend was observed in the rate of RNA-positive donors among first-time donors (or those not previously HCV tested) for the 2013-2022 period (IRR: 0.98; 95% CI: 0.94-1.03).

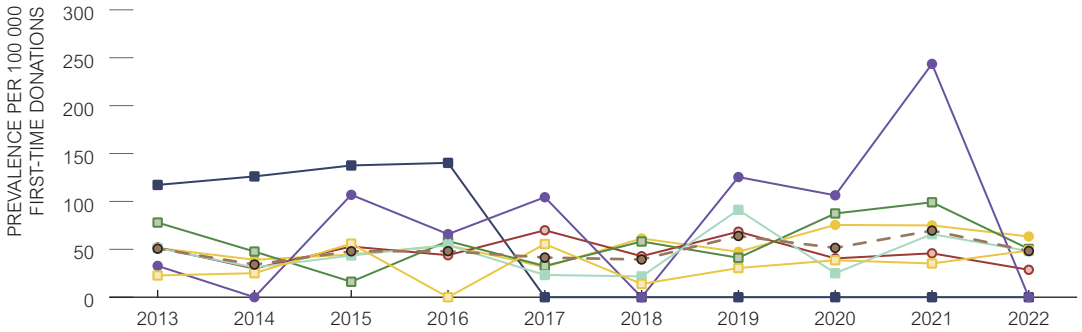
Importantly, first-time HCV-positive donors do not correlate directly with an increase in the HCV residual transmission risk. This is because the increase is among prevalent (long-standing) infections, readily detectable by Lifeblood's dual NAT/antibody testing strategy. The transmission risk for transfused 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 three in 2018, to one each in 2019, 2020 and 2022, however it increased to four 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 2022, ranging from 0.0 to 63.42 per 100 000 donations. During the past 10 years, 2013-2022, a significant increasing trend was observed for New South Wales (IRR: 1.05; 95% CI: 1.00-1.11), where the highest prevalence among first-time donors compared to other states was recorded in 2022, at 63.42 per 100 000 donations (Figure 17) (equating to 24 HCV-positive first-time donors). During the same period, no significant trend was observed for any other jurisdiction. Notably, in each year 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 10 years should be interpreted with caution due to small numbers of

positive donors, ranging between zero and seven. National notifications data indicate the notification rate of HCV in Australia in 2022 was highest in Queensland (34.0 per 100 000), followed by the Northern Territory (31.8 per 100 000), New South Wales and Western Australia (29.9 and 29.2 per 100 000 respectively).[2]

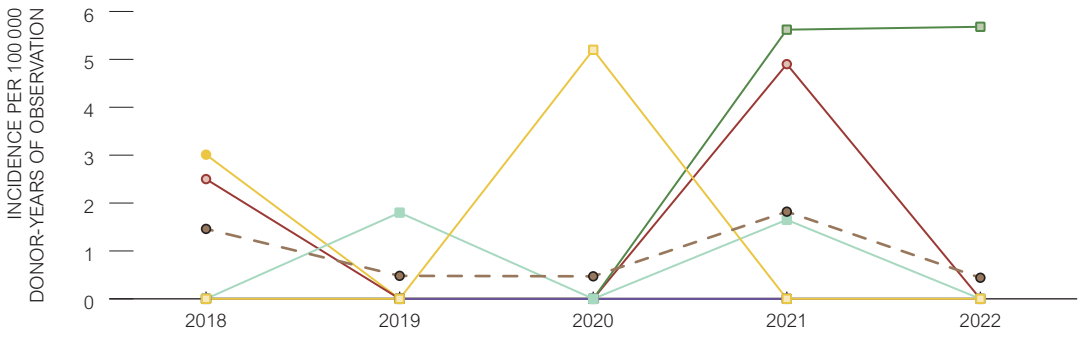
Figure 17 HCV prevalence among first-time donors, by state/territory and year of donation, 2013-2022



	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022
NSW/ACT	51.34	39.09	44.55	54.26	31.48	61.26	47.41	75.46	74.92	63.42
NT	117.23	126.10	137.55	140.25	0.00	0.00	0.00	0.00	0.00	0.00
QLD	51.93	29.94	52.87	43.87	69.88	42.81	68.44	40.55	45.82	28.63
SA	77.92	47.65	16.12	58.62	32.57	58.15	41.15	87.43	99.09	50.40
TAS	32.70	0.00	106.88	65.85	104.38	0.00	125.43	106.38	243.56	0.00
VIC	51.32	31.00	43.54	54.34	23.21	21.74	91.22	25.05	65.83	48.13
WA	22.69	25.09	55.92	0.00	55.51	13.85	30.48	38.60	35.21	48.73
National	50.64	34.10	47.92	48.05	41.42	39.36	63.91	51.50	69.54	48.22

There was no significant annual trend observed for HCV incidence in repeat donors nationally during the 2018-2022 study period (IRR: 0.92; 95% CI: 0.59-1.43). 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, in 2022, HCV incidence in South Australia was at 5.68, similar to 5.62 per 100 000 donor-years of observation in 2021, after remaining zero during the 2018-2020 period. This increase in incidence in 2021 and 2022 in South Australia should be interpreted with caution as it equates to just one incident donor each year. Notably, in the Northern Territory and Tasmania, HCV incidence has remained zero since 2018.

Figure 18 HCV Incidence among repeat donors, by state/territory and year of donation, 2018-2022



	2018	2019	2020	2021	2022
NSW/ACT	3.01	0.00	0.00	0.00	0.00
NT	0.00	0.00	0.00	0.00	0.00
QLD	2.50	0.00	0.00	4.90	0.00
SA	0.00	0.00	0.00	5.62	5.68
TAS	0.00	0.00	0.00	0.00	0.00
VIC	0.00	1.80	0.00	1.65	0.00
WA	0.00	0.00	5.20	0.00	0.00
National	1.46	0.48	0.47	1.82	0.44

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 2013-2022 and then 2022 separately. Subsequently, a discussion is presented on the prevalence reduction in first-time donors compared to the general population. Of note, caution must be applied when interpreting this comparison as the prevalence in the general population is based on the estimated number of people living with infectious HCV but the prevalence in first-time donors also includes donors with past resolved infection.

HCV prevalence is much higher in the general population than in blood donors, which is consistent with previous Lifeblood studies.[7,8] The prevalence in first-time donors was 13 and 6 times lower than the prevalence of people living with chronic hepatitis C in the general population for the period 2013-2022, and 2022, respectively (Table 5).

Table 5 Comparison of HCV prevalence in blood donors with population prevalence,* 2022 and 2013-2022

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	
	2013-2022	2022	2013-2022	2022	2013-2022	2022
HCV	653	286	49.86	48.22	13 times lower	6 times lower

* The 2022 HCV prevalence in the general population was calculated by taking the estimated number of people living with chronic HCV,[2] and dividing it by the estimated mid-year resident Australian population in 2022 reported by the Australian Bureau of Statistics. For the period 2013-2022, an average of the 10 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 2022 and the five-year period 2018-2022 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 2022, there was no significant association between donors' sex and state of residence and HCV positivity as compared to the reference groups. Donors over 50 years of age were five times more likely to be HCV-positive compared to the reference group (Supplementary Table 4).

During the five-year period 2018-2022, female donors were 33% 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 2018-2022, donors from Queensland, Victoria and Western Australia were less likely to be HCV positive as compared to the reference group (Supplementary Table 5).

Risk factors associated with HCV-positive donors

Of the 337 HCV-positive donors during 2018-2022, 81% were first-time donors and 59% 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 (64%) of HCV-positive donors during 2018-2022 were born in Australia (Figure 19).

Overall, the main reported putative risk factor for HCV positivity during 2018-2022 was injecting drug use at 27%, while for 19% of the HCV-positive donors the risk factor remained undetermined or unknown.

Table 6 Characteristics of HCV-positive donors, by year of donation, 2018-2022

Characteristics	2018	2019	2020	2021	2022	2018-2022
Number of positive donors	53	74	65	81	64	337
Number of positive first-time donors (%)	32 (60%)	67 (91%)	55 (85%)	66 (81%)	55 (86%)	274 (81%)
Number of male donors (%)	27 (51%)	44 (59%)	42 (65%)	51 (63%)	35 (55%)	199 (59%)
Mean age (range) in years	45 (18-67)	47 (18-70)	45 (20-69)	49 (18-72)	50 (18-72)	47 (18-72)
Number of incident donors	3	1	1	4	1	10
Number of donors born in Australia (%)	40 (75%)	47 (64%)	36 (55%)	57 (70%)	37 (58%)	217 (64%)
Main reported risk factor	TBP[1]	IDU[2]	IDU[2] & undetermined	IDU[2]	IDU[2]	IDU[2]
	26%	26%	20%	32%	33%	27%
Second reported risk factor	IDU[2]	TBP[1]	TBP[1]	Undetermined	Undetermined	Undetermined
	21%	23%	15%	21%	30%	19%

1 TBP= Tattoo/Body piercing
2 IDU= Injecting drug use

Figure 19 HCV-positive donors, by country/region of birth, 2022 (n=64)

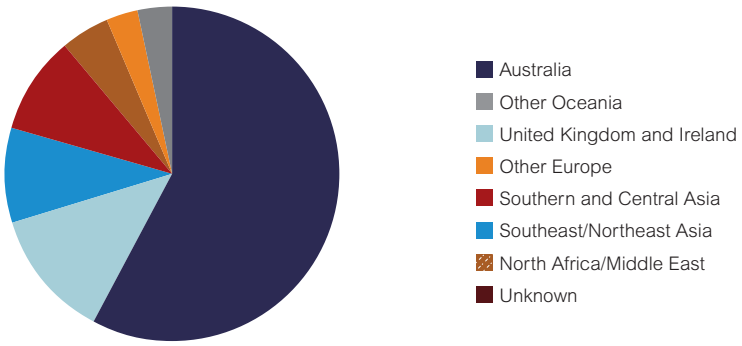
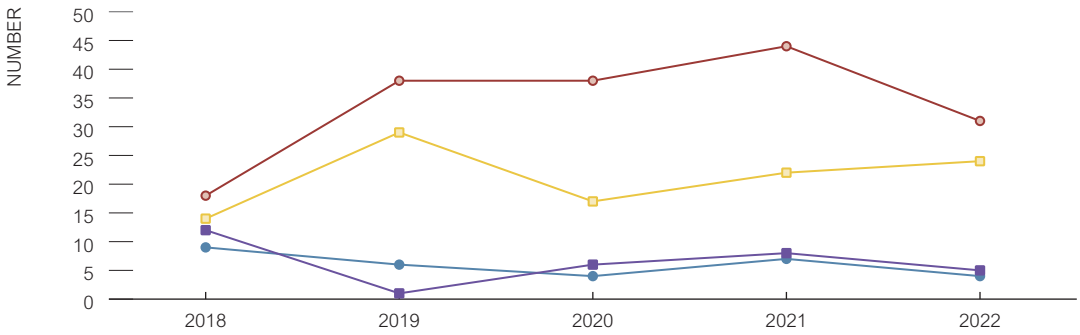


Figure 20 HCV-positive donors, by sex and donor status, 2018-2022



	2018	2019	2020	2021	2022
Male (first-time)	18	38	38	44	31
Male (repeat)	9	6	4	7	4
Female (first-time)	14	29	17	22	24
Female (repeat)	12	1	6	8	5

Over the five-year period 2018-2022, 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 five years. During the same period, the number of HCV-positive male and female repeat donors remained relatively stable (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 2022 and the period 2018-2022, see Supplementary Tables 6-12. In comparison, there have been gradual declines in HCV notification rates by sex in the ten-year period 2013-2022, from 58.1 to 36.2 per 100 000 male population and 31.0 to 15.5 per 100 000 female population.[2] 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, 2022

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 general population data which only relates to newly acquired HCV (newly diagnosed HCV with laboratory or clinical evidence of acquisition in the 24 months prior to diagnosis) and 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 2022 was IDU (32.8%), while tattoo or body piercing was low at 3.1%. Of note, in 2022, for 29.7% blood donors, the risk factor remained unknown/undetermined. In comparison, for newly acquired HCV in the general population in 2022, 66.1% had imprisonment as their major risk factor, followed by 13.6% that had IDU as their major risk factor. This difference could potentially be due to enhanced testing in prisons owing to the availability of treatment. Of note, for 19.8% of newly acquired HCV infections in the general population, the risk factor could not be identified.[12]

Table 7 Comparison between HCV-positive blood donors and general population in Australia, by major potential risk categories, 2022

	HCV	
Major risk category	Newly acquired HCV cases in general population (2022) (%)	Blood donors (2022) (%)
Injecting drug use	13.6	32.8
Country of birth/Ethnicity	0.0	14.1
Sexual contact[i]	0.3	7.8
Blood or tissue recipient	0.1	3.1
Tattoo or body piercing	0.0	3.1
Exposure in health care setting	0.0	1.6
Household contact/Family history	0.0	3.1
Other blood to blood contact	0.1	0.0
Undetermined/unknown/not reported	0.0	29.7
Imprisonment	66.1	4.7
Occupational risk	0.0	0.0
Other	0.0	0.0
No risk factor Identified	19.8	0.0

i 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 increased significantly during 2013-2022. Higher rates since 2018 may be explained in some part at least by donors with 'cured' HCV, or IDU more than five 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 2022 and for the period 2013-2022 was 6 and 13 times lower among first-time blood donors than the general population estimates in 2022, and for the period 2013-2022, respectively.
- HCV incidence, the best correlate of transfusion-transmission risk, has not shown a significant trend in the five-year study period 2018-2022. 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 2022 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

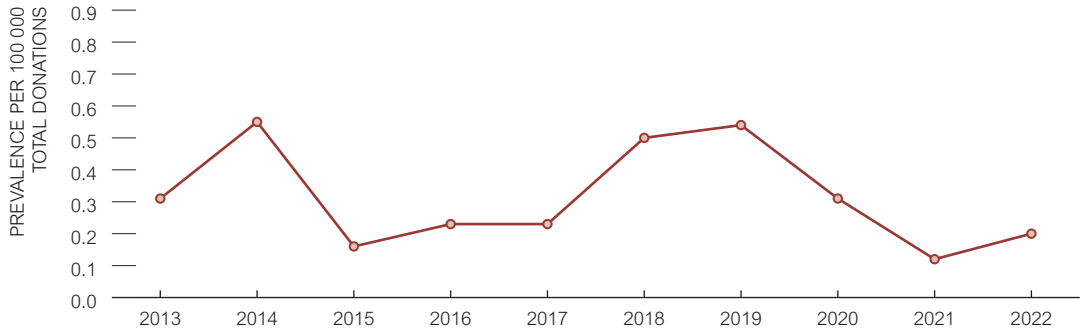
During 2022, an estimated 28 870 people were living with HIV and an estimated majority (93%) or 26 850 were diagnosed.[1] Transmission of HIV in Australia continues to occur primarily through sexual contact between men, with 57% cases of HIV first ever diagnosed in Australia in 2022 involving men who reported sexual contact with men (including those reporting male-to-male sex and injecting drug use).[2] The annual number of new HIV diagnoses (first ever in Australia) has decreased by 34% over the past five years, from 840 diagnoses in 2018 to 555 in 2022. Of those newly diagnosed HIV in 2022, 83% were in men, 49% occurred among men who have sex with men, 8% due to male-to-male sex and injecting drug use, 30% were attributed to heterosexual sex, and 3.2% to injecting drug use. At 0.1%, the prevalence or overall proportion of people in Australia who have HIV is lower than other comparable high-income countries, and countries in the region.[2]

Trends in prevalence

All donations:

In the past 10 years, 2013-2022, a total of 44 HIV-positive donors have been detected (22 first-time donors & 22 repeat donors) (Table 1A). During this period, no significant trend was observed in HIV prevalence among all donations (IRR: 0.95; 95% CI: 0.86-1.06). Overall, the prevalence has fluctuated within a tight range in the past 10 years between 0.1 and 0.5 per 100 000 donations (Figure 21). For detail on the number and prevalence rate of HIV among all donations for 2022, see Supplementary Table 2.

Figure 21 **HIV prevalence in all blood donations in Australia, by year of donation, 2013-2022**

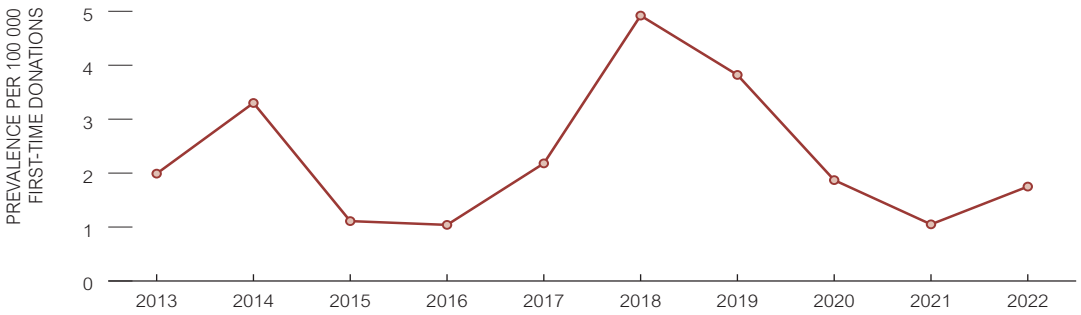


	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022
Prevalence in all donations	0.31	0.55	0.16	0.23	0.23	0.50	0.54	0.31	0.12	0.20

First-time donors:

HIV prevalence in first-time donors remained very low at 2.2 per 100 000 over the ten-year period 2013-2022 (Table 1A); it peaked at 4.9 per 100 000 donations in 2018 before declining to 1.0 in 2021 and fluctuating to 1.7 per 100 000 donations in 2022 (Figure 22). Overall, no significant trends were observed in HIV prevalence among first-time donors in the past 10 years (IRR: 0.99; 95% CI: 0.85-1.14). In comparison, the number of newly diagnosed HIV in the general Australian population decreased by 46%, from 1 037 diagnoses in 2013 to 555 cases of newly diagnosed HIV in Australia in 2022.[2] 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.

Figure 22 HIV prevalence in first-time blood donors in Australia, by year of donation, 2013-2022



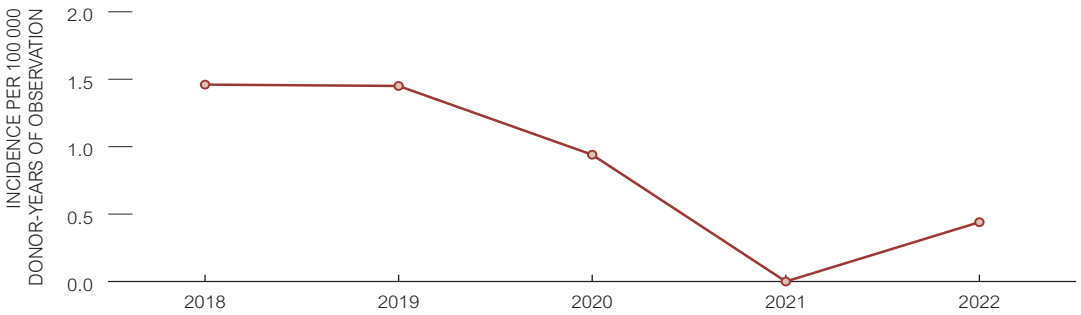
	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022
Prevalence in first-time donors	1.99	3.30	1.11	1.04	2.18	4.92	3.82	1.87	1.05	1.75

Trends in incidence

There was one incident HIV donor detected in 2022, equating to an incidence of 0.44 per 100 000 donor-years of observation (Figure 23). For the five years 2018-2022, there were a total of nine incident donors identified for HIV, and no significant trend was observed for HIV incidence during this time (IRR: 0.63; 95% CI: 0.38-1.06). While not directly comparable, the HIV incidence during 2018-2022 among gay and bisexual men attending sexual health services remained less than 0.2 per 100 persons years (fluctuating between 0.07 per 100 person years to 0.13 per 100 person years).[2]

No transfusion-transmitted HIV cases were reported in Australia during 2018-2022.

Figure 23 Incidence of HIV in repeat blood donors in Australia, by year of donation, 2018-2022

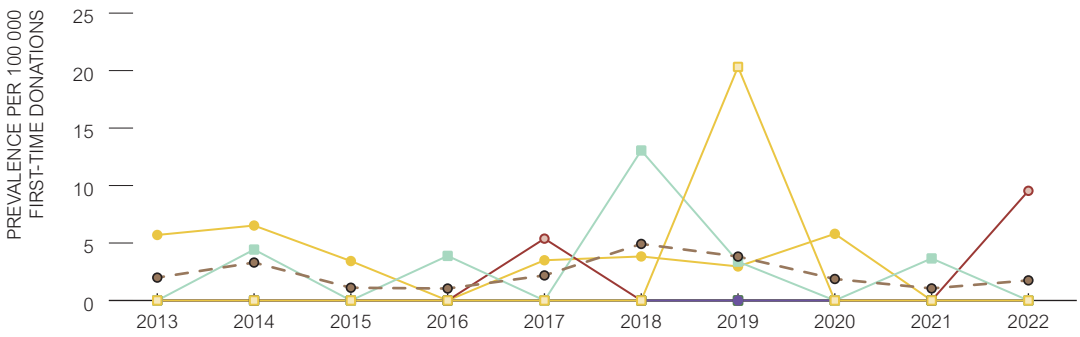


	2018	2019	2020	2021	2022
Incidence	1.46	1.45	0.94	0.00	0.44

Trends in HIV by state/territory

HIV prevalence in first-time donors remained substantially lower than for HBV and HCV throughout the 2013-2022 period, with an average national prevalence of 2.2 per 100 000 donations (Table 1A). No significant annual trend was observed during the 2013-2022 period in any jurisdiction (Figure 24). There were two HIV-positive first-time donors in 2022, both from Queensland, where the HIV prevalence in first-time donors was 9.54 per 100 000 donations (Figure 24), the highest for the state in the past 10 years. Given small numbers, caution should be taken in interpretation. During 2013-2022, HIV prevalence in first-time donors was zero in the Northern Territory, South Australia and Tasmania (Table 1A and Figure 24).

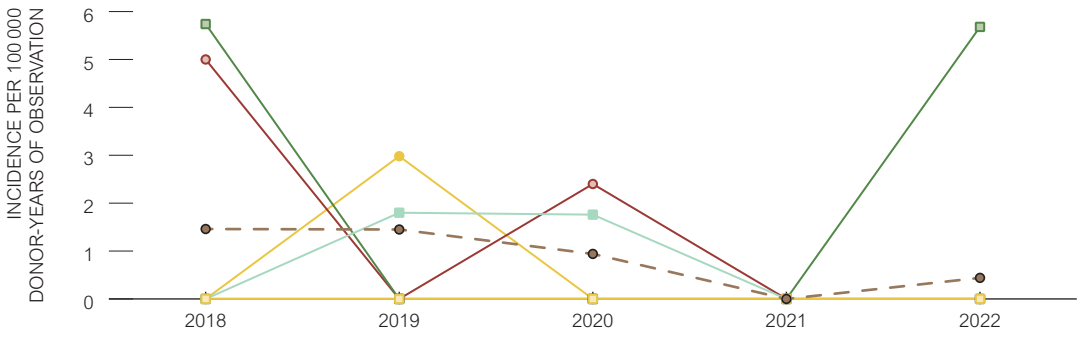
Figure 24 HIV prevalence among first-time donors, by state/territory and year of donation, 2013-2022



	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022
NSW/ACT	5.70	6.52	3.43	0.00	3.50	3.83	2.96	5.80	0.00	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	5.38	0.00	0.00	0.00	0.00	9.54
SA	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
TAS	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
VIC	0.00	4.43	0.00	3.88	0.00	13.05	3.38	0.00	3.66	0.00
WA	0.00	0.00	0.00	0.00	0.00	0.00	20.32	0.00	0.00	0.00
National	1.99	3.30	1.11	1.04	2.18	4.92	3.82	1.87	1.05	1.75

In 2022, there was only one HIV incident donor, from South Australia, equating to an incidence rate of 5.68 per 100 000 donor-years of observation. No incident HIV donors were recorded in Tasmania, Western Australia or the Northern Territory in the past five years, 2018-2022 (Figure 25). No significant annual trend was observed in any jurisdiction during 2018-2022.

Figure 25 HIV incidence among repeat donors, by state/territory and year of donation, 2018-2022



	2018	2019	2020	2021	2022
NSW/ACT	0.00	2.98	0.00	0.00	0.00
NT	0.00	0.00	0.00	0.00	0.00
QLD	5.00	0.00	2.40	0.00	0.00
SA	5.74	0.00	0.00	0.00	5.68
TAS	0.00	0.00	0.00	0.00	0.00
VIC	0.00	1.80	1.76	0.00	0.00
WA	0.00	0.00	0.00	0.00	0.00
National	1.46	1.45	0.94	0.00	0.44

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 2013-2022 and then 2022 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.[7,8] Prevalence in first-time donors was 49 times lower for the period 2013-2022, and 64 times lower in 2022 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,* 2022 and 2013-2022

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	
	2013-2022	2022	2013-2022	2022	2013-2022	2022
HIV	112	111	2.27	1.75	49 times lower	64 times lower

* The 2022 HIV prevalence in the general population was calculated by taking the estimated number of people living with HIV,[2] and dividing it by the estimated mid-year resident Australian population in 2022 reported by the Australian Bureau of Statistics. For the period 2013-2022, an average of the 10 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 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 2022 and the five-year period 2018-2022 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 2022, there was no significant association between gender, age or state/territory and HIV positivity (Supplementary Table 4). During the five-year period 2018-2022, female donors and donors between 40-49 years and 50-years-and-above age groups were 84%, 80% and 66% 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

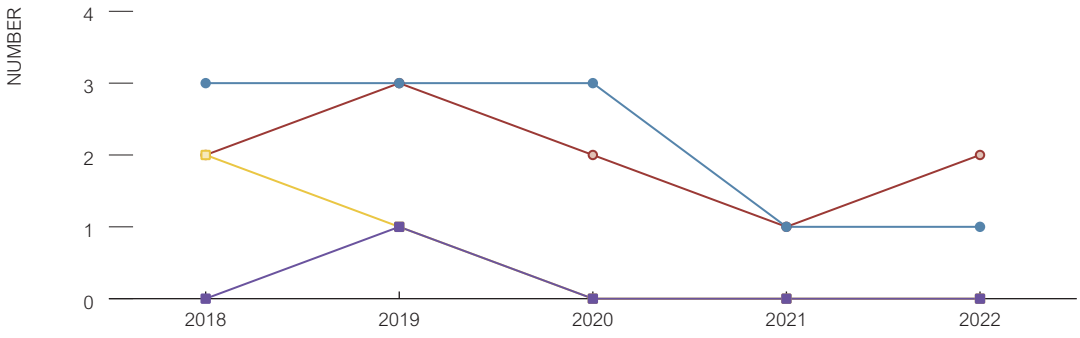
During 2018-2022, 52% of the 25 HIV-positive donors were first-time donors (Table 9). Most donors were male (84%) and had a mean age of 37 years, with a wide range of 20-70 years. Of 25 HIV-positive donors in the five-year period 2018-2022, nine were incident HIV donors. Having a sexual partner with unspecified risk for HIV and male-to-male sexual contact were the main reported risk factors for HIV positivity in blood donors during 2018-2022 (28% each), while for 32% of the HIV positive donors, the risk factor could not be determined. In comparison, male-to-male sexual contact and heterosexual contact accounted for 57% and 30% of the new HIV diagnoses in the general population in 2022, respectively.

Table 9 Characteristics of HIV-positive donors, by year of donation, 2018-2022

Characteristics	2018	2019	2020	2021	2022	2018-2022
Number of positive donors	7	8	5	2	3	25
Number of positive first-time donors (%)	4 (57%)	4 (50%)	2 (40%)	1 (50%)	2 (67%)	13 (52%)
Number of male donors (%)	5 (71%)	6 (75%)	5 (100%)	2 (100%)	3 (100%)	21 (84%)
Mean age (range) in years	32 (20-66)	37 (21-70)	38 (25-67)	44 (30-58)	43 (24-68)	37 (20-70)
Number of incident donors	3	3	2	0	1	9
Number of donors born in Australia (%)	2 (29%)	4 (50%)	2 (40%)	1 (50%)	2 (67%)	11 (44%)
Main reported risk factor	MSM[1] contact	MSM[1], PRP[2], PUSR[3], undetermined each	PUSR[3]	PUSR[3]	Undetermined	Undetermined
	43%	25%	40%	100%	100%	32%
Second reported risk factor	PUSR[3], undetermined each	…	MSM[1], PRP[2], undetermined each	…	…	MSM[1],PUSR[3] each
	29%		20%	…	…	28%

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, 2018-2022



	2018	2019	2020	2021	2022
Male (first-time)	2	3	2	1	2
Male (repeat)	3	3	3	1	1
Female (first-time)	2	1	0	0	0
Female (repeat)	0	1	0	0	0

Over the past five years, 2018-2022, 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 2018-2022, 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 2022, the majority of newly diagnosed HIV in the general population was attributed to sexual contact (83.1%).[2] However, in 2022, no risk factor could be determined for 100% (n=3) of the positive donors.

Table 10 Comparison between HIV-positive blood donors and general population in Australia, by major potential risk categories, 2022

	HIV[i]	
Major risk category	**Newly diagnosed HIV cases in general population (2022) (%)**	**Blood donors (2022) (%)**
Injecting drug use[ii]	7.9	0.0
Country of birth/Ethnicity	0.0	0.0
Sexual contact[iii]	83.1	0.0
Blood or tissue recipient	0.0	0.0
Tattoo or body piercing	0.0	0.0
Exposure in health care setting	0.2	0.0
Household contact/Family history	0.0	0.0
Other blood to blood contact	0.0	0.0
Other/undetermined/unknown	8.8	100.0
Imprisonment	0.0	0.0
Occupational risk	0.0	0.0
No risk factor identified	0.0	0.0

i Includes exposure categories for new HIV diagnoses only in general population
ii for general population, it includes injecting drug use and MSM that are IDUs
iii 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 remained low in 2022 and showed no significant trend during 2013-2022. It was 64 times lower than in the general population in 2022, and 49 times lower for the period 2013-2022.
- 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.
- The putative risk factors in the HIV positive donors in 2022 could not be determined.

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 it was found to be more pathogenic than HTLV-2, with disease outcomes including HTLV-1-associated myelopathy and adult T-cell leukaemia/lymphoma.[14,15] While HTLV-2 has not been linked to malignancy like HTLV-1, it has been shown to cause myelopathy and other neurological conditions, albeit less frequently (1% of a prospective cohort compared to 4% for HTLV-1).[16,17] Unlike HTLV-1, HTLV-2 is more prevalent in urban areas among people who inject drugs, with high prevalence detected in this population in several European, South-East Asian, and North American cities.[18] 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.[19-21] From 2014 to 2018, a large-scale community survey in Central Australia reported HTLV-1 prevalence of 39% in adults, and 6% among children aged 3 to 17 years. Consistent with global findings, HTLV-1 prevalence increased with age. Yet in contrast to international studies, higher prevalence was reported among older men than older women.[22]

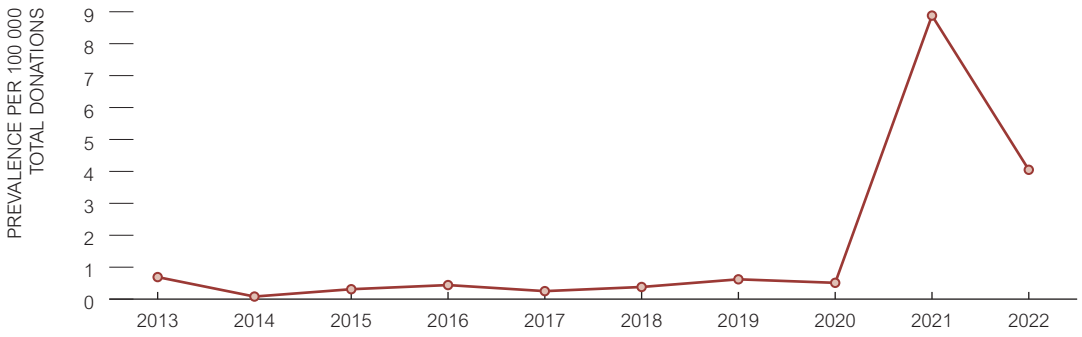
Trends in prevalence

All donations:

From September 2016 to December 2020, repeat donors donating plasma for fractionation no longer required testing for HTLV, and from 6 December 2020, repeat donors no longer required 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; or 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 reviewed by medical staff, and they can proceed to donation if their results are considered acceptable.

In the past 10 years, 2013-2022, a total of 47 HTLV-positive donors have been detected (43 first-time donors and four repeat donors) (Table 1B). During the period 2013-2022, the overall HTLV prevalence among all donations was 0.56 per 100 000 donations (Table 1B) and has shown a statistically significant upward trend (IRR: 1.28; 95% CI: 1.14-1.44) (Figure 27). The rate fluctuated between 0.08 and 0.69 per 100 000 donations during 2013-2020, however a sharp increase was observed in 2021 where the rate went up to 8.88 before reducing to 4.05 per 100 000 donations in 2022. These increased rates in all donations in 2021 and 2022 should be interpreted with caution as they were due to smaller denominators in these years, composed almost entirely of first-time donors (112 455 average annual donations in 2021 and 2022 versus one million average annual donations tested for HTLV for the 2013-2020 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 2022, see Supplementary Table 3A.

Figure 27 HTLV prevalence in all tested blood donations in Australia, by year of donation, 2013-2022

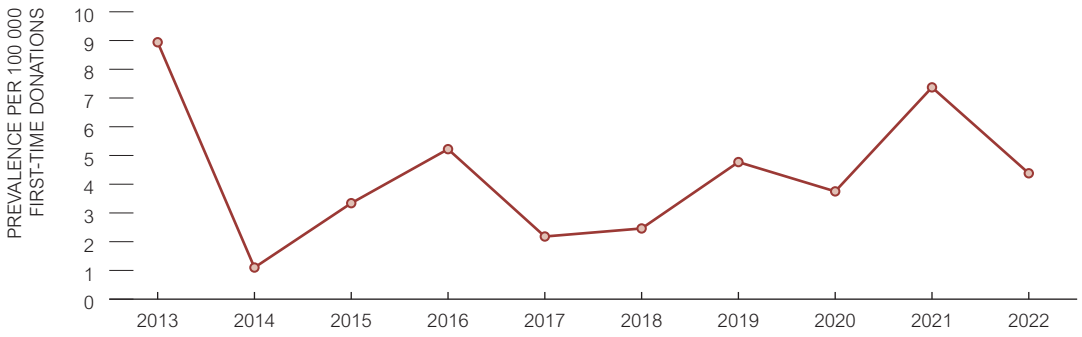


	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022
Prevalence in all donations	0.69	0.08	0.31	0.44	0.25	0.38	0.62	0.51	8.88	4.05

First-time donors:

HTLV prevalence in first-time donors remained low over the past 10 years, 2013-2022 with an overall rate of 4.4 per 100 000 donations and has shown no significant trend (Table 1B) (IRR: 0.99; 95% CI: 0.90-1.10). 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, by year of donation, 2013-2022



	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022
Prevalence in first-time donors	8.94	1.10	3.34	5.22	2.18	2.46	4.77	3.75	7.37	4.38

Trends in incidence

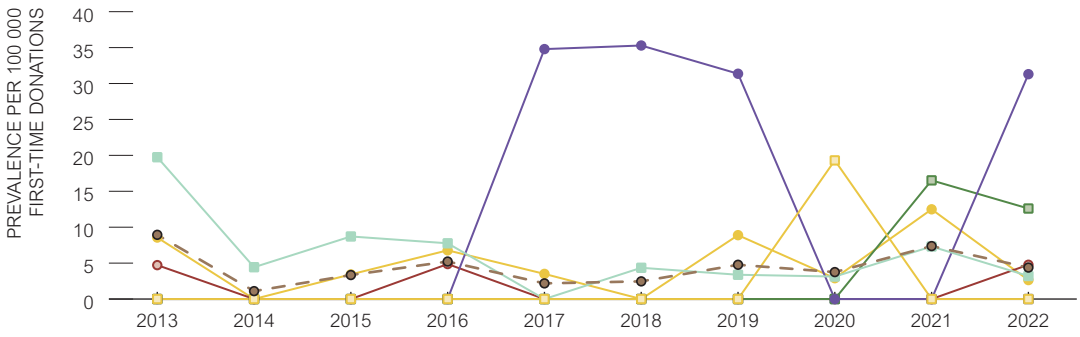
No incident donors have been identified since 2004. Given so few repeat donors are now tested for HTLV, it is no longer appropriate to derive an incidence rate from tested repeat donors. Lifeblood has derived a calculation method to indirectly derive the incidence from prevalence in first-time donors. 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.[23] 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 2018-2022.

Trends in HTLV by state/territory

In 2022, HTLV prevalence in first-time donors was the highest in Tasmania, at 31.30 per 100 000 donations, followed by South Australia at 12.60 per 100 000 donations (Figure 29). Caution should be taken in interpretation of HTLV prevalence in first-time donors in Tasmania and South Australia as these rates equate to only one positive donor per state. No significant trend was observed for prevalence in first-time donors during the period 2013-2022 in any jurisdiction. HTLV prevalence in first-time donors has remained zero in the Northern Territory during the ten-year study period, 2013-2022 (Figure 29).

Figure 29 HTLV prevalence among first-time donors, by state/territory and year of donation, 2013-2022



	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022
NSW/ACT	8.56	0.00	3.43	6.78	3.50	0.00	8.89	2.90	12.49	2.64
NT	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
QLD	4.72	0.00	0.00	4.87	0.00	0.00	0.00	0.00	0.00	4.77
SA	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	16.52	12.60
TAS	0.00	0.00	0.00	0.00	34.79	35.29	31.36	0.00	0.00	31.30
VIC	19.74	4.43	8.71	7.76	0.00	4.35	3.38	3.13	7.31	3.21
WA	0.00	0.00	0.00	0.00	0.00	0.00	0.00	19.30	0.00	0.00
National	8.94	1.10	3.34	5.22	2.18	2.46	4.77	3.75	7.37	4.38

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 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 2022 and the five-year period 2018-2022 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 2022, there was no significant association between gender, donors' age group or location and HTLV positivity (Supplementary Table 4). During the five-year period 2018-2022, female donors were 58% less likely to be HTLV positive compared to male donors, however there was no significant association between age or location and HTLV positivity (Supplementary Table 5).

Risk factors associated with HTLV-positive donors

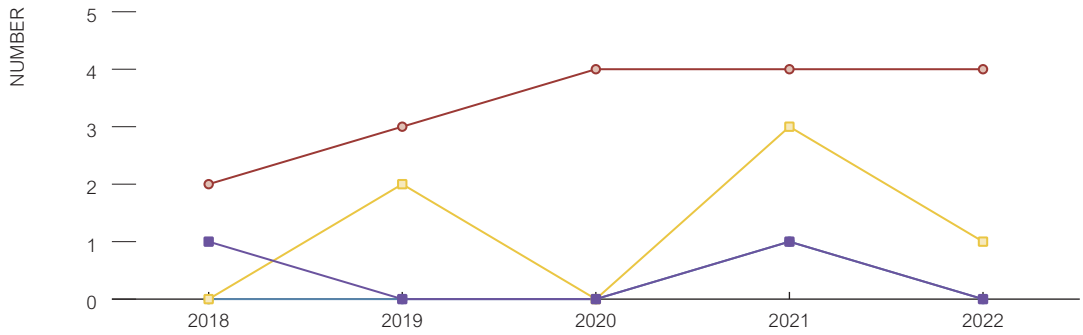
Only 26 HTLV-positive donors were detected during the 2018-2022 period; 23 (88%) were first-time donors, while three were repeat positive donors – one in 2018 and two in 2021, who did not meet the incident donor criterion; 69% were male, and the mean age was 41 years with a wide range (24-67 years) (Table 11). The majority of HTLV-positive donors (85%) were born overseas. Ethnicity or country of birth (73%) 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 (15%). 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 2018-2022. Of note, the literature also identifies self-flagellation as a possible unique risk factor for HTLV.[24] This was also noted in the Australian setting where 28% (7 of 25) of HTLV-positive donors had a history of self-flagellation during the 2012-2018 period.[25]

Table 11 Characteristics of HTLV-positive donors, by year of donation, 2018-2022

Characteristics	2018	2019	2020	2021	2022	2018-2022
Number of positive donors	3	5	4	9	5	26
Number of positive first-time donors (%)	2 (67%)	5 (100%)	4 (100%)	7 (78%)	5 (100%)	23 (88%)
Number of male donors (%)	2 (67%)	3 (60%)	4 (100%)	5 (56%)	4 (80%)	18 (69%)
Mean age (range) in years	38 (26-54)	44 (32-60)	35 (27-41)	45 (24-67)	35 (26-49)	41 (24-67)
Number of incident donors	0	0	0	0	0	0
Number of donors born in Australia (%)	1 (33%)	2 (40%)	1 (25%)	0 (0%)	0 (0%)	4 (15%)
Main reported risk factor	Ethnicity/COB[1] 67%	Ethnicity/COB[1] 40%	Ethnicity/COB[1] 100%	Ethnicity/COB[1] 67%	Ethnicity/COB[1] 100%	Ethnicity/COB[1] 73%
Second reported risk factor	PRP[2] 33%	PRP[2], PUSR[3], Other each 20%	…	PRP[2] 22%	…	PRP[2] 15%

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, 2018-2022



	2018	2019	2020	2021	2022
Male (first-time)	2	3	4	4	4
Male (repeat)	0	0	0	1	0
Female (first-time)	0	2	0	3	1
Female (repeat)	1	0	0	1	0

During the past five years, 2018-2022, there was an upward trend in the number of HTLV-positive first-time male donors. No discernible overall trend has been observed for first-time female donors and 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 2022 and period 2018-2022, see Supplementary Tables 6-12.

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

Due to the scarcity of reliable data on prevalence of key risk factors for HTLV in the Australian population, no meaningful comparison is possible. Nonetheless, Aboriginal and/or Torres Strait Islander populations in inland Australian regions are known to represent a high HTLV-1-prevalence population.[26] In addition, HTLV-1 is highly endemic in certain geographic regions including Japan, the Caribbean and central Africa and to a lesser extent in Iran, Iraq, southern India and China.[27] This is consistent with the finding that ethnicity or country of birth was the likely exposure risk for all HTLV-positive donors in 2022.

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

Epidemiology of infectious syphilis in Australia

Potentially infectious syphilis is a blood safety definition designed to capture donors that have a theoretical risk of transmitting syphilis by transfusion. Importantly, the risk of syphilis transfusion-transmission is quite distinct from the viral TTIs. Storage of blood products reduces the transmission risk; red cell storage at <20°C for >120 hours inactivates *T. pallidum* spirochaetes (the causative agent),[28] plasma stored at -20°C for 48 hours was shown to be non-infectious in an animal model,[29] and oxygen flow levels in platelet storage bags are believed to be toxic to *T. pallidum*.[30] Hence, the infectivity of transfused products is expected to be low even without syphilis testing. A published Lifeblood analysis concluded that the residual risk of syphilis transmission is currently negligible (1 in 49.5 million per unit transfused).[31] Since blood bags and cold storage were implemented in Australia during the 1970s, 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 potentially infectious syphilis and infectious syphilis, the two definitions are presented here: Potentially infectious syphilis 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 potentially infectious syphilis 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, including trend data presented in this report between 2013 to 2016. Active syphilis was defined by reactivity on treponemal and non-treponemal syphilis testing +/- clinically apparent infection (i.e. excluding past treated infections and may also exclude latent syphilis[32]). Infectious syphilis, on the other hand, is defined in the national case definition as syphilis infection of less than two years' duration (including primary, secondary and early latent stages[33]). 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 has been included in the number of infectious syphilis notifications since 2015.[33] Although the potentially infectious syphilis 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.

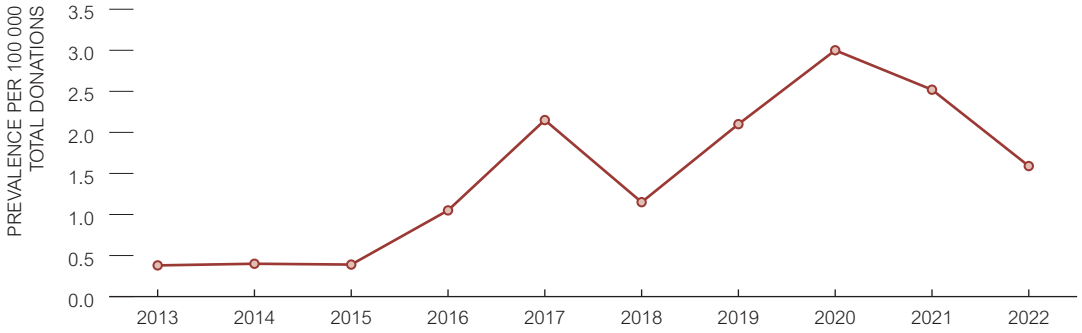
Infectious syphilis in Australia was primarily an infection of men having male to male sex in urban settings, and of heterosexual Aboriginal and/or Torres Strait Islander people in remote and outer regional areas. However, the epidemiology has changed in recent years to expand beyond these subgroups, with an increase observed in females and heterosexual males. The number of cases of infectious syphilis notified in 2022 was 6 036.[2] The notification rate of infectious syphilis tripled from 7.6 to 24.3 per 100 000 between 2013 and 2022. Notification rates among males remained higher than females for the entire 2013-2022 period.[2]

Trends in prevalence

All donations:

From September 2016, repeat donors donating plasma for fractionation no longer required testing for syphilis, resulting in fewer donations screened. The impact of this needs due consideration when assessing recent trends. Notwithstanding this, in the past 10 years, 2013-2022, a total of 131 donors with potentially infectious syphilis/active syphilis have been detected (52 first-time donors and 79 repeat donors) (Table 1C). During the period 2013-2022, the prevalence of potentially infectious syphilis among all donations remained very low at 1.3 per 100 000 donations (Table 1C); however, the prevalence in all donations has increased substantially in recent years from ~0.4 per 100 000 donations in 2013 to 3.0 per 100 000 donations in 2020 and 1.6 per 100 000 donations in 2022. As a result, a significant increase in the prevalence of potentially infectious syphilis among all donations was observed during 2013-2022 (IRR 1.21; 95% CI: 1.14-1.28) (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 2022, see Supplementary Table 3B.

Figure 31 **Prevalence of potentially infectious syphilis in all tested blood donations in Australia, by year of donation, 2013-2022**

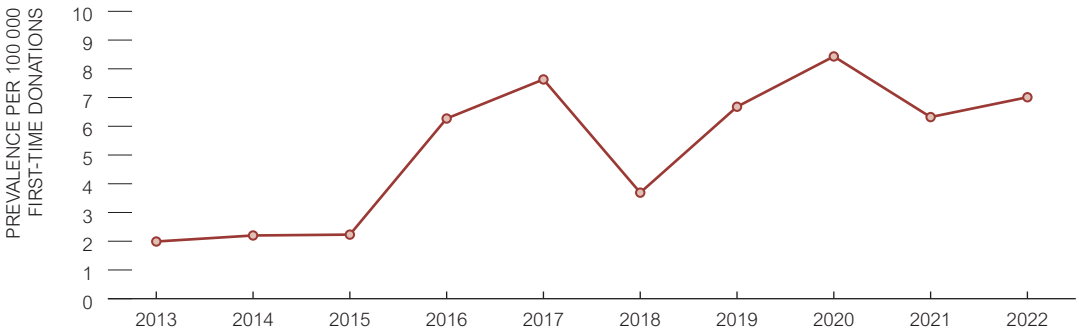


	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022
Prevalence in all donations	0.38	0.40	0.39	1.05	2.15	1.15	2.10	3.00	2.52	1.59

First-time donors:

In the 10 years, 2013-2022, the prevalence of potentially infectious syphilis in first-time donors was 5.3 per 100 000 donations (Table 1C). Overall, the prevalence of potentially infectious syphilis in first-time donors showed no significant trend during 2013-2022 (IRR: 1.07; 95% CI: 0.97-1.18) (Figure 32). In 2022, the rate was 7.01 as compared to 6.3 per 100 000 first-time donations in 2021 (Figure 32). By comparison, the national rate of diagnoses of infectious syphilis was 7.6 per 100 000 population in 2013, which tripled to 24.3 per 100 000 in 2022.[2] Caution should be taken in interpretation, as the infectious case definition changed in July 2015, to include more cases of likely recent acquisition.[33]

Figure 32 Prevalence of potentially infectious syphilis in first-time blood donors in Australia, by year of donation, 2013-2022

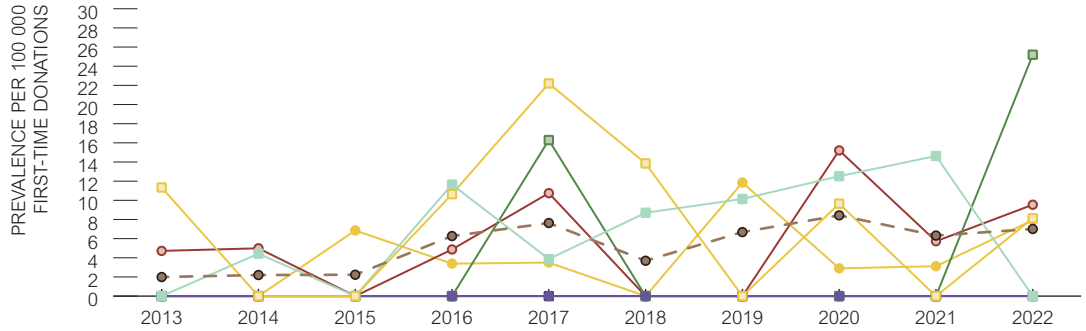


	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022
Prevalence in first-time donors	1.99	2.20	2.23	6.27	7.63	3.69	6.68	8.43	6.32	7.01

Trends in potentially infectious syphilis by state/territory

In 2022, potentially infectious syphilis prevalence in first-time donors was zero for the Northern Territory, Tasmania and Victoria. The prevalence rate in first-time donors was the highest in South Australia at 25.2 per 100 000 donations, followed by Western Australia and New South Wales / the Australian Capital Territory where rates were 8.1 and 7.9 per 100 000 first-time donations, respectively (Figure 33). Prevalence in first-time donors in Northern Territory and Tasmania remained zero over the 2013-2022 period. There were no significant trends observed in any jurisdictions during 2013-2022. In comparison, infectious syphilis rates were the highest in the Northern Territory in 2022, at 85.1 per 100 000.[2] The trend in the general population during the period 2013-2019 showed an increase in rates of diagnosis of infectious syphilis in all jurisdictions except Tasmania (where the rate declined), followed by declines in most states and territories between 2019-2021, except for South Australia and Western Australia (where the rates increased).[2]

Figure 33 **Prevalence of potentially infectious syphilis among first-time donors, by state/territory and year of donation, 2013-2022**



	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022
NSW/ACT	0.00	0.00	6.85	3.39	3.50	0.00	11.85	2.90	3.12	7.93
NT	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
QLD	4.72	4.99	0.00	4.87	10.75	0.00	0.00	15.21	5.73	9.54
SA	0.00	0.00	0.00	0.00	16.29	0.00	0.00	0.00	0.00	25.20
TAS	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
VIC	0.00	4.43	0.00	11.65	3.87	8.70	10.14	12.52	14.63	0.00
WA	11.34	0.00	0.00	10.64	22.20	13.85	0.00	9.65	0.00	8.12
National	1.99	2.20	2.23	6.27	7.63	3.69	6.68	8.43	6.32	7.01

Comparison of prevalence of potentially infectious syphilis among blood donors and the general population

As noted above, prevalence of potentially infectious syphilis in first-time donors in 2022 and the ten-year study period 2013-2022 was 7.01 and 5.36 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.[2] It is therefore difficult to compare the prevalence of 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 potentially infectious 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 potentially infectious syphilis among Australian blood donors in 2022 and the five-year period 2018-2022 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 2022, there was no significant association between gender, donors' age group or location and potentially infectious syphilis positivity (Supplementary Table 4).

During the five-year period 2018-2022, female donors were 70% less likely to have potentially infectious syphilis as compared to male donors. Donors between 40-49 years and 50-years-and-above age groups were 64% and 82% less likely to have potentially infectious syphilis, respectively, as compared to the reference group of 20-29 years (Supplementary Table 5). There was no association between state/territory of the donors and syphilis status among Australian blood donors during this period.

Risk factors associated with potentially infectious syphilis positive donors

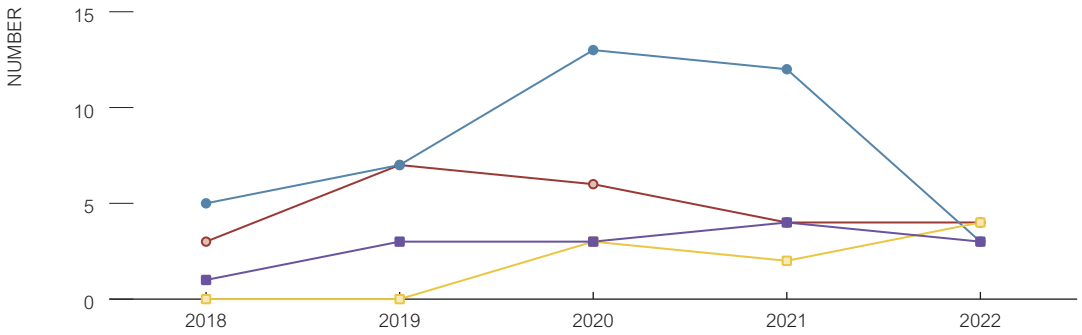
During 2018-2022, a total of 87 donors were classified as having potentially infectious syphilis, of which 33 (38%) were first-time donors, 64 (74%) were male, and 52 (60%) were born in Australia (Table 12). The mean age was 34 (range 19-66). Partner with unspecified risk (38%) was the most frequent likely risk factor for potentially infectious syphilis status. In comparison, in 2022, nationally, 82% of infectious syphilis diagnoses were in males, and 63% were in people aged 20 – 39 years.[2]

Table 12 Characteristics of donors with potentially infectious syphilis, by year of donation, 2018-2022

Characteristics	2018	2019	2020	2021	2022	2018-2022
Number of positive donors	9	17	25	22	14	87
Number of positive first-time donors (%)	3 (33%)	7 (41%)	9 (36%)	6 (27%)	8 (57%)	33 (38%)
Number of male donors (%)	8 (89%)	14 (82%)	19 (76%)	16 (73%)	7 (50%)	64 (74%)
Mean age (range) in years	42 (25-63)	30 (21-42)	36 (20-66)	32 (19-66)	36 (19-59)	34 (19-66)
Number of donors born in Australia (%)	7 (78%)	10 (59%)	10 (40%)	18 (82%)	7 (50%)	52 (60%)
Main reported risk factor	PUSR[1]	MSM[2]	PUSR[1]	PUSR[1], undetermined each	PUSR[1], undetermined each	PUSR[1]
	56%	41%	48%	36%	29%	38%
Second reported risk factor	MSM[2]/ Undetermined each	PUSR[1]	Undetermined/ unknown	MSM[2]	MSM[2]	Undetermined/ unknown
	22%	24%	36%	23%	23%	31%

1 PUSR= Partner with unspecified risk
2 MSM= Men who have sex with men

Figure 34 **Potentially infectious syphilis donors, by sex and donor status, 2018-2022**



	2018	2019	2020	2021	2022
Male (first-time)	3	7	6	4	4
Male (repeat)	5	7	13	12	3
Female (first-time)	0	0	3	2	4
Female (repeat)	1	3	3	4	3

Over the past five years, 2018-2022, there has been a slight upward trend in the number of potentially infectious syphilis cases in first-time / repeat female donors (Figure 34), while the trend in the repeat male donors showed a sharp decrease in 2022 as compared to 2020 and 2021. No discernible trend was observed in first-time male donors. For more information on the number and percentage of donors with potentially infectious syphilis status by sex, age group, donor status, country of birth and exposure category for year 2022 and period 2018-2022, see Supplementary Tables 6-12.

Conclusion

- Overall, during 2013-2022, the prevalence of potentially infectious syphilis among first-time blood donations has shown no significant trend. In comparison, since 2013, the national rate of diagnoses of infectious syphilis in general population has tripled by 2022.
- A meaningful comparison between the prevalence of potentially infectious 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

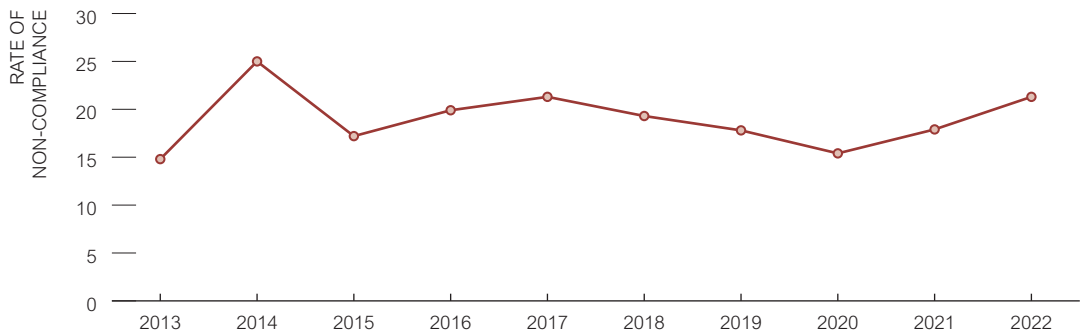
Screening compliance

Every donor is required to self-complete a comprehensive Donor Questionnaire (DQ) prior to each donation. 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 (168/921) of TTI-positive donors in 2018-2022 disclosed risk factors or clinical history during their post-donation interview that would have deferred them from donating had they disclosed it at the pre-donation interview (Table 13). Of these, 77% (129 donors) were first-time donors. The rate of reported non-compliance in TTI positive donors has been relatively stable for the past 10 years (ranging between 15-21%) after peaking at 25% in 2014 (Figure 35).

Figure 35 **Rate of reported non-compliance in TTI-positive donors, 2013-2022**



	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022
Rate of non-compliance	14.8	25.0	17.2	19.9	21.3	19.3	17.8	15.4	17.9	21.3

Table 13 Non-compliance category and rate among donors who were positive for any transfusion-transmissible infection, 2018-2022

Non-compliance by year and reason for deferral	2018*	2019*	2020	2021*	2022	2018-2022
Number (%) of non-compliant donors by reasons for deferral						
Injecting drug use	9 (31.0%)	7 (20.6%)	1 (3.1%)	4 (11.4%)	0 (0)	**21 (12.5%)**
Known status/previous positive^	17 (58.6%)	17 (50.0%)	26 (81.3%)	31 (88.6%)	36 (94.7%)	**127 (75.6%)**
Male-to-male-sexual contact	4 (13.8%)	5 (14.7%)	2 (6.3%)	1 (2.8%)	1 (2.6%)	**13 (7.7%)**
Partner with known risk or known to be positive	3 (10.3%)	6 (17.6%)	3 (9.4%)	0 (0)	1 (2.6%)	**13 (7.7%)**
Others	1 (3.4%)	2 (5.9%)	0 (0)	1 (2.8%)	0 (0)	**4 (2.4%)**
Total number (%) of non-compliant donors by year	29 (19.3%)	34 (17.8%)	32 (15.4%)	35 (17.9%)	38 (21.4%)	168 (18.2%)

^ 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 2018-2022 the most common risk behaviour identified was known status of previously being positive for a virus (including history of jaundice): 58.6% in 2018, 50.0% in 2019, 81.3% in 2020, 88.6% in 2021, and 94.7% in 2022. 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 2018-2022, 75.6% of non-compliance was attributed to known status of previously being positive for a virus, followed by injecting drug use (12.5%) and male-to-male sex and having a sexual partner with known risk or known to be positive for any transfusion-transmissible infection (7.7%, each) (Table 13).

Viral residual risk estimates

The rate of incident donors can be used to estimate the risk of collecting a unit of blood from a donor with very early infection (window period) which might test negative. 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.[34] More recent estimation indicate an increasing proportion of OBI risk, about 99% for the 2021/2022 period (Lifeblood, unpublished).

In 2017, Lifeblood changed the method of estimating the window period risk for HIV and HCV, bringing it in line with the method for HBV adopted in 2016. This addressed the existing limitation that the models applied were overly conservative, estimating the probability of collecting a window period donation, rather than the more appropriate estimate of the risk of infection in a recipient. The adoption in 2017 of the method of Weusten *et al*[35] lead generally to lower estimates and standardised the method with HBV. Using viral testing data including the number of incident donors reported for the 2021 and 2022 calendar year periods and applying these to Lifeblood[35] and Weusten risk models, residual risk estimates[36] (per unit transfused) were derived for the four transfusion-transmissible viral infections subject to mandatory testing (Table 14). Of note, the HBV risk estimate includes a separate model specifically addressing the risk of OBI.[37] The risk estimate for syphilis is derived periodically with the most recent estimate being less than 1 in 49 million per unit transfused.[31] The estimates for all fall below the 'negligible' risk threshold of 1 in 1 million per unit transfused used by Lifeblood to contextualise the risks for transfusion recipients. Further information can be obtained from the following website http://www.transfusion.com.au/adverse_events/risks/estimates.

Table 14 Estimated risk of window period donation/risk of not detecting true HBV, HCV, HIV, HTLV and syphilis in Australian blood donations (2021-2022)

	HBV	HCV	HIV	HTLV	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 2005-2022 period. Notably, no HIV or HCV transfusion-transmissions have been identified since the introduction of NAT testing in 2000.

Testing for malaria

In Australia, donation testing for malaria infection is limited to 'at risk' donors. This includes donors who report at the pre-donation interview travel to or residence in malaria endemic countries, as well as those with a previous history of infection.[38] The availability of malaria antibody testing results in significant recovery of valuable fresh blood components (red blood cells and platelets), as prior to the commencement of testing such donors were restricted to donating plasma for fractionation only, for 1-3 years. Annually, approximately 65 000 red cells and 7 000 platelets are 'recovered' as a result of non-reactive malaria antibody test results. Since malaria antibodies can indicate both recent and past infection (and false positive results), all antibody repeat reactive donors in 2022 were referred to their doctor with a copy of their results.

In 2022, 50 981 donations were tested for malaria antibody, lower than the 69 125 donations tested in 2021, and substantially less than the 132 338 donations tested in 2020. The decline in 2021 and 2022 was due to decreased overseas travel by donors due to COVID-19 associated international border closures. The border closures have now lifted however the number of donations tested have not yet returned to pre-pandemic levels because they are based on travel in the past three years. Of the tested donations, 1 451 (2.8%) were repeatedly reactive for malaria antibodies. This rate is similar compared to the 2.7% for 2021. No cases of transfusion-transmitted malaria were reported in Australia in 2022 with the last recorded Australian case in 1991.[39] The residual risk for transfusion-transmitted malaria is estimated to be substantially less than 1 in 1 million per unit transfused.

Minimising bacterial contamination of blood components

Transfusion with platelets or red cells carries the highest risk of bacterial transmission, with international data indicating that the risk of a clinically apparent reaction is at least 1 in 75 000 for platelets[40] and 1 in 500 000 for red cells.[41] Contamination may be due to bacteraemia at the time of blood donation (presumably asymptomatic), contamination with commensal skin bacteria during collection or introduction during processing (e.g. when pooling buffy coats).

Platelets are stored at room temperature which provides a more favourable growth environment for most pathogenic bacteria than the storage conditions used for red cells (refrigeration) or plasma (freezing). This increases the risk that even small initial numbers of contaminating bacteria in a platelet pack may replicate to levels sufficient to result in a transfusion reaction.[42]

Lifeblood reduces this risk using a combination of strategies:

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

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

3. **Flow diversion**
   The first 30 mL (minimum) of blood collected is diverted away from the collection bag. Introduced in Australia in 2006,[43] this procedure had been previously shown to reduce the bacterial contamination of platelet concentrates by more than 70%.[44]

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

5. **Pre-release bacterial contamination screening (BCS)**
   Since April 2008, all platelets produced by Lifeblood have been screened for bacterial contamination. Until late November 2019, BCS utilised the automated BACT/ALERT 3D system.[45] The 3D system was replaced by the BACT/ALERT VIRTUO system at Melbourne Processing Centre on 27 November 2019, at Perth Processing Centre 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.[46]

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

Bacterial pre-release testing for platelets

Platelet components are manufactured either directly by apheresis, or by pooling the buffy coats from four whole blood donations into a single platelet component. Apheresis collections may be split into one, two or three platelet components. 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.

When BCS was introduced in 2008, a minimum sample volume of 15 mL was removed from the pooled platelet pack, or from the combined apheresis platelet collection, between 24 and 48 hours after collection. The sample was divided 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 centres, 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 seven 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.

Finally, from 21 March 2021, the full protocol for large-volume delayed sampling was implemented with sample collection occurring between 36 and 72 hours after collection and platelet shelf-life extended to seven days.

Due to the short shelf life of platelet components, 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 has a Therapeutic Goods Administration (TGA) licence with an appropriate microbial testing manufacturing step. 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 2022 a total of 123 751 BCS samples were tested.

Of 102 328 pooled platelet components tested, 295 (0.29%) were flagged by the BACT/ALERT as initial machine positive. Of these, 121 (0.12%) were designated "confirmed positive", 90 (0.09%) were "indeterminate" and the remaining 84 (0.08%) were considered to be "false positive".

Of 21 423 apheresis collections tested, 73 (0.34%) were flagged by the BACT/ALERT as initial machine positive. Of the total apheresis collections tested, nine (0.04%) were designated "confirmed positive", 27 (0.13%) were "indeterminate" and the remaining 37 (0.17%) were considered to be "false positive" (Table 15).

Table 15 Summary of bacterial testing of platelets by BACT/ALERT VIRTUO, 2022

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]	102 328 (82.69)	295 (0.29)	121 (0.12)	90 (0.09)	84 (0.08)
Apheresis platelets[v]	21 423 (17.31)	73 (0.34)	9 (0.04)	27 (0.13)	37 (0.17)
Total	**123 751 (100)**	**368 (0.30)**	**130 (0.11)**	**117 (0.09)**	**121 (0.10)**

i At least one culture bottle reported ("flagged") as positive by the 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 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 total apheresis-derived platelet units manufactured. 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.

Of the 130 confirmed positives, the most frequently isolated genera were *Cutibacterium* species, which were isolated from 116 samples (89.23%). Coagulase-negative staphylococci (CoNS) were isolated from five BCS samples (3.85%). *Cutibacterium* and CoNS cultured from 121 of the 130 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 one confirmed positive donation and most likely represents environmental contamination unlikely to be clinically significant in the absence of history of recent injury or trauma in the donor. 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 eight (6.15%) 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.

Seven products with indeterminate bacterial growth on BCS were transfused. Six were pooled platelet components and one was an apheresis component. Four were from components growing CoNS, two growing *Corynebacterium* species and one unidentified gram-positive rods resembling corynebacteria. All other associated components were recalled and discarded. The recipients remained asymptomatic with no adverse transfusion reaction and donors remained well.

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

- Larger total sample volume with consequent greater sensitivity for detection of facultative contaminants
- Detection of strictly anaerobic bacteria, particularly the spores of *Clostridium* species which may persist within the aerobic platelet environment and cause sepsis in the recipient.[48]

There was one isolate of *Bacteroides* species that could not be confirmed on repeat culture and was classified as indeterminate. Platelet components had not been transfused in this instance. 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).[49]

There were no confirmed cases of transfusion-transmitted bacterial infection (TTBI) in 2022.

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 and there have been no confirmed cases of TTBI since October 2019. In the 15 years following the introduction of universal BCS for platelet components, Lifeblood's rate of TTBI is 0.34 per 100 000 platelet components issued.[49] This compares favourably with the Canadian Blood Services who reported a rate of 0.41 per 100 000 platelet components transfused, when they implemented large-volume delayed sampling.[50] For red cells, Lifeblood's rate was similarly low at 0.03 per 100 000 issued.[49]

Table 16 Summary of confirmed positive contaminants from platelets, 2022 (n=130 BCS samples)

Confirmed positives: organism isolated	Number
Cutibacterium species	116
Coagulase-negative staphylococci	5
Staphylococcus aureus	2
Bacillus species	1
Escherichia coli	1
Streptococcus gallolyticus	1
Streptococcus pneumoniae	1
Streptococcus pyogenes	1
Staphylococcus lugdunensis	1
Staphylococcus saprophyticus	1
Total	130

Surveillance and risk assessment for emerging infections

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

2022-2023 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 14 September 2022 to 13 September 2023, there were no reported cases of locally acquired dengue fever in Queensland.[51]	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. The mean annual number of reported cases for the pre-pandemic 5-year period 2015-19 was 244.[52] Reported case numbers declined to 86 in 2020 and 25 in 2021. Case numbers subsequently increased to 144 in 2022 and 177 in 2023 (to 13 September). 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 several European countries, Japan, India and Australia.	Most HEV infections (>95%) are subclinical. The incubation period ranges from 10 to 60 days (average 40 days). HEV RNA becomes detectable during the incubation period (10 to 60 days 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 transfusion-transmission 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 given country is directly related to the incidence in the donor population. Whilst countries in Europe moved to screening based on their higher prevalence compared to Australia, the risk and cost-benefit in Australia, as documented in our risk assessment,[53] stands if the incidence in Australia does not appreciably change. Similar to reported HAV cases, the number of reported HEV cases in Australia has decreased since the start of the COVID-19 pandemic. The mean number of reported cases for the 5-year period 2015-19 was 44.[52] Reported case numbers declined to 32 in 2020 and 6 in 2021. 15 cases were reported in 2022 and 20 in 2023 (to 13 September).	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.[54]	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.[55]	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. From the start of the outbreak to 31 December 2022, there were 41 human cases in four states: 14 in New South Wales, 4 in Queensland, 10 in South Australia, 12 in Victoria and 1 in Northern Territory.[52] No human JEV cases have been reported in Australia in 2023 (to 13 September). An internal Lifeblood risk assessment has indicated that the JEV risk to blood safety in Australia associated with the 2022 outbreak is negligible.[56]	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. Donors with a current flavivirus infection are deferred for 4 months from date of recovery; donors who have visited areas known to have outbreaks are deferred for 4 weeks after leaving the risk exposure area.
Murray Valley encephalitis virus (MVEV)	Transfusion transmission of MVEV has not been reported.	Most human MVEV infections are asymptomatic. For symptomatic infections, the incubation period can vary from 1 to 4 weeks with an average of about 2 weeks. The blood phase of MVEV has not been well characterised but it is considered to be relatively brief, similar to related flaviviruses such as WNV and JEV.[57]	Between 1991 and 2022, the annual reported number of human MVEV cases varied between 0 and 4 cases except for 2011 when 16 cases were reported. In 2023 to 24 October, 26 human cases of MVEV had been reported: 6 each in WA, NSW and VIC, 5 in NT, 2 in QLD and 1 in SA. Given the typically small number of reported human MVEV cases, the epidemiology of MVEV and the absence of reported transfusion transmission cases, MVEV represents a negligible risk to blood safety in Australia. Lifeblood continues to perform enhanced surveillance of MVEV.[52]	Lifeblood defers donors who report encephalitis for 6 months from the date of recovery. Donors with a current flavivirus infection are deferred for 4 months from date of recovery; donors who have visited areas known to have outbreaks are deferred for 4 weeks after leaving the risk exposure area.
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[58] but this has not been confirmed to be live virus.	Prior to 2022, human mpox was rarely reported outside Africa. In May 2022, an mpox outbreak in historically non-endemic countries was reported. The World Health Organization declared the outbreak a Public Health Emergency of International Concern on 23 July. The outbreak become the largest reported human mpox outbreak. Reported case numbers declined from late August. By late 2022 (13 December) there had been 83 539 confirmed cases globally, predominantly in countries that had not historically reported human mpox. Countries reporting highest case numbers were the US (29 792 cases), Spain (7 496), Brazil (10 398), Germany (3 676), the UK (3 730), France (4 110) and Peru (3 629). Cases of human mpox have continued to be reported during 2023, albeit in lower numbers than the peak of the outbreak in mid-2022. As at 12 of September 2023, WHO had reported 6 900 cases in 2023. Since 1 January 2022, 113 WHO member countries have reported mpox cases. In a number of these countries, there was evidence of substantial local transmission.[59,60] Australia's Chief Medical Officer declared the mpox outbreak a Communicable Disease Incident of National Significance (CDINS) on 26 July 2022. By the end of 2022, 144 cases (confirmed and probable) of mpox had been reported in Australia: 70 in Victoria, 56 in New South Wales, 7 in Western Australia, 6 in Queensland, 3 in the Australian Capital Territory, and 2 in South Australia.[52,61] On 25 November 2022, the Chief Medical Officer stood down Australia's CDINS declaration for mpox. In 2023 to 13 September, 14 cases of confirmed and probable mpox had been reported in Australia: 9 in NSW, 3 in Victoria and 2 in WA. MPXV is a negligible risk to blood safety.[62,63]	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.

Pathogen	Transfusion-transmission reported	Infectious risk period	Surveillance/Risk assessment	Additional risk management for blood safety
Primate erythroparvovirus 1 (B19V)	Yes, three probable cases of transfusion-transmission have occurred in the last 10 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.[64] 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 (typically via respiratory transmission) 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.
Ross River virus (RRV)	Yes, a single case in Australia has been reported.[65]	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 in Australia, Lifeblood has completed a comprehensive risk assessment for RRV.[66] During the largest outbreak in Australia to date in 2015 (9 532 reported cases),[52] no transfusion-transmitted-RRV cases were reported and polymerase chain reaction (PCR) testing for RRV RNA 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 (6 930 cases) and 2020 (6 361 cases). Reported RRV case numbers declined to 3 089 in 2021, 2 900 in 2022 and 1 274 in 2023 to 14 September).[52] 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.

Pathogen	Transfusion-transmission reported	Infectious risk period	Surveillance/Risk assessment	Additional risk management for blood safety
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 RNAaemic 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.[67]	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 (and possibly Omicron recombinant variants) have shorter incubation periods compared to other variants.[68] 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 2023, WHO had reported almost 770 million confirmed cases globally since late 2019.[69,70] During the course of the COVID-19, 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 2023 (to August), based on SARS-CoV-2 isolates that were sequenced, recombinant Omicron subvariants have been predominately reported globally and in Australia.[71,72] A very high proportion of the Australian population has now been vaccinated against SARS-CoV-2.[73]	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 coronaviruses including 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.
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).[74,75] 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.[76] This has resulted in a significant donation gain and has resulted in the increase in first-time donors in the 2022 period.[77]	Because of the negligible risk there are now no restrictions specific for vCJD. The last deferral for 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 was removed on November 13th 2023.

Pathogen	Transfusion-transmission reported	Infectious risk period	Surveillance/Risk assessment	Additional risk management for blood safety
West Nile virus (WNV)	Yes, transmission of West Nile virus (WNV) by blood, tissue and organ transplantation has been documented.[78]	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,[55] WNV RNA becomes detectable 1–2 days post-infection followed by anti-WNV IgM and IgG approximately 8–11 days post-infection, respectively.[79]	Lifeblood monitors WNV outbreaks in the European Union 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).[80] 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 larger than usual 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 WNV cases in all EU and neighbouring countries reaches a specified number or trigger point.[81]	Donors with a current flavivirus infection are deferred for 4 months from date of recover. If a donor has travelled to areas known to have outbreaks of a specific flavivirus infection, a 'plasma only for fractionation' restriction applies for 4 weeks from date of leaving the risk area.
Zika virus (ZIKV)	Yes, at least four cases of probable transfusion-transmitted ZIKV infection were reported during the 2014-16 outbreak in the Americas.[82] However, adverse clinical outcomes from transfusion transmission have 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.[83] 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.[84]	Between 2014 to 2016, the largest ever reported ZIKV 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.	Donors with a current flavivirus infection are deferred for 4 months from date of recover. If a donor has travelled to areas known to have outbreaks of a specific flavivirus infection, a 'plasma only for fractionation' restriction applies for 4 weeks from date of leaving the risk area. For ZIKV, donation is not possible for 4 weeks after sexual contact with someone who has a current Zika virus infection, or has recovered from Zika virus infection in the preceding 6 months.

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 2022, 130 (0.11%) of a total 123 751 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 2022.
- 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 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 primate erythroparvovirus 1 (B19) in Australia and a significant change in the risk profile has not occurred since the risk assessments were performed.

Supplementary Tables

Supplementary Table 1 **Screening tests for transfusion-transmissible infections**

Transfusion-transmissible infection	Mandatory screening tests	Test target	Year of introduction	Median window period estimate	Estimated risk of window period donation (per million transfusion)
Syphilis	*Treponema pallidum* antibodies[1]	Antibodies to *Treponema pallidum*	~1949	30 days	<1 in 1 million[31]
	HBsAg[2]	Hepatitis B surface antigen (HBsAg)	1970	38 days	---
HBV	Nucleic Acid Test for HBV	HBV DNA	2010	17 days	<1 in 1 million
	anti-HIV 1[2]	Antibody to both HIV 1 and HIV 2	1985 (HIV-1)		---
	anti-HIV 2[2]	(anti-HIV-1/2)	1992 (HIV-1/HIV-2)	22 days	
	p24 antigen[2]	HIV-1 p24 antigen	2013 (HIV Ag/Ab)	15 days	---
HIV	Nucleic Acid Test for HIV 1[3]	HIV 1/2 RNA	2000 (HIV-1) 2021 (HIV-1/HIV-2)	5 days	<1 in 1 million
	anti-HCV[2]	Antibody to HCV	1990	66 days	---
HCV	Nucleic Acid Test for HCV[3]	HCV RNA	2000	3 days	<1 in 1 million
	anti-HTLV 1[2]				
HTLV	anti-HTLV 2[2]	Antibody to both HTLV 1 and HTLV 2	1993	51 days	<1 in 1 million

1 *Treponema pallidum* haemagglutination assay (TPHA) until December 2020, subsequently Abbott Alinity s (Abbott Diagnostics, Wiesbaden-Delkenheim, Germany) Chemiluminescent Immunoassay system.
2 Abbott PRISM (Abbott Diagnostics, Wiesbaden-Delkenheim, Germany) Chemiluminescent Immunoassay system until October 2020, subsequently Abbott Alinity s (Abbott Diagnostics, Wiesbaden-Delkenheim, Germany) Chemiluminescent Immunoassay system.
3 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. Ultrio 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, 2022**

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	37 845	443 800	481 645	24	6	30	24	3	27	0	0	0	48	9	57
Number *(Number per 100 000 donations)*				*63.42*	*1.35*	*6.23*	*63.42*	*0.68*	*5.61*	*0.00*	*0.00*	*0.00*	*126.83*	*2.03*	*11.83*
NT	652	10 000	10 652	0	0	0	0	0	0	0	0	0	0	0	0
Number *(Number per 100 000 donations)*				*0.00*	*0.00*	*0.00*	*0.00*	*0.00*	*0.00*	*0.00*	*0.00*	*0.00*	*0.00*	*0.00*	*0.00*
QLD	20 958	264 113	285 071	16	0	16	6	1	7	2	0	2	24	1	25
Number *(Number per 100 000 donations)*				*76.34*	*0.00*	*5.61*	*28.63*	*0.38*	*2.46*	*9.54*	*0.00*	*0.70*	*114.51*	*0.38*	*8.77*
SA	7 937	110 292	118 229	6	0	6	4	2	6	0	1	1	10	3	13
Number *(Number per 100 000 donations)*				*75.60*	*0.00*	*5.07*	*50.40*	*1.81*	*5.07*	*0.00*	*0.91*	*0.85*	*125.99*	*2.72*	*11.00*
TAS	3 195	51 490	54 685	3	0	3	0	1	1	0	0	0	3	1	4
Number *(Number per 100 000 donations)*				*93.90*	*0.00*	*5.49*	*0.00*	*1.94*	*1.83*	*0.00*	*0.00*	*0.00*	*93.90*	*1.94*	*7.31*
VIC	31 163	400 881	432 044	25	4	29	15	1	16	0	0	0	40	5	45
Number *(Number per 100 000 donations)*				*80.22*	*1.00*	*6.71*	*48.13*	*0.25*	*3.70*	*0.00*	*0.00*	*0.00*	*128.36*	*1.25*	*10.42*
WA	12 312	134 816	147 128	7	1	8	6	1	7	0	0	0	13	2	15
Number *(Number per 100 000 donations)*				*56.86*	*0.74*	*5.44*	*48.73*	*0.74*	*4.76*	*0.00*	*0.00*	*0.00*	*105.59*	*1.48*	*10.20*
National	114 062	1 415 392	1 529 454	81	11	92	55	9	64	2	1	3	138	21	159
Number *(Number per 100 000 donations)*				*71.01*	*0.78*	*6.02*	*48.22*	*0.64*	*4.18*	*1.75*	*0.07*	*0.20*	*120.99*	*1.48*	*10.40*

Supplementary Table 3 The number and prevalence rate of TTI-positive (HTLV and potentially infectious syphilis) donors in Australia, by state/territory, 2022

S. Table 3A HTLV, by state/territory, 2022

State/Territory of donation	All accepted donations			HTLV		
	First time	Repeat	All	First time	Repeat	All
NSW/ACT	37 845	4 166	42 011	1	0	1
Number *(Number per 100 000 donations)*				*2.64*	*0.00*	*2.38*
NT	652	52	704	0	0	0
Number *(Number per 100 000 donations)*				*0.00*	*0.00*	*0.00*
QLD	20 958	1 519	22 477	1	0	1
Number *(Number per 100 000 donations)*				*4.77*	*0.00*	*4.45*
SA	7 937	541	8 478	1	0	1
Number *(Number per 100 000 donations)*				*12.60*	*0.00*	*11.80*
TAS	3 195	158	3 353	1	0	1
Number *(Number per 100 000 donations)*				*31.30*	*0.00*	*29.82*
VIC	31 163	2 429	33 592	1	0	1
Number *(Number per 100 000 donations)*				*3.21*	*0.00*	*2.98*
WA	12 312	575	12 887	0	0	0
Number *(Number per 100 000 donations)*				*0.00*	*0.00*	*0.00*
National	114 062	9 440	123 502	5	0	5
Number *(Number per 100 000 donations)*				*4.38*	*0.00*	*4.05*

S. Table 3B Potentially infectious syphilis, by state/territory, 2022

State/Territory of donation	All accepted donations			Potentially infectious syphilis		
	First time	Repeat	All	First time	Repeat	All
NSW/ACT	37 845	260 296	298 141	3	2	5
Number *(Number per 100 000 donations)*				*7.93*	*0.77*	*1.68*
NT	652	3 470	4 122	0	0	0
Number *(Number per 100 000 donations)*				*0.00*	*0.00*	*0.00*
QLD	20 958	139 433	160 391	2	0	2
Number *(Number per 100 000 donations)*				*9.54*	*0.00*	*1.25*
SA	7 937	56 337	64 274	2	1	3
Number *(Number per 100 000 donations)*				*25.20*	*1.78*	*4.67*
TAS	3 195	19 106	22 301	0	0	0
Number *(Number per 100 000 donations)*				*0.00*	*0.00*	*0.00*
VIC	31 163	219 634	250 797	0	2	2
Number *(Number per 100 000 donations)*				*0.00*	*0.91*	*0.80*
WA	12 312	68 625	80 937	1	1	2
Number *(Number per 100 000 donations)*				*8.12*	*1.46*	*2.47*
National	114 062	766 901	880 963	8	6	14
Number *(Number per 100 000 donations)*				*7.01*	*0.78*	*1.59*

Supplementary Table 4 Association of demographic characteristics with TTI-positive blood donors in Australia, 2022

		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	*256 655*	*71 (27.66)*	*1 (ref)*	*…*	*35 (13.64)*	*1 (ref)*	*…*
Female	*267 251*	*21 (7.86)*	*0.28 (0.17-0.46)*	***0.00***	*29 (10.85)*	*0.83 (0.51-1.36)*	*0.47*
Age group (years)							
20-29	*112 404*	*21 (18.68)*	*1 (ref)*	*…*	*6 (5.34)*	*1 (ref)*	*…*
Less than 20	*12 574*	*0 (0)*	*…*	*0.99*	*1 (7.95)*	*1.5 (0.18-12.47)*	*0.70*
30-39	*113 262*	*34 (30.02)*	*1.46 (0.85-2.53)*	*0.16*	*8 (7.06)*	*1.31 (0.45-3.78)*	*0.61*
40-49	*97 512*	*21 (21.54)*	*1.08 (0.59-1.98)*	*0.79*	*9 (9.23)*	*1.72 (0.61-4.84)*	*0.30*
50 and above	*188 154*	*16 (8.5)*	*0.41 (0.21-0.79)*	***0.01***	*40 (21.26)*	*3.95 (1.68-9.39)*	***0.00***
State/Territory*							
NSW	*155 379*	*27 (17.38)*	*1 (ref)*	*…*	*24 (15.45)*	*1 (ref)*	*…*
ACT	*17 227*	*3 (17.41)*	*0.95 (0.29-3.15)*	*0.94*	*3 (17.41)*	*1.20 (0.36-4.00)*	*0.76*
NT	*3 443*	*0 (0)*	*…*	*0.99*	*0 (0)*	*…*	*0.99*
QLD	*94 771*	*16 (16.88)*	*0.99 (0.53-1.84)*	*0.98*	*7 (7.39)*	*0.46 (0.19-1.07)*	*0.07*
SA	*39 708*	*6 (15.11)*	*0.91 (0.37-2.21)*	*0.98*	*6 (15.11)*	*0.90 (0.36-2.20)*	*0.81*
TAS	*15 730*	*3 (19.07)*	*1.1 (0.35-3.89)*	*0.78*	*1 (6.36)*	*0.38 (0.05-2.8)*	*0.35*
VIC	*148 547*	*29 (19.52)*	*1.11 (0.66-1.88)*	*0.41*	*16 (10.77)*	*0.70 (0.37-1.32)*	*0.28*
WA	*48 740*	*8 (16.41)*	*0.91 (0.41-2.00)*	*0.82*	*7 (14.36)*	*0.91 (0.39-2.11)*	*0.82*
Total	523 906	92 (17.56)			64 (12.22)		

		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	*256 655*	*3 (1.17)*	*1 (ref)*	*…*	*4 (1.56)*	*1 (ref)*	*…*
Female	*267 251*	*0 (0)*	*..*	*0.99*	*1 (0.37)*	*0.22 (0.02-2.00)*	*0.18*
Age group (years)							
20-29	*112 404*	*1 (0.89)*	*1 (ref)*	*…*	*2 (1.78)*	*1 (ref)*	*…*
Less than 20	*12 574*	*0 (0)*	*..*	*0.99*	*0 (0)*	*…*	*0.99*
30-39	*113 262*	*1 (0.88)*	*0.84 (0.05-13.56)*	*0.90*	*2 (1.77)*	*0.90 (0.12-6.41)*	*0.91*
40-49	*97 512*	*0 (0)*	*..*	*0.99*	*1 (1.03)*	*0.53 (0.04-5.87)*	*0.60*
50 and above	*188 154*	*1 (0.53)*	*0.42 (0.02-6.77)*	*0.54*	*0 (0)*	*…*	*0.99*
State/Territory*							
NSW	*155 379*	*0 (0)*	*1 (ref)*	*…*	*1 (0.64)*	*1 (ref)*	*…*
ACT	*17 227*	*0 (0)*	*..*	*1.00*	*0 (0)*	*…*	*0.99*
NT	*3 443*	*0 (0)*	*..*	*1.00*	*0 (0)*	*…*	*0.99*
QLD	*94 771*	*2 (2.11)*	*..*	*0.99*	*1 (1.06)*	*1.74 (0.10-27.89)*	*0.69*
SA	*39 708*	*1 (2.52)*	*..*	*0.99*	*1 (2.52)*	*4.35 (0.27-69.64)*	*0.29*
TAS	*15 730*	*0 (0)*	*..*	*1.00*	*1 (6.36)*	*11.29 (0.70-180.58)*	*0.08*
VIC	*148 547*	*0 (0)*	*…*	*1.00*	*1 (0.67)*	*1.03 (0.06-16.53)*	*0.98*
WA	*48 740*	*0 (0)*	*..*	*1.00*	*0 (0)*	*…*	*0.99*
Total	523 906	3 (0.57)			5 (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	*256 655*	*7 (2.73)*	*1 (ref)*	*…*
Female	*267 251*	*7 (2.62)*	*0.95 (0.33-2.73)*	*0.93*
Age group (years)				
20-29	*112 404*	*3 (2.67)*	*1 (ref)*	*…*
Less than 20	*12 574*	*1 (7.95)*	*2.95 (0.30-28.47)*	*0.34*
30-39	*113 262*	*6 (5.3)*	*1.96 (0.49-7.88)*	*0.34*
40-49	*97 512*	*2 (2.05)*	*0.75 (0.12-4.51)*	*0.75*
50 and above	*188 154*	*2 (1.06)*	*0.37 (0.06-2.28)*	*0.29*
State/Territory*				
NSW	*155 379*	*4 (2.57)*	*1 (ref)*	*…*
ACT	*17 227*	*1 (5.8)*	*2.13 (0.23-19.07)*	*0.49*
NT	*3 443*	*0 (0)*	*…*	*0.99*
QLD	*94 771*	*2 (2.11)*	*0.84 (0.15-4.60)*	*0.84*
SA	*39 708*	*3 (7.56)*	*3.16 (0.70-14.18)*	*0.13*
TAS	*15 730*	*0 (0)*	*…*	*0.99*
VIC	*148 547*	*2 (1.35)*	*0.51 (0.09-2.82)*	*0.44*
WA	*48 740*	*2 (4.1)*	*1.58 (0.29-8.67)*	*0.59*
Total	523 906	14 (2.67)		

* 361 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, 2018-2022

		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	*1 212 318*	*331 (27.3)*	*1 (ref)*	*…*	*199 (16.41)*	*1 (ref)*	*…*
Female	*1 277 700*	*121 (9.47)*	*0.34 (0.28-0.42)*	***0.00***	*138 (10.8)*	*0.67 (0.54-0.84)*	***0.00***
Age group (years)							
20-29	*600 692*	*86 (14.32)*	*1 (ref)*	*…*	*39 (6.49)*	*1 (ref)*	*…*
Less than 20	*80 272*	*5 (6.23)*	*0.47 (0.19-1.16)*	*0.10*	*7 (8.72)*	*1.36 (0.61-3.05)*	*0.44*
30-39	*544 126*	*160 (29.4)*	*1.87 (1.44-2.44)*	***0.00***	*64 (11.76)*	*1.76 (1.18-2.62)*	***0.00***
40-49	*446 102*	*95 (21.3)*	*1.39 (1.04-1.86)*	***0.02***	*59 (13.23)*	*1.98 (1.32-2.98)*	***0.00***
50 and above	*630 671*	*106 (16.81)*	*0.86 (0.64-1.14)*	*0.30*	*168 (26.64)*	*3.15 (2.22-4.48)*	***0.00***
State/Territory*							
NSW	*732 291*	*135 (18.44)*	*1 (ref)*	*…*	*123 (16.8)*	*1 (ref)*	*…*
ACT	*80 819*	*15 (18.56)*	*0.94 (0.55-1.61)*	*0.84*	*7 (8.66)*	*0.50 (0.23-1.09)*	*0.08*
NT	*16 774*	*7 (41.73)*	*2.12 (1.00-4.54)*	***0.05***	*0 (0)*	*…*	*0.98*
QLD	*472 870*	*59 (12.48)*	*0.65 (0.48-0.89)*	***0.00***	*55 (11.63)*	*0.64 (0.46-0.88)*	***0.00***
SA	*195 348*	*25 (12.8)*	*0.68 (0.44-1.05)*	*0.08*	*26 (13.31)*	*0.70 (0.46-1.07)*	*0.10*
TAS	*78 098*	*15 (19.21)*	*1.05 (0.61-1.79)*	*0.84*	*15 (19.21)*	*1.03 (0.60-1.76)*	*0.91*
VIC	*685 300*	*156 (22.76)*	*1.19 (0.94-1.50)*	*0.13*	*89 (12.99)*	*0.73 (0.56-0.96)*	***0.02***
WA	*227 973*	*40 (17.55)*	*0.89 (0.62-1.26)*	*0.52*	*22 (9.65)*	*0.53 (0.34-0.84)*	***0.00***
Total**	2 490 019	452 (18.15)			337 (13.53)		

		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	*1 212 318*	*21 (1.73)*	*1 (ref)*	*…*	*18 (1.48)*	*1 (ref)*	*…*
Female	*1 277 700*	*4 (0.31)*	*0.16 (0.05-0.47)*	***0.00***	*8 (0.63)*	*0.42 (0.18-0.97)*	***0.04***
Age group (years)							
20-29	*600 692*	*12 (2)*	*1 (ref)*	*…*	*5 (0.83)*	*1 (ref)*	*…*
Less than 20	*80 272*	*0 (0)*	*…*	*0.99*	*0 (0)*	*…*	*0.99*
30-39	*544 126*	*5 (0.92)*	*0.40 (0.14-1.15)*	*0.09*	*9 (1.65)*	*1.84 (0.61-5.51)*	*0.27*
40-49	*446 102*	*2 (0.45)*	*0.20 (0.04-0.90)*	***0.03***	*6 (1.34)*	*1.51 (0.46-4.98)*	*0.49*
50 and above	*630 671*	*6 (0.95)*	*0.34 (0.12-0.91)*	***0.03***	*6 (0.95)*	*0.81 (0.24-2.68)*	*0.73*
State/Territory*							
NSW	*732 291*	*7 (0.96)*	*1 (ref)*	*…*	*9 (1.23)*	*1 (ref)*	*…*
ACT	*80 819*	*1 (1.24)*	*…*	*0.99*	*2 (2.47)*	*1.91 (0.41-8.86)*	*0.40*
NT	*16 774*	*0 (0)*	*…*	*0.99*	*0 (0)*	*…*	*0.99*
QLD	*472 870*	*5 (1.06)*	*0.90 (0.29-2.76)*	*0.85*	*1 (0.21)*	*0.17 (0.02-1.34)*	*0.09*
SA	*195 348*	*2 (1.02)*	*0.90 (0.19-4.27)*	*0.89*	*3 (1.54)*	*1.25 (0.33-4.65)*	*0.73*
TAS	*78 098*	*0 (0)*	*…*	*0.99*	*3 (3.84)*	*3.22 (0.86-11.92)*	*0.08*
VIC	*685 300*	*7 (1.02)*	*0.87 (0.31-2.42)*	*0.80*	*6 (0.88)*	*0.69 (0.24-1.94)*	*0.48*
WA	*227 973*	*3 (1.32)*	*1.13 (0.29-4.26)*	*0.85*	*2 (0.88)*	*0.67 (0.14-3.12)*	*0.61*
Total**	2 490 019	25 (1)			26 (1.04)		

	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	*1 212 318*	*64 (5.28)*	*1 (ref)*	*…*
Female	*1 277 700*	*0*	*0.30 (0.19-0.49)*	***0.00***
Age group (years)				
20-29	*600 692*	*37 (6.16)*	*1 (ref)*	*…*
Less than 20	*80 272*	*2 (2.49)*	*0.44 (0.10-1.86)*	*0.27*
30-39	*544 126*	*27 (4.96)*	*0.72 (0.44-1.19)*	*0.21*
40-49	*446 102*	*11 (2.47)*	*0.36 (0.18-0.72)*	***0.00***
50 and above	*630 671*	*10 (1.59)*	*0.18 (0.09-0.37)*	***0.00***
State/Territory*				
NSW	*732 291*	*27 (3.69)*	*1 (ref)*	*…*
ACT	*80 819*	*1 (1.24)*	*0.30 (0.04-2.24)*	*0.24*
NT	*16 774*	*0 (0)*	*…*	*0.99*
QLD	*472 870*	*17 (3.6)*	*0.99 (0.54-1.82)*	*0.99*
SA	*195 348*	*4 (2.05)*	*0.59 (0.20-1.70)*	*0.33*
TAS	*78 098*	*0 (0)*	*…*	*0.99*
VIC	*685 300*	*31 (4.52)*	*1.20 (0.72-2.02)*	*0.47*
WA	*227 973*	*7 (3.07)*	*0.81 (0.35-1.87)*	*0.63*
Total**	2 490 019	87 (3.49)		

* 547 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, 2018-2022, 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, 2022

	HBV (2022)				HCV (2022)				HIV (2022)				HTLV (2022)				Potentially infectious syphilis (2022)			
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	1.6	0	0	0	0.0	0	0	0	0.0	0	1	1	7.1
20-29 years	16	5	21	22.8	3	2	5	7.8	1	0	1	33.3	2	0	2	40.0	0	2	2	14.3
30-39 years	25	6	31	33.7	3	2	5	7.8	0	0	0	0.0	2	0	2	40.0	4	0	4	28.6
40-49 years	12	6	18	19.6	5	4	9	14.1	0	0	0	0.0	0	1	1	20.0	0	1	1	7.1
50-59 years	5	2	7	7.6	8	10	18	28.1	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0
60 years and above	3	1	4	4.3	12	5	17	26.6	1	0	1	33.3	0	0	0	0.0	0	0	0	0.0
Repeat donors																				
<20 years	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0
20-29 years	0	0	0	0.0	1	0	1	1.6	0	0	0	0.0	0	0	0	0.0	1	0	1	7.1
30-39 years	2	1	3	3.3	1	2	3	4.7	1	0	1	33.3	0	0	0	0.0	0	2	2	14.3
40-49 years	3	0	3	3.3	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0	0	1	1	7.1
50-59 years	1	0	1	1.1	2	3	5	7.8	0	0	0	0.0	0	0	0	0.0	2	0	2	14.3
60 years and above	4	0	4	4.3	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0
Total	71	21	92	100	35	29	64	100	3	0	3	100	4	1	5	100	7	7	14	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, 2018-2022

	HBV (2018-2022)				HCV (2018-2022)				HIV (2018-2022)				HTLV (2018-2022)				Potentially infectious syphilis (2018-2022)			
Donor status	M	F	Total	%	M	F	Total	%	M	F	Total	%	M	F	Total	%	M	F	Total	%
First time donors																				
<20 years	3	2	5	1.1	2	4	6	1.8	0	0	0	0.0	0	0	0	0.0	1	1	2	2.3
20-29 years	55	29	84	18.6	23	6	29	8.6	7	1	8	32.0	4	1	5	19.2	10	4	14	16.1
30-39 years	112	34	146	32.3	39	12	51	15.1	1	1	2	8.0	8	1	9	34.6	9	1	10	11.5
40-49 years	57	19	76	16.8	25	26	51	15.1	0	0	0	0.0	4	2	6	23.1	4	3	7	8.0
50-59 years	29	12	41	9.1	39	33	72	21.4	0	1	1	4.0	0	0	0	0.0	0	0	0	0.0
60 years and above	24	3	27	6.0	41	25	66	19.6	2	0	2	8.0	1	2	3	11.5	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	0	0	0	0.0
20-29 years	2	0	2	0.4	8	6	14	4.2	4	0	4	16.0	0	0	0	0.0	16	7	23	26.4
30-39 years	8	6	14	3.1	2	7	9	2.7	2	1	3	12.0	0	0	0	0.0	12	5	17	19.5
40-49 years	11	8	19	4.2	3	5	8	2.4	2	0	2	8.0	0	0	0	0.0	3	1	4	4.6
50-59 years	11	5	16	3.5	7	10	17	5.0	1	0	1	4.0	1	1	2	7.7	4	1	5	5.7
60 years and above	19	3	22	4.9	9	4	13	3.9	2	0	2	8.0	0	1	1	3.8	5	0	5	5.7
Total	331	121	452	100	199	138	337	100	21	4	25	100	18	8	26	100	64	23	87	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^, 2018-2022

Region of birth	HBV (2018-2022)		HCV (2018-2022)		HIV (2018-2022)		HTLV (2018-2022)		Potentially infectious syphilis (2018-2022)	
	Number	%	Number	%	Number	%	Number	%	Number	%
Australia	36	8.0	217	64.4	11	44.0	4	15.4	52	59.8
Overseas born										
Other Oceania	32	7.1	11	3.3	0	0.0	0	0.0	3	3.4
United Kingdom and Ireland	0	0.0	13	3.9	0	0.0	0	0.0	3	3.4
Other Europe	20	4.4	14	4.2	2	8.0	0	0.0	4	4.6
Middle East/North Africa	15	3.3	8	2.4	0	0.0	1	3.8	2	2.3
Sub-Saharan Africa	14	3.1	1	0.3	1	4.0	0	0.0	2	2.3
South & North East Asia	236	52.2	31	9.2	3	12.0	4	15.4	12	13.8
Southern and Central Asia	91	20.1	36	10.7	7	28.0	17	65.4	7	8.0
Americas	3	0.7	2	0.6	1	4.0	0	0.0	2	2.3
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	447	98.9	333	98.8	25	100.0	26	100.0	87	100.0
Not reported	5	1	4	1	0	0	0	0	0	0
Total	452	100	337	100	25	100	26	100	87	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, 2022

	HBV (2022)				HCV (2022)				HIV (2022)				HTLV (2022)				Potentially infectious syphilis (2022)			
Exposure categories	M	F	Total	%	M	F	Total	%	M	F	Total	%	M	F	Total	%	M	F	Total	%
Ethnicity/Country of birth	54	11	65	80.2	7	0	7	12.7	0	0	0	0.0	4	1	5	100.0	0	0	0	0.0
Injecting drug use	0	0	0	0.0	13	7	20	36.4	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0
Tattoo/Piercing	0	0	0	0.0	0	2	2	3.6	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	2	3	5	9.1	0	0	0	0.0	0	0	0	0.0	0	2	2	25.0
Partner with unspecified risks	0	1	1	1.2	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0	1	1	2	25.0
Male-to-male sexual contact	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0	3	0	3	37.5
Exposure in health care setting	0	0	0	0.0	1	0	1	1.8	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0
Engaged in sex work	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0
Blood or tissue recipient	0	0	0	0.0	1	1	2	3.6	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0
Household contact/Family history	6	8	14	17.3	0	2	2	3.6	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0
Other blood to blood contact	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0
Other*	0	0	0	0.0	2	1	3	5.5	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0
No risk factors identified/Unknown	1	0	1	1.2	5	8	13	23.6	2	0	2	100.0	0	0	0	0.0	0	1	1	12.5
Total	61	20	81	100.0	31	24	55	100.0	2	0	2	100.0	4	1	5	100.0	4	4	8	100.0

* For HCV, all three first-time donors 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, 2018-2022

	HBV (2018-2022)				HCV (2018-2022)				HIV (2018-2022)				HTLV (2018-2022)				Potentially infectious syphilis (2018-2022)			
Exposure categories	M	F	Total	%	M	F	Total	%	M	F	Total	%	M	F	Total	%	M	F	Total	%
Ethnicity/Country of birth	247	70	317	83.6	27	1	28	10.2	0	0	0	0.0	15	3	18	78.3	0	0	0	0.0
Injecting drug use	1	0	1	0.3	55	27	82	29.8	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0
Tattoo/Piercing	1	0	1	0.3	17	22	39	14.2	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	7	11	18	6.5	0	1	1	7.7	1	2	3	13.0	3	2	5	15.2
Partners with unspecified risks	2	2	4	1.1	1	1	2	0.7	2	0	2	15.4	0	1	1	4.3	4	4	8	24.2
Male-to-male sexual contact	2	0	2	0.5	1	0	1	0.4	3	0	3	23.1	0	0	0	0.0	11	0	11	33.3
Exposure in health care setting	0	1	1	0.3	5	3	8	2.9	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	5	15	5.5	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0
Household contact/Family history	20	22	42	11.1	2	7	9	3.3	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	2.5	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0
Other*	0	0	0	0.0	17	3	20	7.3	0	2	2	15.4	1	0	1	4.3	0	0	0	0.0
No risk factors identified/Unknown	7	4	11	2.9	22	24	46	16.7	5	0	5	38.5	0	0	0	0.0	6	3	9	27.3
Total	280	99	379	100	169	106	275	100.0	10	3	13	100.0	17	6	23	100.0	24	9	33	100.0

* For HCV, 53% (9/17) 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, 2022

	HBV (2022)				HCV (2022)				HIV (2022)				HTLV (2022)				Potentially infectious syphilis (2022)			
Exposure categories	M	F	Total	%	M	F	Total	%	M	F	Total	%	M	F	Total	%	M	F	Total	%
Ethnicity/Country of birth	9	0	9	81.8	2	0	2	22.2	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0
Injecting drug use	0	0	0	0.0	1	0	1	11.1	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0
Tattoo/Piercing	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
Partners with known risks or known to be positive	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0	0	1	1	16.7
Partner with unspecified risks	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0	1	1	2	33.3
Male-to-male sexual contact	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0
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	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	1	1	9.1	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0
Other blood to blood contact	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0
Other	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0
																	0	0		
No risk factors identified/Unknown	1	0	1	9.1	1	5	6	66.7	1	0	1	100.0	0	0	0	0.0	2	1	3	50.0
Not reported	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0
Total	10	1	11	100.0	4	5	9	100.0	1	0	1	100	0	0	0	0.0	3	3	6	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, 2018-2022

	HBV (2018-2022)				HCV (2018-2022)				HIV (2018-2022)				HTLV (2018-2022)				Potentially infectious syphilis (2018-2022)			
Exposure categories	M	F	Total	%	M	F	Total	%	M	F	Total	%	M	F	Total	%	M	F	Total	%
Ethnicity/Country of birth	38	14	52	71.2	2	1	3	4.8	0	0	0	0.0	0	1	1	33.3	0	0	0	0.0
Injecting drug use	1	0	1	1.4	6	2	8	12.9	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0
Tattoo/Piercing	1	0	1	1.4	8	5	13	21.0	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0
Partners with known risks or known to be positive	2	0	2	2.7	1	4	5	8.1	1	1	2	16.7	0	1	1	33.3	1	2	3	5.6
Partners with unspecified risks	2	1	3	4.1	0	0	0	0.0	3	0	3	25.0	1	0	1	33.3	19	6	25	46.3
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	14.8
Exposure in health care setting	0	0	0	0.0	5	3	8	12.9	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0
Engaged in sex work	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0
Blood or tissue recipient	0	0	0	0.0	0	2	2	3.2	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0
Household contact/Family history	3	4	7	9.6	1	1	2	3.2	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0
Other blood to blood contact	0	0	0	0.0	0	1	1	1.6	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0
Other	1	0	1	1.4	0	1	1	1.6	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0
No risk factors identified/Unknown	3	3	6	8.2	7	12	19	30.6	3	0	3	25.0	0	0	0	0.0	12	6	18	33.3
Total	51	22	73	100.0	30	32	62	100.0	11	1	12	100.0	1	2	3	100.0	40	14	54	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 (although there is no upper age restriction for existing donors, donors over 80 years of age make up a small proportion of this cohort, while for new donors, the eligibility is at <76 years). Each donor is required to self-complete a comprehensive donor questionnaire (DQ) every time they donate. 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 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.

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.[85] 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.[86] 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 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, twelve 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.

This is the thirteenth 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 2013-2022 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 2013 to 2022. Anonymous donor data for all donors who donated blood between January 2013 and December 2022 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 2013-2022. Demographic factors associated with TTIs in blood donors were analysed for donations made in 2022 and were compared with the findings from 2018-2022. Likely routes of exposure (termed 'putative risk factors') for each TTI in blood donors were also identified and analysed. Data from the 2021 and 2022 calendar years were combined, and risk modelling conducted to derive estimates of the risk of transmission for HIV, HCV, and HTLV in Australia. HIV and HCV WP risk estimates are based on Lifeblood data from 1 January 2021 to 31 December 2022, and the HBV WP risk estimate based on Lifeblood data from 1 January 2020 to 31 December 2022. HBV OBI risk based on Lifeblood data from 1 January to 31 December 2022. 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 2021 to 31 December 2022.

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 2022 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 2022, 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, 2018-2022, was calculated as follows:

$$\text{Incidence per 100 000 donor-years of observation} = \left(\frac{\text{Total number of incident donors in 2018-2022}}{\text{Average of 2018-2022 total donor-years of observation}} \right) \times 100\,000$$

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. From 2020 onward, 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 both modifications, updated data were used for a five-year period and the updated DYO calculation retrospectively applied, for that report.

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*[35] 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*.[87]

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, 2013-2022, and the five-year period, 2018-2022, 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 2013-2022 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 2022, and five-year period, 2018-2022 (for HBV, HCV, HIV, HTLV and potentially infectious syphilis). The association between demographic factors and TTI positivity among Australian blood donors was 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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