Transfusion-transmissible infections in Australia

2024

Surveillance Report

Australian Red Cross Lifeblood®

UNSW SYDNEY

UNSW Kirby Institute

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in collaboration with

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Foreword

This report is jointly produced by Australian Red Cross Lifeblood (Lifeblood) and the Kirby Institute. 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.

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 higher 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. human immunodeficiency virus (HIV), hepatitis B virus (HBV), hepatitis C virus (HCV), human T-lymphotropic virus (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. In 2023, 213 TTIs were detected in 212 donations, marking the highest number recorded in the past ten years, from 2014 to 2023. Of these donations, 85% were from first-time donors and 83% were either HBV or HCV. Reflecting the effectiveness of donor screening strategies, the prevalence of TTIs in first-time donors in 2023 continues to be substantially lower (4-24 times) than the estimated national population prevalence for 2022/2023 (the 2023 estimates of population level prevalence for HBV were not available at the time of the report preparation, therefore comparisons were made with the 2022 data). There were no incident infections (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 eight-year period, 2016-2023.

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 2023, 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.

Contents

Glossary

Active syphilis
Defined by reactivity on treponemal and non treponemal 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 HBV surface antigen, HBV 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 vertical transmission of HBV, and to detect the presence of occult HBV 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 HCV 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. In blood donors, false positive results also occur. 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 is indicative of 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 blood.

Positive donor
A donor confirmed (by additional testing as necessary) to have tested positive to the relevant TTI.

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 (WP)
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 2014-2023, 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 1.26 to 1.63 million.
2. Of the 'age-eligible' Australian population (aged between 18-80 years), 2.8% donated blood during 2023. Male donors constituted 49.9% of all donors in 2023, which aligns with their proportional representation of 49.5% among the Australian general population aged 16-80 years.
3. On average, first-time donors comprised 18.7% of all blood donors in Australia over the period 2014-2023. The percentage of first-time donors increased gradually, from 13.2% in 2014, to 17.5% in 2018 and 21.8% in 2022, before slightly decreasing to 19.1% in 2023. The proportion of total donations made by first-time donors fluctuated between 5.8% and 7.4% during the past ten years. The overall increase in total donations over the 2014-2023 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 2023, a total of 212 blood donors were detected as positive for at least one of the TTIs for which testing is in place, namely, hepatitis B virus (HBV), hepatitis C virus (HCV), human immunodeficiency virus (HIV), human T-lymphotropic virus (HTLV), or potentially infectious syphilis, with a total of 213 TTIs detected (one donor was positive for both HBV and HIV). In the ten-year period 2014-2023 a total of 1 752 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 2023, 83.5% were positive for either HBV or HCV, slightly lower than 87.2% in 2022.
3. Overall, HIV was the least common TTI detected among all donors in 2023, with six donors testing positive. In the ten-year period 2014-2023, HIV was the least common TTI detected among all donors, with 46 donors, followed by HTLV, with 47 donors.
4. Although representing 19.1% of the donor population, first-time blood donors contributed to 85% of detected TTIs in Australia in 2023. This proportion has fluctuated since 2014 (77-85% range), except for 2014 and 2018 where the proportion went down to 67% and 68%, respectively (see Main Findings below).
5. No probable or confirmed transfusion-transmitted HIV, HBV, HCV, HTLV or syphilis cases were reported in Australia during 2023.
6. Consistent with previous years, in 2023, the prevalence of TTIs was substantially lower among first-time blood donors (4 to 24 times) compared with national prevalence estimates for 2023.

HBV-positive Australian blood donors

1. There were 94 HBV-positive donors detected among all donations in 2023 (81 in first-time donors and 13 in repeat donors).
2. Of all TTIs detected, HBV continued to have the highest prevalence among first-time donors.
3. During 2014-2023, no significant trend was observed in HBV prevalence in first-time donors in Australia. The prevalence among first-time donations in 2023 has remained relatively stable at 76.9 per 100 000 donations. This equates to 0.08% of the total first-time donations in 2023, which is 10 times lower than the estimated ~0.8% prevalence reported in national HBV surveillance data for 2022.
4. Among the 94 HBV-positive donors, 16 (six first-time and 10 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 (~94%), and half were Asian born (50%) and had an average age of 53 years.
5. There were no incident HBV donors in 2023. There was no significant temporal trend in HBV donor incidence nationally or in any state/territory during the eight-year study period 2016-2023.
6. In 2023, HBV-positive donors were younger as compared to all donors (40 years versus the mean age 44 years), more likely to be male (73% in HBV-positive donors versus ~50% in all donors) and more likely to be born in Northeast/Southeast Asia (48%). 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 2019-2023 was ethnicity/country of birth (78%). In Australia, an estimated 70% of people living with chronic hepatitis B were born overseas at the end of 2022.
8. No probable or confirmed transfusion-transmitted HBV cases were reported in Australia during 2016-2023. 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 83 HCV-positive donors detected among all donors in 2023 (76 in first-time donors and seven in repeat donors). In 2023, the proportion of HCV RNA positive (considered infectious) donors was 27.7% (23/83 – 22 or over 95% were first-time donors). This figure has incrementally declined from around 75% when HCV RNA donation testing was introduced in 2000.
2. In 2023, HCV was the second most common TTI detected in first-time blood donors after HBV.
3. During 2014-2023, a small but 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 0.07% first-time donation prevalence in 2023 is four times lower than the estimated ~0.3% living with chronic hepatitis C reported for HCV national surveillance data for 2023. However, these figures are not directly comparable as the majority of HCV-positive donors represent past exposure.
4. Of the seven repeat donors who tested positive in 2023, none met the incidence definition. The average incidence rate of HCV among previously negative repeat donors during 2016-2023 was low at 0.63 per 100 000 donor-years of observation (see Methodological Notes for details). HCV incidence has shown no significant trend during the study period 2016-2023.
5. In 2023, the mean age of HCV-positive donors was 50 years compared to 44 years for all donors. They were more likely to be male (55% versus ~50% in all donors), and the majority (57%) were born in Australia, similar to 2022 (58%), and 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 2019-2023 was injecting drug use (28%), however, for 22% of HCV-positive donors, the risk factor remained undetermined or unknown. By comparison, for people with newly acquired HCV in the general population, 63% had imprisonment as their route of exposure in 2023, followed by injecting drug use at 12%.
7. No probable or confirmed transfusion-transmitted HCV cases were reported in Australia during 2016-2023.

HIV-positive Australian blood donors

1. There were six HIV-positive donors detected among all donations in 2023 (five first-time and one repeat donors).
2. The prevalence of HIV-positive first-time donors during 2014-2023 remained very low at 2.5 per 100 000 donations (or 0.003% of total first-time donations) and comparatively much lower than HBV (74.0 per 100 000 donations) and HCV (52.1 per 100 000 donations). No significant HIV prevalence trend was observed during 2014-2023. The 0.003% HIV prevalence in first-time donors is 24 times lower than the 0.1% prevalence reported for HIV national surveillance data in 2023.
3. There were no incident HIV donors in 2023. There was no statistically significant incidence trend in the 2016-2023 period.
4. In 2023, the mean age of HIV-positive donors was 31 years, much younger than the 44 years for all donors. Like HBV and HCV, HIV-positive donors were more likely to be male as compared to all donors (83% vs ~50%). In 2023, 33% (2/6) of the HIV-positive donors were born in Australia.
5. The most common reported route of exposure for HIV-positive donors during 2019-2023 was male to male sexual activity (25%), while for 38%, the risk factor was undetermined. In comparison, men who have sex with men accounted for 63% of cases of HIV first ever diagnosed in Australia in 2023 (including those who reported injecting drug use), followed by heterosexual sex (28%).
6. No probable or confirmed transfusion-transmitted HIV cases were reported in Australia during 2016-2023.

HTLV-positive Australian blood donors

1. There were nine HTLV-positive donors detected among all donations in 2023 (all nine in first-time donors).
2. The prevalence of HTLV-positive first-time donors during 2014-2023 has remained low at 4.4 per 100 000 donations but has shown a significant upward trend. The majority (88%) of these donors were from high prevalence regions. 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 2023, the mean age of the nine HTLV-positive donors was 45 years; unlike previous years where the majority were male, in 2023, 56% of the HTLV-positive donors were female. All HTLV-positive donors were born overseas (100%).
4. The most common putative risk factor for HTLV-positive donors during 2019-2023 was ethnicity or country of birth (81%). There are no data to compare risk factors in the general population.
5. No probable or confirmed transfusion-transmitted HTLV cases were reported in Australia during 2016-2023.

Potentially infectious syphilis infection among Australian blood donors

1. There were 21 potentially infectious syphilis donors (11 first-time and 10 repeat donors) detected in 2023.
2. During the past 10 years, 2014-2023, the prevalence of potentially infectious syphilis in first-time donors has shown a significant increasing trend. Likewise, there has been an increase in the rate of notification of infectious syphilis in the general population between 2014 and 2023.
3. The mean age of donors with potentially infectious syphilis in 2023 was 35 years (compared to 44 years for all donors), and the majority (62%) were male.
4. The most common reported route of exposure by donors with potentially infectious syphilis during 2019-2023 period was having a partner with an unspecified risk (37%).

Donor compliance

1. Of the 984 TTI-positive donors in 2019-2023, 18.7% (184 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 80% (148 donors) of 'non-compliant' donors.
2. The detected non-compliance rate of all TTI-positive donors has fluctuated in the past decade between 15.4 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 2012-2013 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 2023, 78 638 donations were tested for malaria antibody, higher than recent years but 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. Testing numbers have not yet returned to pre-pandemic levels as testing for travel is based on travel in past three years. Of the tested donations, 1 325 (1.7%) were repeatedly reactive for malaria antibodies, which is lower than the rate of 2.8% for 2022.
2. There were no reported cases of transfusion-transmitted malaria during 2023 with the last reported Australian case occurring in 1991.

Bacterial pre-release testing for platelets

1. In 2023, 159 (0.12%) of a total of 131 486 screened platelet donations had confirmed bacterial contamination.
2. Consistent with previous years, by far the most common species isolated (131 donations) was *Cutibacterium* species, commensal skin organisms of low pathogenicity which are rarely (if ever) associated with septic transfusion reactions. The next most common group was coagulase-negative staphylococci (13 donations), which are usually considered skin contaminants.
3. The remaining 15 donations contained potentially pathogenic species (two donations each unless stated): *Bacillus* species (one donation), *Campylobacter fetus,* mucoid *Klebsiella pneumoniae* (one donation), *Serratia marcescens, Staphylococcus aureus, Streptococcus agalactiae, Streptococcus dysgalactiae, Streptococcus pneumoniae* and *Parabacteroides distasonis* / *Parabacteroides johnsonii* / *Phocaeicola vulgatus* (one donation).
4. In 2023, there were no confirmed cases of transfusion-transmitted bacterial infection.

Emerging infections

1. During 2023-2024, Murray Valley encephalitis, mpox and one local outbreak of dengue were monitored. The increased cases of Oropouche virus observed overseas and seasonal arboviral outbreaks such as the West Nile virus outbreak in Europe were also monitored. The risk to blood safety in Australia remains negligible.

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Abbreviations

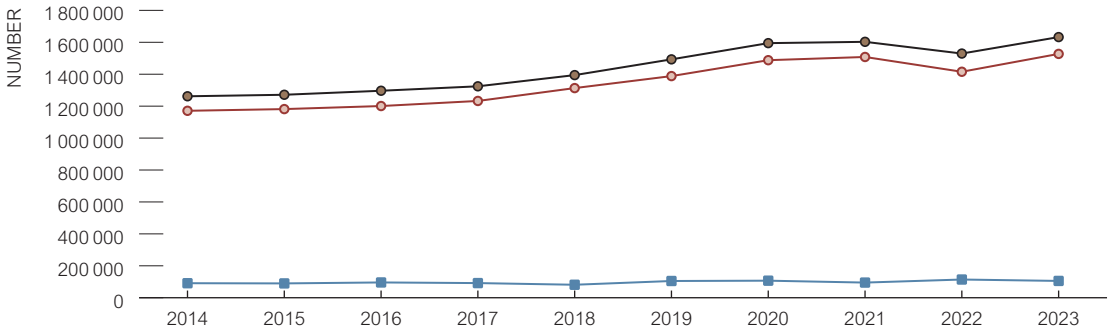
ACCESS	the Australian Collaboration for Coordinated Enhanced Sentinel Surveillance
anti-HBc	antibody to hepatitis B core antigen
BCS	bacterial contamination screening
DQ	donor questionnaire
DENV	dengue virus
DYO	donor-years of observation
HBsAg	hepatitis B surface antigen
HBV	hepatitis B virus
HCV	hepatitis C virus
HIV	human immunodeficiency virus
HTLV	human T-lymphotropic virus
IDU	injecting drug use
Lifeblood	Australian Red Cross Lifeblood
mpox	mpox (formerly Monkeypox)
MPXV	monkeypox virus
MVEV	Murray Valley encephalitis virus
NAT	nucleic acid testing
OBI	occult hepatitis B virus infection
OROV	Oropouche virus
TPHA	Treponema pallidum haemagglutination
TTIs	transfusion-transmissible infections
vCJD	variant Creutzfeldt-Jakob disease
WNV	West Nile virus
WP	window period

Main Findings

Blood donors in Australia

Over 14 million donations were tested for TTIs in Australia during the ten-year period 2014-2023, with an average of 1.4 million donations per year. There were 1.6 million donations in 2023, an increase of 6.7% as compared to 2022. Over the ten-year period 2014-2023, there was a significant increasing trend in the number of donations, from 1.26 to 1.63 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 1.63 million donations were tested for HBV, HCV and HIV in 2023, as compared to slightly over 0.11 million donations for HTLV and 0.90 million donations for syphilis.

Figure 1 **Number of blood donations in Australia, by year of donation, 2014-2023**

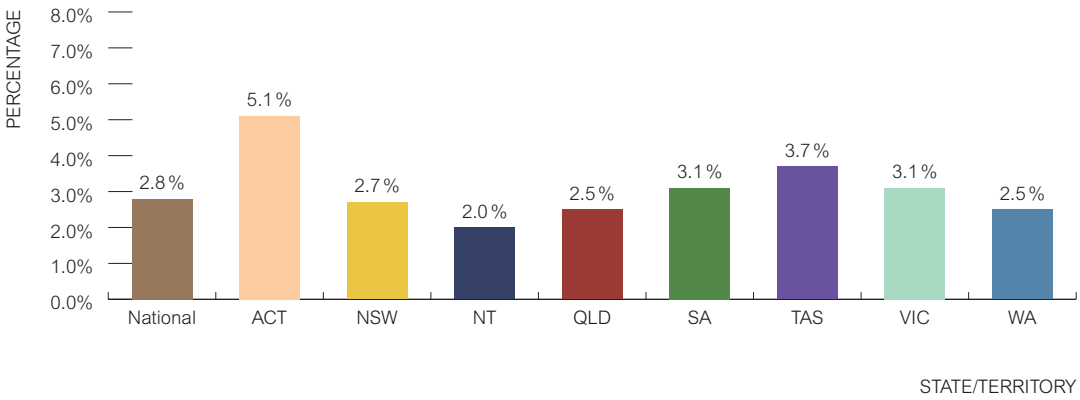


	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023
Total	1.26 M	1.27 M	1.30 M	1.32 M	1.39 M	1.49 M	1.59 M	1.60 M	1.53 M	1.63 M
First-time	0.09 M	0.09 M	0.10 M	0.09 M	0.08 M	0.10 M	0.11 M	0.09 M	0.11 M	0.11 M
Repeat	1.17 M	1.18 M	1.20 M	1.23 M	1.31 M	1.39 M	1.49 M	1.51 M	1.42 M	1.53 M

In 2023, 2.8% 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 2023 was the Australian Capital Territory (5.1%), followed by Tasmania at 3.7% (Figure 2).

The number of first-time donors decreased by over 8% from 0.114 million in 2022 to 0.105 million in 2023. However, there was an 18% increase in the number of repeat donors, from 0.40 million in 2022 to 0.48 million in 2023, the highest since 2015. This notable increase in repeat donors in 2023 may be attributed to the removal of the vCJD geographical deferral for United Kingdom donors in July 2022. This policy change led to a significant rise in first-time donors in 2022, with 42% of the new donors coming from this cohort. This suggests that many of these individuals returned as repeat donors in 2023, contributing to the observed increase.

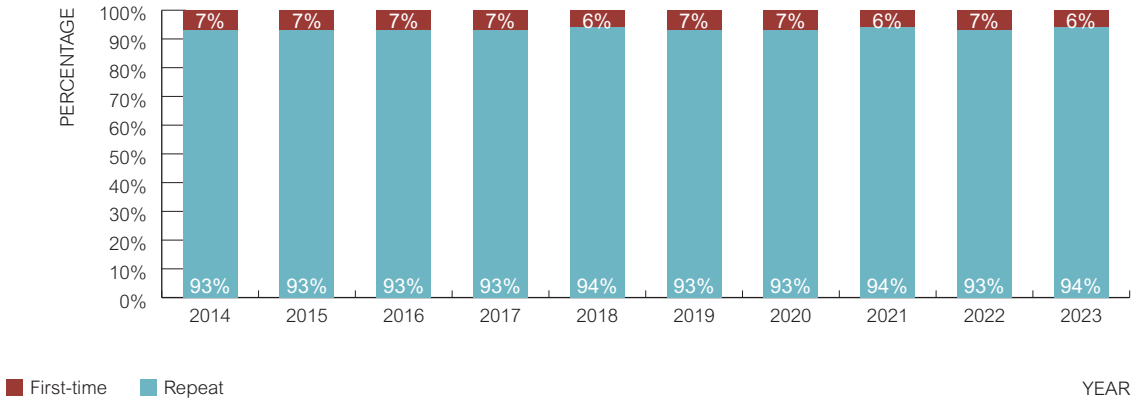
Figure 2 **Percentage of age eligible* general population who donated blood in 2023, by state/territory**



Note: for 101 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

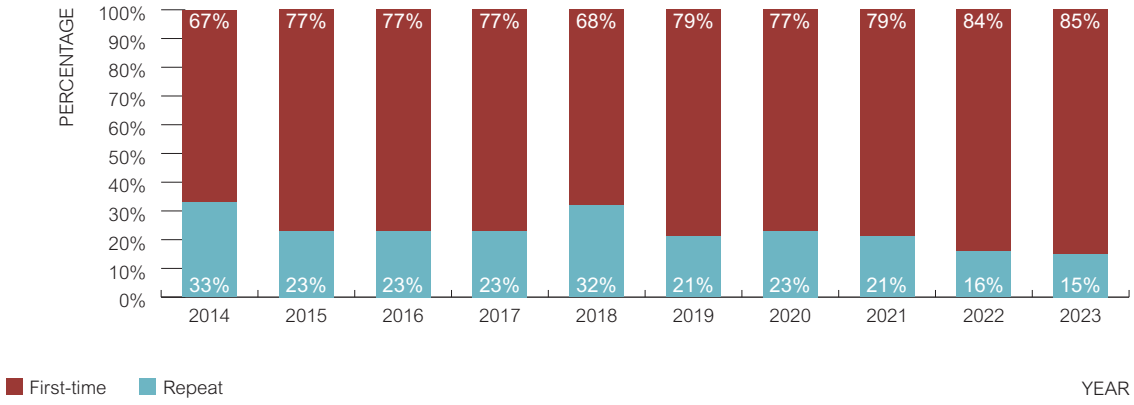
As in previous years, more than 90% of all donations in 2023 were from repeat donors (Figure 3). In the past 10 years, 2014-2023, the percentage of donations by first-time donors remained stable, between 6 and 7%. While first-time blood donors represented only 19% of the donor population, and 6% of the total donations, they contributed the majority (85%) of TTIs in Australian blood donors in 2023, 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, 2014-2023**



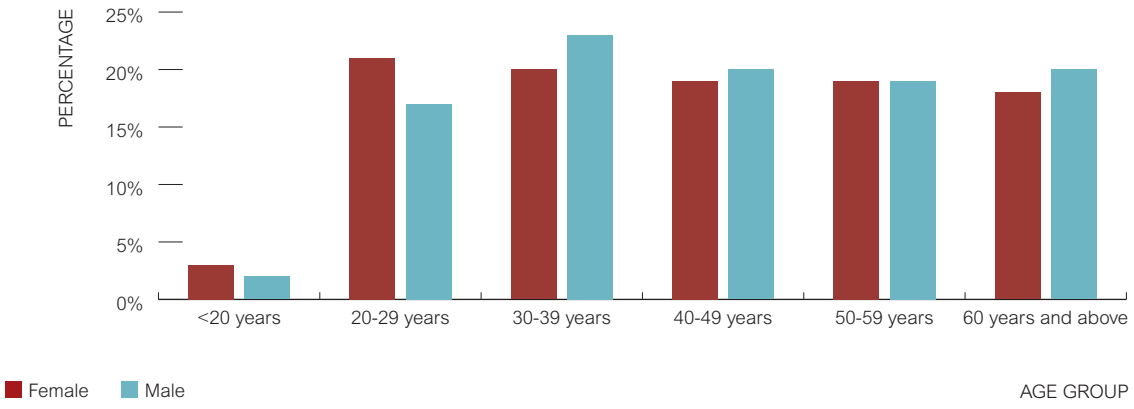
During 2014-2021, the proportion of repeat donors among all TTI-positive blood donations in Australia was generally stable (21-23%), except for 2014 and 2018, where the proportions increased to 33% and 32%, respectively (Figure 4). However, in 2022 this proportion decreased to 16%, and 15% in 2023, the lowest in the past 10 years, 2014-2023. 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, 2014-2023**



Among all blood donors who donated in 2023, 50% were male (Figure 5). More than a third (38%) of donors were aged 50 years and above; the median age of male and female donors was 44 and 43 years, respectively.

Figure 5 **Distribution of blood donors in Australia, by age group and sex, 2023**



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 2014-2023 and the eight-year period 2016-2023, respectively. In addition, the association of demographic characteristics with the presence of TTIs for the year 2023 and the five-year period 2019-2023 are discussed. Putative risk factors associated with positive blood donors in Australia are also reported for the five-year period, 2019-2023. 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 2023, trends in the ten-year period 2014-2023, notifications of newly diagnosed TTIs in Australia, and risk exposure categories associated with respective infections. Of note, the 2023 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 2022 estimates. The information is drawn from the Kirby Institute's report - HIV, viral hepatitis and sexually transmissible infections in Australia: Annual Surveillance report 2024.[1]

Prevalence is defined separately as the test-positive rate among all blood donors and first-time blood donors, whereas incidence is the rate of new test-positive repeat donors meeting the incidence definition. 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.

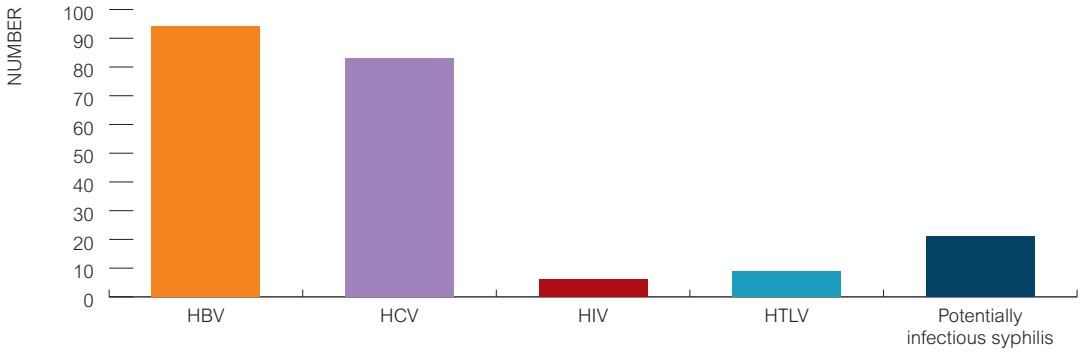
Lifeblood closely monitors donor incidence rates since these correlates directly with the risk of transmission in the window period. Incident donors are defined as positive repeat donors whose last donation tested negative for the same TTI within the last 12 months (with some exceptions; see glossary). 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 2014-2023, a total of 1 752 donations (1 360 first-time and 392 repeat donations) were positive for at least one of the TTIs subject to mandatory donation testing. Of these, 1 557 were positive for HBV, HCV and HIV (10.8 per 100 000 donations), 148 (1.5 per 100 000 donations) were positive for potentially infectious syphilis and 47 (0.7 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 2014-2023, (14.4 million donations for HBV, HCV and HIV, as opposed to 7.1 million and 9.5 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 2014-2023, 86.2% were positive for either HBV or HCV. Of note, in this report, the 2022 data have been updated with one repeat donor retrospectively added as positive for potentially infectious syphilis. As a result, the 2022 TTI numbers in this report differ from those in the Transfusion-transmissible infections in Australia 2023 Surveillance Report. Readers must consider this when comparing the two reports.

In 2023, a total of 212 donors were found positive for at least one of the TTIs subject to mandatory donation testing; one donor was positive for HBV and HIV, making a total of 213 TTIs detected in 2023. Overall, HBV and HCV were the two most frequent TTIs identified in Australian blood donors in 2023, together contributing 83.5% of positive donations (Figure 6). This proportion has decreased by a relative 8.8% as compared to 91.5% in 2014.

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 an eight-year period, 2016-2023, which retrospectively applies the updated DYO calculation method. During 2016-2023, a total of 30 incident donors were identified, eight for HBV, 11 for HCV and 11 for HIV. In 2023, no incident donors were detected.

Figure 6 Distribution of test positive blood donations in Australia, in 2023



	HBV	HCV	HIV	HTLV	Potentially infectious syphilis
Positive Donations 2023	94	83	6	9	21

Note: Although a total of 212 donors were found positive for at least one of the TTIs, one donor was positive for HBV and HIV, making a total of 213 TTIs detected in 2023

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 2023 and the five-year period 2019-2023 separately.

Standardised national data on reported putative risk factors associated with donors positive for HBV, HCV, HIV and HTLV are available since 1999. Importantly, assessing the strength of association of disclosed risk factors is complex and this must be borne in mind when interpreting the data. Risk varies based on a number of variables including the timing and location of the risk event. For the more commonly reported 'risk events', these represent the background population prevalence of the event and little inference on causation should be interpreted. For instance, tattooing performed in some settings (e.g., in Australian prisons or high-risk countries) is a recognised risk for HCV transmission, in contrast to tattooing currently performed in Australian commercial tattooing parlours, where the risk is very low.[2] Lifeblood undertook a risk assessment which determined that the HCV incidence rate in donors returning after a tattoo was negligible,[3] and 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,[4] 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 2019 to 2023. A total of 984 positive donors with at least one of the TTIs were observed over the period 2019-2023 (representing a total of 990 TTIs). The data on these donors were analysed for the period 2019-2023 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, 2014-2023

1A HBV, HCV and HIV, by state/territory, 2014-2023

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	318 648	4 147 559	4 466 207	228	47	274	183	43	226	8	5	13	419	95	513
Number *(Number per 100 000 donations)*				*71.55*	*1.13*	*6.13*	*57.43*	*1.04*	*5.06*	*2.51*	*0.12*	*0.29*	*131.49*	*2.29*	*11.49*
NT	6 887	97 076	103 963	9	2	11	3	3	6	0	0	0	12	5	17
Number *(Number per 100 000 donations)*				*130.68*	*2.06*	*10.58*	*43.56*	*3.09*	*5.77*	*0.00*	*0.00*	*0.00*	*174.24*	*5.15*	*16.35*
QLD	192 394	2 655 080	2 847 474	107	15	122	96	33	129	5	6	11	208	54	262
Number *(Number per 100 000 donations)*				*55.62*	*0.56*	*4.28*	*49.90*	*1.24*	*4.53*	*2.60*	*0.23*	*0.39*	*108.11*	*2.03*	*9.20*
SA	66 435	1 171 079	1 237 514	38	11	49	37	13	50	0	2	2	75	26	101
Number *(Number per 100 000 donations)*				*57.20*	*0.94*	*3.96*	*55.69*	*1.11*	*4.04*	*0.00*	*0.17*	*0.16*	*112.89*	*2.22*	*8.16*
TAS	28 704	509 594	538 298	16	5	21	24	4	28	0	0	0	40	9	49
Number *(Number per 100 000 donations)*				*55.74*	*0.98*	*3.90*	*83.61*	*0.78*	*5.20*	*0.00*	*0.00*	*0.00*	*139.35*	*1.77*	*9.10*
VIC	267 972	3 525 889	3 793 861	262	49	311	131	34	165	9	6	15	402	89	491
Number *(Number per 100 000 donations)*				*97.77*	*1.39*	*8.20*	*48.89*	*0.96*	*4.35*	*3.36*	*0.17*	*0.40*	*150.02*	*2.52*	*12.94*
WA	94 259	1 319 499	1 413 758	62	14	76	35	7	42	3	2	5	100	23	123
Number *(Number per 100 000 donations)*				*65.78*	*1.06*	*5.38*	*37.13*	*0.53*	*2.97*	*3.18*	*0.15*	*0.35*	*106.09*	*1.74*	*8.70*
National	975 299	13 425 776	14 401 075	722	143	865	509	137	646	25	21	46	1 256	301	1 557
Number *(Number per 100 000 donations)*				*74.03*	*1.07*	*6.01*	*52.19*	*1.02*	*4.49*	*2.56*	*0.16*	*0.32*	*128.78*	*2.24*	*10.81*

1B HTLV, by state/territory, 2014-2023

State/Territory of donation	All accepted donations			HTLV		
	First time	Repeat	All	First time	Repeat	All
NSW/ACT	318 648	1 975 652	2 294 300	16	3	19
Number *(Number per 100 000 donations)*				*5.02*	*0.15*	*0.83*
NT	6 887	38 873	45 760	0	0	0
Number *(Number per 100 000 donations)*				*0.00*	*0.00*	*0.00*
QLD	192 394	1 263 824	1 456 218	4	0	4
Number *(Number per 100 000 donations)*				*2.08*	*0.00*	*0.27*
SA	66 435	537 686	604 121	4	1	5
Number *(Number per 100 000 donations)*				*6.02*	*0.19*	*0.83*
TAS	28 704	221 615	250 319	4	0	4
Number *(Number per 100 000 donations)*				*13.94*	*0.00*	*1.60*
VIC	267 972	1 595 800	1 863 772	12	0	12
Number *(Number per 100 000 donations)*				*4.48*	*0.00*	*0.64*
WA	94 259	570 939	665 198	3	0	3
Number *(Number per 100 000 donations)*				*3.18*	*0.00*	*0.45*
National	975 299	6 204 389	7 179 688	43	4	47
Number *(Number per 100 000 donations)*				*4.41*	*0.06*	*0.65*

1C Potentially infectious syphilis, by state/territory, 2014-2023

State/Territory of donation	All accepted donations			Potentially infectious syphilis		
	First time	Repeat	All	First time	Repeat	All
NSW/ACT	318 648	2 788 928	3 107 576	16	36	52
Number *(Number per 100 000 donations)*				*5.02*	*1.29*	*1.67*
NT	6 887	49 535	56 422	0	1	1
Number *(Number per 100 000 donations)*				*0.00*	*2.02*	*1.77*
QLD	192 394	1 701 174	1 893 568	10	16	26
Number *(Number per 100 000 donations)*				*5.20*	*0.94*	*1.37*
SA	66 435	710 252	776 687	4	2	6
Number *(Number per 100 000 donations)*				*6.02*	*0.28*	*0.77*
TAS	28 704	280 300	309 004	1	2	3
Number *(Number per 100 000 donations)*				*3.48*	*0.71*	*0.97*
VIC	267 972	2 264 582	2 532 554	22	26	48
Number *(Number per 100 000 donations)*				*8.21*	*1.15*	*1.90*
WA	94 259	781 969	876 228	8	4	12
Number *(Number per 100 000 donations)*				*8.49*	*0.51*	*1.37*
National	975 299	8 576 740	9 552 039	61	87	148
Number *(Number per 100 000 donations)*				*6.25*	*1.01*	*1.55*

Hepatitis B Virus (HBV)

Epidemiology of HBV in Australia

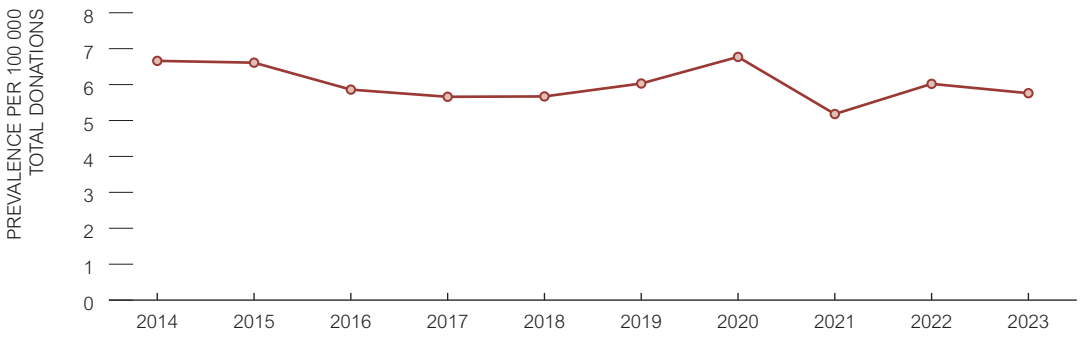
At the end of 2022, an estimated 205 549 people were living with chronic HBV in Australia, of whom an estimated 72.1% (148 159) were diagnosed with chronic HBV, 23.0% and 22.5% were born in the Northeast and Southeast Asia, respectively, and 6.7% were among Aboriginal and Torres Strait Islander peoples.[1] In total, there were 5 390 notifications of newly diagnosed HBV in Australia in 2023; of these, over half (53.5%) were male, and 93.0% 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; Aboriginal and Torres Strait Islander peoples; and people who inject drugs. Over the ten-year period, 2014-2023, the population rate of diagnosis of HBV in Australia has declined in younger age groups: 30-39 years (from 9.1 to 5.5 per 100 000); 20-29 years (from 6.3 to 2.4 per 100 000); and <20 years (from 1.2 to 0.4 per 100 000).[1] This decline could be attributable to the successful implementation of immunisation programs for HBV and high levels of vaccine coverage in the younger age groups. 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, 2014-2023, a total of 865 HBV-positive donors have been detected (722 first-time donors & 143 repeat donors) (Table 1A). During this period, no significant trend was observed in HBV prevalence among all donations (IRR 0.98; 95% CI: 0.96-1.01). Overall, in the past 10 years HBV prevalence in all donations has fluctuated between 5.1 to 6.7 per 100 000 donations (Figure 7). However, the average prevalence among all donations for the period 2014-2023 shows a decline to 6.0 per 100 000 donations (0.01% of the total donations) (Table 1A) as compared to 8.6 and 7.1 per 100 000 donations for the 2006-2015 and 2010-2019 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=164) 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 2023, see Supplementary Table 2.

Figure 7 **HBV prevalence in all blood donations in Australia, by year of donation, 2014-2023**

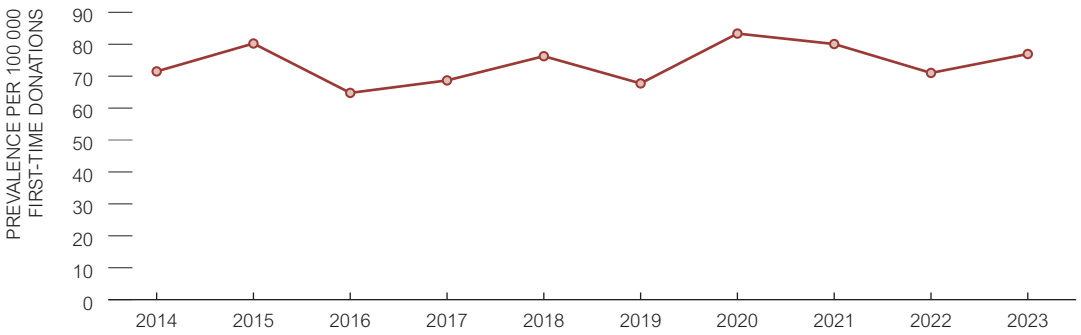


	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023
Prevalence in all donations	6.66	6.61	5.86	5.66	5.67	6.03	6.77	5.18	6.02	5.76

First-time donors:

Over the ten-year period 2014-2023, no significant annual trend is apparent among first-time donors (Figure 8) (IRR: 1.00; 95% CI: 0.98-1.03). However, the average prevalence for the period 2014-2023 shows a decline to 74.0 per 100 000 donations (0.08% of the total first-time donations) (Table 1A) as compared to 81.6 and 75.5 per 100 000 donations for the 2006-2015 and 2010-2019 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 27.7 per 100 000 in 2014, 23.7 per 100 000 in 2018, and 19.8 per 100 000 in 2023.[1]

Figure 8 **HBV prevalence in first-time blood donors in Australia, by year of donation, 2014-2023**



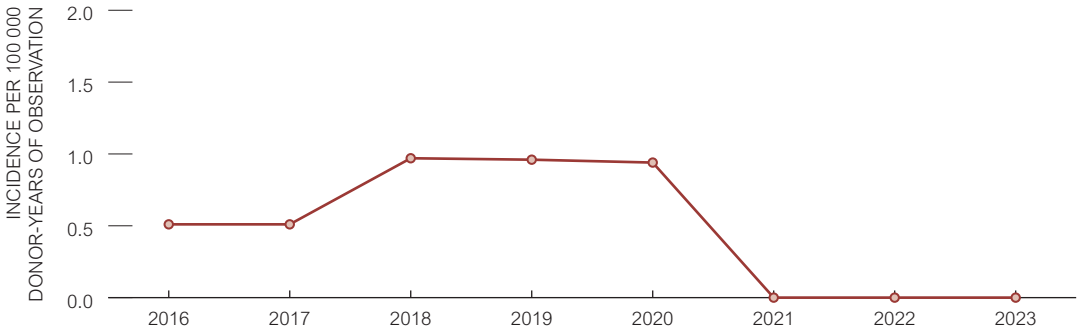
	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023
Prevalence in first-time donors	71.49	80.23	64.76	68.67	76.26	67.73	83.34	80.07	71.01	76.94

Trends in incidence

For the eight-year period 2016-2023, there was a total of eight 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: 0.76; 95% CI: 0.55-1.06) (Figure 9). Similar to 2021 and 2022, no incident HBV donors were detected in 2023.

No probable or confirmed transfusion-transmitted HBV cases were reported in Australia during 2016-2023. 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, 2016-2023**

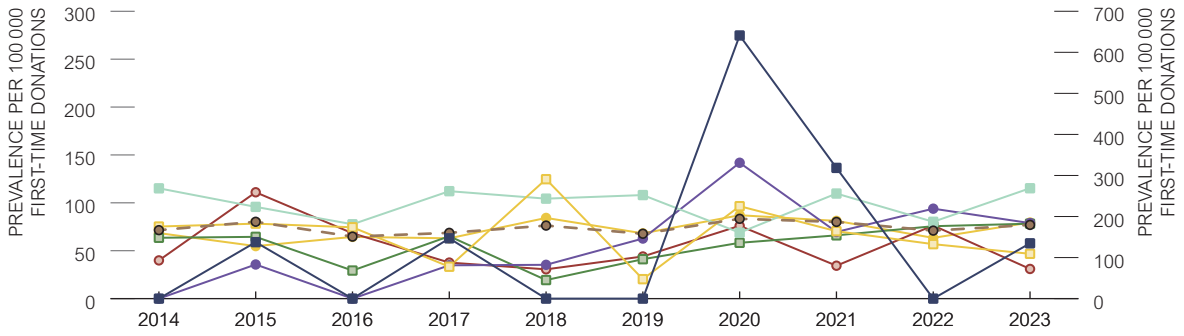


	2016	2017	2018	2019	2020	2021	2022	2023
Incidence	0.51	0.51	0.97	0.96	0.94	0.00	0.00	0.00

Trends in HBV by state/territory

Consistent with previous TTI surveillance reports, the HBV prevalence among first-time donors varied markedly by jurisdiction in 2023, which is expected given random variation with small numbers. While the national prevalence was 76.9 per 100 000 donations, this ranged from 30.9 (Queensland) to 134.7 (Northern Territory) per 100 000 donations across jurisdictions (Figure 10). During the past 10 years, 2014-2023, a significant increasing trend was observed for Tasmania (IRR: 1.24; 95% CI: 1.02-1.51). All 16 HBV-positive first-time donors in Tasmania were born overseas, of which 10 (62.5%) were from high-prevalence countries; the average number of HBV-positive first-time donors from high-prevalence countries increased from 0.2 per year in the first five years, 2014-2018, to 1.8 per year during the latter five years, 2019-2024. For the ten-year period 2014-2023, the highest average prevalence among first-time donors was observed in the Northern Territory, at 137.87 per 100 000 donations, followed by Victoria at 98.7 per 100 000 donations; given the small number of positive donors for the Northern Territory, which ranged between 0-4 per year, this should be interpreted with caution. However, no significant trend was observed during this period in the Northern Territory and Victoria or in any other state and territories except Tasmania. In comparison, the Northern Territory had the highest rate of diagnosis of HBV reported in national surveillance data for the 2014-2023 period (between 62.7 per 100 000 in 2014 and 37.1 per 100 000 in 2023), followed by New South Wales (between 33.0 per 100 000 in 2014 and 23.0 per 100 000 in 2023) and Victoria (between 29.4 per 100 000 in 2014 and 20.1 per 100 000 in 2023).[1] No noticeable trend was observed for Tasmania in national surveillance data for the 2014-2023 period.

Figure 10 HBV prevalence among first-time donors, by state/territory and year of donation, 2014-2023[i]

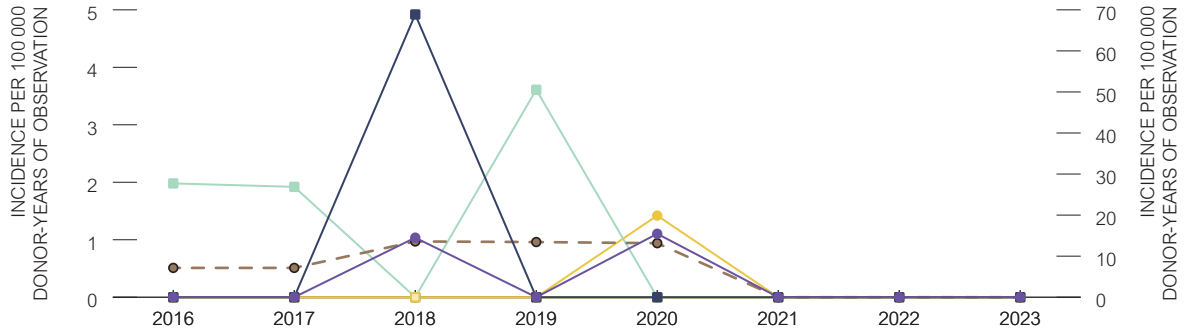


	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023
NSW/ACT	68.41	54.83	64.44	62.97	84.23	68.16	87.07	81.16	63.42	79.45
QLD	39.91	111.03	68.25	37.63	30.58	43.99	76.03	34.37	76.34	30.98
SA	63.53	64.50	29.31	65.15	19.38	41.15	58.28	66.06	75.60	78.24
TAS	0.00	35.63	0.00	34.79	35.29	62.72	141.84	69.59	93.90	78.86
VIC	115.15	95.79	77.63	112.18	104.37	108.11	68.87	109.71	80.22	115.24
WA	75.26	78.28	74.48	33.31	124.69	20.32	96.50	70.41	56.86	46.80
NT	0.00	137.55	0.00	146.84	0.00	0.00	641.03	318.47	0.00	134.77
National	71.49	80.23	64.76	68.67	76.26	67.73	83.34	80.07	71.01	76.94

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

Similar to 2021 and 2022, there were no HBV incident donors recorded nationally in 2023. Overall, there was no apparent trend in HBV incidence in any state/territory during the eight-year study period 2016-2022 (Figure 11). Among donors in Queensland, South Australia and Western Australia, HBV incidence has been zero since 2016.

Figure 11 HBV incidence among repeat donors, by state/territory and year of donation, 2016-2023[i]



	2016	2017	2018	2019	2020	2021	2022	2023
NSW/ACT	0.00	0.00	0.00	0.00	1.42	0.00	0.00	0.00
QLD	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
SA	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
VIC	1.98	1.92	0.00	3.61	0.00	0.00	0.00	0.00
WA	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
NT	0.00	0.00	68.87	0.00	0.00	0.00	0.00	0.00
TAS	0.00	0.00	14.50	0.00	15.45	0.00	0.00	0.00
National	0.51	0.51	0.97	0.96	0.94	0.00	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 2023, 250 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 2023, 16 of the 94 (17.0%) HBV-positive donors detected were classified as OBI, as compared to 19 of 92 (20.7%) in 2022. All but one (93.7%) OBIs in 2023 were men and most (10/16; 62.5%) were repeat donors, with an average age of 53 years. Half (8/16; 50%) of donors with OBI in 2023 were born in Asia (Southeast/Northeast Asia – 6, Southern and Central Asia – 2).

Comparison of HBV prevalence among blood donors and the general population

This section presents a comparison of HBV prevalence among first-time blood donors and the general population. As noted above, the 2023 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 2014-2023 and 2023, comparison with the general population was made with a combined period of 2013-2022 and 2022, 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 10-times lower prevalence in first-time donors during the period 2013/2014-2022/2023 and for the year 2022/2023, 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,* 2022/2023 and 2013/2014-2022/2023

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	
	2013-2022	2022	2014-2023	2023	2013/2014-2022/2023	2022/2023
HBV	871	791	74.03	76.94	12 times lower	10 times lower

* The 2022 HBV prevalence in the general population was calculated by taking the estimated number of people living with chronic HBV in 2022,1 and dividing it by the estimated mid-year resident Australian population in 2022 as 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 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 2023 and the five-year period 2019-2023 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 2023, donors between 40-49 and over 50 years of age were 62% and 53% less likely to be HBV positive compared to the reference age group of 20-29 years, respectively. This may be partially explained by confounding due to donor status. Older donors are more likely to be repeat donors, where HBV prevalence is lower due to prior screening. Without this confounding, higher rates of HBV might be expected in older age groups due to cumulative risk of infection and a less likelihood of benefiting from the National HBV Immunization Programme. Donors from Queensland were 63% less likely to be HBV positive as compared to the reference group of New South Wales (Supplementary Table 4).

In the five-year period 2019-2023, donors aged between 30-39 years were 1.5 times more likely and donors over 50 years of age were 32% less likely to be HBV positive than the reference age group, respectively. During the same period, donors from the Northern Territory had a significantly higher rate of HBV positivity (2.1 times) as compared to the reference group (Supplementary Table 5), while donors from Queensland were 32% less likely to be HBV positive. In comparison, during 2014-2023, the notification rates of HBV in Australia have been consistently higher in male (30.2 per 100 000 in 2014 to 21.6 per 100 000 in 2023), than female persons (25.3 per 100 000 in 2014 to 18.0 per 100 000 in 2023). 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 2014-2020 (62.7 per 100 000 in 2014 to 36.0 per 100 000 in 2020) but fell by ~50% in 2022 to 18.3 per 100 000 population before increasing to 37.1 per 100 000 population in 2023. In all other jurisdictions the rate of HBV diagnosis has also declined during the ten-year period 2014-2023, with the greatest decline observed in South Australia (42%) where the rate decreased from 23.1 per 100 000 in 2014 to 13.3 per 100 000 in 2023.[1]

Risk factors associated with HBV-positive donors

Of the 467 HBV positive donors during 2019-2023, 85% were first-time donors, 72% 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 HBV in the general population. Ethnicity or country of birth (78%) was the most frequent risk factor for HBV positivity, with 48% born in Northeast & Southeast Asia in 2023 (Figure 12). There were only four incident HBV 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, 2019-2023

Characteristics	2019	2020	2021	2022	2023	2019-2023
Number of positive donors	90	108	83	92	94	467
Number of positive first-time donors (%)	71 (79%)	89 (82%)	76 (92%)	81 (88%)	81 (86%)	398 (85%)
Number of male donors (%)	73 (81%)	68 (63%)	59 (71%)	71 (77%)	69 (73%)	340 (72%)
Mean age (range) in years	40 (19-73)	41 (18-74)	41 (20-76)	39 (21-75)	40 (18-75)	40 (18-76)
Number of incident donors	2	2	0	0	0	4
Number of donors born in Australia (%)	11 (15%)	9 (8%)	2 (2%)	6 (7%)	8 (8%)	36 (8%)
Main reported risk factor	Ethnicity/COB[1] 90%*	Ethnicity/COB[1] 71%*	Ethnicity/COB[1] 78%*	Ethnicity/COB[1] 80%*	Ethnicity/COB[1] 76%*	Ethnicity/COB[1] 78%
Second reported risk factor	PUSR[2] 3%	FH/HC[3] 16%	FH/HC[3] 18%	FH/HC[3] 16%	FH/HC[3] 19%	FH/HC[3] 14%

1 COB= Country of birth
2 PUSR= Partner with unspecified risk
3 FH/HC= Family history/Household contact
* 4 out of 11, 1 out of 9, 1 out of 2, 1 out of 6 and 1 out of 8 donors born in Australia had Ethnicity as their major risk factor in 2019, 2020, 2021, 2022 and 2023, respectively

Figure 12 HBV-positive donors, by country/region of birth, 2023 (n=94)

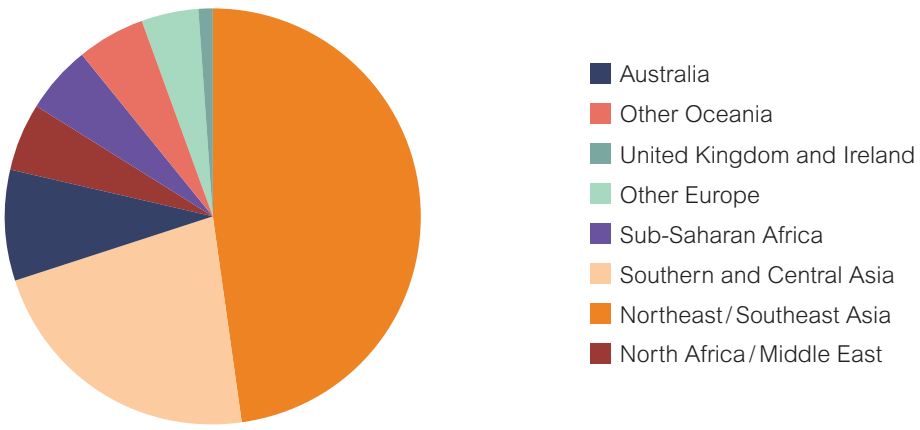
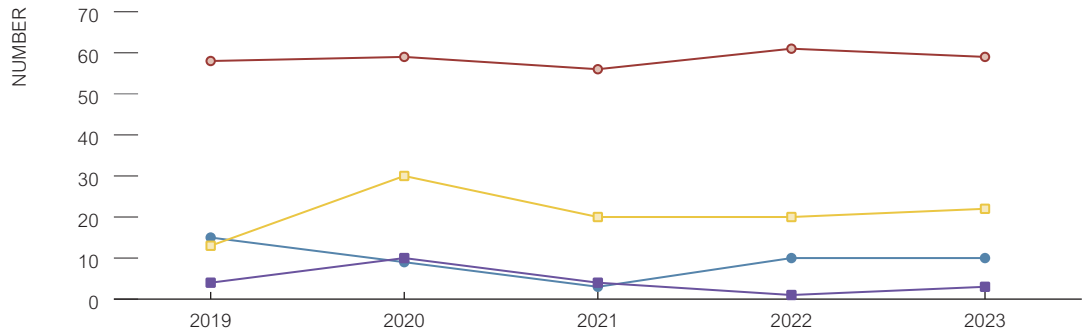


Figure 13 **HBV-positive donors, by sex and donor status, 2019-2023**



	2019	2020	2021	2022	2023
Male (first-time)	58	59	56	61	59
Male (repeat)	15	9	3	10	10
Female (first-time)	13	30	20	20	22
Female (repeat)	4	10	4	1	3

Over the past five years, 2019-2023, no discernible overall trend was seen in repeat or first-time male and female HBV positive donors (Figure 13). In comparison, there have been declines in HBV notification rates by sex in the ten-year period 2014-2023, from 30.2 to 21.6 per 100 000 male population and 25.3 to 18.0 per 100 000 female population.[1] 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 2023 and the period 2019-2023, 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 75.5% of the HBV-positive donors in 2023. 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 2023, for newly acquired HBV in the general population, 18.6% had injecting drug use and 6.9% had sexual contact and tattoo or body piercing as their major risk factors, separately; importantly, for 46.9% of newly acquired HBV in the general population, the risk factor was either not reported or could not be identified (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, 2023**

	HBV	
Major risk category	Newly acquired HBV cases in general population (2023) (%)	Blood donors (2023) (%)
Injecting drug use	18.6	0.0
Country of birth/Ethnicity	14.9	75.5
Sexual contact[i]	6.9	3.2
Blood or tissue recipient	2.3	0.0
Tattoo or body piercing	6.9	0.0
Exposure in health care setting	1.2	0.0
Household contact/Family history	0.0	19.1
Other blood to blood contact	2.3	1.1
Undetermined/unknown/not reported	46.9	1.1
Imprisonment	0.0	0.0
Occupational risk	0.0	0.0
Other	0.0	0.0
No risk factor identified	0.0	0.0

i Includes four sub-groups: Male to male sexual activity, Partner with known risk or known to be positive, Partners with unspecified risks and Engaged in sex work
Note: Percentages may not add to exactly 100% due to rounding

Conclusion

- HBV prevalence in first-time blood donors has shown no significant trend since 2014 and is substantially lower (12 times) than the general population estimates for the period 2013/2014-2022/2023.
- 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 16 OBI among 94 HBV infections in 2023.
- 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

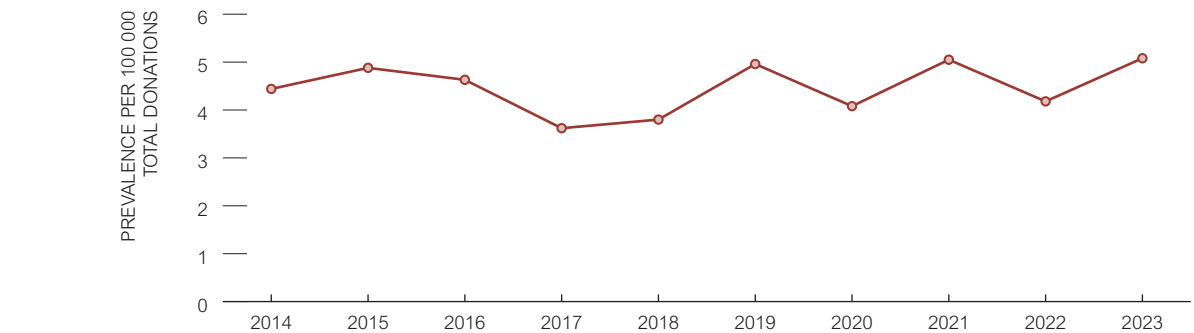
To the end of 2023, an estimated 68 890 people were living with chronic HCV in Australia, of which an estimated 84% or 57 900 were diagnosed with chronic HCV.[1] Australia has a concentrated chronic HCV epidemic among key populations: people who inject drugs, prisoners, people from high prevalence countries and HIV-positive men who have sex with men. The rate of diagnosis of HCV in 2023 was 28.1 per 100 000 which reflects a 36% decline from 43.9 per 100 000 population in 2014.[1] 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 28% in the past 10 years, 2014-2023.[1] Between 2019 and 2023, the rate of diagnosis in the Aboriginal and Torres Strait Islander population aged 15-24 years declined by 27%, from 323.1 to 236.1 per 100 000 in 2023, whereas the rate in non-indigenous people in the same age group declined by 18.5% from 27.5 to 22.4 per 100 000 in 2023.[1] Similarly, in 2023, the diagnosis rate of HCV was more than six times higher in the Aboriginal and Torres Strait Islander population (165.5 per 100 000) than that of the non-indigenous population (25.7 per 100 000). In 2023, most cases (71.7%) of newly diagnosed HCV were in male persons and 88% were in people aged 25 years and above.[1]

Trends in prevalence

All donations:

In the past 10 years, 2014-2023, 646 HCV-positive donors have been detected (509 first-time donors & 137 repeat donors) (Table 1A). During this period, no significant trend (IRR: 1.00 95% CI: 0.98-1.03) 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 5.0 per 100 000 donations (Figure 14). For detail on the number and prevalence rate of HCV among all donations for 2023 see Supplementary Table 2.

Figure 14 **HCV prevalence in all blood donations in Australia, by year of donation, 2014-2023**



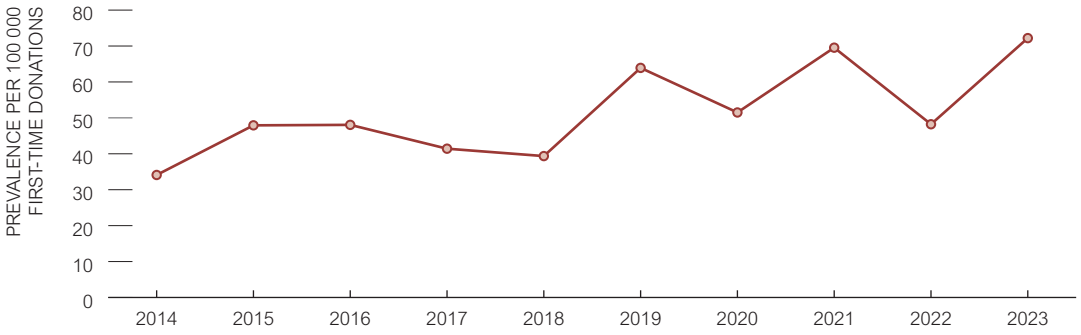
	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023
Prevalence in all donations	4.44	4.88	4.63	3.62	3.80	4.96	4.08	5.05	4.18	5.08

First-time donors:

Overall, HCV prevalence in first-time donors was 52.1 per 100 000 over the ten-year period 2014-2023. During this period, there was a small but significant increase in HCV prevalence for first-time donors (IRR: 1.06; 95% CI: 1.02-1.09) from 34.1 in 2014 to 72.2 per 100 000 donations in 2023 (Figure 15). This increase in HCV prevalence in first-time donors, especially in the recent years 2018-2023, 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 43.9 per 100 000 in 2014 to 28.1 per 100 000 in 2023.[1] In addition, there has also been a decrease in the prevalence of HCV antibody among people seen at needle and syringe programs between 2014-2022, from 54% to 32% before increasing to 45% in 2023. 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, 2014-2023



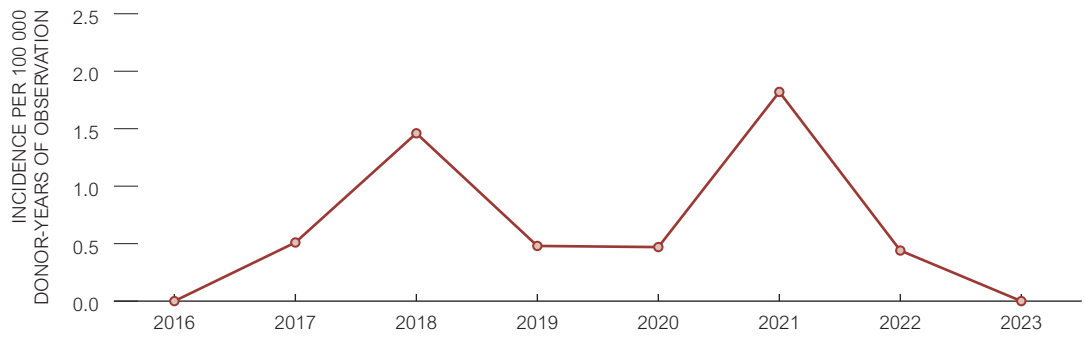
	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023
Prevalence in first-time donors	34.10	47.92	48.05	41.42	39.36	63.91	51.50	69.54	48.22	72.20

Trends in incidence

Over the eight-year period 2016-2023, a total of 11 incident HCV donors were detected with no statistically significant trend observed for incidence rates (between 0.0 and 1.8 per 100 000 donor-years of observation; IRR: 0.98; 95% CI: 0.76-1.27) (Figure 16). No HCV incident donors were identified in 2023. The modelled national HCV incidence estimates show a 61% decline in the number of incident cases between 2017 and 2023 (from 4 470 to 1 740 incident cases). Among people attending the Australian Collaboration for Coordinated Enhanced Sentinel Surveillance (ACCESS) care sites, HCV incidence declined from 1.1 to 0.2 new infections per 100 person-years between 2014-2023 before slightly increasing to 0.5 new infections per 100 person-years in 2021.[1]

No probable or confirmed transfusion-transmitted HCV cases were reported in Australia during 2016-2023.

Figure 16 **HCV incidence in repeat blood donors in Australia, by year of donation, 2016-2023**



	2016	2017	2018	2019	2020	2021	2022	2023
Incidence	0.00	0.51	1.46	0.48	0.47	1.82	0.44	0.00

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. This proportion then dropped to 29.7% and 27.7% in 2022 and 2023, respectively. This increase during 2019-2021 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.

Over 95% (22/23) of the HCV RNA-positive donors in 2023 were first-time donors, equating to a rate of RNA-positive donors among first-time donors at 20.9 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 2014-2023 period (IRR: 1.01; 95% CI: 0.96-1.05).

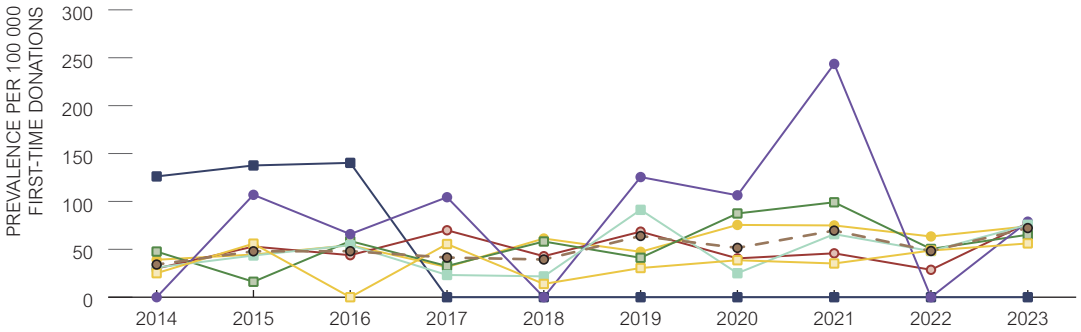
Importantly, first-time HCV-positive donors do not correlate directly with an increase in the HCV residual transmission risk. This is because the increase is among prevalent (long-standing) infections, readily detectable by Lifeblood's dual NAT/antibody testing strategy. The transmission risk for transfused 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. The number of HCV incident donors identified by Lifeblood fluctuated between 0-4 during the past eight years, 2016-2023. 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 2023, ranging from 0.0 (Northern Territory) to 78.8 (Tasmania) per 100 000 donations. During the past 10 years, 2014-2023, a significant increasing trend was observed for New South Wales (IRR: 1.07; 95% CI: 1.02-1.12) and Victoria (IRR: 1.07; 95% CI: 1.00-1.14) (Figure 17). 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 2023 was highest in Queensland (41.5 per 100 000), followed by the Northern Territory (38.9 per 100 000), Western Australia and New South Wales (31.8 and 30.3 per 100 000 respectively).[1]

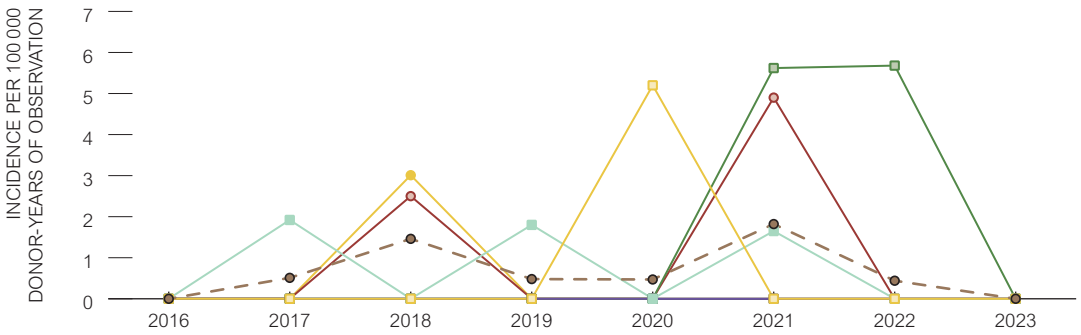
Figure 17 HCV prevalence among first-time donors, by state/territory and year of donation, 2014-2023



	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023
NSW/ACT	39.09	44.55	54.26	31.48	61.26	47.41	75.46	74.92	63.42	73.97
NT	126.10	137.55	140.25	0.00	0.00	0.00	0.00	0.00	0.00	0.00
QLD	29.94	52.87	43.87	69.88	42.81	68.44	40.55	45.82	28.63	77.44
SA	47.65	16.12	58.62	32.57	58.15	41.15	87.43	99.09	50.40	65.20
TAS	0.00	106.88	65.85	104.38	0.00	125.43	106.38	243.56	0.00	78.86
VIC	31.00	43.54	54.34	23.21	21.74	91.22	25.05	65.83	48.13	75.62
WA	25.09	55.92	0.00	55.51	13.85	30.48	38.60	35.21	48.73	56.16
National	34.10	47.92	48.05	41.42	39.36	63.91	51.50	69.54	48.22	72.20

Generally, HCV incidence in repeat donors has remained low across most Australian jurisdictions during the past eight years (Figure 18) and no significant decrease was observed for any state or territory. Notably, in the Northern Territory and Tasmania, HCV incidence has remained zero since 2016.

Figure 18 HCV Incidence among repeat donors, by state/territory and year of donation, 2016-2023



	2016	2017	2018	2019	2020	2021	2022	2023
NSW/ACT	0.00	0.00	3.01	0.00	0.00	0.00	0.00	0.00
NT	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
QLD	0.00	0.00	2.50	0.00	0.00	4.90	0.00	0.00
SA	0.00	0.00	0.00	0.00	0.00	5.62	5.68	0.00
TAS	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
VIC	0.00	1.92	0.00	1.80	0.00	1.65	0.00	0.00
WA	0.00	0.00	0.00	0.00	5.20	0.00	0.00	0.00
National	0.00	0.51	1.46	0.48	0.47	1.82	0.44	0.00

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 2014-2023 and then 2023 separately. Subsequently, a discussion is presented on the prevalence reduction in first-time donors compared to the general population. 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 10 and 4 times lower than the prevalence of people living with chronic hepatitis C in the general population for the period 2014-2023, and 2023, respectively (Table 5).

Table 5 Comparison of HCV prevalence in blood donors with population prevalence,* 2023 and 2014-2023

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	
	2014-2023	**2023**	**2014-2023**	**2023**	**2014-2023**	**2023**
HCV	547	259	52.19	72.2	10 times lower	4 times lower

* The 2023 HCV prevalence in the general population was calculated by taking the estimated number of people living with chronic HCV in 2023,1 and dividing it by the estimated mid-year resident Australian population in 2023 reported by the Australian Bureau of Statistics. For the period 2014-2023, 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 2023 and the five-year period 2019-2023 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 2023, there was no significant association between donors' sex and state of residence and HCV positivity as compared to the reference groups. Donors between 30-39 and over 50 years of age were over four and five times more likely to be HCV-positive compared to the reference group, respectively (Supplementary Table 4).

During the five-year period 2019-2023, female donors were 31% 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 2019-2023, donors from 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 367 HCV-positive donors during 2019-2023, 87% were first-time donors and 59% were male. Over the last five years, the mean age was 48 years with a wide range (18-72) (Table 6). Unlike HBV where birth overseas predominated, the majority (61%) of HCV-positive donors during 2019-2023 were born in Australia (Figure 19).

Overall, the main reported putative risk factor for HCV positivity during 2019-2023 was injecting drug use at 28%, while for 22% of the HCV-positive donors the risk factor remained undetermined or unknown.

Table 6 Characteristics of HCV-positive donors, by year of donation, 2019-2023

Characteristics	2019	2020	2021	2022	2023	2019-2023
Number of positive donors	74	65	81	64	83	367
Number of positive first-time donors (%)	67 (91%)	55 (85%)	66 (81%)	55 (86%)	76 (92%)	319 (87%)
Number of male donors (%)	44 (59%)	42 (65%)	51 (63%)	35 (55%)	46 (55%)	218 (59%)
Mean age (range) in years	47 (18-70)	45 (20-69)	49 (18-72)	50 (18-72)	50 (18-70)	48 (18-72)
Number of incident donors	1	1	4	1	0	7
Number of donors born in Australia (%)	47 (64%)	36 (55%)	57 (70%)	37 (58%)	47 (57%)	224 (61%)
Main reported risk factor	IDU[2]	IDU[2] & undetermined	IDU[2]	IDU[2]	Undetermined	IDU[2]
	26%	20%	32%	32%	31%	28%
Second reported risk factor	TBP[1]	TBP[1]	Undetermined	Undetermined	IDU[2]	Undetermined
	23%	15%	21%	30%	26%	22%

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

Figure 19 HCV-positive donors, by country/region of birth, 2023 (n=83)

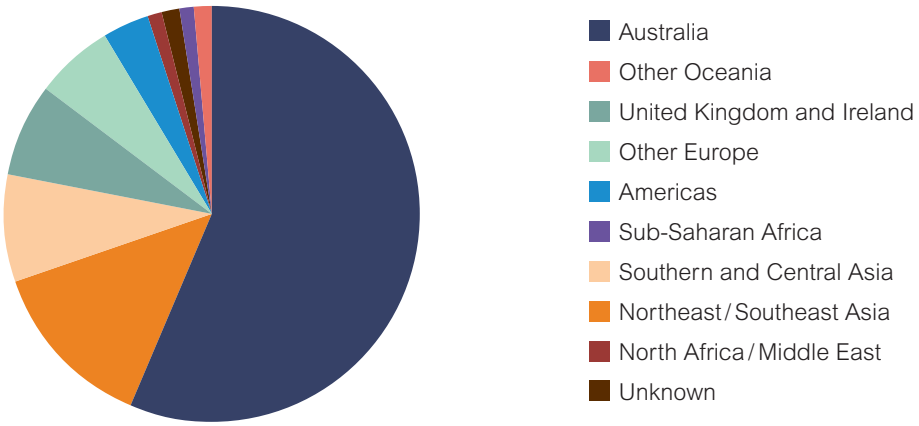
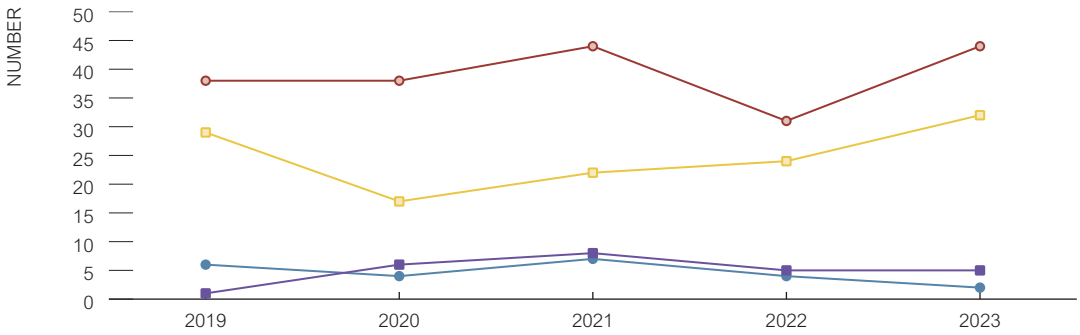


Figure 20 HCV-positive donors, by sex and donor status, 2019-2023



	2019	2020	2021	2022	2023
Male (first-time)	38	38	44	31	44
Male (repeat)	6	4	7	4	2
Female (first-time)	29	17	22	24	32
Female (repeat)	1	6	8	5	5

Over the five-year period 2019-2023, a small increase in the number of HCV-positive first-time male and female donors has continued. This increase in numbers 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 2023 and the period 2019-2023, see Supplementary Tables 6-12. In comparison, there have been gradual declines in HCV notification rates by sex in the ten-year period 2014-2023, from 57.9 to 41.1 per 100 000 male population and 30.1 to 15.2 per 100 000 female population.[1] As the trends in general population are presented in rates as compared to numbers in blood donors, caution must be applied when comparing the two.

HCV – Comparison of major exposure categories between blood donors and the general population, 2023

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 2023 was IDU (26.5%) followed by country of birth (21.7%), while tattoo or body piercing was low at 2.4%. Of note, in 2023, for 31.3% blood donors, the risk factor remained unknown/undetermined. In comparison, for newly acquired HCV in the general population in 2023, 63.2% had imprisonment as their major risk factor, followed by 12.3% 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 20.9% 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, 2023

	HCV	
Major risk category	Newly acquired HCV cases in general population (2023) (%)	Blood donors (2023) (%)
Injecting drug use	12.3	26.5
Country of birth/Ethnicity	1.2	21.7
Sexual contact[i]	0.23	4.8
Blood or tissue recipient	0.4	3.6
Tattoo or body piercing	0.2	2.4
Exposure in health care setting	0.4	4.8
Household contact/Family history	0.0	2.4
Other blood to blood contact	0.0	1.2
Undetermined/unknown/not reported	0.0	31.3
Imprisonment	63.2	1.2
Occupational risk	0.2	0.0
Other	1.4	0.0
No risk factor Identified	20.9	0.0

i Includes four sub-groups: Male to male sexual activity, Partner with known risk or known to be positive, Partner with unspecified risks and Engaged in sex work
Note: Percentages may not add to exactly 100% due to rounding

Conclusion

- A small but significant increase in HCV prevalence among first-time blood donors during 2014-2023. 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 blood donors in 2023 and for the period 2014-2023 was 4 and 10 times lower than the general population estimates in 2023 and for the period 2014-2023, respectively.
- HCV incidence, the best correlate of transfusion-transmission risk, has not shown a significant trend in the eight-year study period 2016-2023. 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 2023 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

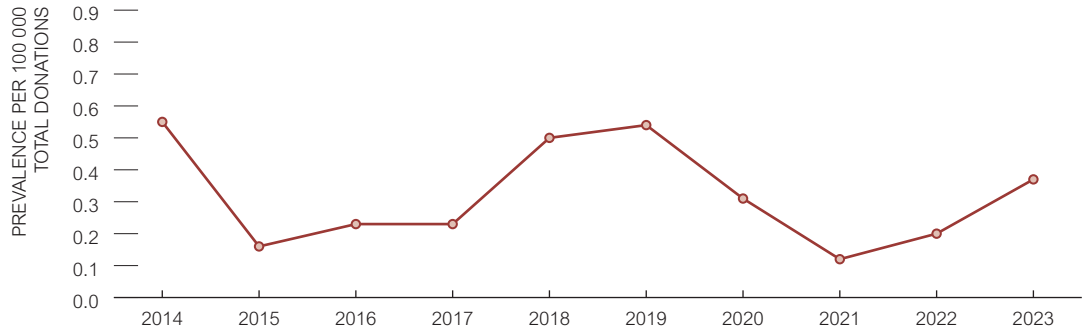
During 2023, an estimated 30 010 people were living with HIV and an estimated majority (92%) or 27 650 were diagnosed.[1] Transmission of HIV in Australia continues to occur primarily through sexual contact between men, with 63% cases of HIV first ever diagnosed in Australia in 2023 involving men who reported sexual contact with men (including those reporting male to male sexual activity and injecting drug use).[1] The annual number of new HIV diagnoses (first ever in Australia) has decreased by 19% over the past five years, from 895 diagnoses in 2019 to 722 in 2023. Of those newly diagnosed HIV in 2023, 86% were in men, 55% occurred among men who have sex with men, 8% due to male to male sexual activity and injecting drug use, 28% were attributed to heterosexual sex, and 2.3% to injecting drug use. At 0.12%, the prevalence or overall proportion of people in Australia who have HIV is lower than other comparable high-income countries, and countries in the region.[1]

Trends in prevalence

All donations:

In the past 10 years, 2014-2023, a total of 46 HIV-positive donors have been detected (25 first-time donors & 21 repeat donors) (Table 1A). During this period, no significant trend was observed in HIV prevalence among all donations (IRR: 0.96; 95% CI: 0.87-1.07). 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 2023, see Supplementary Table 2.

Figure 21 **HIV prevalence in all blood donations in Australia, by year of donation, 2014-2023**

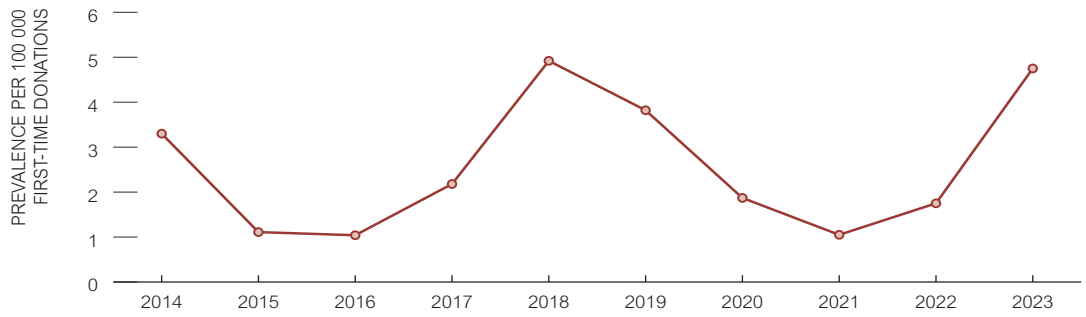


	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023
Prevalence in all donations	0.55	0.16	0.23	0.23	0.50	0.54	0.31	0.12	0.20	0.37

First-time donors:

Overall, HIV prevalence in first-time donors remained very low at 2.5 per 100 000 over the ten-year period 2014-2023 (Table 1A); it peaked at 4.9 per 100 000 donations in 2018 and fluctuated between 1.0 and 3.8 during 2019-2022 before increasing to 4.7 per 100 000 donations in 2023 (Figure 22). Overall, no significant trends were observed in HIV prevalence among first-time donors in the past 10 years (IRR: 1.03; 95% CI: 0.90-1.19). In comparison, the number of newly diagnosed HIV in the general Australian population decreased by 33%, from 1 079 diagnoses in 2014 to 722 cases of newly diagnosed HIV in Australia in 2023.[1] The annual number of new HIV cases has been declining in Australia since 2015, thanks to a combination of prevention measures, including sustained community-led responses, increased testing and treatment strategies and high uptake of the HIV prevention medication or pre-exposure prophylaxis (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, followed by an increase of 33% from 2021 (n=541) to 2023 (n=722).

Figure 22 HIV prevalence in first-time blood donors in Australia, by year of donation, 2014-2023



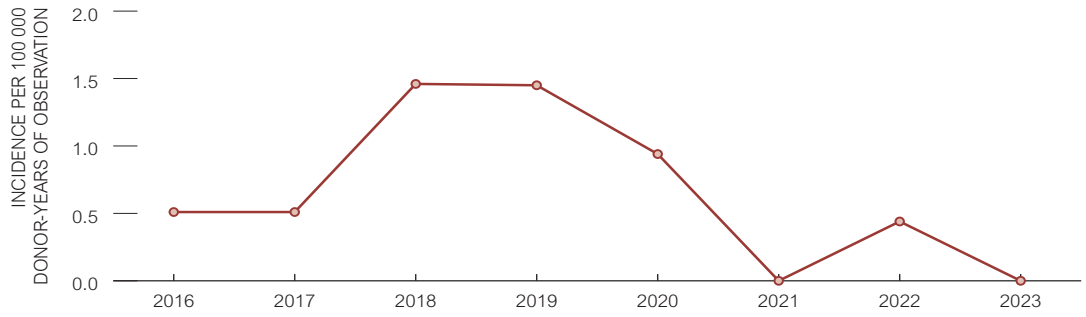
	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023
Prevalence in all donations	3.30	1.11	1.04	2.18	4.92	3.82	1.87	1.05	1.75	4.75

Trends in incidence

There was no incident HIV donor detected in 2023 (Figure 23). For the eight years 2016-2023, there were a total of 11 incident donors identified for HIV, and no significant trend was observed for HIV incidence during this time (IRR: 0.82; 95% CI: 0.63-1.07). While not directly comparable, the HIV incidence during 2019-2023 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 0.14 per 100 person years).[1]

No probable or confirmed transfusion-transmitted HIV cases were reported in Australia during 2016-2023.

Figure 23 Incidence of HIV in repeat blood donors in Australia, by year of donation, 2016-2023

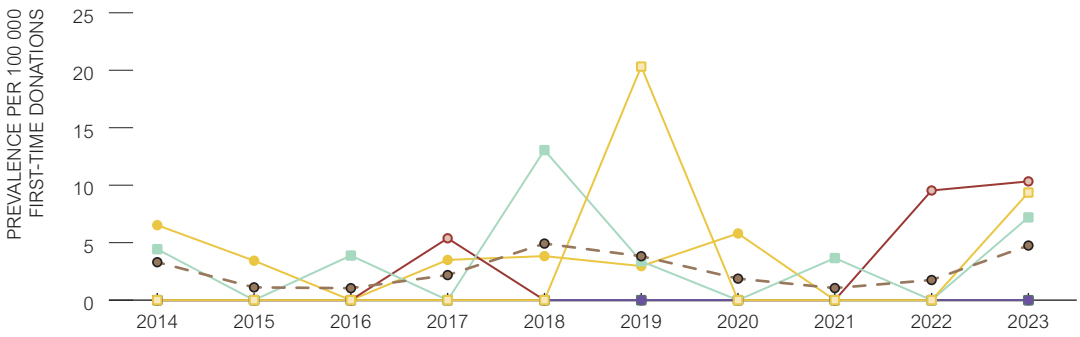


	2016	2017	2018	2019	2020	2021	2022	2023
Incidence	0.51	0.51	1.46	1.45	0.94	0.00	0.44	0.00

Trends in HIV by state/territory

No significant annual trend was observed during the 2014-2023 period in any jurisdiction (Figure 24). There were five HIV-positive first-time donors in 2023, two from Queensland, two from Victoria and one from Western Australia. In 2023, the highest prevalence among first-time donors compared to other states was recorded in Queensland, at 10.33 per 100 000 donations (Figure 24), which was also the highest for the state in the past 10 years. Given small numbers, caution should be taken in interpretation. During 2014-2023, HIV prevalence in first-time donors was zero in the Northern Territory, South Australia and Tasmania (Table 1A and Figure 24).

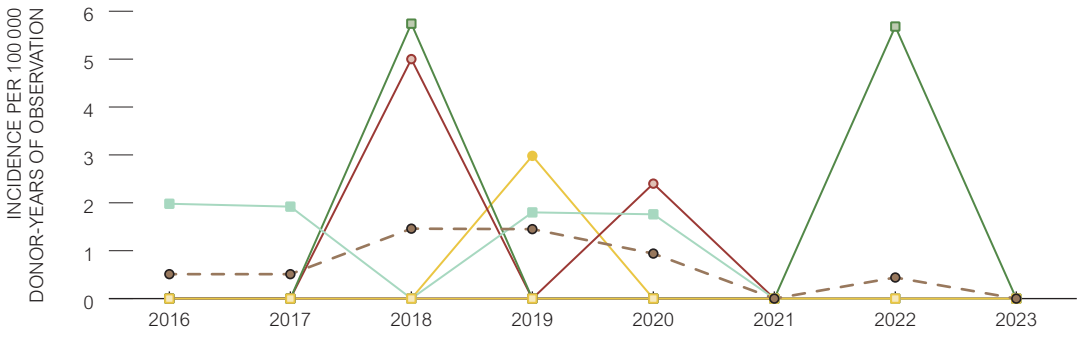
Figure 24 HIV prevalence among first-time donors, by state/territory and year of donation, 2014-2023



	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023
NSW/ACT	6.52	3.43	0.00	3.50	3.83	2.96	5.80	0.00	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	5.38	0.00	0.00	0.00	0.00	9.54	10.33
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	4.43	0.00	3.88	0.00	13.05	3.38	0.00	3.66	0.00	7.20
WA	0.00	0.00	0.00	0.00	0.00	20.32	0.00	0.00	0.00	9.36
National	3.30	1.11	1.04	2.18	4.92	3.82	1.87	1.05	1.75	4.75

Overall, HIV incidence in repeat donors has remained very low across all Australian jurisdictions during the past eight years (Figure 25) and no significant trend was observed for any state or territory. In 2023, there were no HIV incident donors, nationally. No incident HIV donors were recorded in Tasmania, Western Australia or the Northern Territory in the past eight years, 2016-2023 (Figure 25).

Figure 25 HIV incidence among repeat donors, by state/territory and year of donation, 2016-2023



	2016	2017	2018	2019	2020	2021	2022	2023
NSW/ACT	0.00	0.00	0.00	2.98	0.00	0.00	0.00	0.00
NT	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
QLD	0.00	0.00	5.00	0.00	2.40	0.00	0.00	0.00
SA	0.00	0.00	5.74	0.00	0.00	0.00	5.68	0.00
TAS	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
VIC	1.98	1.92	0.00	1.80	1.76	0.00	0.00	0.00
WA	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
National	0.51	0.51	1.46	1.45	0.94	0.00	0.44	0.00

Comparison of HIV prevalence among blood donors and the general population

This section presents a comparison of HIV prevalence among first-time blood donors and the general population for a combined period of 2014-2023 and then 2023 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 44 times lower for the period 2014-2023, and 24 times lower in 2023 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,* 2023 and 2014-2023

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	
	2014-2023	**2023**	**2014-2023**	**2023**	**2014-2023**	**2023**
HIV	112	113	2.56	4.75	44 times lower	24 times lower

* The 2023 HIV prevalence in the general population was calculated by taking the estimated number of people living with HIV in 2023,[1] and dividing it by the estimated mid-year resident Australian population in 2023 reported by the Australian Bureau of Statistics. For the period 2014-2023, 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 2023 and the five-year period 2019-2023 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 2023, there was no significant association between gender, age or state/territory and HIV positivity (Supplementary Table 4). During the five-year period 2019-2023, female donors and donors over 50 years of age were 87% and 68% less likely to be HIV-positive, respectively, compared to the reference groups. There was no association between state/territory and HIV positivity (Supplementary Table 5).

Risk factors associated with HIV-positive donors

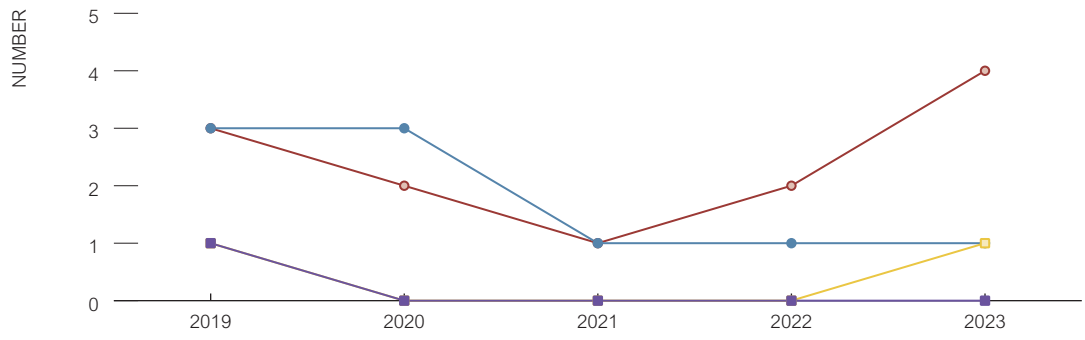
During 2019-2023, 58% of the 24 HIV-positive donors were first-time donors (Table 9). Most donors were male (88%) and had a mean age of 37 years, with a wide range of 21-70 years. Of 24 HIV-positive donors in the five-year period 2019-2023, six were incident HIV donors. Male to male sexual activity was the main reported risk factors for HIV positivity in 25% of blood donors during 2019-2023, while for 38% of the HIV positive donors, the risk factor could not be determined. In comparison, male to male sexual activity (excluding those reporting male to male sexual activity and injecting drug use) and heterosexual contact accounted for 55% and 28% of the new HIV diagnoses in the general population in 2023, respectively.

Table 9 Characteristics of HIV-positive donors, by year of donation, 2019-2023

Characteristics	2019	2020	2021	2022	2023	2019-2023
Number of positive donors	8	5	2	3	6	24
Number of positive first-time donors (%)	4 (50%)	2 (40%)	1 (50%)	2 (67%)	5 (83%)	14 (58%)
Number of male donors (%)	6 (75%)	5 (100%)	2 (100%)	3 (100%)	5 (83%)	21 (88%)
Mean age (range) in years	37 (21-70)	38 (25-67)	44 (30-58)	43 (24-68)	31 (21-40)	37 (21-70)
Number of incident donors	3	2	0	1	0	6
Number of donors born in Australia (%)	4 (50%)	2 (40%)	1 (50%)	2 (67%)	2 (33%)	11 (46%)
Main reported risk factor	MSM[1], PRP[2], PUSR[3], undetermined each	PUSR[3]	PUSR[3]	Undetermined	Undetermined	Undetermined
	25%	40%	100%	100%	50%	38%
Second reported risk factor	…	MSM[1], PRP[2], undetermined each	…	…	MSM[1]	MSM[1]
		20%	…	…	33%	25%

1 MSM= Male to male sexual activity
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, 2019-2023



	2019	2020	2021	2022	2023
Male (first-time)	3	2	1	2	4
Male (repeat)	3	3	1	1	1
Female (first-time)	1	0	0	0	1
Female (repeat)	1	0	0	0	0

Over the past five years, 2019-2023, 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 2019-2023, 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.

The most frequent potential risk factor reported for HIV positivity in blood donors in 2023 was sexual contact (all male to male) at 33.3%, followed by tattoo and body piercing at 16.7%, while for 50.0% blood donors, the risk factor remained unknown/undetermined. As in previous years, in 2023, the majority of newly diagnosed HIV in the general population was attributed to sexual contact (85.7%).[1]

Table 10 Comparison between HIV-positive blood donors and general population in Australia, by major potential risk categories, 2023

		HIV[i]
Major risk category	**Newly diagnosed HIV cases in general population (2023) (%)**	**Blood donors (2023) (%)**
Injecting drug use[ii]	7.3	0.0
Country of birth/Ethnicity	0.0	0.0
Sexual contact[iii]	85.7	33.3
Blood or tissue recipient	0.4	0.0
Tattoo or body piercing	0.0	16.7
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
Undetermined/unknown/not reported	6.4	50.0
Imprisonment	0.0	0.0
Occupational risk	0.0	0.0
Other	0.0	0.0
No risk factor identified	0.0	0.0

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 activity, Partner with known risk or known to be positive, Partner with unspecified risk and Engaged in sex work
Note: Percentages may not add to exactly 100% due to rounding

Conclusion

- HIV prevalence among first-time blood donors remained low in 2023 and showed no significant trend during 2014-2023. It was 24 times lower than in the general population in 2023, and 44 times lower for the period 2014-2023.
- The incidence of newly acquired HIV measured by the rate of incident donors is also much lower than incidence estimates from specific at-risk populations in Australia.
- There was no unique putative risk factor identified in HIV-positive blood donors in 2023.

Human T-Lymphotropic Virus (HTLV)

Epidemiology of HTLV in Australia

Human T-lymphotropic virus (HTLV) is a human retrovirus of the family *Retroviridae*, genus *Deltaretrovirus* with four known types. HTLV-1 was the first human retrovirus to be discovered, and was the first virus known to cause cancer in humans.[14] HTLV-1 is distributed globally, and is classified into seven major molecular and geographic subtypes: the Cosmopolitan subtype (a) distributed worldwide, the Australo/Melanesian subtype (c), and five African subtypes (b, d, e, f, g).[15] Areas with known high prevalence of HTLV-1 include regions in Central and West Africa, the Caribbean basin, South America, Melanesia, southwestern Japan, Central Australia, and other discrete geographic areas.[16] HTLV-1 causes adult T-cell leukemia-lymphoma (ATL),[17,18] and both HTLV-1 and HTLV-2 cause HTLV-associated myelopathy (HAM).[19] HTLV-1 is further associated with other inflammatory and infectious conditions, and a 50% increase in all-cause mortality.[20] HTLV transmission occurs primarily via direct contact between infected and uninfected cells, enabled by cell-containing bodily fluids (blood, breastmilk, and semen). In Australia, HTLV-1 was first detected in the late 1980's. It is not a notifiable infection except in the Northern Territory. While blood donor studies and surveillance data on the national blood supply consistently indicate low overall prevalence, several community surveys from the Northern Territory, particularly in the Alice Springs region, have reported very high prevalences among select Aboriginal communities, in some cases exceeding 50% among older age groups.[21-23] Consistent with global findings, there is a marked association with increased age, however the sex distribution within Central Australian Aboriginal communities is different from many other HTLV-1 affected populations with higher rates reported among males.

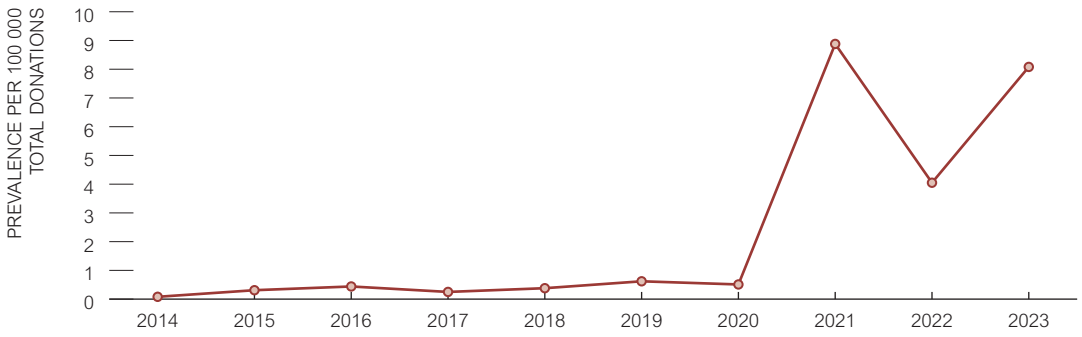
Trends in prevalence

All donations:

From September 2016 to December 2020, repeat donors donating plasma for fractionation were no longer required to test 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 2021 and onward 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, 2014-2023, a total of 47 HTLV-positive donors have been detected (43 first-time donors & four repeat donors) (Table 1B). During the same period, the overall HTLV prevalence among all donations was 0.65 per 100 000 donations (Table 1B) and has shown a statistically significant upward trend (IRR: 1.61; 95% CI: 1.42-1.82) (Figure 27). The rate fluctuated between 0.08 and 0.62 per 100 000 donations during 2014-2020, however a sharp increase was observed in 2021 where the rate went up to 8.88 and then fluctuated at 4.05 and 8.08 per 100 000 donations in 2022 and 2023, respectively. These increased rates in all donations post 2020 should be interpreted with caution as they were due to smaller denominators in these years, composed almost entirely of first-time donors (112 104 average annual donations in 2021, 2022 and 2023 versus 0.97 million average annual donations tested for HTLV for the 2014-2020 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 2023, see Supplementary Table 3A.

Figure 27 HTLV prevalence in all tested blood donations in Australia, by year of donation, 2014-2023

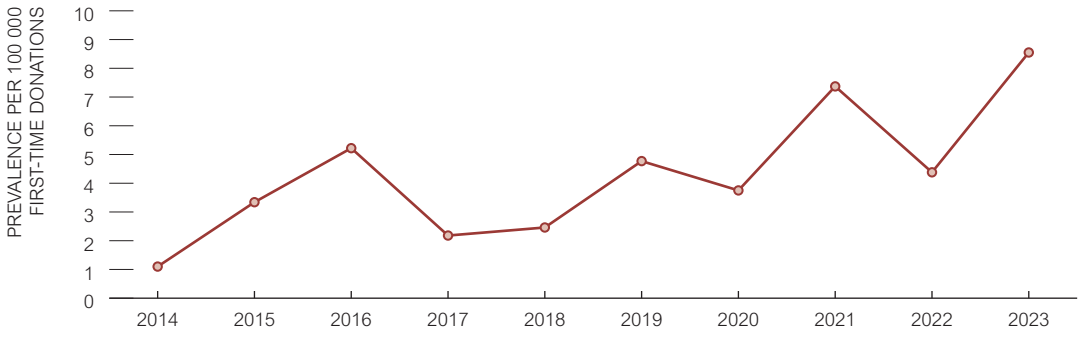


	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023
Prevalence in all donations	0.08	0.31	0.44	0.25	0.38	0.62	0.51	8.88	4.05	8.08

First-time donors:

HTLV prevalence in first-time donors over the past 10 years, 2014-2023 had an overall rate of 4.4 per 100 000 donations and has shown a statistically significant upward trend (Table 1B) (IRR: 1.13; 95% CI: 1.02-1.27). Whilst the prevalence fluctuated, it increased from a nadir of 1.1 in 2014 to 8.5 per 100 000 donations in 2023 (Figure 28). Overall, 88% (38/43) of the HTLV-positive first-time donors were from high prevalence regions. Caution must be applied when interpreting this trend given the low numbers of positive first-time donors (between 1-9 each year).

Figure 28 HTLV prevalence in first-time blood donors in Australia, by year of donation, 2014-2023



	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023
Prevalence in first-time donors	1.10	3.34	5.22	2.18	2.46	4.77	3.75	7.37	4.38	8.55

Trends in incidence

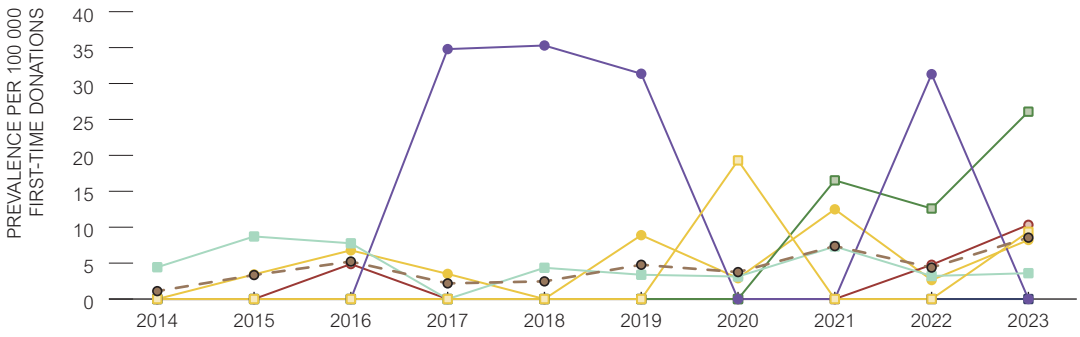
No incident donors have been identified since 2004. Given so few repeat donors are now tested for HTLV, it is no longer appropriate to derive an incidence rate from tested repeat donors. Lifeblood has derived a calculation method to indirectly derive the incidence from prevalence in first-time donors. 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.[24] Lifeblood monitors HTLV prevalence and will trigger risk assessment should it exceed the threshold.

No probable or confirmed transfusion-transmitted HTLV cases were reported in Australia during 2016-2023.

Trends in HTLV by state/territory

In 2023, HTLV prevalence in first-time donors was the highest in South Australia, at 26.08 per 100 000 donations, followed by Queensland at 10.33 per 100 000 donations (Figure 29). Caution should be taken in interpretation of HTLV prevalence in first-time donations in South Australia and Queensland as these rates equate to only two positive donors per state. No significant trend was observed for prevalence in first-time donors during the period 2014-2023 in any jurisdiction. HTLV prevalence in first-time donors has remained zero in the Northern Territory during the ten-year study period, 2014-2023 (Figure 29).

Figure 29 HTLV prevalence among first-time donors, by state/territory and year of donation, 2014-2023



	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023
NSW/ACT	0.00	3.43	6.78	3.50	0.00	8.89	2.90	12.49	2.64	8.22
NT	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
QLD	0.00	0.00	4.87	0.00	0.00	0.00	0.00	0.00	4.77	10.33
SA	0.00	0.00	0.00	0.00	0.00	0.00	0.00	16.52	12.60	26.08
TAS	0.00	0.00	0.00	34.79	35.29	31.36	0.00	0.00	31.30	0.00
VIC	4.43	8.71	7.76	0.00	4.35	3.38	3.13	7.31	3.21	3.60
WA	0.00	0.00	0.00	0.00	0.00	0.00	19.30	0.00	0.00	9.36
National	1.10	3.34	5.22	2.18	2.46	4.77	3.75	7.37	4.38	8.55

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 2023 and the five-year period 2019-2023 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 2023 and during the five-year period 2019-2023, there was no significant association between gender, donors' age group or location and HTLV positivity (Supplementary Table 4 and Supplementary Table 5).

Risk factors associated with HTLV-positive donors

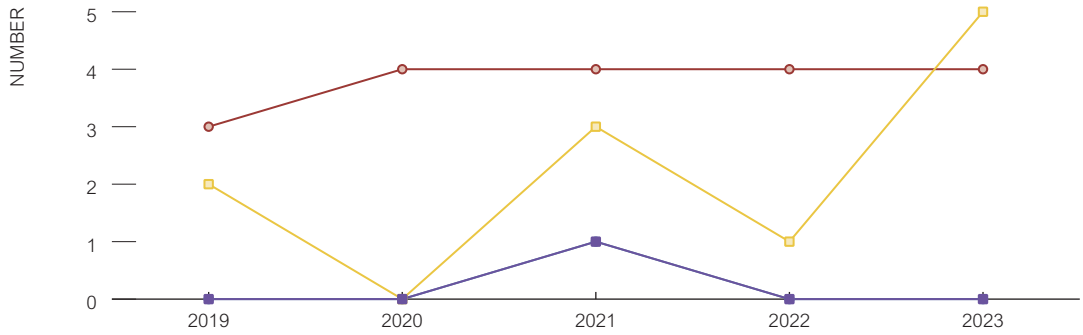
Only 32 HTLV-positive donors were detected during the 2019-2023 period; 30 (94%) were first-time donors, while two were repeat positive donors – both in 2021, who did not meet the incident donor criterion; 63% were male, and the mean age was 42 years with a wide range (24-67 years) (Table 11). The majority of HTLV-positive donors (91%) were born overseas. Ethnicity or country of birth (81%) 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 (9%). 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 2019-2023.

Table 11 Characteristics of HTLV-positive donors, by year of donation, 2019-2023

Characteristics	2019	2020	2021	2022	2023	2019-2023
Number of positive donors	5	4	9	5	9	32
Number of positive first-time donors (%)	5 (100%)	4 (100%)	7 (78%)	5 (100%)	9 (100%)	30 (94%)
Number of male donors (%)	3 (60%)	4 (100%)	5 (56%)	4 (80%)	4 (44%)	20 (63%)
Mean age (range) in years	44 (32-60)	35 (27-41)	45 (24-67)	35 (26-49)	45 (26-63)	42 (24-67)
Number of incident donors	0	0	0	0	0	0
Number of donors born in Australia (%)	2 (40%)	1 (25%)	0 (0%)	0 (0%)	0 (0%)	3 (9%)
Main reported risk factor	Ethnicity/COB[1] 40%	Ethnicity/COB[1] 100%	Ethnicity/COB[1] 67%	Ethnicity/COB[1] 100%	Ethnicity/COB[1] 100%	Ethnicity/COB[1] 81%
Second reported risk factor	PRP[2], PUSR[3], Other each 20%	…	PRP[2] 22%	…	…	PRP[2] 9%

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, 2019-2023



	2019	2020	2021	2022	2023
Male (first-time)	3	4	4	4	4
Male (repeat)	0	0	1	0	0
Female (first-time)	2	0	3	1	5
Female (repeat)	0	0	1	0	0

During the past five years, 2019-2023, there was an upward trend in the number of HTLV-positive first-time female donors. No discernible overall trend has been observed for first-time male 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 2023 and period 2019-2023, 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.[25] In addition, HTLV-1 is highly endemic in certain geographic regions including Japan, the Caribbean and central Africa and to a lesser extent in Iran, Iraq, southern India and China.[26] This is consistent with the finding that ethnicity or country of birth was the likely exposure risk for all HTLV-positive donors in 2023.

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.

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),[27] plasma stored at -20°C for 48 hours was shown to be non-infectious in an animal model,[28] and oxygen flow levels in platelet storage bags are believed to be toxic to *T. pallidum*.[29] Hence, the infectivity of transfused products is expected to be low even without syphilis testing. A published Lifeblood analysis concluded that the residual risk of syphilis transmission is currently negligible (1 in 49.5 million per unit transfused).[30] Since blood bags and cold storage were implemented in Australia during the 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 2014 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[31]). Infectious syphilis, on the other hand, is defined in the national case definition as syphilis infection of less than two years' duration (including primary, secondary and early latent stages[32]). 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.[32] 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.

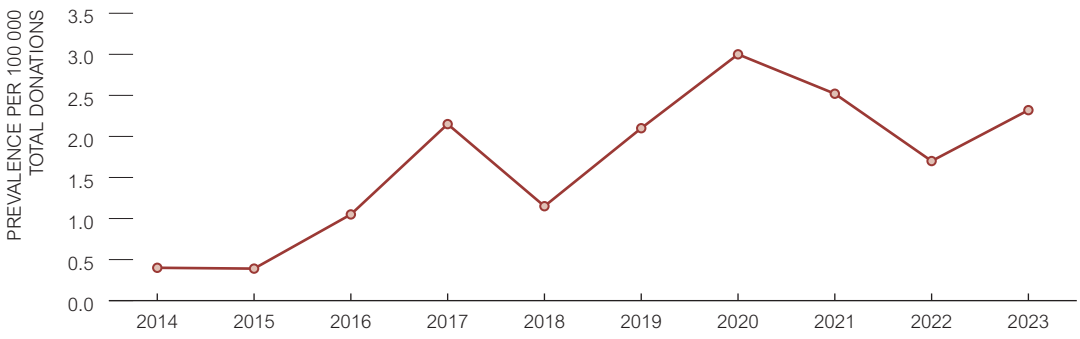
Infectious syphilis in Australia was primarily an infection of men having male to male sexual activity in urban settings, and of heterosexual Aboriginal and/or Torres Strait Islander people in remote and outer regional areas. However, the epidemiology has changed in recent years to expand beyond these subgroups, with an increase observed in females and heterosexual males. The number of cases of infectious syphilis notified in 2023 was 6 390.[1] The notification rate of infectious syphilis tripled from 8.8 to 24.4 per 100 000 between 2014 and 2023. Notification rates among males remained higher than females for the entire 2014-2023 period.[1]

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, 2014-2023, a total of 148 donors with potentially infectious syphilis/active syphilis have been detected (61 first-time donors & 87 repeat donors) (Table 1C). During the period 2014-2023, the prevalence of potentially infectious syphilis among all donations remained very low at 1.5 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 2014 to 3.0 per 100 000 donations in 2020 and 2.3 per 100 000 donations in 2023. As a result, a significant increase in the prevalence of potentially infectious syphilis among all donations was observed during 2014-2023 (IRR 1.16; 95% CI: 1.10-1.23) (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 2023, see Supplementary Table 3B. Of note, one repeat donor was retrospectively added as positive for potentially infectious syphilis for 2022. As a result, the number of donors positive for potentially infectious syphilis in 2022 in this report differ from those presented in the Transfusion-transmissible infections in Australia 2023 Surveillance Report.

Figure 31 **Prevalence of potentially infectious syphilis in all tested blood donations in Australia, by year of donation, 2014-2023**

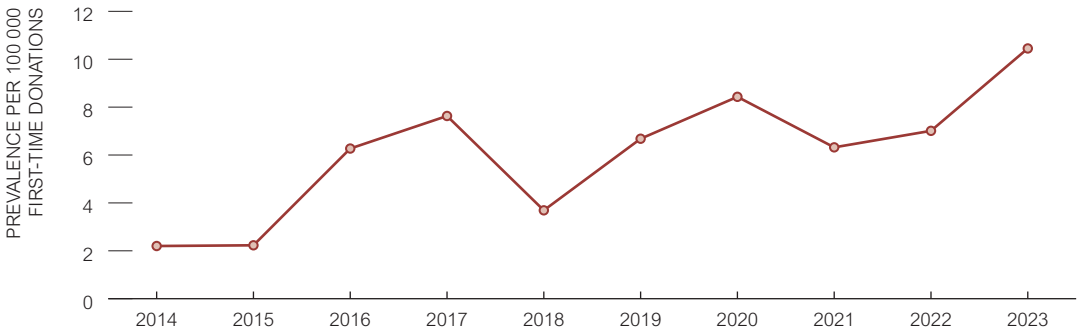


	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023
Prevalence in all donations	0.40	0.39	1.05	2.15	1.15	2.10	3.00	2.52	1.70	2.32

First-time donors:

In the 10 years, 2014-2023, the prevalence of potentially infectious syphilis in first-time donors was 6.2 per 100 000 donations (Table 1C). Overall, the prevalence of potentially infectious syphilis in first-time donors has shown a significant upward trend during 2014-2023, increasing from 2.2 in 2014 to 10.4 per 100 000 donations in 2023 (IRR: 1.11; 95% CI: 1.02-1.22) (Figure 32). By comparison, the national rate of diagnoses of infectious syphilis was 8.8 per 100 000 population in 2014, which tripled to 24.3 per 100 000 in 2023.[1] Caution should be taken in interpretation, as the infectious case definition changed in July 2015, to include more cases of likely recent acquisition.[32]

Figure 32 **Prevalence of potentially infectious syphilis in first-time blood donors in Australia, by year of donation, 2014-2023**

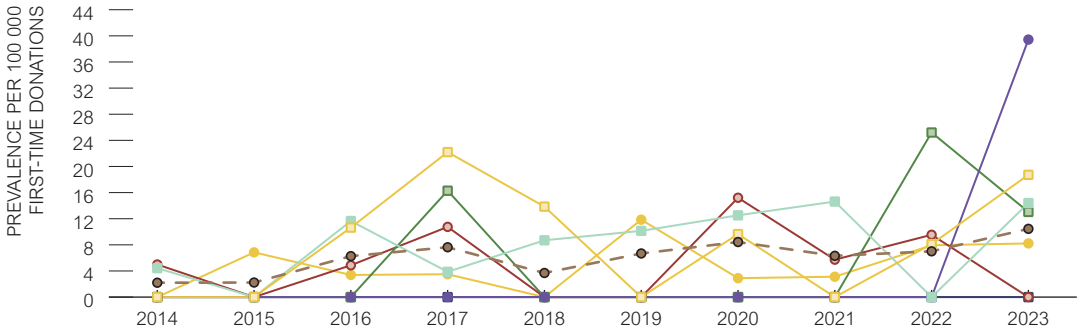


	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023
Prevalence in first-time donors	2.20	2.23	6.27	7.63	3.69	6.68	8.43	6.32	7.01	10.45

Trends in potentially infectious syphilis by state/territory

In 2023, potentially infectious syphilis prevalence in first-time donors was zero for the Northern Territory and Queensland. The prevalence rate in first-time donors was the highest in Tasmania at 39.43 per 100 000 donations (equating to just one positive first-time donor, and first ever in the past ten years, 2014-2023), followed by Western Australia and Victoria where rates were 18.72 and 14.40 per 100 000 first-time donations, respectively (Figure 33). Prevalence in first-time donors in Northern Territory remained zero over the 2014-2023 period. There were no significant trends observed in any jurisdictions during 2014-2023. In comparison, infectious syphilis rates were the highest in the Northern Territory in 2023, at 86.5 per 100 000, followed by Queensland and New South Wales at 26.1 and 24.8 per 100 000, respectively.[1] The trend in the general population during the period 2014-2023 showed an increase in rates of diagnosis of infectious syphilis in all jurisdictions.[1]

Figure 33 **Prevalence of potentially infectious syphilis among first-time donors, by state/territory and year of donation, 2014-2023**



	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023
NSW/ACT	0.00	6.85	3.39	3.50	0.00	11.85	2.90	3.12	7.93	8.22
NT	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
QLD	4.99	0.00	4.87	10.75	0.00	0.00	15.21	5.73	9.54	0.00
SA	0.00	0.00	0.00	16.29	0.00	0.00	0.00	0.00	25.20	13.04
TAS	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	39.43
VIC	4.43	0.00	11.65	3.87	8.70	10.14	12.52	14.63	0.00	14.40
WA	0.00	0.00	10.64	22.20	13.85	0.00	9.65	0.00	8.12	18.72
National	2.20	2.23	6.27	7.63	3.69	6.68	8.43	6.32	7.01	10.45

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 2023 and the ten-year study period 2014-2023 was 10.4 and 6.2 per 100 000 donations, respectively (Supplementary Table 3B and Table 1C). However, estimates on population prevalence for infectious syphilis are unknown and information is only available on infectious syphilis notifications.[1] It is therefore difficult to compare the prevalence of 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 2023 and the five-year period 2019-2023 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 2023, there was no significant association between gender, donors' location and potentially infectious syphilis positivity. Donors aged 50 years and above were 87% less likely to be positive with potentially infectious syphilis as compared to the reference group (Supplementary Table 4).

During the five-year period 2019-2023, female donors were 63% 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 63% and 87% 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

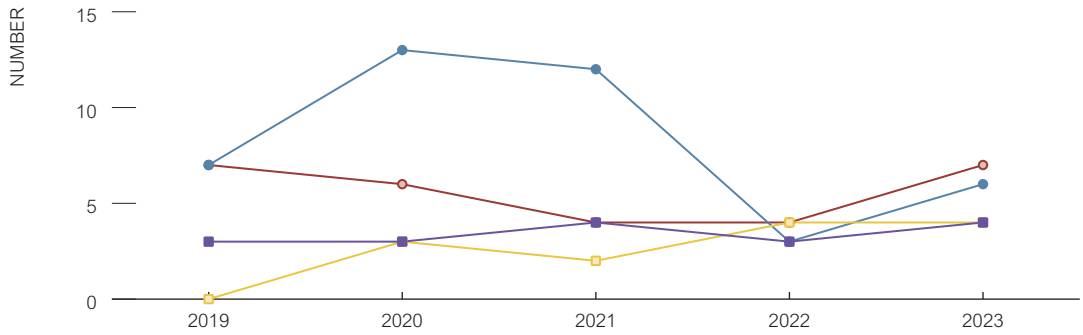
During 2019-2023, a total of 100 donors were classified as having potentially infectious syphilis, of which 41 (41%) were first-time donors, 70 (70%) were male, and 53 (53%) were born in Australia (Table 12). The mean age was 34 (range 19-66). Partner with unspecified risk (37%) was the most frequent likely risk factor for potentially infectious syphilis status. In comparison, in 2023, nationally, 79% of infectious syphilis diagnoses were in males, and 62% were in people aged 20-39 years.[1]

Table 12 Characteristics of donors with potentially infectious syphilis, by year of donation, 2019-2023

Characteristics	2019	2020	2021	2022	2023	2019-2023
Number of positive donors	17	25	22	15	21	100
Number of positive first-time donors (%)	7 (41%)	9 (36%)	6 (27%)	8 (53%)	11 (52.3)	41 (41%)
Number of male donors (%)	14 (82%)	19 (76%)	16 (73%)	8 (53%)	13 (62%)	70 (70%)
Mean age (range) in years	30 (21-42)	36 (20-66)	32 (19-66)	37 (19-59)	35 (22-61)	34 (19-66)
Number of donors born in Australia (%)	10 (59%)	10 (40%)	18 (82%)	8 (53%)	7 (33%)	53 (53%)
Main reported risk factor	MSM[2]	PUSR[1]	PUSR[1], undetermined each	Undetermined/ unknown	PUSR[1]	PUSR[1]
	41%	48%	36%	33%	43%	37%
Second reported risk factor	PUSR[1]	Undetermined/ unknown	MSM[2]	PUSR[1]	MSM[2], undetermined each	Undetermined/ unknown
	24%	36%	23%	27%	24%	31%

1 PUSR= Partner with unspecified risk
2 MSM= Male to male sexual activity

Figure 34 **Potentially infectious syphilis donors, by sex and donor status, 2019-2023**



	2019	2020	2021	2022	2023
Male (first-time)	7	6	4	4	7
Male (repeat)	7	13	12	3	6
Female (first-time)	0	3	2	4	4
Female (repeat)	3	3	4	3	4

Over the past five years, 2019-2023, there has been a slight upward trend in the number of potentially infectious syphilis cases in first-time female donors (Figure 34), while no discernible trend was observed in repeat female and first-time / repeat 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 2023 and period 2019-2023, see Supplementary Tables 6-12.

Conclusion

- Overall, during 2014-2023, the prevalence of potentially infectious syphilis among all donations and first-time blood donors has shown a significant upward trend. Likewise, since 2014, the national rate of diagnoses of infectious syphilis in general population has tripled by 2023.
- 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 donation and donors 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.

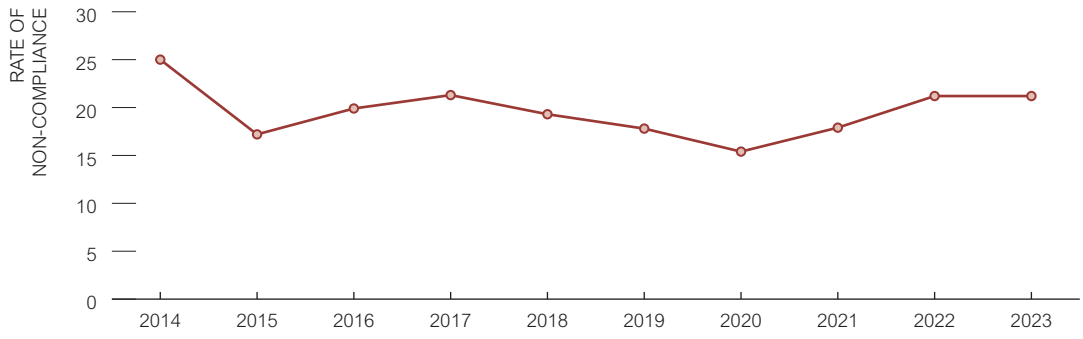
Over 18% (184/984) of TTI-positive donors in 2019-2023 disclosed risk factors or clinical history during their post-donation interview that would have deferred them from donating had they disclosed it at the pre-donation interview (Table 13). Of these, 80% (148 donors) were first-time donors. The rate of reported non-compliance in TTI positive donors has been relatively stable for the past 10 years (ranging between 15-21%), following a peak of 25% in 2014 (Figure 35).

Table 13 Non-compliance category and rate among donors who were positive for any transfusion-transmissible infection, 2019-2023

Non-compliance by year and reason for deferral	2019*	2020	2021*	2022	2023*	2019-2023
Number (%) of non-compliant donors by reasons for deferral						
Intravenous drug use	7 (20.6%)	1 (3.1%)	4 (11.4%)	0 (0)	1 (2.2%)	**13 (7.1%)**
Known status/previous positive^	17 (50.0%)	26 (81.3%)	31 (88.6%)	36 (94.7%)	42 (93.3%)	**152 (82.6%)**
Male-to-male-sexual contact	5 (14.7%)	2 (6.3%)	1 (2.8%)	1 (2.6%)	2 (4.4%)	**11 (5.9%)**
Partner with known risk or known to be positive	6 (17.6%)	3 (9.4%)	0 (0)	1 (2.6%)	1 (2.2%)	**11 (5.9%)**
Others	2 (5.9%)	0 (0)	1 (2.8%)	0 (0)	0 (0)	**3 (1.6%)**
Total number (per 100 positive donors) of non-compliant donors by year	**34 (17.8%)**	**32 (15.4%)**	**35 (17.9%)**	**38 (21.2%)**	**45 (21.2%)**	**184 (18.7%)**

^ 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%

Figure 35 Rate of reported non-compliance in TTI-positive donors, 2014-2023



	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023
Rate of non-compliance	25.0	17.2	19.9	21.3	19.3	17.8	15.4	17.9	21.2	21.2

Each year between 2019-2023 the most common risk behaviour identified was known status of previously being positive for a virus (including history of jaundice): 50.0% in 2019, 81.3% in 2020, 88.6% in 2021, 94.7% in 2022, and 93.3% in 2023. This reflects 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. It is important to note that most non-compliance events are non-intentional. Donors may not fully understand the significance of declaring their past medical history, such as declaring a distant past history of jaundice. An increase in non-compliant HBV positive donors might be associated with expanding migration from HBV endemic countries. Overall, during the period of 2019-2023, 82.6% of non-compliance was attributed to known status of previously being positive for a virus, followed by injecting drug use (7.1%) and male to male sexual activity and having a sexual partner with known risk or known to be positive for any TTI (~6.0%, 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 transmission risk because they may be missed by testing if donating in the window period, 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.[33] More recent estimation indicates an increasing proportion of OBI risk, about 99% for the 2022/2023 period (Lifeblood, unpublished).

Lifeblood uses the method of Weusten *et al* to estimate the window period risk for HBV, HIV and HCV.[34] Unlike earlier window period models which only estimated the risk of collecting a blood donation in the window period, this model includes the risk of infection in a recipient. Viral testing data, including the number of incident donors reported for the 2022 and 2023 calendar year periods, were used to estimate the residual risk per unit transfused (Table 14). The HBV risk estimate includes a separate model specifically addressing the risk of OBI.[35]

As there were no incident donors for HTLV, the residual risk estimate is based on an updated version of Lifeblood's published HTLV model.[36] The estimated risk for syphilis is 1 in 49 million per unit transfused.[30]

The estimates for all are 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 https://www.lifeblood.com.au/health-professionals/clinical-practice/adverse-events/other-transfusion-transmitted-infections/transfusion-transmissible-infections.

Table 14 Estimated risk of detecting HBV, HCV, HIV, HTLV and syphilis in Australian blood donations (2022-2023)^

	HBV	HCV	HIV	HTLV	Potentially infectious 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

^ may include earlier calendar years if there were no incident donors in this period

Based on the estimates for the above-mentioned infectious agents and assuming approximately 1.6 million donations collected per annum, less than one transfusion-transmission 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 1993, none for HIV since 1998 and three probable cases of HBV between 2005 and 2011. 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 that they have travelled to or resided in malaria endemic countries, as well as those with a previous history of infection.[37] 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' due to 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 2023 were referred to their doctor with a copy of their results.

In 2023, 78 638 donations were tested for malaria antibody, which is higher than the number of donations tested in both 2022 (50 560) and 2021 (69 125) but remains substantially lower 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 number of donations tested has not yet returned to pre-pandemic levels because they are based on travel in the past three years. Of the tested donations, 1 325 (1.7%) were repeatedly reactive for malaria antibodies. This represents a decrease from the rates observed in 2022 (3.0%) and 2021 (2.7%) which was due to the lower proportion of travellers compared to residents being tested because of COVID-19 travel restrictions.

No cases of transfusion-transmitted malaria were reported in Australia in 2023 with the last recorded Australian case in 1991.[38]

The residual risk for transfusion-transmitted malaria was recently modelled and estimated to be 1 in 67.9 million per unit transfused.[39]

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 occur from commensal skin bacteria introduced during collection or processing (e.g. when pooling buffy coats), or bacteraemia at the time of blood donation (presumably asymptomatic).

Platelets are stored at room temperature (20-24ºC) which provides a more favourable growth environment for most pathogenic bacteria than the storage conditions used for red cells (refrigeration at 2-6ºC) or plasma (freezing <-25ºC). This increases the risk that even small initial numbers of contaminating bacteria in a platelet component 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 skin at the venepuncture site is carefully disinfected using a standardised, validated technique with chlorhexidine and isopropyl alcohol or alcohol alone if allergic to chorhexidine. 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% due to the skin plug being discarded.[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 unsuitable at this time.

Pre-release bacterial contamination screening 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 was first introduced in 2008, and 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. For apheresis platelet donations, the BCS sample was collected from the combined platelet volume, before the collection was split into individual components. The sample was divided equally (6-7 mL) between a pair of specialised platelet culture bottles, comprising one aerobic (BPA) and one anaerobic (BPN) culture medium. The culture bottles were monitored for bacterial growth by the automated microbial detection system.

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 spore-forming organisms such as *Clostridium* species, which may survive within the aerobic platelet environment and cause sepsis in the recipient.[48]

To improve the sensitivity for testing, the minimum sample volume was increased from 15 mL to 16-20 mL in May 2020, with the inoculation volume for each culture bottle being 8-10 mL. In November 2020, the number of culture bottles from apheresis platelet collections was 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).

On 21 March 2021, platelet shelf-life was extended to seven days with large-volume delayed sampling, with BCS sampling occurring between 36 and 72 hours after collection. Due to the short shelf life of platelet components, platelet components 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 microbial detection system as "initial machine positive". All unused platelet components and any associated components are immediately recalled or quarantined. If any components have already been transfused, the treating clinician is notified immediately, and then updated regularly as further information becomes available.

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

In 2023 a total of 131 486 platelet donations were tested.

Of 106 904 pooled platelet components tested, 323 (0.30%) were flagged by the microbial detection system as initial machine positive. Of these, 147 (0.14%) were classified as "confirmed positive", 125 (0.12%) as "indeterminate" and the remaining 51 (0.05%) were considered to be "machine false positive".

Of 24 582 apheresis donations tested, 84 (0.34%) were flagged by the microbial detection system as initial machine positive. Of these, 12 (0.05%) were classified as "confirmed positive", 32 (0.13%) as "indeterminate" and the remaining 41 (0.17%) were considered to be "machine false positive" (Table 15).

Table 15 Summary of bacterial testing of platelets by BACT/ALERT VIRTUO, 2023

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	106 904 (81.30)	323 (0.30)	147 (0.14)	125 (0.12)	51 (0.05)
Apheresis platelets	24 582 (18.70)	84 (0.34)	12 (0.05)	32 (0.13)	41 (0.17)
Total	131 486 (100)	407 (0.31)	159 (0.12)	157 (0.12)	92 (0.07)

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 component and/or the associated components are not available for resampling, or
- the original platelet component and/or the associated components were resampled but was culture-negative or a different organism was identified, or
- organism may be seen on Gram but could not be cultured e.g., Gram negative bacilli

iv 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

Of the 159 confirmed positives (listed in Table 16), the most frequently isolated genera were *Cutibacterium* species, which were isolated from 131 samples (82.39%). Coagulase-negative staphylococci (CoNS) were isolated from 13 samples (8.18%). *Cutibacterium* and CoNS are unlikely to represent donor bacteraemia in the absence of artificial intravascular materials such as prosthetic heart valves, cardiac pacemaker leads, central intravenous lines or vascular grafts. Both groups of bacteria were most likely skin contaminants which entered the blood at the time of collection. *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 15 (9.43%) confirmed positives were potentially pathogenic species. Only one of the associated components from these donations was transfused. The recipient did not develop an adverse transfusion reaction and was well at the time of follow-up. All donors were followed up and reported to be healthy with no specific risk factors.

Of the 157 classified with indeterminate bacterial growth on BCS (listed in Table 17), eight products were transfused. Six were pooled platelet components and two were apheresis components. Five were from components growing CoNS (with one growing *C. acnes* also) and three growing *Bacteroides* species. All other associated components were recalled and discarded. The recipients remained asymptomatic with no adverse transfusion reaction and donors remained well.

The clinical significance of non-spore forming strict anaerobes (e.g., *Bacteroides* species) is questionable, since these would be unlikely to survive and replicate to levels which would cause a septic transfusion reaction in a recipient. This is in contrast with presence of spore-forming anaerobes like *Clostridium* species as described before. 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 2023.

Red cell components are not universally screened for bacterial contamination due to the lower storage temperature (2-6°C) and overall lower observed risk of TTBIs 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.

TTBIs are rare overall and there have been no confirmed cases 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, 2023 (n=159 BCS samples)

Confirmed positives: organism isolated	Number
Cutibacterium species	131
Coagulase-negative staphylococci	13
Campylobacter fetus	2
Serratia marcescens	2
Staphylococcus aureus	2
Streptococcus agalactiae	2
Streptococcus dysgalactiae	2
Streptococcus pneumoniae	2
Bacillus species	1
Mucoid *Klebsiella pneumoniae*	1
Parabacteroides distasonis, Phocaeicola vulgatus, Parabacteroides johnsonii	1
Total	159

Table 17 Summary of indeterminate contaminants from platelets, 2023 (n=157 BCS samples)

Indeterminates: organisms isolated	Number
Cutibacterium species	125
Coagulase-negative staphylococci	20
Micrococcus species	3
Bacteroides species	3
C. acnes, Staphylococcus epidermidis	1
Bacillus species	1
Niallia circulans	1
Providencia rettgeri	1
Streptococcus pneumoniae	1
Gram positive rods resembling *Bacillus* species	1
Total	157

Surveillance and risk assessment for emerging infections

Lifeblood maintains surveillance for emerging infections through liaison with Australian Government communicable disease control departments, 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).

2023-2024 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.	Between 22 May 2024 and 26 July 2024, an outbreak of locally acquired dengue virus infections occurred in the Torres Strait Island Region, with 9 confirmed cases and 38 probable cases.[51] The affected areas included isolated islands with small populations of <500 residents. Given the isolation of the islands and the small number of inhabitants, the risk to blood safety was assessed as low with no restrictions applied to blood donations. Additionally, cases of autochthonous dengue infection were higher than usual during the 2024 European transmission season. As of 18 October, cases were reported by France (80), Italy (194) and Spain (5).[52] No restrictions were applied to blood donations as the risk from donors travelling to areas with much larger outbreaks has been previously assessed and found to be negligible.[53]	During local outbreaks in Queensland, donations in outbreak areas are restricted to the manufacture of plasma products during outbreak period.
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.[54]	Between 1991 and 2023, the annual reported number of human MVEV cases varied between 0 and 4 cases except in 2011 and 2023, where 16 and 26 cases were reported respectively.[51] In 2024, 4 cases (all in WA) have been reported (up to 23 October). 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 ongoing surveillance of MVEV.	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 significant outbreaks are deferred for 4 weeks after leaving the risk exposure area.

Pathogen	Transfusion-transmission reported	Infectious risk period	Surveillance/risk assessment	Additional risk management for blood safety
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[55] but this has not been confirmed to be live virus.	The mpox outbreak in historically non-endemic countries that occurred in 2022 had declined significantly by May 2023, when the related public health emergency of international concern (PHEIC) was stood down. A significant upsurge in mpox cases has been occurring in the Democratic Republic of the Congo (DRC) since late 2023, including geographic expansion to several previously unaffected areas and observation of sexual transmission of clade 1 MPXV for the first time. The outbreak spread to other African countries, including some that had not previously reported cases, and was again declared a PHEIC in August 2024. As of 20 October, 18 African countries have active outbreaks and have reported a total of 9 320 confirmed cases.[56] A novel clade 1 sub-lineage, clade 1b, emerged first in the DRC and has been associated with sustained human-to-human transmission.[57] It appears to be the predominant strain in the North and South Kivu provinces of DRC, Burundi, Rwanda, Kenya, and Uganda. As of 25 October 2024, there have been only four detections of clade 1b outside Africa, of which at least two were known to be acquired in Africa. A low level of transmission is continuing in other areas globally. Australia is currently experiencing a resurgence that has significantly exceeded the 2022 case numbers, with 1 012 mpox notifications in 2024 as of 23 October. The majority have been reported from NSW (546 cases) and VIC (348).[51,58] MPXV is a negligible risk to blood safety.[59,60]	The numbers in the outbreak are relatively small and primarily associated with men who have sex with men with casual partners who are ineligible to donate blood. In addition, Lifeblood performs ongoing surveillance of mpox outbreaks.
Oropouche virus (OROV)	Transfusion transmission of OROV has not been reported.	OROV infection causes a dengue-like illness with an incubation period between 3 and 8 days. The viraemic period is not well characterised, but viraemia is known to occur 2-4 days after the onset of symptoms at high enough levels to be infectious to biting midges.[61]	Detected cases of OROV infection increased significantly in 2024 and expanded to geographical areas in the Americas not known to be endemic. As of 15 October, a total of 10 275 confirmed cases had been recorded from seven countries.[62] Also occurring in 2024 were the first-ever reports of deaths associated with OROV infection, potential vertical transmissions including microcephaly, possible association with Guillain-Barré syndrome, and detection of replication-competent virus from semen.[63,64] Given that OROV is isolated to areas that are also endemic for malaria and/or flaviviruses and the absence of reported transfusion transmission cases, OROV represents a negligible risk to blood safety in Australia. Lifeblood continues to perform ongoing surveillance.	All countries that have reported OROV outbreaks to date are subject to malaria- and/or flavivirus-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
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).[65,66] 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. 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.[67] This has resulted in a significant donation gain and an increase in first-time donors in the 2022 period.[68]	Due to the negligible risk, there are now no geographical restrictions specific for vCJD. The deferral for donors who have received fresh blood products in the UK since 1980 or received fractionated plasma products in the UK between 1980 and 2001 was removed on 13 November 2023.
West Nile virus (WNV)	Yes, transmission of West Nile virus (WNV) by blood, tissue and organ transplantation has been documented.[69]	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.[70] WNV RNA becomes detectable 1–2 days post-infection followed by anti-WNV IgM and IgG approximately 8–11 days post-infection.[71]	Lifeblood monitors WNV outbreaks in the European Union (EU) and neighbouring countries, most of which do not have specific donor deferrals, based on regular updates provided by the European Centre for Disease Prevention and Control.[72] Lifeblood performed weekly risk modelling during the larger than usual 2018 WNV transmission season 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 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.[73] This trigger point was not reached in 2023 or 2024.	Donors with a current flavivirus infection are deferred for 4 months from date of recovery. 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.

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 2023, 159 (0.12%) of a total of 131 486 screened platelet donations 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. Only one of the associated components from these donations was transfused. The recipient did not develop an adverse transfusion reaction and was well at the time of follow-up. All 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 2023.
- In addition to established transfusion-transmissible infections, emerging infectious diseases continue to demand vigilant surveillance and risk assessment. During 2023-2024, Murray Valley encephalitis, mpox and one local dengue outbreak were monitored. The seasonal West Nile virus outbreak in Europe and the increased cases of Oropouche virus infection seen overseas, were also monitored. The risk to blood safety in Australia remains negligible.

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Supplementary Tables

Supplementary Table 1 Screening tests for transfusion-transmissible infections

Transfusion-transmissible infection	Mandatory screening tests	Test target	Year of introduction	Median window period estimate	Estimated residual risk (per million units transfused)
Syphilis	*Treponema pallidum* antibodies[1]	Antibodies to *Treponema pallidum*	~1949	30 days	<1 in 1 million[30]
HBV	HBsAg[2]	Hepatitis B surface antigen (HBsAg)	1970	38 days	---
	nucleic acid test for HBV	HBV DNA	2010	17 days	<1 in 1 million
HIV	anti-HIV 1[2] anti-HIV 2[2] p24 antigen[2]	Antibody to both HIV 1 and HIV 2 (anti-HIV-1/2) HIV-1 p24 antigen	1985 (HIV-1) 1992 (HIV-1/HIV-2) 2013 (HIV Ag/Ab)	 22 days 15 days	--- ---
	nucleic acid test for HIV 1/2[3]	HIV 1/2 RNA	2000 (HIV-1) 2021 (HIV-1/HIV-2)	5 days	<1 in 1 million
HCV	anti-HCV[2]	Antibody to HCV	1990	66 days	---
	nucleic acid Test for HCV[3]	HCV RNA	2000	3 days	<1 in 1 million
HTLV	anti-HTLV 1[2] anti-HTLV 2[2]	Antibody to both HTLV 1 and HTLV 2	1993	51 days	<1 in 1 million[36]

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, 2023

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	36 500	487 850	524 350	29	6	35	27	2	29	0	0	0	56	8	64
Number *(Number per 100 000 donations)*				*79.45*	*1.23*	*6.67*	*73.97*	*0.41*	*5.53*	*0.00*	*0.00*	*0.00*	*153.42*	*1.64*	*12.21*
NT	742	10 338	11 080	1	0	1	0	0	0	0	0	0	1	0	1
Number *(Number per 100 000 donations)*				*134.77*	*0.00*	*9.03*	*0.00*	*0.00*	*0.00*	*0.00*	*0.00*	*0.00*	*134.77*	*0.00*	*9.03*
QLD	19 370	283 097	302 467	6	1	7	15	1	16	2	1	3	23	3	26
Number *(Number per 100 000 donations)*				*30.98*	*0.35*	*2.31*	*77.44*	*0.35*	*5.29*	*10.33*	*0.35*	*0.99*	*118.74*	*1.06*	*8.60*
SA	7 669	116 458	124 127	6	1	7	5	1	6	0	0	0	11	2	13
Number *(Number per 100 000 donations)*				*78.24*	*0.86*	*5.64*	*65.20*	*0.86*	*4.83*	*0.00*	*0.00*	*0.00*	*143.43*	*1.72*	*10.47*
TAS	2 536	54 883	57 419	2	1	3	2	0	2	0	0	0	4	1	5
Number *(Number per 100 000 donations)*				*78.86*	*1.82*	*5.22*	*78.86*	*0.00*	*3.48*	*0.00*	*0.00*	*0.00*	*157.73*	*1.82*	*8.71*
VIC	27 769	428 334	456 103	32	3	35	21	3	24	2	0	2	55	6	61
Number *(Number per 100 000 donations)*				*115.24*	*0.70*	*7.67*	*75.62*	*0.70*	*5.26*	*7.20*	*0.00*	*0.44*	*198.06*	*1.40*	*13.37*
WA	10 684	146 351	157 035	5	1	6	6	0	6	1	0	1	12	1	13
Number *(Number per 100 000 donations)*				*46.80*	*0.68*	*3.82*	*56.16*	*0.00*	*3.82*	*9.36*	*0.00*	*0.64*	*112.32*	*0.68*	*8.28*
National	105 270	1 527 311	1 632 581	81	13	94	76	7	83	5	1	6	162	21	183
Number *(Number per 100 000 donations)*				*76.94*	*0.85*	*5.76*	*72.20*	*0.46*	*5.08*	*4.75*	*0.07*	*0.37*	*153.89*	*1.37*	*11.21*

Supplementary Table 3 The number and prevalence rate of TTI-positive (HTLV and potentially infectious syphilis) donors in Australia, by state/territory, 2023

Table 3A HTLV, by state/territory, 2023

State/Territory of donation	All accepted donations			HTLV		
	First time	Repeat	All	First time	Repeat	All
NSW/ACT	36 500	2 279	38 779	3	0	3
Number *(Number per 100 000 donations)*				*8.22*	*0.00*	*7.74*
NT	742	25	767	0	0	0
Number *(Number per 100 000 donations)*				*0.00*	*0.00*	*0.00*
QLD	19 370	1 015	20 385	2	0	2
Number *(Number per 100 000 donations)*				*10.33*	*0.00*	*9.81*
SA	7 669	511	8 180	2	0	2
Number *(Number per 100 000 donations)*				*26.08*	*0.00*	*24.45*
TAS	2 536	82	2 618	0	0	0
Number *(Number per 100 000 donations)*				*0.00*	*0.00*	*0.00*
VIC	27 769	1 807	29 576	1	0	1
Number *(Number per 100 000 donations)*				*3.60*	*0.00*	*3.38*
WA	10 684	414	11 098	1	0	1
Number *(Number per 100 000 donations)*				*9.36*	*0.00*	*9.01*
National	105 270	6 133	111 403	9	0	9
Number *(Number per 100 000 donations)*				*8.55*	*0.00*	*8.08*

Table 3B Potentially infectious syphilis, by state/territory, 2023

State/Territory of donation	All accepted donations			Potentially infectious syphilis		
	First time	Repeat	All	First time	Repeat	All
NSW/ACT	36 500	274 114	310 614	3	6	9
Number *(Number per 100 000 donations)*				*8.22*	*2.19*	*2.90*
NT	742	3 459	4 201	0	0	0
Number *(Number per 100 000 donations)*				*0.00*	*0.00*	*0.00*
QLD	19 370	146 040	165 410	0	2	2
Number *(Number per 100 000 donations)*				*0.00*	*1.37*	*1.21*
SA	7 669	57 827	65 496	1	0	1
Number *(Number per 100 000 donations)*				*13.04*	*0.00*	*1.53*
TAS	2 536	19 160	21 696	1	2	3
Number *(Number per 100 000 donations)*				*39.43*	*10.44*	*13.83*
VIC	27 769	228 935	256 704	4	0	4
Number *(Number per 100 000 donations)*				*14.40*	*0.00*	*1.56*
WA	10 684	72 030	82 714	2	0	2
Number *(Number per 100 000 donations)*				*18.72*	*0.00*	*2.42*
National	105 270	801 565	906 835	11	10	21
Number *(Number per 100 000 donations)*				*10.45*	*1.25*	*2.32*

Supplementary Table 4 Association of demographic characteristics with TTI-positive blood donors in Australia, 2023

		HBV			HCV			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	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	*273 085*	*69 (25.27)*	*1 (ref)*	*…*	*46 (16.84)*	*1 (ref)*	*…*	*5 (1.83)*	*1 (ref)*	*…*	*4 (1.46)*	*1 (ref)*	*…*
Female	*273 948*	*25 (9.13)*	*0.35 (0.22-0.56)*	***0.00***	*37 (13.51)*	*0.83 (0.54-1.28)*	*0.41*	*1 (0.37)*	*0.19 (0.02-1.66)*	*0.13*	*5 (1.83)*	*1.28 (0.34-4.80)*	*0.70*
Age group (years)													
20-29	*103 346*	*27 (26.13)*	*1 (ref)*	*…*	*4 (3.87)*	*1 (ref)*	*…*	*2 (1.94)*	*1 (ref)*	*…*	*1 (0.97)*	*1 (ref)*	*…*
Less than 20	*11 775*	*2 (16.99)*	*0.46 (0.06-3.45)*	*0.45*	*1 (8.49)*	*2.6 (0.29-23.55)*	*0.70*	*0 (0)*	*..*	*0.99*	*0 (0)*	*…*	*0.99*
30-39	*116 875*	*27 (23.1)*	*0.81 (0.47-1.39)*	*0.45*	*20 (17.11)*	*4.37 (1.49-12.81)*	***0.01***	*3 (2.57)*	*1.15 (0.19-6.95)*	*0.87*	*2 (1.71)*	*1.80 (0.162-19.91)*	*0.63*
40-49	*105 239*	*11 (10.45)*	*0.38 (0.18-0.77)*	***0.01***	*12 (11.4)*	*2.92 (0.94-9.05)*	*0.06*	*1 (0.95)*	*0.42 (0.03-4.72)*	*0.48*	*2 (1.9)*	*1.93 (0.17-21.41)*	*0.58*
50 and above	*209 798*	*27 (12.87)*	*0.47 (0.27-0.80)*	***0.01***	*46 (21.93)*	*5.61 (2.01-15.60)*	***0.00***	*0 (0)*	*..*	*0.99*	*4 (1.91)*	*1.88 (0.21-16.94)*	*0.57*
State/Territory*													
NSW	*164 707*	*33 (20.04)*	*1 (ref)*	*…*	*27 (16.39)*	*1 (ref)*	*…*	*0 (0)*	*1 (ref)*	*…*	*3 (1.82)*	*1 (ref)*	*…*
ACT	*17 637*	*2 (11.34)*	*0.55 (0.13-2.33)*	*0.42*	*2 (11.34)*	*7.13 (0.16-2.99)*	*0.64*	*0 (0)*	*..*	*1.00*	*0 (0)*	*…*	*0.99*
NT	*3 658*	*1 (27.34)*	*1.33 (0.18-9.75)*	*0.77*	*0 (0)*	*…*	*0.99*	*0 (0)*	*..*	*1.00*	*0 (0)*	*…*	*0.99*
QLD	*97 817*	*7 (7.16)*	*0.37 (0.16-0.84)*	***0.02***	*16 (16.36)*	*0.96 (0.52-1.79)*	*0.91*	*3 (3.07)*	*..*	*0.99*	*2 (2.04)*	*1.11 (0.18-6.64)*	*0.90*
SA	*41 842*	*7 (16.73)*	*0.88 (0.39-2.00)*	*0.77*	*6 (14.34)*	*0.82 (0.34-2.00)*	*0.67*	*0 (0)*	*..*	*1.00*	*2 (4.78)*	*2.55 (0.42-15.33)*	*0.30*
TAS	*16 020*	*3 (18.73)*	*1.01 (0.30-3.30*	*0.98*	*2 (12.48)*	*0.72 (0.17-3.02*	*0.65*	*0 (0)*	*..*	*1.00*	*0 (0)*	*…*	*0.99*
VIC	*154 423*	*35 (22.67)*	*1.15 (0.71-1.86)*	*0.55*	*24 (15.54)*	*0.93 (0.54-1.62)*	*0.82*	*2 (1.3)*	*…*	*0.99*	*1 (0.65)*	*0.35 (0.36-3.39)*	*0.36*
WA	*50 828*	*6 (11.8)*	*0.60 (0.25-1.43)*	*0.25*	*6 (11.8)*	*0.69 (0.28-1.67)*	*0.41*	*1 (1.97)*	*..*	*0.99*	*1 (1.97)*	*1.06 (0.11-10.21)*	*0.95*
Total	547 033	94 (17.18)			83 (15.17)			6 (1.1)			9 (1.65)		

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

	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	*273 085*	*13 (4.76)*	*1 (ref)*	*…*
Female	*273 948*	*8 (2.92)*	*0.59 (0.24-1.44)*	*0.25*
Age group (years)				
20-29	*103 346*	*7 (6.77)*	*1 (ref)*	*…*
Less than 20	*11 775*	*0 (0)*	*…*	*0.99*
30-39	*116 875*	*9 (7.7)*	*1.09 (0.40-2.94)*	*0.86*
40-49	*105 239*	*3 (2.85)*	*0.40 (0.10-1.58)*	*0.19*
50 and above	*209 798*	*2 (0.95)*	*0.13 (0.27-0.64)*	***0.01***
State/Territory*				
NSW	*164 707*	*1 (0.61)*	*1 (ref)*	*…*
ACT	*17 637*	*8 (45.36)*	*1.10 (0.13-8.82)*	*0.92*
NT	*3 658*	*0 (0)*	*…*	*0.99*
QLD	*97 817*	*2 (2.04)*	*0.44 (0.09-2.09)*	*0.30*
SA	*41 842*	*1 (2.39)*	*0.53 (0.06-4.31)*	*0.56*
TAS	*16 020*	*3 (18.73)*	*4.2 (1.1-16.18)*	***0.03***
VIC	*154 423*	*4 (2.59)*	*0.52 (0.15-1.74)*	*0.29*
WA	*50 828*	*2 (3.93)*	*0.81 (0.17-3.85)*	*0.80*
Total	547 033	21 (3.84)		

* 101 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, 2019-2023

		HBV			HCV			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	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	*1 258 362*	*340 (27.02)*	*1 (ref)*	*…*	*218 (17.32)*	*1 (ref)*	*…*	*21 (1.67)*	*1 (ref)*	*…*	*20 (1.59)*	*1 (ref)*	*…*
Female	*1 315 140*	*127 (9.66)*	*0.35 (0.29-0.43)*	***0.00***	*149 (11.33)*	*0.69 (0.56-0.85)*	***0.00***	*3 (0.23)*	*0.13 (0.03-0.43)*	***0.00***	*12 (0.91)*	*0.59 (0.29-1.21)*	*0.15*
Age group (years)													
20-29	*589 087*	*100 (16.98)*	*1 (ref)*	*…*	*35 (5.94)*	*1 (ref)*	*…*	*9 (1.53)*	*1 (ref)*	*…*	*5 (0.85)*	*1 (ref)*	*…*
Less than 20	*72 918*	*5 (6.86)*	*0.43 (0.17-1.07)*	*0.07*	*6 (8.23)*	*1.41 (0.59-3.35)*	*0.43*	*0 (0)*	*…*	*0.99*	*0 (0)*	*…*	*0.99*
30-39	*564 012*	*162 (28.72)*	*1.55 (1.21-2.00)*	***0.00***	*75 (13.3)*	*2.18 (1.46-3.26)*	***0.00***	*7 (1.24)*	*0.70 (0.26-1.89)*	*0.48*	*10 (1.77)*	*1.98 (0.67-5.81)*	*0.21*
40-49	*470 170*	*90 (19.14)*	*1.06 (0.80-1.42)*	*0.64*	*60 (12.76)*	*2.10 (1.38-3.20)*	***0.00***	*3 (0.64)*	*0.37 (0.10-1.37)*	*0.13*	*8 (1.7)*	*1.90 (0.62-5.82)*	*0.26*
50 and above	*877 314*	*110 (12.54)*	*0.68 (0.52-0.90)*	***0.01***	*191 (21.77)*	*3.54 (2.46-5.08)*	***0.00***	*5 (0.57)*	*0.32 (0.10-0.96)*	***0.04***	*9 (1.03)*	*1.11 (0.37-3.32)*	*0.85*
State/Territory*													
NSW	*761 676*	*140 (18.38)*	*1 (ref)*	*…*	*127 (16.67)*	*1 (ref)*	*…*	*6 (0.79)*	*1 (ref)*	*…*	*12 (1.58)*	*1 (ref)*	*…*
ACT	*84 231*	*16 (19)*	*1.00 (0.59-1.68)*	*0.99*	*8 (9.5)*	*0.59 (0.29-1.21)*	*0.15*	*1 (1.19)*	*…*	*0.99*	*2 (2.37)*	*1.49 (0.33-6.69)*	*0.59*
NT	*17 113*	*7 (40.9)*	*2.14 (1.00-4.57)*	***0.05***	*0 (0)*	*…*	*0.98*	*0 (0)*	*…*	*0.99*	*0 (0)*	*…*	*0.99*
QLD	*480 004*	*60 (12.5)*	*0.68 (0.50-0.93)*	***0.01***	*60 (12.5)*	*0.73 (0.53-0.99)*	*0.47*	*6 (1.25)*	*1.38 (0.46-4.12)*	*0.55*	*3 (0.62)*	*0.39 (0.11-1.41)*	*0.15*
SA	*199 668*	*29 (14.52)*	*0.81 (0.54-1.21)*	*0.31*	*29 (14.52)*	*0.82 (0.54-1.23)*	*0.34*	*1 (0.5)*	*0.57 (0.07-4.64)*	*0.60*	*4 (2)*	*1.28 (0.41-4.00)*	*0.66*
TAS	*78 475*	*16 (20.39)*	*1.16 (0.69-1.95)*	*0.56*	*17 (21.66)*	*1.23 (0.74-2.05)*	*0.40*	*0 (0)*	*…*	*0.99*	*2 (2.55)*	*1.66 (0.37-7.46)*	*0.50*
VIC	*714 484*	*162 (22.67)*	*1.23 (0.98-1.54)*	*0.07*	*102 (14.28)*	*0.86 (0.66-1.11)*	*0.26*	*6 (0.84)*	*0.92 (0.30-2.74)*	*0.88*	*6 (0.84)*	*0.52 (0.19-1.41)*	*0.20*
WA	*237 209*	*37 (15.6)*	*0.82 (0.57-1.18)*	*0.29*	*24 (10.12)*	*0.59 (0.38-0.91)*	***0.01***	*4 (1.69)*	*1.81 (0.53-6.19)*	*0.34*	*3 (1.26)*	*0.77 (0.21-2.76)*	*0.69*
Total**	2 573 503	467 (18.15)			367 (14.26)			24 (0.93)			32 (1.24)		

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

** The total of over 2.5 million donors over a five-year period, 2019-2023, 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)

	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	*1 258 362*	*70 (5.56)*	*1 (ref)*	*…*
Female	*1 315 140*	*0*	*0.37 (0.24-0.58)*	***0.00***
Age group (years)				
20-29	*589 087*	*41 (6.96)*	*1 (ref)*	*…*
Less than 20	*72 918*	*2 (2.74)*	*0.42 (0.10-1.74)*	*0.23*
30-39	*564 012*	*35 (6.21)*	*0.82 (0.52-1.30)*	*0.41*
40-49	*470 170*	*13 (2.76)*	*0.37 (0.20-0.69)*	***0.00***
50 and above	*877 314*	*9 (1.03)*	*0.13 (0.06-0.27)*	***0.00***
State/Territory*				
NSW	*761 676*	*27 (3.54)*	*1 (ref)*	*…*
ACT	*84 231*	*9 (10.68)*	*0.49 (0.11-2.04)*	*0.32*
NT	*17 113*	*0 (0)*	*…*	*0.99*
QLD	*480 004*	*18 (3.75)*	*0.87 (0.49-1.54)*	*0.64*
SA	*199 668*	*5 (2.5)*	*0.61 (0.23-1.56)*	*0.30*
TAS	*78 475*	*3 (3.82)*	*0.94 (0.29-3.09)*	*0.93*
VIC	*714 484*	*31 (4.34)*	*0.96 (0.59-1.57)*	*0.90*
WA	*237 209*	*7 (2.95)*	*0.65 (0.29-1.48)*	*0.31*
Total**	2 573 503	100 (3.89)		

* 643 donors with unknown state/territory of residence are not included in the state/territory stratification of the Poisson regression analysis
** The total of over 2.5 million donors over a five-year period, 2019-2023, 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, 2023

	HBV (2023)				HCV (2023)				HIV (2023)				HTLV (2023)				Potentially infectious syphilis (2023)			
Donor status	M	F	Total	%	M	F	Total	%	M	F	Total	%	M	F	Total	%	M	F	Total	%
First time donors																				
<20 years	1	0	1	1.1	0	1	1	1.2	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0
20-29 years	14	13	27	28.7	4	0	4	4.8	1	0	1	16.7	1	0	1	11.1	4	2	6	28.6
30-39 years	23	3	26	27.7	10	8	18	21.7	2	1	3	50.0	1	1	2	22.2	2	2	4	19.0
40-49 years	6	1	7	7.4	8	4	12	14.5	1	0	1	16.7	1	1	2	22.2	0	0	0	0.0
50-59 years	6	3	9	9.6	7	10	17	20.5	0	0	0	0.0	1	2	3	33.3	1	0	1	4.8
60 years and above	9	2	11	11.7	15	9	24	28.9	0	0	0	0.0	0	1	1	11.1	0	0	0	0.0
Repeat donors																				
<20 years	0	1	1	1.1	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0
20-29 years	0	0	0	0.0	0	0	0	0.0	1	0	1	16.7	0	0	0	0.0	0	1	1	4.8
30-39 years	1	0	1	1.1	1	1	2	2.4	0	0	0	0.0	0	0	0	0.0	4	1	5	23.8
40-49 years	4	0	4	4.3	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0	1	2	3	14.3
50-59 years	2	0	2	2.1	0	2	2	2.4	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0
60 years and above	3	2	5	5.3	1	2	3	3.6	0	0	0	0.0	0	0	0	0.0	1	0	1	4.8
Total	69	25	94	100	46	37	83	100	5	1	6	100	4	5	9	100	13	8	21	100

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

Supplementary Table 7 Number and percentage of TTI-positive donors, by sex and age group, 2019-2023

	HBV (2019-2023)				HCV (2019-2023)				HIV (2019-2023)				HTLV (2019-2023)				Potentially infectious syphilis (2019-2023)			
Donor status	M	F	Total	%	M	F	Total	%	M	F	Total	%	M	F	Total	%	M	F	Total	%
First time donors																				
<20 years	3	1	4	0.9	2	4	6	1.6	0	0	0	0.0	0	0	0	0.0	1	1	2	2.0
20-29 years	59	40	99	21.2	25	5	30	8.2	6	0	6	25.0	4	1	5	15.6	12	6	18	18.0
30-39 years	121	30	151	32.3	44	17	61	16.6	3	1	4	16.7	8	2	10	31.3	11	3	14	14.0
40-49 years	53	17	70	15.0	31	27	58	15.8	1	0	1	4.2	5	3	8	25.0	3	3	6	6.0
50-59 years	28	12	40	8.6	38	39	77	21.0	0	1	1	4.2	1	2	3	9.4	1	0	1	1.0
60 years and above	29	5	34	7.3	55	32	87	23.7	2	0	2	8.3	1	3	4	12.5	0	0	0	0.0
Repeat donors																				
<20 years	0	1	1	0.2	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0
20-29 years	1	0	1	0.2	7	2	9	2.5	3	0	3	12.5	0	0	0	0.0	15	8	23	23.0
30-39 years	5	6	11	2.4	3	7	10	2.7	2	1	3	12.5	0	0	0	0.0	15	6	21	21.0
40-49 years	13	7	20	4.3	1	1	2	0.5	2	0	2	8.3	0	0	0	0.0	4	3	7	7.0
50-59 years	10	3	13	2.8	4	9	13	3.5	1	0	1	4.2	1	0	1	3.1	4	0	4	4.0
60 years and above	18	5	23	4.9	8	6	14	3.8	1	0	1	4.2	0	1	1	3.1	4	0	4	4.0
Total	340	127	467	100	218	149	367	100	21	3	24	100	20	12	32	100	70	30	100	100

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

Supplementary Table 8 Number and percentage of TTI-positive donors, by country/region of birth^, 2019-2023

Region of birth^	HBV (2019-2023)		HCV (2019-2023)		HIV (2019-2023)		HTLV (2019-2023)		Potentially infectious syphilis (2019-2023)	
	Number	%	Number	%	Number	%	Number	%	Number	%
Australia	36	7.7	224	61.0	11	45.8	3	9.4	53	53.0
Overseas born										
Other Oceania	29	6.2	10	2.7	1	4.2	1	3.1	4	4.0
United Kingdom and Ireland	1	0.2	18	4.9	1	4.2	0	0.0	6	6.0
Other Europe	19	4.1	18	4.9	1	4.2	1	3.1	4	4.0
Middle East/North Africa	16	3.4	9	2.5	0	0.0	2	6.3	3	3.0
Sub-Saharan Africa	14	3.0	2	0.5	1	4.2	1	3.1	1	1.0
Northeast/Southeast Asia	243	52.0	38	10.4	4	16.7	6	18.8	18	18.0
Southern and Central Asia	101	21.6	38	10.4	4	16.7	18	56.3	8	8.0
Americas	3	0.6	5	1.4	1	4.2	0	0.0	3	3.0
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	462	98.9	362	98.6	24	100.0	32	100.0	100	100.0
Not reported	5	1	5	1	0	0	0	0	0	0
Total	467	100	367	100	24	100	32	100	100	100

^ Region of birth from the Australian Bureau of Statistics
Note: Percentages may not add to exactly 100% due to rounding

Supplementary Table 9 Number and percentage of TTI-positive first-time donors, by potential reported exposure category and sex, 2023

	HBV (2023)				HCV (2023)				HIV (2023)				HTLV (2023)				Potentially infectious syphilis (2023)			
Exposure categories	M	F	Total	%	M	F	Total	%	M	F	Total	%	M	F	Total	%	M	F	Total	%
Ethnicity/Country of birth	45	14	59	72.8	11	7	18	23.7	0	0	0	0.0	4	5	9	100.0	0	0	0	0.0
Injecting drug use	0	0	0	0.0	15	5	20	26.3	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0
Tattoo/Piercing	0	0	0	0.0	1	1	2	2.6	1	0	1	20.0	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	1	3	3.9	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0
Partner with unspecified risks	2	0	2	2.5	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0	3	3	6	54.5
Male to male sexual activity	1	0	1	1.2	1	0	1	1.3	2	0	2	40.0	0	0	0	0.0	3	0	3	27.3
Exposure in health care setting	0	0	0	0.0	2	1	3	3.9	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0
Engaged in sex work	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0
Blood or tissue recipient	0	0	0	0.0	1	2	3	3.9	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0
Household contact/Family history	9	8	17	21.0	0	2	2	2.6	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0
Other blood to blood contact	1	0	1	1.2	0	1	1	1.3	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0
Other*	0	0	0	0.0	1	0	1	1.3	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	10	12	22	28.9	1	1	2	40.0	0	0	0	0.0	1	1	2	18.2
Total	59	22	81	100.0	44	32	76	100.0	4	1	5	100.0	4	5	9	100.0	7	4	11	100.0

* For HCV, one out of one male first-time donor in the 'Other' category had imprisonment as a risk factor

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

Supplementary Table 10 Number and percentage of TTI-positive first-time donors, by potential reported exposure category and sex, 2019-2023

	HBV (2019-2023)				HCV (2019-2023)				HIV (2019-2023)				HTLV (2019-2023)				Potentially infectious syphilis (2019-2023)			
Exposure categories	M	F	Total	%	M	F	Total	%	M	F	Total	%	M	F	Total	%	M	F	Total	%
Ethnicity/Country of birth	248	68	316	79.4	38	8	46	14.4	0	0	0	0.0	17	8	25	83.3	0	0	0	0.0
Injecting drug use	1	0	1	0.3	64	29	93	29.2	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0
Tattoo/Piercing	0	0	0	0.0	13	19	32	10.0	1	0	1	7.1	0	0	0	0.0	0	0	0	0.0
Partners with known risks or known to be positive	0	0	0	0.0	9	11	20	6.3	0	1	1	7.1	1	2	3	10.0	3	2	5	12.2
Partners with unspecified risks	4	2	6	1.5	1	1	2	0.6	2	0	2	14.3	0	1	1	3.3	4	7	11	26.8
Male to male sexual activity	3	0	3	0.8	2	0	2	0.6	4	0	4	28.6	0	0	0	0.0	14	0	14	34.1
Exposure in health care setting	0	1	1	0.3	7	2	9	2.8	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	10	7	17	5.3	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0
Household contact/Family history	29	30	59	14.8	2	8	10	3.1	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0
Other blood to blood contact	1	0	1	0.3	3	3	6	1.9	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0
Other*	0	0	0	0.0	16	2	18	5.6	0	0	0	0.0	1	0	1	3.3	0	0	0	0.0
No risk factors identified/Unknown	7	4	11	2.8	30	34	64	20.1	5	1	6	42.9	0	0	0	0.0	7	4	11	26.8
Total	293	105	398	100	195	124	319	100.0	12	2	14	100.0	19	11	30	100.0	28	13	41	100.0

* For HCV, 63% (10/16) first-time male donors and 50% (1/2) first-time female donors in 'Other' had imprisonment as a risk factor

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

Supplementary Table 11 Number and percentage of TTI-positive repeat donors, by potential reported exposure category and sex, 2023

	HBV (2023)				HCV (2023)				HIV (2023)				HTLV (2023)				Potentially infectious syphilis (2023)			
Exposure categories	M	F	Total	%	M	F	Total	%	M	F	Total	%	M	F	Total	%	M	F	Total	%
Ethnicity/Country of birth	10	2	12	92.3	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0
Injecting drug use	0	0	0	0.0	1	1	2	28.6	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	1	1	2	20.0
Partner with unspecified risks	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0	1	2	3	30.0
Male to male sexual activity	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0	2	0	2	20.0
Exposure in health care setting	0	0	0	0.0	0	1	1	14.3	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0
Engaged in sex work	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0
Blood or tissue recipient	0	0	0	0.0	0	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	7.7	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
No risk factors identified/Unknown	0	0	0	0.0	1	3	4	57.1	1	0	1	100.0	0	0	0	0.0	0 2	0 1	3	30.0
Total	10	3	13	100.0	2	5	7	100.0	1	0	1	100	0	0	0	0.0	6	4	10	100.0

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

Supplementary Table 12 Number and percentage of TTI-positive repeat donors, by potential reported exposure category and sex, 2019-2023

	HBV (2019-2023)				HCV (2019-2023)				HIV (2019-2023)				HTLV (2019-2023)				Potentially infectious syphilis (2019-2023)			
Exposure categories	M	F	Total	%	M	F	Total	%	M	F	Total	%	M	F	Total	%	M	F	Total	%
Ethnicity/Country of birth	39	13	52	75.4	2	0	2	4.2	0	0	0	0.0	0	1	1	50.0	0	0	0	0.0
Injecting drug use	0	0	0	0.0	5	3	8	16.7	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0
Tattoo/Piercing	1	0	1	1.4	6	2	8	16.7	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0
Partners with known risks or known to be positive	1	0	1	1.4	1	2	3	6.3	1	1	2	20.0	0	0	0	0.0	2	3	5	8.5
Partners with unspecified risks	2	1	3	4.3	0	0	0	0.0	3	0	3	30.0	1	0	1	50.0	18	8	26	44.1
Male to male sexual activity	0	0	0	0.0	0	0	0	0.0	2	0	2	20.0	0	0	0	0.0	8	0	8	13.6
Exposure in health care setting	0	0	0	0.0	4	2	6	12.5	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0
Engaged in sex work	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0
Blood or tissue recipient	0	0	0	0.0	0	1	1	2.1	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0
Household contact/Family history	3	5	8	11.6	1	1	2	4.2	0	0	0	0.0	0	0	0	0.0	0	0	0	0.0
Other blood to blood contact	0	0	0	0.0	0	1	1	2.1	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
No risk factors identified/Unknown	1	3	4	5.8	4	13	17	35.4	3	0	3	30.0	0	0	0	0.0	14	6	20	33.9
Total	47	22	69	100.0	23	25	48	100.0	9	1	10	100.0	1	1	2	100.0	42	17	59	100.0

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

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 (except 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.

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 Donor Engagement 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/reduction technologies). Currently used for manufactured plasma products but is not routinely available in Australia for all fresh blood components.

Even the best testing is not 100% effective in identifying infection, primarily due to the existence of a 'window period' (WP). This is 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 testing used by Lifeblood has progressively improved; prior to June 2000, only serological assays were available, and the WPs for HIV, HCV and HBV were approximately 22, 66 and 38 days. Significant improvements included the introduction of nucleic acid tests (NAT) for HIV-1 and HCV in June 2000, HBV in 2010 and HIV-2 in 2021. Current WPs are approximately 5 days (HIV-1/2), 3 days (HCV) and 17 days (HBV), as outlined at https://www.lifeblood.com.au/health-professionals/clinical-practice/adverse-events/other-transfusion-transmitted-infections/transfusion-transmissible-infections. 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 WP.

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 Lifeblood and the Surveillance and Evaluation Program for Public Health at the Kirby Institute. 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, annual surveillance reports have summarised data from the current year and trends for TTI-positive blood donors.

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 the interval between each donation by all donors who donated at least twice in the reporting year were obtained. 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 the reporting year, 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 activity
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 activity* 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 activity
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 eight-year period, 2016-2023, was calculated as follows:

$$\text{Incidence per 100 000 donor-years of observation} = \left(\frac{\text{Total number of incident donors in 2016-2023}}{\text{Average of 2016-2023 total donor-years of observation}} \right) \times 100\,000$$

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 the reporting 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*[34] 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 anti-HBc negative or positive, HBsAg negative and HBV DNA positive outside the acute phase of infection.[35] 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.

The estimated residual risk for HTLV is based on an updated version of Lifeblood's published HTLV model.[36]

Further information is available at https://www.lifeblood.com.au/health-professionals/clinical-practice/adverse-events/other-transfusion-transmitted-infections/transfusion-transmissible-infections.

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, 2014-2023, and the eight-year period, 2016-2023, 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 2014-2023 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 2023, and five-year period, 2019-2023 (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.

References

1. King J, McManus H, Kwon A, Gray R and McGregor S. HIV, viral hepatitis and sexually transmissible infections in Australia: Annual surveillance report 2023, The Kirby Institute, UNSW Sydney, Sydney, Australia. 2024. (In print).
2. Tohme RA and Holmberg SD. Transmission of hepatitis C virus infection through tattooing and piercing: a critical review. *Clinical infectious diseases* 2012; 54: 1167-1178.
3. Hoad VC, Guy RJ, Seed CR and R H. Tattoos, blood-borne viruses and blood donors: a blood donor cohort and risk assessment. Vox Sanguinis 2019; 114: 687-693.
4. Styles CE, Hoad VC, Harley R, Kaldor J and Gosbell IB. New tatt? We're ok with that! Relaxing the tattoo deferral for plasmapheresis donors maintains safety and increases donations. *Vox Sanguinis* 2024; 119: 927-935.
5. Health and Safety Executive Government of UK. Hepatitis B virus. Available at: https://www.hse.gov.uk/biosafety/blood-borne-viruses/hepatitis-b.htm Access date: October 30, 2024.
6. Kiely P, Margaritis AR, Seed CR, Yang H and Australian Red Cross Blood Service NATSG. Hepatitis B virus nucleic acid amplification testing of Australian blood donors highlights the complexity of confirming occult hepatitis B virus infection. *Transfusion* 2014; 54: 2084-2091.
7. Polizzotto MN, Wood EM, Ingham H and Keller AJ. Reducing the risk of transfusion-transmissible viral infection through blood donor selection: the Australian experience 2000 through 2006. *Transfusion* 2008; 48: 55-63.
8. Lucky TT, Seed CR, Keller A, Lee J, McDonald A, Ismay S, Wand H and Wilson DP. Trends in transfusion-transmissible infections among A ustralian blood donors from 2005 to 2010. *Transfusion* 2013; 53: 2751-2762.
9. Nguyen VTT, Razali K, Amin J, Law MG and Dore GJ. Estimates and projections of hepatitis B-related hepatocellular carcinoma in Australia among people born in Asia-Pacific countries. *Journal of gastroenterology and hepatology* 2008; 23: 922-929.
10. O'Sullivan BG, Gidding HF, Law M, Kaldor JM, Gilbert GL and Dore GJ. Estimates of chronic hepatitis B virus infection in Australia, 2000. *Australian and New Zealand journal of public health* 2004; 28: 212-216.
11. Williams S, Vally H, Fielding J and Cowie B. Hepatitis B prevention in Victoria, Australia: the potential to protect. *Euro Surveill* 2011; 16: 19879.
12. Australian Government Department of Health. National Notifiable Diseases Surveillance System (NNDSS). Available at: https://www.health.gov.au/our-work/nndss Access date: October 30, 2024.
13. Heard S, Zolala F and Maher L. Australian Needle Syringe Program Survey National Data Report 2018-2022: Prevalence of HIV, HCV and injecting and sexual behaviour among NSP attendees. Sydney: Kirby Institute, UNSW Sydney. 2023.
14. Poiesz BJ, Ruscetti FW and Gazdar AF. Detection and isolation of type C retrovirus particles from fresh and cultured lymphocytes of a patient with cutaneous T-cell lymphoma. *Proc Natl Acad Sci USA* 1980; 77: 7415-7419.
15. Cassar O, Einsiedel L, Afonso PV and Gessain A. Human T-cell lymphotropic virus type 1 subtype C molecular variants among indigenous Australians: new insights into the molecular epidemiology of HTLV-1 in Australo-Melanesia. *PLoS Negl Trop Dis* 2013; 7: e2418.
16. Legrand N, McGregor S, Bull R, Bajis S, Valencia BM, Ronnachit A, Einsiedel L, Gessain A, Kaldor J and Martinello M. Clinical and Public Health Implications of Human T-Lymphotropic Virus Type 1 Infection. *Clin Microbiol Rev* 2022; 35: e0007821.
17. Yoshida M, Miyoshi I and Hinuma Y. Isolation and characterization of retrovirus from cell lines of human adult T-cell leukemia and its implication in the disease. *Proc Natl Acad Sci USA* 1982; 79: 2031-2035.
18. Watanabe T, Seiki M and Yoshida M. HTLV type I (U.S. isolate) and ATLV (Japanese isolate) are the same species of human retrovirus. *Virology* 1984; 133: 238-241.
19. Osame M, Usuku K, Izumo S, Ijichi N, Amitani H, Igata A, Matsumoto M and Tara M. HTLV-I associated myelopathy, a new clinical entity. *Lancet* 1986; 1: 1031-1032.

20. Schierhout G, McGregor S, Gessain A, Einsiedel L, Martinello M and Kaldor J. Association between HTLV-1 infection and adverse health outcomes: a systematic review and meta-analysis of epidemiological studies. *Lancet Infect Dis* 2020; 20: 133-143.
21. Einsiedel L, Pham H, Talukder MRR, Liddle J, Taylor K, Wilson K, Jersmann H, Gessain A, Woodman R and Kaldor J. Pulmonary Disease Is Associated With Human T-Cell Leukemia Virus Type 1c Infection: A Cross-sectional Survey in Remote Aboriginal Communities. *Clin Infect Dis* 2021; 73: e1498-e1506.
22. Einsiedel L, Pham H, Talukder MR, Taylor K, Wilson K, Kaldor J, Gessain A and Woodman R. Very high prevalence of infection with the human T cell leukaemia virus type 1c in remote Australian Aboriginal communities: Results of a large cross-sectional community survey. *PLoS Negl Trop Dis* 2021; 15: e0009915.
23. Einsiedel LJ, Pham H, Woodman RJ, Pepperill C and Taylor KA. The prevalence and clinical associations of HTLV-1 infection in a remote Indigenous community. *Med J Aust* 2016; 205: 305-309.
24. Styles CE, Hoad VC and Seed CR. Estimation of human T-lymphotropic virus incidence in blood donors from observed prevalence. *Vox sanguinis* 2018; 113: 814-815.
25. May J, Stent G and Schnagl R. Antibody to human T-cell lymphotropic virus type I in Australian aborigines. *The Medical journal of Australia* 1988; 149: 104-104.
26. Verdonck K, González E, Van Dooren S, Vandamme A-M, Vanham G and Gotuzzo E. Human T-lymphotropic virus 1: recent knowledge about an ancient infection. *The Lancet infectious diseases* 2007; 7: 266-281.
27. Van der Sluis J, Onvlee P, Kothe F, Vuzevski V, Aelbers G and Menke H. Transfusion Syphilis, Survival of Treponema pallidum in Donor Blood: I. Report of an Orientating Study. *Vox sanguinis* 1984; 47: 197-204.
28. Ravitch MM and Chambers JW. Spirochetal survival in frozen plasma. *Bull Johns Hopkins Hosp* 1942; 71: 299.
29. Orton S. Syphilis and blood donors: what we know, what we do not know, and what we need to know. *Transfusion medicine reviews* 2001; 15: 282-292.
30. Jayawardena T, Hoad V, Styles C, Seed C, Bentley P, Clifford V, Lacey S and Gastrell T. Modelling the risk of transfusion-transmitted syphilis: a reconsideration of blood donation testing strategies. *Vox sanguinis* 2019; 114: 107-116.
31. Ratnam S. The laboratory diagnosis of syphilis. *Canadian Journal of Infectious Diseases and Medical Microbiology* 2005; 16: 45-51.
32. Australian Government Department of Health. Syphilis, less than 2 years duration. Australian national notifiable diseases case definition. Available at: https://www.health.gov.au/sites/default/files/documents/2022/06/syphilis-less-than-2-years-duration-surveillance-case-definition.pdf Access date: October 10, 2024.
33. Seed C and Kiely P. A method for estimating the residual risk of transfusion-transmitted HBV infection associated with occult hepatitis B virus infection in a donor population without universal anti-HBc screening. *Vox sanguinis* 2013; 105: 290-298.
34. Weusten J, Vermeulen M, van Drimmelen H and Lelie N. Refinement of a viral transmission risk model for blood donations in seroconversion window phase screened by nucleic acid testing in different pool sizes and repeat test algorithms. *Transfusion* 2011; 51: 203-215.
35. Seed C, Kiely P, Hoad V and Keller A. Refining the risk estimate for transfusion-transmission of occult hepatitis B virus. *Vox Sanguinis* 2017; 112: 3-8.
36. Styles CE, Seed C, Hoad V, Gaudieri S and Keller A. Reconsideration of blood donation testing strategy for human T-cell lymphotropic virus in Australia. *Vox sanguinis* 2017; 112: 723-732.
37. Seed C, Kee G, Wong T, Law M and Ismay S. Assessing the safety and efficacy of a test-based, targeted donor screening strategy to minimize transfusion transmitted malaria. *Vox sanguinis* 2010; 98: e182-e192.
38. Stickland J, Roberts A and Williams V. Transfusion-induced malaria in Victoria. *The Medical journal of Australia* 1992; 157: 499-500.
39. Schenberg K, Hoad VC, Harley R and Bentley P. Managing the risk of transfusion-transmitted malaria from Australian blood donations: Recommendation of a new screening strategy. *Vox Sanguinis* 2024; 119: 945-952.
40. Eder AF, Kennedy JM, Dy BA, Notari EP, Weiss JW, Fang CT, Wagner S, Dodd RY, Benjamin RJ and Centers ARCRB. Bacterial screening of apheresis platelets and the residual risk of septic transfusion reactions: the American Red Cross experience (2004-2006). *Transfusion* 2007; 47: 1134-1142.
41. Kuehnert MJ, Roth VR, Haley NR, Gregory KR, Elder KV, Schreiber GB, Arduino MJ, Holt SC, Carson LA and Banerjee SN. Transfusion-transmitted bacterial infectionin the United States, 1998 through 2000. *Transfusion* 2001; 41: 1493-1499.
42. Wood E. Prevention of bacterial contamination, including initial flow diversion. *ISBT Science Series* 2009; 4: 221-229.

43. Thyer J, Perkowska-Guse Z, Ismay S, Keller A, Chan H, Dennington P, Bell B, Kotsiou G and Pink J. Bacterial testing of platelets–has it prevented transfusion-transmitted bacterial infections in Australia? *Vox sanguinis* 2018; 113: 13-20.

44. Satake M, Mitani T, Oikawa S, Nagumo H, Sugiura S, Tateyama H, Awakihara S, Mitsutomi Y, Muraoka M and Tadokoro K. Frequency of bacterial contamination of platelet concentrates before and after introduction of diversion method in Japan. *Transfusion* 2009; 49: 2152-2157.

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

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

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

48. Horth RZ, Jones JM, Kim JJ, Lopansri BK, Ilstrup SJ, Fridey J, Kelley WE, Stramer SL, Nambiar A, Ramirez-Avila L, Nichols A, Garcia W, Oakeson KF, Vlachos N, McAllister G, Hunter R, Nakashima AK and Basavaraju SV. Fatal Sepsis Associated with Bacterial Contamination of Platelets - Utah and California, August 2017. *MMWR Morbidity and mortality weekly report* 2018; 67: 718-722.

49. Cheng A, Das A, Chaw K, Dennington PM, Styles CE and Gosbell IB. Safety Analysis of Extended Platelet Shelf-Life with Large-Volume Delayed Sampling on BACT/ALERT® VIRTUO® in Australia. *Microorganisms* 2023; 11: 2346.

50. Ramirez-Arcos S, Evans S, McIntyre T, Pang C, Yi QL, DiFranco C and Goldman M. Extension of platelet shelf life with an improved bacterial testing algorithm. *Transfusion* 2020; 60: 2918-2928.

51. Australian Government Department of Health. National Notifiable Diseases Surveillance System (NNDSS). National Communicable Disease Surveillance Dashboard. Available at: https://nindss.health.gov.au/pbi-dashboard/ Access date: October 23, 2024.

52. European Centre for Disease Prevention and Control. Local transmission of dengue virus in mainland EU/EEA, 2010-present. Available at: https://www.ecdc.europa.eu/en/all-topics-z/dengue/surveillance-and-disease-data/autochthonous-transmission-dengue-virus-eueea Access date: October 18, 2024

53. Coghlan A, Hoad V, Seed C, Flower RL, Harley R, Herbert D and Faddy HM. Emerging infectious disease outbreaks: estimating disease risk in Australian blood donors travelling overseas. *Vox sanguinis* 2018; 113: 21-30.

54. Mackenzie JS, Lindsay MD, Smith DW and Imrie A. The ecology and epidemiology of Ross River and Murray Valley encephalitis viruses in Western Australia: examples of One Health in Action. *Transactions of the Royal Society of Tropical Medicine and Hygiene* 2017; 111: 248-254.

55. Thornhill JP, Barkati S, Walmsley S, Rockstroh J, Antinori A, Harrison LB, Palich R, Nori A, Reeves I and Habibi MS. Monkeypox virus infection in humans across 16 countries—April–June 2022. *New England Journal of Medicine* 2022; 387: 679-691.

56. World Health Organization. 2022-24 Mpox (Monkeypox) Outbreak: Global Trends. Available at: https://worldhealthorg.shinyapps.io/mpx_global/ Access date: October 28, 2024.

57. Masirika LM, Udahemuka JC, Schuele L, Ndishimye P, Otani S, Mbiribindi JB, Marekani JM, Mambo LM, Bubala NM and Boter M. Ongoing mpox outbreak in Kamituga, South Kivu province, associated with monkeypox virus of a novel Clade I sub-lineage, Democratic Republic of the Congo, 2024. *Eurosurveillance* 2024; 29: 2400106.

58. Australian Government Department of Health and Aged Care. Mpox (monkeypox) Available at: https://www.health.gov.au/diseases/monkeypox-mpox Access date: October 25, 2024.

59. Greninger A, Alcorn K, Pagano MB, Hermelin D and Katz L. Monkeypox and the safety of the blood supply. *Transfusion* 2022; 62: 1933-1935.

60. Kiely P, Hoad VC, Styles CE and Gosbell IB. Mpox outbreak in 2022: implications for blood component and donor human milk safety in Australia. *The Medical Journal of Australia* 2023; 218: 206-208.

61. Da Rosa JFT, De Souza WM, de Paula Pinheiro F, Figueiredo ML, Cardoso JF, Acrani GO and Nunes MRT. Oropouche virus: clinical, epidemiological, and molecular aspects of a neglected Orthobunyavirus. *The American journal of tropical medicine and hygiene* 2017; 96: 1019.

62. Pan American Health Organization and World Health Organization. Epidemiological Update Oropouche in the Americas Region - 15 October 2024. Available at: https://www.paho.org/en/documents/epidemiological-update-oropouche-americas-region-15-october-2024 Access date: October 25, 2024.

63. de Armas Fernández JR, Peña García CE, Acosta Herrera B, Betancourt Plaza I, Gutiérrez de la Cruz Y, Resik Aguirre S, Kourí Cardellá V, Guzmán Tirado MG. Report of an unusual association of Oropouche Fever with Guillain-Barré syndrome in Cuba, 2024. *Eur J Clin Microbiol Infect Dis*. 2024 Nov; 43(11): 2233-2237.

64. Castilletti C, Huits R, Mantovani RP, Accordini S, Alladio F and Gobbi F. Replication-Competent Oropouche Virus in Semen of Traveler Returning to Italy from Cuba, 2024. *Emerg Infect Dis*. 2024; 30(12): 2684-2686.

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

66. Ghani AC, Donnelly CA, Ferguson NM and Anderson RM. Updated projections of future vCJD deaths in the UK. *BMC Infectious Diseases* 2003; 3: 1-8.

67. McManus H, Seed CR, Hoad VC, Kiely P, Kaldor JM, Styles CE, Yang H, Law M and Gosbell IB. Risk of variant Creutzfeldt–Jakob disease transmission by blood transfusion in Australia. *Vox Sanguinis* 2022; 117: 1016-1026.

68. Hoad VC, Seed CR, Kiely P, Styles CE, McManus H, Law M, Kaldor J and Gosbell IB. Removal of UK-donor deferral for variant Creutzfeldt–Jakob disease: A large donation gain in Australia. *Vox Sanguinis* 2023; 118: 891-894.

69. Marka A, Diamantidis A, Papa A, Valiakos G, Chaintoutis SC, Doukas D, Tserkezou P, Giannakopoulos A, Papaspyropoulos K and Patsoula E. West Nile virus state of the art report of MALWEST Project. *International journal of environmental research and public health* 2013; 10: 6534-6610.

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

71. Busch MP, Kleinman SH, Tobler LH, Kamel HT, Norris PJ, Walsh I, Matud JL, Prince HE, Lanciotti RS and Wright DJ. Virus and antibody dynamics in acute West Nile virus infection. *The Journal of infectious diseases* 2008; 198: 984-993.

72. European Centre For Disease Prevention and Control. West Nile virus infection. Weekly updates. Available at: https://www.ecdc.europa.eu/en/west-nile-virus-infection Access date: October 24, 2024.

73. Kiely P, Seed CR, Hoad VC, Gambhir M, Cheng AC, McQuilten ZK and Wood EM. Modeling the West Nile virus transfusion transmission risk in a nonoutbreak country associated with traveling donors. *Transfusion* 2020; 60: 2611-2621.

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